TRAINING MODULE

On

Health System Research Proposal Development

Supported by

World Health Organization

Prepared by

Nepal Health Research Council

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Acknowledgement

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Prof. Dr. Chop Lal Bhusal
Executive Chairman
Nepal Health Research Council

Session 1: Course Orientation

Time frame: 1 hour

Course objectives: At the end of this course, participants (trainee) will be able to:

1. **Describe** Health System Research (HSR) and explain its contribution towards solving priority problems in health care within the local context.
2. **Prepare** a health systems research proposal by completing the following steps:
    - Identification, analysis and description of a research problem
    - Review of relevant literature and other available information
    - Formulation of research objectives, research questions and hypothesis
    - Development of an appropriate research methodology
    - Preparation of a work plan for the study
    - Identification of resources required and preparation of a budget
    - Development of Logical Framework

Whom is the health systems research proposal development course aimed at?

The health systems research proposal development (HSRPD) course has been developed for mid and higher level managers, health workers and health-related staff, as well as interested researchers. The criteria for selecting the participants for HSRPD are as follows.

Qualification and Experience

1. At least Bachelor Degree in Health Sciences (Medicine, Ayurveda, Public Health, Nursing, Pharmacy) + At least one year experience in health sector
2. At least Bachelor Degree in Health Related Sciences (Health Education, Sociology, Anthropology, Psychology, Population Studies, Rural development, Environmental Sciences, Microbiology, Geography, Statistics, Economics) and at least two year working experiences in health sector after the completion of Bachelor Degree

Documents to be submitted

1. Updated Curriculum Vitae (CV)
2. Photocopy of Highest Degree Received
3. Filled up Application Form with recent Photo
4. Photocopy of Experience Letter
5. Recommendation Letter from Institute (Who are affiliated with Institution)

Course Duration

The duration of the course will be one week.

Teaching Methods

The course has been organized in such a way that each module can be dealt with independently. A module includes:

- A **presentation** of the necessary theory and concepts to enable the participants to carry out the specific step in proposal development. Presentations last between 30 minutes and an hour and include opportunity for questions and discussion.
- **Group work** during which groups, with assistance of their facilitator, utilize these concepts in the development of their proposal. The modules for proposal development, in particular, contain detailed instructions for group work. Group work may last from 1-3 hours per module, and sometimes longer.
- **Reporting** of the results of the group work in **plenary** by a member of each group, so that other groups and facilitators can comment. Plenary are of crucial importance during the workshop. On the average, each group has 15 minutes for presentation and discussion, but for important topics this may be 30 minutes.
- Sometimes a module contains an **exercise**, either using examples provided during the presentation or using the group work results of other groups.

Materials

- LCD projector and Computer
- Name tags for participants and trainers
- Flipcharts and markers
- Course training materials for participants
- Power point slides for presentation

Personal introduction of participants and facilitators

Let to make all the participants (including the facilitators) introduce themselves. Make certain everyone indicates his or her profession, major activities and research experiences and interests. This may be done by having participants interview each other in pairs and then each introduces the person he or she interviewed. Names and affiliated institution can be put in ID card and can be hang in neck which helps to remember the name of each participant for themselves and to the facilitators. The introduction may take half an hour.

Course orientation

- Present the major objectives of the course and stress its practical orientation. It should be clear to all participants that they will each work as part of a small group to develop a research proposal which they themselves will carry out. It should also be stressed that one important goal of the course is that the research findings will be used to help solve the problem the group has investigated.

- Emphasize the uniqueness of each participant's background and experience, pointing out how important it will be for everyone to contribute to the development of the proposal and to learn from each other.
- Distribute the course-training document to the participants. Describe how the course will be structured and how the training document will be used. Show the flowchart that appears at the beginning of each module. Explain that each session contains a presentation and group work during which each group will apply the concepts presented in the development of its proposal. Indicate that directions for group work are presented in boxes with double lines around them. Mention that some sessions also have exercises, which are presented in boxes with single lines. Discuss the fact that in some modules annexes provide more details on research methodology for those who are interested.
- Stress that the end product of the workshop will be a research proposal that will be written, step by step, by the participants.

Administrative issues

- Present any other information concerning the course and administrative arrangements that may be necessary and ask for final questions.

An Overview of Course Contents

Session 1: Course Orientation

Session 2: Introduction of Health and Health System of Nepal

Session 3: Fundamentals of Health Research

Session 4: An Overview of Proposal Development Steps

Session 5: Identification, Analysis and Formulation of the Health System Research Problem

Session 6: Formulation of Research Title, Objectives, Research Questions and Hypothesis

Session 7: Accessing Health Research Information and Literature Review

Session 8: Concept of Variables and Scales of Measurements

Session 9: An Overview of Research Design and Conceptual framework

Session 10: Study Types

Session 11: Introduction of Sampling Techniques

Session 12: Types of Sampling

Session 13: Study based Sample Size Calculation

Session 14: Data Collection Techniques

Session 15: Data Collection Tools

Session 16: Data Management and Analysis Plan

Session 17: Work Plan and Planning of Budget

Session18: Concept of Logical Framework in Health Research Proposal Development

Session 19: Health Research Ethics

Session 20: Finalizing and reviewing the research proposal

Expected Outcome: At the end of the course each group will prepare a health research proposal on Health System problems of Nepal

Session 2: Introduction to Health and Health Systems of Nepal

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Define Health according to World Health Organization (WHO)
2. Define Health System focusing on district health system
3. Describe health care system in Nepal

Teaching methods: There will be one hour Mini-lecture focusing on definition of health, health system and district health system and also explain the health care delivery system in Nepal. There will be one hour allocated for group exercise. Group will be divided into 5-6 groups and each group will received problem. Thirty minutes will be allocated for group discussion and each group will present their group reports within 5 minutes.

Course Content:

Health: Definition

According to World Health Organization (WHO) - health is physical, mental and social wellbeing and not merely an absence of disease or infirmity.

The Pan American Health Organization (PAHO) - health is physical, mental, spiritual and social wellbeing.

The traditional medicine Ayurveda defines health as the balance of Kaf (cough), Bayu (wind) and Pitta (bile).

Health system: Definition

In every country there is a health system. A national health system is a complex system established by public policy to achieve certain socio-economic goals and it comprises of all organizations, institutions and resources devoted to producing actions whose primary intent is to improve health. The complex components –structure and instruments –used to establish the architecture of a health system is determined by political, institutional and economic considerations.

Health system is defined as "complex of interrelated elements that contribute to health in homes, educational institutions, workplaces, public places, and communities as well as in the physical and psychosocial environment and the health and related sectors".

A health system is a functional network of health care providers, including public sector and privately run services, which range from traditional healers to the most technologically

advanced hospitals. It also includes payers (households, insurer, and donors), managers and regulators. Ideally, all parts of the system act together in an organized way to meet the individual and community health needs of a population. Nearly everyone, healthy or ill, comes in contact with a health system at some time. Health systems have a responsibility not just to improve people's health but also to protect them against financial cost of illness and treat them with dignity.

Most national health systems include public, private, traditional and informal sectors. The four essential functions of a health system have been defined as service provision, resource generation, financing and stewardship. All health systems can be further categorized into national, regional and district health systems.

District Health System: Definition

WHO Global Program Committee adopted the following definition of the district health system in 1986-

"District health system based on primary health care is a more or less self-contained segment of the national health system. It comprises first and foremost a well-defined population, living within a clearly delineated administrative and geographical area, whether urban or rural. It includes all institutions and individuals providing health care in the district, whether governmental, private or traditional. A district health system, therefore, consists of a large variety of interrelated elements that contribute to health in homes, schools, work places and communities through health and other sectors. It includes self-care and all health workers and facilities, up to and including the hospital at first referral level and appropriate laboratory, other diagnostic and logistic support services. Its component elements need to be well coordinated by an officer assigned to this function in order to draw together all these elements and institutions into a fully comprehensive range of promotive, preventive, curative and rehabilitative health activities".

District health systems have vertical relationships with higher-level regional management, horizontal relationships with local departments of other ministries, between different national health programs and with the communities that are being served.

Key features of district health system-

- People oriented
- Clearly defined
- Substantial autonomy to implement and manage the plan and programs at local level

District health system rests on five pillars that are different than the national health system--

- Organization, planning and management
- Financing and resource allocation
- Inter-sectoral action
- Community involvement
- Development of human resources

Health System of Nepal

Health system of Nepal can be broadly defined into three areas- national health system, regional health system and district health system.

National health system comprises of allopathic medicine, traditional medicine, homeopathy, Unani and other systems of medicine. It includes public sector, private sector, NGOs, traditional healers such as Dhami, Jhankri and Amchi healers and female community health volunteers. The major functions of the national health system are- service provision of referral level, health financing, resource allocation and stewardship.

The health system in Nepal can be further categorized into –national, regional and district health systems. The national health system comprises of national hospitals, national medical institutes responsible for training human resource for health, Department of Health Services, national program centers, professional regulatory bodies, national research council and Department of Ayurveda.

The regional health system consists of regional health directorate, regional hospitals, regional TB centers, zonal hospitals, and regional health training centers. Regional health system consists of mainly public sector health system. Regional health systems main functions are service provisions, and monitoring and evaluation.

The district health system consists of district hospitals, district health or public health office and equivalent facilities of other systems of medicine. It includes the sub district level health facilities such as primary health center, health post, sub-health post and Ayurveda health centers and dispensary. It also includes private health practitioners, private and NGO health facilities, traditional healers, female community health volunteers and trained traditional birth attendants. The district health system functions on the broad principles of primary health care. The main functions of the district health system are health planning, health program management and service delivery, coordination, & community mobilization.

Composition of district health system in Nepal

-Individual -Family -Home -Schools -Work places -Community	-FCHV -TBA -MCHW -VHW -Traditional healers -Mother's groups	-Sub health post -Health post -Primary health center or -Health center -Institutionalized family planning clinic	-NGO Clinics -NGO Hospitals -Private hospitals -Alternative health systems both public and private	-District hospital -District health office or -District public health office

The organogram of Ministry of Health and Population, Department of Health services is as follows.

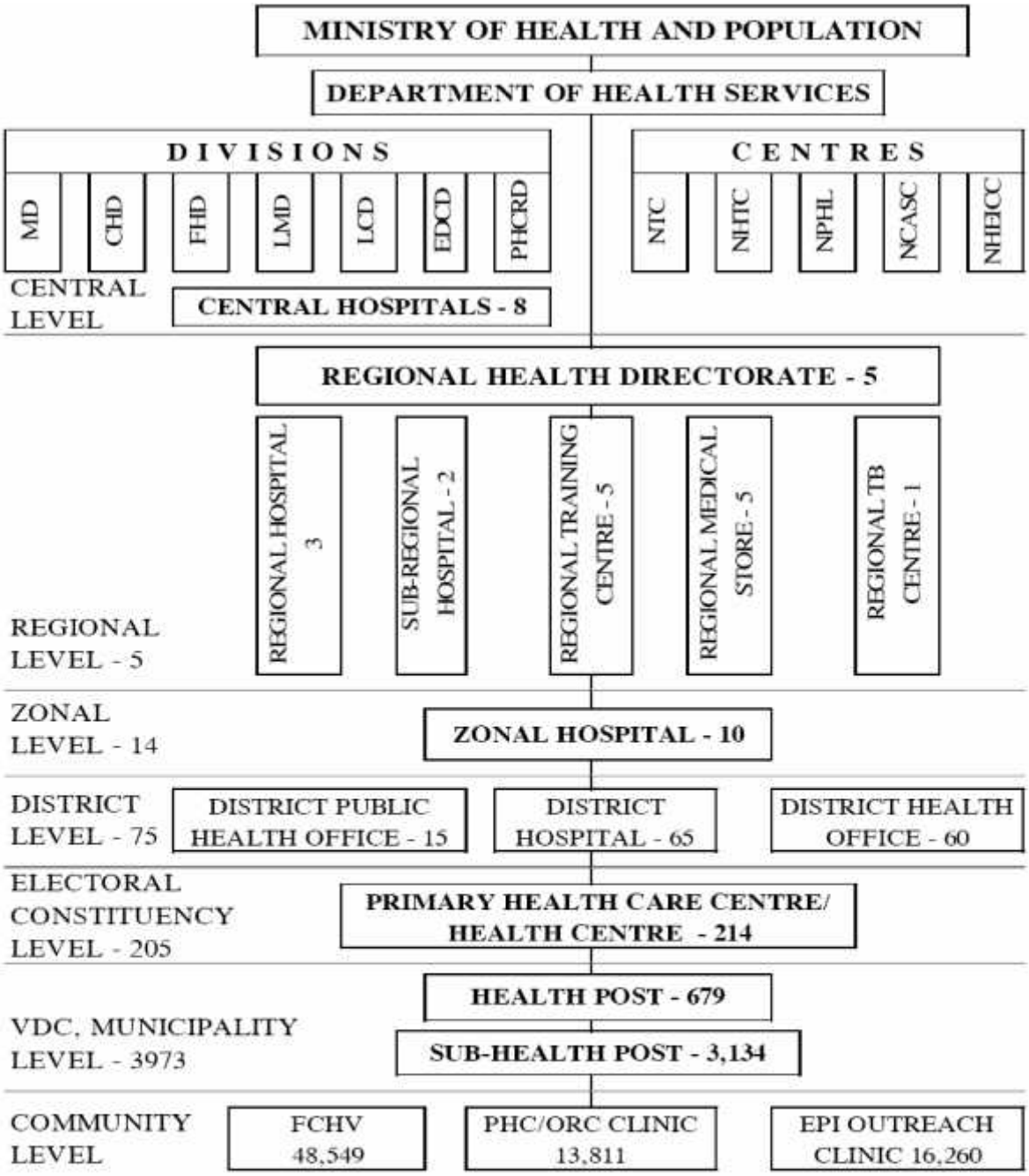


Figure 1b.1 *Source: Administration Section, HMIS/MD, DoHS*

Acronyms

MD	*Management Division*	*NHTC*	*National Health Training Centre*
FHD	*Family Health Division*	*NTC*	*National Tuberculosis Centre*
CHD	*Child Health Division*	*NCASC*	*National Centre for AIDS and STD Control*
EDCD	*Epidemiology and Disease Control Division*	*NPHL*	*National Public Health Laboratory*
LMD	*Logistics Management Division*	*FCHV*	*Female Community Health Volunteer*
LCD	*Leprosy Control Division*	*PHC/ORC*	*Primary Health Care Outreach Clinic*
PHCRD	*Primary Health Care Revitalization Division*	*EPI*	*Expanded Programme on Immunisation*
NHEICC	*National Health Education, Information and Communication Centre*		

Session 3: Fundamental of Health System Research

Time frame: 1 hour

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **Define** health system research and its types
2. **Describe** the major characteristics of research.
3. **Describe** the major categories of research
4. **Describe** types of information for decision-making in the health system and the contribution various disciplines can make in providing such information.
5. **Describe** the purpose, scope and characteristics of HSR.

Teaching methods: There will be one hour Mini-lecture focusing on definition of health system research, characteristics and categories of research.

Course Content:

Introduction

Health systems research is composed of two components: health systems and research. Health systems include the structure of all health outlets, programs and projects engaged in providing health care to the population of a country. These health outlets include: primary health care facilities such as basic health units and rural health centers; secondary health care facilities such as district hospitals; and tertiary health care facilities. Research is defined as the systematic collection, analysis, and interpretation of data to answer a certain question or solve a problem Health systems research relates to health prevention, treatment and promotion within the national health system and is carried out by institutions on the basis of socioeconomic, political and cultural aspects. Scientific research plays a very important role in our efforts to maintain health and combating diseases. Research helps us create new knowledge and develop proper tools for the use of existing knowledge. Not only does it enable health care providers to diagnose and treat diseases, research also provides evidence for policies and decisions on health and development.

The concept of Health Systems Research emerged around 1970's and gained wide acceptance. The meaning of medical or health research became much wider. "Health Systems Research" include all types of research that contributes to improving the functioning of the health system through providing new information for decision making in the health system or providing information to support advocacy for change in the system or through contributing to the body of knowledge relating to theories, concepts and methods that is required for generating such information. Thus health research seems to go beyond discovery of new phenomena, new methods or new concept concerning health".

Health System Research has also been defined as a scientific method of acquiring information that can be used for rational decision working in health management. It is concerned with

population organizational structure and the interaction between them. It is ultimately concerned with improving the health of a community by enhancing the efficiency and effectiveness of health system as an integral part of the overall process of socio economic development.

Why did HSR develop?

By adopting of the philosophy and strategies for **Health For All**, politicians and health staff at all levels are committed to ensuring that *all* people will attain a level of health that enables them to participate actively in the social and economic life of the community in which they live.

Although research has made major contributions to health by providing knowledge of the causes of diseases and by developing the technology to cure and prevent disease and promote health, Health For All is far from being achieved.

Why is there still so much disease that could have been prevented or cured? Because health services by themselves cannot control all of the factors that influence health. Poverty and political systems which either widen or narrow the gap between rich and poor and which promote or neglect the education of girls, for example, influence the health of people. Drought and wars may bring malnutrition and disease with which the health services can hardly cope. While communicable diseases such as smallpox and, to some extent, leprosy may be gradually conquered due to improved environmental conditions and extra effort on the part of the health services, new diseases such as HIV/AIDS may appear which upset the whole health care system and society at large.

This **complex of environmental factors** – geographical, socio-economic, cultural, political, demographic and epidemiological – not only **influences the health of people**, it also affects the **health services**.

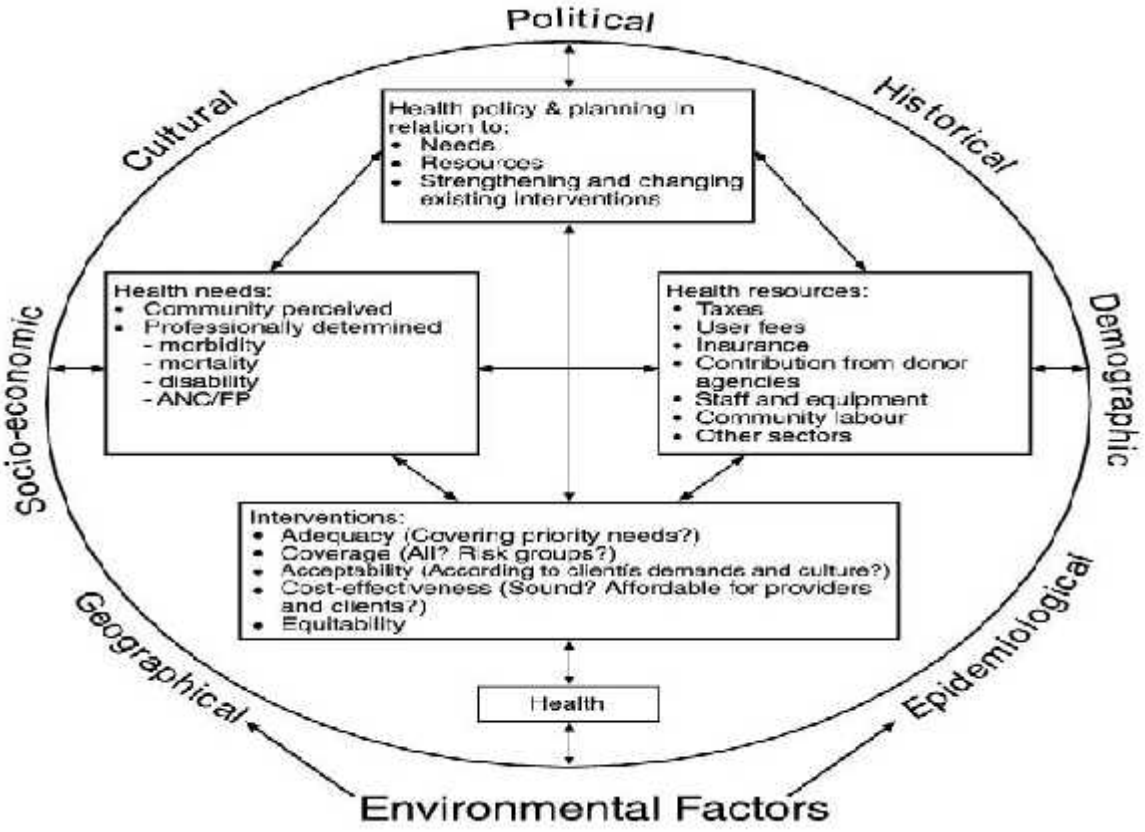
Still, even within less favorable environments, some services function better than others. A very important factor is the **quality of information on which policy makers base their decisions**. Very often this information is vague or missing. Then decisions on interventions can be completely off track, which means that money is wasted. Basic questions which health policy makers need answered include, for example:

- What are the *health needs* of (different groups of) people, not only according to health professionals but also according to the people themselves? Can shared priorities be agreed upon?
- To what extent do the present *health interventions* cover these priority needs? Are the interventions acceptable to the people in terms of culture and cost, especially to the poor? Are they provided as cost-effectively as possible?
- Given the *resources* we have, could we cover more needs, or more people, in a more cost-effective way? Is it possible to introduce or expand cost-sharing through insurance, to reduce the risk of unexpected high costs, in particular for the economically vulnerable?

Could co-operation with the private/NGO sector be improved? Could donor agencies help solve well-defined bottlenecks in the system?

- Is it possible to better *control the environmental factors* which influence health and health care? Can other sectors help (education, agriculture, public works/roads, etc.)? (See **Figure1**.)

Figure 1: Environmental and health system factors influencing attainment of Health for All



These questions cannot be answered without collecting more information through research. That is why, since the end of the 1970's, **Health Systems Research** (HSR) has been developed.

Characteristics of research:

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

Categories of Research

1. Empirical and theoretical research

The philosophical approach to research is basically of two types: empirical and theoretical. Health system research mainly follows the empirical approach, i.e. it is based upon observation and experience more than upon theory and abstraction. Epidemiological research, for example, depends upon the systematic collection of observations on the health related phenomena of interest in defined populations. Moreover, even in abstraction with mathematical models, advances in understanding of disease occurrence and causation cannot be made without a comparison of the theoretical constructs with that which we actually observe in populations. Empirical and theoretical research complement each other in developing an understanding of the phenomena, in predicting future events, and in the prevention of events harmful to the general welfare of the population of interest. Empirical research in the health system research can be qualitative or quantitative in nature. Tin latter days the concept of mixed methods (combining qualitative and quantitative) is ever growing.

2. Basic and applied research

Health research can be functionally divided into basic (or pure) research and applied research. First, **basic research** is necessary to generate new knowledge and technologies to deal with major unresolved health problems. It is usually considered to involve a search for knowledge without a defined goal of utility or specific purpose. Second, **applied research** is necessary to identify priority problems and to design and evaluate policies and programs that will deliver the greatest health benefits, making optimal use of available resources. Applied research is problem oriented , and is directed towards the solution of an existing problem. The findings of basic research are universally applicable/truth while as findings of applied research may not be. There is continuing controversy over the relative benefits and merits to society of basic and applied research.

During the past two (or even three) decades there has been a rapid evolution of concepts and research approaches to support managerial aspects of health development. Many of these have been described by specific terms such as operations/operational research, health services research, health management research, applied research and decision-linked research. Each of these has made crucial contributions to the development of HSR (WHO 1990).

3. Health research triangle

Yet another way of classifying health research, be it empirical or theoretical, basic or applied, is to describe it under three operational interlinked categories of biomedical, health services and behavioral research, the so-called health research triangle. Biomedical research deals primarily with basic research involving processes at the cellular level; health research deals with issues in the environment surrounding man, which promote changes at the cellular level;

and behavioral research deals with the interaction of man and the environment in a manner reflecting the beliefs, attitudes and practices of the individual in society.

HEALTH SYSTEMS RESEARCH is ultimately concerned with improving the health of people and communities, by enhancing the efficiency and effectiveness of the **health system** as an integral part of the overall process of socio-economic development, with full involvement of all partners.

Decision-making in the health sector takes place at the macro level whereas implementation takes place in the regions, going down to the village level through different stages. Health policy is the responsibility of the Ministry of Health and Population with the assistance of the attached health departments. There is a risk of neglect of community interest or a lack of understanding of the problems at the grass-roots level in the existing system of policy-making. In order to achieve a balanced approach, access to the community is required so as to understand the basic problems and needs, and then to design the necessary strategy to solve the problems to be reflected in the health policy of the country. The problems should therefore be studied at the micro level in order to understand the real requirements of the entire population.

The main objective of health systems research is to bring about improvement in the health of the people by increasing the effectiveness and efficiency of the health care system. This is related to the organizational structure of the health care system and the population and their mutual interaction. Therefore, continuous identification of problems and evaluation of the existing health systems are required. Hence, compilation and analysis of facts and figures which facilitate the development of a strategy for the future to meet shortcomings are the identifiable results of the research which will ultimately improve the efficiency as well as the effectiveness of the health systems.

Improvement of the health care system of the country through health systems research involves a variety of disciplines so that adequate information can be given to decision-makers in a systematic way before they make their decisions. Social, cultural, demographic, economic and political aspects of the issues to be resolved must be considered. The actual research will depend upon the precise nature of the problems, and will require the skills of biomedical scientists, sociologists, epidemiologists, environmental health specialists, demographers, economists, and political, organization and management scientists. However, ensuring the availability of all disciplines and their agreed working conditions will not be an easy task. Furthermore, health systems research is dependent upon the existing infrastructure of research and management. These are important factors but unfortunately the infrastructure in Nepal is weak and unable to cope with the problems faced by the health sector and its research needs. However, the need has been recognized and it is anticipated that improvements will be made with time. In latter days the importance of health system research is increasingly recognized by individual researchers, research institutes, external development partners, government bodies and policy makers. The study has shown that many health policy and programs are based on findings of health system research in Nepal.

Development of the health sector in developing countries like Nepal depends upon better use of existing resources, whereas health achievement is a combination of various factors of development, such as the extent of the problems, disease patterns, health needs of the population and availability of resources. Increase in resources and mobilization in the country requires research to determine the starting point and match the resources with the requirements. The research and analysis should be conducted by assessing: what is; what ought to be; how is/was; how ought to be; and when to be. When this analysis is carried out, various sectors and professionals are involved such as economists, medical personnel, epidemiologists, bio-statisticians, planners, and sociologists. It is also important not to depend on one or two factors only but to make a realistic analysis of the variables involved which can provide better assistance to health systems research in determining the ultimate variables. In this regard, a Norwegian author commented:

Thus health systems research studies a vast array of possibilities for action. It tries to establish rational uses of medical knowledge and technology, evaluate methods of investigation and treatment, and develop methods for maintaining high quality. It aims to induce logical thought and action on these matters in the health sector and among the public at large.

Health systems research has the potential to play an important role in the achievement of health for all. Decline in the incidence and impact of infectious diseases and awareness of chronic diseases have raised the public's expectations of the health system. However, only a small portion of the gross national budget 6.0 % approx. is spent on health in the public sector. Low economic and high population growth and demand for resources by other sectors have left little prospect of increasing the budget for the health sector. In this situation, the improvement can only be achieved through greater efficiency, which includes data collection on the inputs and outputs of the health sector, which will provide feedback for planning, implementation, monitoring, evaluation and strengthening of concerned management and administration. As the goals of health systems research are related to the effectiveness, efficiency and cost reduction in the health sector, the economic forces of today are, in fact, of great assistance for encouraging efficiency, cost reduction and effectiveness.

Health policy indicators: These include resource allocation, degree of equity of distribution of resources, community involvement, degree of decentralization in decision-making and organizational framework, and the managerial process.

Indicators of the provision of health care: These include progress in availability, accessibility and use of the health care services and the quality of care. They should be related to the specific types of services that the national health strategy aims at providing.

Health status indicators: These include changes and trends in the health status of the population.

Social and economic indicators: These include demographic and economic trends, income distribution, education, housing and food availability.

Many countries still lack reliable information support for measuring their progress towards health for all. The information is collected at various levels but is not systematically processed, analyzed and utilized. Most countries have many potential sources of data which are capable of providing the information required for monitoring and evaluating their national strategies, such as: vital events registers; population and housing censuses; routine health services records; epidemiological surveillance data; sample surveys; and disease registers. However, lack of coordinating mechanisms in collection and processing of information by different sectors not only makes the process very difficult, but also restricts the possibility of utilization of the available information.

Above all, a positive attitude and a genuine desire to measure progress towards health for all, particularly at the policy-and decision-making level, are basic requirements. Information should be perceived as a tool for decision-making and policy reorientation. The available information needs to be converted and presented in such a way that it can be used by policy- and decision-makers, by managers and by the community itself to assess how much progress is being made, to identify areas where changes are needed, and to specify actions that should be taken to bring about such changes. In this way, monitoring and evaluation will promote learning from experience, and will improve both current activities and future planning, and guide the allocation of human and financial resources in order to achieve equity in health which is the essence of the goal of health for all.

Health Policy and Research

The health policies are based on objectives and provide guidelines for the achievement of certain targets in the health sector. As research provides basic information for the policy-making process, it is important that the research should have close correlation with the health policies of the country.

Research unrelated to health policies means research that drifts from rational priorities, and policies unlinked to research mean policies unsupported by critical inquiry and evaluation. Both ways of stating this fundamental deficiency of linkages between health policy and research are potentially disastrous in terms of the health program development that meets true health needs in equitable and cost effective ways. It is probably no exaggeration to say that when research and policy are not effectively linked, a nation is seriously at risk of health development failure, or at least of underutilized services.

As there is no effective research mechanism and adequately equipped research organization, there exist more complications in the process of decision-making. All these shortcomings originate from the unknown status of the research and the fact that it is not given due importance by policy-makers. There is always a meager allocation for health research in the plans for the country. It is interesting to note that very few plans prepared so far were based on research within the country. Furthermore, in all the plans, health targets and indicators have been set at the levels of other regional countries without comparing resources. The absence of a research-based approach to allocating resources in line with the targets ultimately

creates more problems. The decision-makers are provided with incomplete feedback which results in a gap between targets and achievements.

Are there sufficient resources, i.e. funds, personnel, and other infrastructure available to achieve this target? What was the basis for calculating all these variables? Were these variables based on past trends, and do they provide consolidated ground for the policy-makers to approve the same targets? Were there adequate data available to support the targets and achievements? Most of the questions have no answer because of the absence of health systems research in the country.

The health sector should be seen as a service organization. Tasks, resources, ways of functioning and results should be analyzed. It is the job of health systems research to examine the issues in the health sector and make recommendations to the agency concerned with implementation. The results must be passed on to policy-makers and health personnel with a view to bringing about improvements. The best way to carry out the research is to cooperate with clinical research workers within the health services system. Clinical research aims at evaluating diagnostic and therapeutic methods through controlled trials. The health sector has a clear responsibility to check continually the quality and efficiency of its services. Unfortunately, clinical personnel rarely have time to reflect on the way in which resources are allocated. Not surprisingly, there are regional differences in clinical style which are far greater than can be explained by medical science, and they undoubtedly have important medical and economic implications.

It is important to understand the wide limits within which both patients and health personnel act on a basis of intuition and incomplete knowledge. There are immense variations in the use of resources and in medical outcomes, often to the detriment of efficiency.

As the rate of economic growth decreases, striking the balance referred to earlier becomes more difficult. A number of questions call for research. What, for instance, are the effects of reimbursement systems? Does the new system of block grants make local authorities set their priorities differently from the way they did when they received earmarked grants or the partial refunding of expenses for tasks specified by the central government? Health systems research should provide insight into how organizational structures and decision-making systems influence the capability of central and local authorities to run the health services according to plan and schedule. It has been argued that reduced economic growth makes it impossible to channel more money into such research, but the realistic view indicates the opposite: slower economic growth means that there is a greater need for critical evaluation of the way scarce resources are spent.

The main goal of health systems research is to assist in the provision of better care with wider coverage of the population and at the minimum possible cost. It can do this by providing answers to questions about the functioning of health care systems, and options for remedial action in relation to problems in health care. It is, therefore, a powerful method which should be of use to policy-makers, managers of services and those working in the health care system. Experience shows that as soon as one problem is solved, others arise, so that health systems

research is a continuous activity that should be an integral part of the general process of health care. Health systems research is essentially linked to decision-making and concerned with solving problems of high priority.

If health systems research is potentially so valuable, why is it not more widely used? The reasons seem to be many and they include, firstly, a lack of awareness of the value of health systems research by senior policy-makers, so that they fail to support efforts to develop and use the method. Secondly, service managers are generally unfamiliar with health systems research, and do not understand how they can use it to help solve the problems encountered in their duties. In common with other research, health systems research is seen as an academic activity for which managers have no time or resources. Finally, there are few research workers trained and experienced in health systems research and interested in pursuing this type of research rather than laboratory or clinical research.

There is ambivalence about depending on clinical and laboratory research for proper decision- and policy-making purposes. This might not be directly related to the decision-makers and health managers. The vital aspect of clinical and laboratory research is confirmation of the existence of diseases which allows a strategy to be formulated accordingly. It is, therefore, necessary to encourage clinical and laboratory research within the general health systems research. It is argued that clinical and laboratory research is also part of the health system and interrelated with the overall research of the services.

In Nepal, Less than 1% of the gross national health budget is allocated for health research. The public sector is the major funding agency for research in the health sector. There is a vital need to improve the funding position of research through seeking alternative resources, such as from private organizations. There is a need to implement the international commitment made by the national government and external development partners in various forums. As per International Conference for Health Research Development", Bangkok, 10-13 October, 2000, recommendation , Mexico Ministerial level summit 2004 endorsement and Bamako Mali Ministerial summit 2008 commitment, Nepal Government need to contribute 2% of the total National Health sector budget and 5% of all External Development Partners (EDPs) health sector development budgets to health research.

Who should be involved in HSR?

The participatory nature of health systems research is one of its major characteristics. To ensure that the research is relevant and appropriate, everyone directly concerned with a particular health or health care problem should be involved in the research project(s) focused on it. This may include policymakers, managers from the health and other public services involved, health care providers and the community itself. Their involvement is critical if the research activities are to make a difference:

- If decision-makers are only involved after completion of the study, the report may just be shelved.

- If staffs of health and other public services are only involved in data collection and not in the development of the proposal or in data analysis, they may not be motivated to collect accurate data or carry out the recommendations.
- If the community is only requested to respond to a questionnaire, the recommendations from the study may not be acceptable.
- If professional researchers are not involved in the implementation of recommendations, they may have little concern for the feasibility of the recommendations.

The roles that various types of participants will play in the research project will depend on the level and complexity of the particular study as well as its area of focus. Some projects are very complex and may need expertise from several levels, sectors and disciplines. Others may focus on simpler problems and require a more modest set-up. Health personnel may even play a major role in simple studies focusing on practical problems in their own working situations, although their projects may require assistance from researchers with skills in relevant disciplines.

Guidelines for HSR

Bearing in mind that HSR is undertaken primarily to provide information to support decision-making that can improve the functioning of the health system, we summarize by suggesting some essential guidelines for success:

1. HSR should focus on priority problems in health care.
2. It should be action-oriented, i.e., aimed at developing solutions.
3. An integrated multi-disciplinary approach is required, i.e., research approaches from many disciplines are needed since health is affected by the broader context of socio-economic development.
4. The research should be participatory in nature, involving all parties concerned (from policymakers to community members) in all stages of the project.
5. Studies should be scheduled in such a way that results will be available when needed for key decisions; research must be timely. Otherwise, it loses its purpose.
6. Emphasis should be placed on comparatively simple, short-term research designs that are likely to yield practical results relatively quickly. Simple but effective research designs are difficult to develop but much more likely to yield useful results when needed.
7. The principle of cost-effectiveness is important in the selection of research projects. Program management and operational research should focus, to a large extent, on low-cost studies that can be undertaken by management and service personnel in the course of daily activities. (There is a need for larger studies as well, however, which may require outside funding and full-time research staff.)

8. Results should be presented in formats most useful for administrators, decision-makers and the community. Each report should include:

    - A clear presentation of results with a summary of the major findings adapted to the interests of the party being targeted by the research.
    - Honest discussion of practical or methodological problems that could have affected the findings.
    - Alternative courses of action that could follow from the results and the advantages and drawbacks of each, formulated with inputs from all parties concerned.

9. Evaluation of the research undertaken should concentrate on its ability to influence policy, improve services and ultimately lead to better health, rather than on the number of papers published.

Thus, an HSR project should not stop at finding answers to the questions posed, but include an assessment of what decisions and activities have evolved from the study.

(This module is adapted from Designing and Conducting Health System Research Projects, Health System Research Training Series Volume 2 developed by IDRC and WHO.)

Session 4: An Overview of Health Research Proposal Development Steps

Time frame: 1 hour 15 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **State** the steps for health system research proposal development.
2. **Define** the different steps of research proposal development

Teaching methods: Mini- lecture followed by discussion 60 minutes (lecture 45 minutes and discussion 15 minutes) and 15 minutes will be allocated for questions and answers.

Course contents:

I. Various components of health system research proposal development

Introduction of research proposal

A research proposal is a written document specifying what the investigator proposes to study and is, therefore, written before the project has commenced. Proposals serve to communicate the research problem, its significance, and planned procedures for solving the problem to some interested party.

Proposals are written for various reasons. A student enrolled in a research class is often expected to submit a brief plan to the professor before data collection actually begins. Most universities students are engaged in research for thesis or dissertation. Funding agencies that sponsor research almost always award funds competitively and use proposals as a basis for their funding decisions.

Proposal prepared for different reasons vary in the amount of detail expected but, like research reports, often have similar content. In the next section, we provide some general information regarding the content and preparation of research proposal for the National Institutes of Health (NIH), the federal agency that sponsors a great number of nursing studies.

Overview of proposal preparation

Reviewers of research proposals, whether they are faculty, funding sponsors, or peer reviewers, want a clear idea of what the researcher plans to do, how and various tasks are to be accomplished, and whether the researcher is capable of successfully following the proposed plan of action. Proposals are generally evaluated on a number of criteria, including the importance of the research question, its theoretical relevance, the adequacy of the research methods, the availability of appropriate personnel and facilities, and, if money is being requested, the preparing research proposals follow.

Proposal content

A researcher preparing a proposal will almost always be given a set of instructions that indicate the format to be followed. Funding agencies often supply an application kit that includes forms to be completed and a specified format for organizing the contents of the amount of detail required may vary widely, there is considerable similarly in the type of information that is expected in research proposals. The major "ingredients" normally included in research proposals are described in the following sections.

Proposal summary

Proposal often begin with a brief synopsis of the proposed research. The summary helps to establish a frame of reference for the reviewers as they begin to read the proposal. The abstract should be brief (about 200 to 300 words in length) and should concisely state the study objectives and methods to be used.

Statement of the problem

The problem that the intended research will address is ordinarily identified early in the proposal. The problem should be stated in such a way that its importance is apparent to the reviewer. On the other hand, the researcher should not promise more than can be produced. A broad and complex problem is unlikely to be solvable or manageable.

Significance of the problem

The proposal needs to be clearly described how the proposed research will make a contribution to knowledge. The proposal should indicate the expected generalizability of the research, its contribution to theory its potential for improving nursing practice and patient care, and possible application or consequences of the knowledge to be gained.

Background of the problem

A section of the proposal is often devoted to an exposition of how the indented research builds on what has been done in an area. The background material should strengthen the author's arguments concerning the significance of the study, orient the reader to what is already proposed research will augment that knowledge; it should also serve as a demonstration of the researcher's command of current knowledge in a field.

Objectives

A specific, achievable objective provides the reader with clear criteria against which the proposed research methods can be assessed. Objective stated as research hypotheses or specific models to be tested are often preferred. Whenever the theoretical background of the study, existing knowledge, or the researcher's experience permits an explicit prediction of outcomes, these predictions should be included in the proposal. Avoid the use of null

hypothesis, which create an amateurish impression. In exploratory or descriptive research, the formulation of hypothesis might not be feasible. Objectives may, in such cases, be most conveniently phrased as questions.

Methods

The explanation of the research methods should be thorough enough that a reader will have no question about how the research objectives will be addressed. A thorough methods section includes a description of the sampling plan, research design, instrumentation, specific procedures, and analytic strategies, together with a discussion of the rationale for the methods, potential methodological problems.

The work plan

It is customary for the proposal to describe the plan according to which the various tasks and subtasks will be accomplished. In other words, the researcher indicates the sequence of tasks to be performed, the anticipated length of time required for their accomplishment. The work plan indicates to the reader how realistic and through the researcher has been in designing the study.

Personnel

In proposals addressed to funding agencies, the qualifications of key project personnel should be described. The research competencies of the project director and other team members are typically given major consideration and team members are typically given major consideration in evaluating a proposal.

Facilities

The proposal should document the extent to which special facilities required by extent to which special facilities required by the project will be available. Access to physiologic instrumentation, libraries, data processing equipment, computers, special documents or records, and so forth should be described to reassured sponsors or adviser that project will be able to proceed as planned. The willingness of the institution with which the researcher is affiliated to allocate space, equipment, services, or data should also be indicated.

Budget

The budget translates the project activities into monetary terms. It is a statement of how much money will be required to accomplish the various tasks. A well-conceived work plan greatly facilitates the preparation of the budget. If there are inordinate difficulties in detailing financial needs, there may be reason to suspect that the work plan is insufficiently developed.

General Tips on proposal preparation

Although it would be impossible to tell readers exactly what steps to follow to produce a successful proposal, we can offer some advice that might help to minimize the anxiety and frustration that often accompany the preparation of a proposal. Many of the tips we provide are especially relevant for researchers who are preparing a proposal for the purposes of securing funding for a research project.

1. Review A Successful Proposal

   Although there is no substitute for actually doing ones own proposal as a learning experience, beginning proposal writers can often profit considerably by actual seeing the "real thing." The information in this chapter is useful in providing some guidelines, but reviewing an actual successful proposal can do more to acquaint the novice with how all pieces fit together than all the textbooks in the world.

   Chances are some of your colleagues have written a proposal that has been accepted (either by a funding sponsor or by a dissertation committee), and many people are glad to share their successful efforts with others. Also proposals funded by the federal government are generally in the public domain. That means that have obtained federal funding by writing to the sponsoring agency.

   In recognition of the need of beginning researchers to become familiar with successful proposals, *The Western Journal of Nursing Research* has published proposal in their entirety (with the exception of administrative information such as budgets), together with the critique of the proposal prepared by a panel of expert reviewers. For example, the first such published proposal was a grant application funded by the division of Nursing Management" (Clinton, 1985). Another journal, *Grants Magazine*, also publishes successful proposals.

2. Pay Attention to Reviewers' Criteria

   In most instance in which research funding is at stake, the funding agency will provide the researcher with information about the criteria that reviewers use in making funding decisions. In some cases, the criteria will simply be a listing of questions that reviewers must address in making a global assessment of the proposal's quality. In other cases, however, the agency will be able to specify exactly how many points will be assigned to different aspects of the proposal on the basis of specified criteria. As an example, the development funded some research project relating to fertility regulation using the following evolution criteria:

   Conceptualization of the problem: Ability of the researcher to conceptualization the problem, including the operationalizing and quantifying of measures, and the development of a theoretical/conceptual framework. (0 to 30 points)

Project staff qualifications and availability: Adequacy of relevant training and experience of the proposed staff. (0 to 15 points)

Appropriateness of allocation of personnel and time to accomplish objectives of the project (0 to 10 points)

Data sources and analysis: Demonstration for identifying and obtaining access to pertinent and relevant sources data and adequacy of plans data analysis. (0 to 20 points)

Review and analysis of literature: Adequacy of the review and analysis of the literature in term of scope and depth and extent to which research needs in theoretical, methodological, and analytical area are delineated. (0 to 15 points).

Facilities and equipment: Adequacy of computer facilities and other equipment that would be needed in the performance of the research (0 to 10 points)

Different agencies established different criteria for different types of research projects. The wise researcher will learn what those criteria are and pay careful attention to them in the development of the research proposal. In the example of reviewer's criteria a maximum of 100 points was awarded for each competing proposal. The proposal with the highest scores would ordinarily be most likely to obtain funding. Therefore, the researcher should pay particular attention to those aspects of the proposal that contribute most to an overall high score. In the example, it would have little sense to put 85% of the proposal development effort into the literature review section, when a maximum of 15 points could be given for this part of the proposal.

3. Be Judicious in Developing a Research Team

For projects that are funded, reviewers often give considerable weight to the qualifications of the people who will conduct the research. In the example of reviewers 'criteria, a full 25 of the 100 points were based on the expertise of the research personnel and their time allocations. The person who is in the lead role in the project – often referred to as the principal investigator of PI – should carefully scrutinize the qualifications of the research team. It is not enough to have a team of competence. A project team of three brilliant theories without statistical skills in a project that proposes sophisticated multivariate techniques may have difficulty convincing reviewing that the project would be successful. Gaps and weakness can often be compensated for by the judicious use of consultants.

Another shortcoming of many project teams in that they often look as though there are too many managers. It is generally unwise to load up a project staff with five of more top-level professionals who are only able to contribute 5% to 10% of their time to the project. Such projects often run into management difficulties because of work. Although collaborative efforts are to be commended, you should able to justify the

inclusion of every staff person and identify the unique contribution that each will make to the successful completion of the project.

4. Justify and Document your Decisions

   Unsuccessful Proposals often fail because they do not provide the reviewer with confidence that adequate thought and consideration has been given to a rationale for decisions. Almost every aspect of the proposal involves a decision- the problem selected, the population studied the size of the sample, the data collection procedures to be used, and the personnel who will work on the project and the so on. These decisions should be carefully made, keeping in mind the costs and benefits of an alternative decision. When you are satisfied, you should be ready to define your decision by sharing the rationale with the reviewers. In general, insufficient detail is more detrimental to the proposal than an overabundance of detail, although page constraints may make full detail impossible.

5. Arrange for a Critique of the Proposal

   Before formal submission of proposal, a draft should be reviewed by at one other person, preferably someone with relevant methodological and substantive strengths in the proposed area of research. (Ideally, if the proposal is being submitted for funding, then reviewer will be someone who is knowledgeable about the funding source.) If a constant has been proposal because of specialized expertise that you believe will strength the study, then it would be very advantageous to have that consultant participate in the proposal development by reviewing the draft and making recommendations for its improvement.

The steps of health system research proposal development

Questions you must ask	Steps you will take	Important elements of each step
What is the problem and Why should it be studied?	Selection, analysis, and statement of the research problem	- Problem identification - Prioritizing problem - analysis - justification
What information is already available?	Literature review	- Literature and other available information
Why do we want to carry out the research? What do we hope to achieve?	Formulation of objectives	- general and specific objectives - hypothesis - Variables
What additional data do we need to meet our research objectives? How are we going to collect this information?	Research methodology	- types - data-collection techniques - sampling - plan for data processing and analysis - ethical considerations - pretest or pilot study
Who will do what and when?	Work plan	- personnel - timetable
How will the project be administered? How will utilization of results be ensured?	Plan for project	- administration - monitoring - identification of potential users
What resource do we need to carry out the study? What resource do we have?	Budget	- material support and equipment - money
How will we present our proposal to relevant authorities and potential funding agencies?	Proposal summary	N.B. Development of a research proposal is often a cyclical process. The arrows indicate that the process is not always linear

Session 5: Identification, Analysis and Formulation of Health Systems Research Problem

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Define and identify the health systems research (HSR) problem,
2. Analyze a selected HSR problem and the factors influencing it, and
3. Justify the HSR problem in the form of statement.

Teaching Methods:

Mini-Lecture (30 minutes and group exercise (1 hour 30 minutes) on identification and analysis of HSR problem including the factors influencing it

Course Content:

Definition of the HSR problem
Identification of the HSR problem
Analyzing the HSR problem
Justification of the HSR problem

Introduction

A research necessarily begins any study with a problem. The source of research problems will vary according to the experience of the person contemplating an investigation, but it is generally agreed that the process begins with an idea or need. Wherever the process starts, it will always end in a problem area.

Broadly speaking, any question that you want answered and any assumption or assertion that you want to challenge or investigate can become a research problem. However, it is important to remember that not all questions can be transformed into research problems and some may prove to be extremely difficult to study.

The beginner in research, most frequently the one with no previous research experience, oftentimes confuses a problem with the problem area. If asked, “In what areas are you particularly interested?” they may reply, “Well, I am interested mostly in health systems administration.” Or, they may mention health promotion, outdoor education, or some other problem area, but are vague as to a specific problem. Each of those areas contains innumerable research problems. There are many reasons why people engage in research. Curiosity is as good a motivational factor as any.

"Potential research questions may occur to us on a regular basis, but the process of formulating them in a meaningful way is not at all an easy task".

Identification of the Research Problem

First and foremost step in a scientific method is the identification of the problem. An investigation is not carried out simply for the sake of investigation. To initiate an investigation, there should be pre-occurred ideas that generated the necessity for the investigation to be carried out. The ideas are developed while going though literatures, discourses with experts and continuation of activities related to the subject matter. These ideas develop into some specific topics that will be interesting or rewarding if investigated. These topics generally called problems.

Problems are identified by means of group participation. A group of knowledgeable persons are identified and their statements in negative sense are collected and grouped into different groups. Then, from each group, a statement which appears most representative of the group is selected. These statements are arranged in sequential order as they appear to the group of experts in the subject matter. These statements are called problems.

The research problem serves as the foundation of a research study: if it is well formulated, you can expect a good study to follow.

Guidelines for selecting problems are:

1. The problem should be such in which the researcher may be deeply interested.
2. The problem should be allied with the chain of thinking. Stray problems if selected become difficult to co-ordinate and do not add to the wholesale development of the theory.
3. The problem selected should not necessarily be new one. It may be old problem or one on which work has already been done i.e., verification of old problem may be equally useful.
4. The problem should be within manageable limits i.e. it should not be too comprehensive.

Criteria of Good Problem are:

1. It should express a relation between two or more variables.
2. It should be stated clearly and unambiguously.

Problem definition may include information on:

1. **Magnitude:** What is the incidence and prevalence of the problem?
2. **Time Frame:** When does it occur? Is it current?
3. **Geographic area:** Where does the problem generally occur?
4. **Population:** Does the problem affect certain groups of people? If so, what are their characteristics?

5. **Why?** What are the probable reasons for the problem? Is there agreement or conflict over these reasons?
6. **Solutions:** What solutions have already been tried? How successful have they been? What untried solutions might there be?
7. **Unanswered Questions:** What parts of the problem need further research?

Research Problem Analysis

In HSR, the researcher is often required to do research on a problem with which he or she is not very familiar. Health workers and managers or community members may be mush more familiar with the problem. But even they may never have given critical attention to the various aspects of the problem.

A systematic analysis of the problem, completed jointly by the researchers, health workers, managers, and community representatives is a very step in designing the research because it:

1. Enables those concerned to pool their knowledge of the problem,
2. Clarifies the problem and the possible factors that may be contributing to it, and
3. Facilitates decisions concerning the focus and scope of the research.

Steps in analyzing the problem:

Step 1 Clarify the viewpoints of managers, health-care workers, and researchers in relation to the problem

Areas of concern within the health system are often expressed in broad or vague terms by managers and health care workers.

For Example,

"Care of diabetic patient needs review"
"Outpatient services must be evaluated"

"Bypassing of peripheral facilities should be investigated"

During initial discussions with managers and health-care workers who are involved in the problem area, clarify the issues by **listing all the problems** in the area of concern, as they **perceive** them.

Remember that a problem exists when there is a discrepancy between "what is" and "what should be". Therefore, the perceived problems should be worded in such a way as to illustrate this discrepancy.

For example, health care managers and workers may determine that the general concern that "care of diabetic patients needs review" includes the following problems:

- *Insufficient awareness of diabetes and of self care measures among diabetic patients and their relatives;*
- *Insufficient peripheral facilities for long-term follow-up care;*
- *Excessive rate or re-admissions among diabetics;*
- *Inappropriate management of complications in diabetic patients;*
- *High rate of diabetic complications;*
- *Poor compliance of patients with therapy; etc.*

Step 2 Further specify and describe the core problem

You should then try to identify the core problem and quantity it. Looking at the example discussed in step 1, you may decide that the core problem includes:

- The high rate of re-admissions among diabetes (a discrepancy between what is and what should be in the services)
- The high rate of diabetic complications (a discrepancy between what is and what should be in the health of the patients);

You should attempt to describe more elaborately:

- The **nature** of the problem; the discrepancy between "what is" and what you prefer the situation to be, in terms of re-admissions and /or complications;
- The **distribution** of the problem - who is effected, when, and where; and
- The **size** and **intensity** of the problem - is it widespread, how server is it, what are its consequences (such as disability, death, and waste or resources).

Step 3 Analyze the problem

After identifying the core problem you should:

- Identify factors that may have contributed to the problem.
- Clarify the relationship between the problem and contributing factors.

It is helpful to visualize this inter-relationship in the form of a **DIAGRAM**.
Perceived problems and factors contributing to these problems may be placed in "balloons". The relationship between them can be indicated by arrows that can be either one-way arrows (for cause effect relationships) or two-way arrows (for mutual relationships). The core problem can be identified by drawing a double line around it.

Analysis of the problem involves several sub-steps:

Step 3.1 Write down the core problem(s) as defined in step 2 in the center of a blackboard or flip chart.
Step 3.2 Brainstorm on possible causes or factors contributing to the problem.
Step 3.3 Identify further contributing factors.
Step 3.4 Attempt to organize related factors together into larger categories, and develop your final draft of the diagram.

Justification of the Research Problem

Research is often expensive and time consuming and most funding agencies are reluctant to support studies unless the results have direct program implications. When funds are limited (as they almost always are), it is especially important for the research investigator to justify the proposed research problem / study carefully. In writing the justification, it is usually helpful to consider the following questions and then arrange the answers to these questions into a few concise paragraphs.

1. **Is the problem a current and timely one?** In other words, does problem exist now? Current problems are more likely than past problems to receive funding.

2. **Does the problem have life-threatening or serious morbidity consequences?** Poor surgical technique during sterilization can have life-threatening or serious morbidity consequences for the patient, whereas occasional spotting from IUD use generally does not have serious consequences.

3. **Does the problem affect or potentially affect a large number of people?** Some problems, such as thromboembolism from contraceptive pill use, are life threatening, but of all the people who use oral contraceptives, relatively few are affected. In countries where sterilization is widely used, other problems, such as anesthesia overdose, tetanus and intra-peritoneal hemorrhage, may affect a large number of people.

4. **Does the problem relate to on-going program activities?** That is, does the problem have implications for current programs? For example, a study comparing failure rates and complications of different IUDs is not likely to have major program implications in a country where the IUD is not commonly used.

5. **Does the problem have broad social, economic, political or health implications?** Some studies may impact many different activities. For example, using non medical personnel to provide contraceptive methods may lower maternal mortality and fertility rates and thus have broad social, economic and political ramifications.

6. **Is the problem viewed as a concern by many different people?** A research problem that evokes the concern of many different people - administrative, politicians, health professionals, the general public-is more likely to receive priority funding than one that only a small group of researchers view as a concern.

7. **Have many studies already addressed the problem?** For some reproductive health issues study has been extensive, and much is already known about the etiologies of the problem. For example, the complications and failure rates of different IUDs have been widely studied. Would another IUD study add significant new information?

What information should be included in the statement of the problem?

1. A brief description of socioeconomic and cultural characteristics and an overview of health status and the health –care system in the country or district in as for as these are relevant to the problem. Include a few illustrative statistics, if available, to help describe the context in which the problem occurs.

2. A concise description of the nature of the problem (the discrepancy between what is and what should be) and of its size, distribution, and severity (who is affected, where, since when, and what are the consequences for those affected and for the services)?

3. An analysis of the major factors that may influence the problem and a convincing argument that available knowledge is insufficient to solve it.

4. A brief description of any solutions that have been tried in the past, how well they have worked, and why further research is needed?

5. A description of the type of information expected to result from the project and how this information will be used to help to solve the problem.

6. If necessary, a short list of definitions of crucial concepts used in the statement of the problem.

A list of abbreviations may be annexed to the proposal, but each abbreviation also has to be written out in full when introduced in the text for the first time.

Group Exercise I

How to identify the problem?

Country X has a shortage of trained health professionals to provide intrauterine devices (IUDs) to women in rural regions. Therefore, the government initiated a program in 1985 to provide two months of training in family planning to traditional midwives. A study will be conducted to determine IUD retention rates for village women who received IUDs from rural midwives and those who received IUDs from physicians or nurse-midwives in a clinic setting.

Trained health professionals are currently in short supply in rural areas of country X. Consequently, women residing in rural areas have not adopted effective methods of birth control.

In many developing countries, and particularly in rural areas, where there are few trained health providers, auxiliary personnel serve as health care providers. Thus, since 1985, traditional midwives have been providing family planning services to rural women in country X.

The traditional midwives are well accepted as paramedics in rural areas. Their traditional tasks of delivery and care of the mother and child permit them to easily provide family planning services to those mothers who wish them. The effect of traditional midwives on people's decisions to use contraceptives and their continued use in rural country X has never been evaluated.

In addition, this problem needs to be studied in the context of previous studies about IUD insertion performed by rural midwives versus insertion by physicians and trained nurse-midwives.

Read the above statement and identify following things:

- Magnitude of the problem
- Time frame
- Geographic area
- Population
- Why
- Solution
- Unanswered questions

Solution

Country X has a shortage of trained health professionals to provide intrauterine devices (IUDs) to women in rural regions. Therefore, the government initiated a program in 1985 to provide two months of training in family planning to traditional midwives. A study will be conducted to determine IUD retention rates for village women who received IUDs from rural midwives and those who received IUDs from physicians or nurse-midwives in a clinic setting. Trained health professionals are currently (time frame) in short supply ***(magnitude of the problem)*** *in rural areas of country X* ***(geographic area)***. *Consequently, women residing in rural areas* ***(population)*** *have not adopted effective methods of birth control.*

In many developing countries, and particularly in rural areas, where there are few trained health providers, auxiliary personnel serve as health care providers. Thus, since 1985, traditional midwives have been providing family planning services to rural women in country X ***(solution)***.

The traditional midwives are well accepted as paramedics in rural areas. Their traditional tasks of delivery and care of the mother and child permit them to easily provide family planning services to those mothers who wish them ***(elaboration)***. *The effect of traditional*

midwives on people's decisions to use contraceptives and their continued use in rural country X has never been evaluated ***(unanswered questions)***.

In addition, this problem needs to be studied in the context of previous studies about IUD insertion performed by rural midwives versus insertion by physicians and trained nurse-midwives.

Group Exercise II
How to identify the HSR problem?
There is a village in a rural area, composed of 500 household with the population of 2000 persons. Most of the people lived there were Tharu. About 80 percent of the people were farmers and 20 percent were working in town. Most of the households were scattered along the small canals. In general, the villagers looked healthy. People did not consider themselves sick if they were able to work. There were two outbreaks of Cholera in the past causing a few death. Tuberculosis and intestinal diseases were fairly prevalent but were rarely cause of death. Folk healers and traditional medicine were common means of treatment of illness among the villagers. However, a health center was somewhat 10 km away from the village.

One day a three year old girl got sick with Japanese Encephalitis (JE). Her parents, who were farmers after an initial period of apparent unconcern, consulted with their neighbors and were taking some traditional medicine. A week later, the small son of a town worker family contracted the same disease. His parents rushed him to the hospital in town. The child treated by the folk healer died and the child who went to the hospital cured.

Local administrative and health officers were alert by this event and arranged for emergency immunization program. The villagers were informed to take their children for JE vaccination on a certain date. The message from the officer was given to the VDC Chairperson who in turn asked his relatives to inform the villagers.

On the day of vaccination, the response was spotty and patently inconsistent. It was found that most of the families around the houses of the child who was survived from the disease came for vaccination, the rest were not interested.

(Read above statement and identify the major HSR problem)
Solution

Spotty and inconsistent response towards JE vaccination campaign
Difference in treatment seeking behavior between farmer's family and town workers family.

Group Exercise III
How to identify the HSR problem including the factors influencing it?
In district X (population 250,000), sanitary condition are poor (5% of households have latrines) and diseases connected with poor sanitation, such as hepatitis, gastroenteritis, and worms, are very common. The MoHP has initiated a sanitation project that aims at increasing the number of households with latrines by 15% each year. The project provides materials and

the population should provide labour. Two years later, less than half of the target has been reached.

(Read above statement and identify the major HSR problem including the factors that may be influencing it)

Solution

Difference in having latrines after two years (35% of the households should have latrines, but only 15% do have them)

Service-related factors:

Forgetting to adequately inform and involve the population,
Bottlenecks in the supply of materials, differences in training, effectiveness of sanitary staff etc.

Population-related factors:

Situations where community members lack an understanding of the relationship between disease and sanitation or have a greater interest in other problems etc.

SAMPLE for writing Problem Justification

Prophylactic use of Antibiotics at the Time of Intrauterine Device Insertion

The Ministry of Health and the Women's Development Movement have completed negotiations with an international donor for a US$ 5 million loan that will be distributed over the next 5 years. The funding will be used to double the existing network of family planning clinics in an effort to increase contraceptive prevalence from 12% to 35% by 1996.

Considerable controversy exists over whether or not to promote the use of IUDs in existing and future rural and urban family planning clinics because IUD use is associated with an increased incidence of pelvic inflammatory disease (PID) (Faulkner and Ory, 1976; Kaufman et al., 1980; Vessey et al., 1981). Two studies were conducted in Country X-one at the National Teaching Hospital in 1980 and one in three provincial hospitals in 1981. The findings indicated that between 28% and 35% of women examined in the obstetrics and gynecology wards had PID and suggested that PID may be a prevalent condition. PID is expensive and difficult to treat in most clinics. If untreated, PID can lead to infertility, a problem that is thought to be widespread in certain areas of Country X.

Thus, before the Ministry of Health can promote IUD use in these areas, methods for decreasing IUD-associated PID need to be identified. If IUDs can be used safely and if one-third of the new users of contraceptives used IUDs, the costs associated with family planning visits for resupply of oral pills and other contraceptives could be reduced by as much as 50%. Service providers could spend more time promoting family planning among unsaved high-risk women and thus increase the likelihood of achieving the country's goal for contraception.

A recent study conducted in the United States concluded that IUDs were associated with PID only at times of insertion or reinsertion (Burkman et al., 1981). Consequently, antibiotics given prophylactically to women at the time of IUD insertion may decrease the incidence of IUD-associated PID. However, no research has been conducted to test this hypothesis. The randomized clinical trial to be described is designed to test this hypothesis in rural and urban service delivery clinics in Country X.

Session 6: Formulation of Research Title, Objectives, Research Questions and Hypothesis

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **State** the reasons for writing objectives for research project.
2. **Define** and describe the difference between general and specific objectives.
3. **Define** the characteristics of research objectives.
4. **Prepare** research objectives in an appropriate format for the project.
5. **Develop** further research questions, and research hypotheses, if appropriate for study.
6. **Sate** the steps of formulating the title of research
7. **List** the criteria of formulating the title of research

Teaching Methods:

- Mini- lecture followed by discussion 45 minutes (lecture 30 minutes and discussion 15 minutes)
- Questions and answer (15 minutes)
- Brain storming exercise for selecting the title (15 minutes)
- Group work (45 minutes)

1. Choose a chairperson and a recorder.
2. Hang up the flip charts that you used to present your statement of the problem so they are visible to all group members. Incorporate useful suggestions for changes that were made when you presented them in plenary. Then, use the analysis diagram as a starting point for formulating objectives, focusing, for example, on:
    - Further quantifying and specifying the problem, if required;
    - Exploring the key factors or major groups of factors that, in your opinion, might influence or cause the problem; and/or

- Any other major research activities you propose.

3. Prepare a general objective and specific objectives for the research proposal you are developing.

4. After formulating your objectives ask yourself the following questions:

    - Do the objectives deal with all aspects of the research problem in a logical and coherent way?

    - Are the objectives clearly phrased?

    - Are the objectives defined in operational terms that can be measured? Are they realistic?

    - Do they indicate where the study will be conducted?

    - Do they include the development of recommendations for how the research results will be used to solve the problem?

5. Prepare a flip chart with your objectives for use in the **exercise** and in the plenary discussion. Add on the title of your study and revise it, if necessary, to match the objectives

6. Review of the objective of the other groups and comment on the given sheets.

Components	**Existing**	**comments**
Objectives		
Research questions		
Hypothesis		
Title		

Course contents

I. **Research objectives** /questions: basis for research objectives, characteristics of objectives, problems in formulating research objective

II. **Hypotheses**: need of research hypotheses, process of developing hypotheses, characteristics of hypotheses and testing of hypotheses,

III. **Title of the study,** essential of title**,** process of selecting title, tips for better title, criteria of selecting title, example of research titles,

I. Research objectives

The **OBJECTIVES** of a research project summarize what is to be achieved by the study and it should be closely related to the statement of the problem. For example,

- If the problem identified is low utilization of child welfare clinics, the general objective of the study could be to identify the reasons for this low utilization, in order to find solutions.
- If the problem identified is low utilization of maternal health services, the objectives could be identify factors that affect utilization of institutional delivery services.
- If the problem is the high level of hospital acquired infection, the objective would be to identify the reasons for high level of hospital acquired infection.
- If the problems of less patience compliance during the treatment of tuberculosis then the objective would be explore the reasons for non compliance.
- If the problem is unknown cause for example diarrhea outbreak in Jajarkot, the objective would be to identify the relationships between diarrhea and other environmental factors.

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

It is possible (and advisable) to break down a general objective into smaller, logically connected parts. These are normally referred to as **specific objectives.**

Specific objectives should systematically address the various aspects of the problem as defined under 'Statement of the Problem' and the key factors that are assumed to influence or cause the problem. They should specify **what** you will do in your study, **where** and **for what purpose**.

To explore to what extent community home-based care (CHBC) projects in Nepal provide adequate, affordable and sustainable care of good quality to people with HIV/AIDS, and to identify ways in which these services can be improved.

It was split up in the following specific objectives:

1. To identify the full range of economic, psychosocial, health/nursing care and other needs of patients and their families affected by AIDS.

2. To determine the extent to which formal and informal support systems address these needs from the viewpoint of service providers as well as patients.

3. To determine the economic costs of CHBC to the patient and family as well as to the formal CHBC programs themselves.

4. To relate the calculated costs to the quality of care provided to the patient by the family and to the family/patient by the CHBC program.

5. To determine how improved CHBC and informal support networks can contribute to the needs of persons with AIDS and other chronically and terminally ill patients.

6. To use the findings to make recommendations on the improvement of CHBC to home care providers, donors and other concerned organizations, including government.

The first specific objective usually focuses on quantifying or specifying the problem.

This is necessary in many studies, especially when a problem has been defined (but not quantified) for which subsequently the major causes have to be identified. Often use can be made of available statistics or of the health information system. In the study on the high defaulter rate of TB patients, this rate should first be established, using the records, and only then would the contributing factors to defaulting be analyzed.

In the example given, the needs of AIDS patients and their relatives for care and support have been defined in the first objective. The objectives which follow concentrate on adequacy, cost and quality of care provided whereas the last two objectives specify possible improvements with respect to CHBC, and to whom the results and recommendations of the study will be fed back.

Note:

It may be helpful to use the diagram as a point of departure and check whether the **problem** and all **major, directly contributing factors** (analytic study) or **major components** (descriptive or evaluation study) have been covered by the objectives. An objective indicating **how the results will be used** should be included in every operational study, either as part of the general objective or as a specific objective.

Why should research objectives be developed?

The formulation of objectives will help you to:

- **Focus** the study (narrowing it down to essentials);

- **Avoid** the collection of data which are not strictly necessary for understanding and solving the problem you have identified; and

- **Organize** the study in clearly defined parts or phases.

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

How should you state your objectives?

Take care that the objectives of your study:

- Cover the different aspects of the problem and its contributing factors in a **coherent** way and in a **logical sequence**;
- Are **clearly phrased** in **operational terms,** specifying exactly what you are going to do, where, and for what purpose;
- Are **realistic** considering local conditions; and
- Use **action verbs** that are specific enough to be evaluated.

Examples of action verbs are: to determine, to compare, to verify, to calculate, to describe, and to establish. Avoid the use of vague non-action verbs such as: to appreciate, to understand, or to study.

Keep in mind that when the project is evaluated, the results will be compared to the objectives. If the objectives have not been spelled out clearly, the project cannot be evaluated.

Using the previous example on cost and quality of CHBC, we may develop more specific **research questions** for the different objectives, such as:

- Do rural and urban CHBC projects differ with respect to the adequacy, quality, affordability and sustainability of HBC provided?
- How satisfied are AIDS patients, relatives and service providers with the care provided? Are there differences in perceptions between those groups?
- Is the stigma attached to being STDs cases?
- Is the stigma attached to being HIV+ the same strong for women as for men? Or are there gender differences in stigma?
- What impact does the care provided to AIDS patients have on the economy of the homestead? Is there competition with other basic needs (e.g. schooling of children, purchases of food)?

II. Hypotheses

Hypotheses are more specific predictions about the nature and direction of the relationship between two variables. *Not all the research need hypothesis, if the purpose of the research is the develop theory, they do not need to test the hypothesis but they can develop the hypothesis to test in future. Most of the interpretative research in social and behavior sciences develops model or theory therefore they need not test hypothesis. You must have hypotheses if you are going to test the theory or your research questions. There is the direct link between the research question and hypothesis development.*

"Those researchers who utilize an online grant writing tutorial will have higher priority scores on their next grant application than those who do not."

(Source: www.stat.ufl.edu/~winner/sta6934/hyptest.ppt)

Example Hypotheses

- **Null hypothesis -** New drug is no better than standard treatment (differences)
  - $H_0 : «_{New} - «_{Std} \le 0 \qquad («_{New} - «_{Std} = 0)$
- **Alternative hypothesis -** New drug is better than standard treatment[differences]
  - $H_1 : «_{New} - «_{Std} > 0$
  - (Source: www.stat.ufl.edu/~winner/sta6934/hyptest.ppt)

- "H_1: Older people will report more positive attitudes towards smoking than younger people." [differences]
- "H_1: There will be a positive linear relationship between attitudes to smoking & age, such that as age increases attitudes become more positive." [correlational]
- "H_1: It is predicted that there will be a positive relationship between self-esteem and academic performance, such that as self-esteem increases academic performance will also increase." [correlational]
  - *Source: http://wilderdom.com/courses/surveyresearch/assessment/labreport/ResearchQuestionsHypotheses.html*
- H_O"There no difference completing 4^{th} ANC visits between younger and older women (difference).
- There will be a positive liner relationship between sleeping and level of sugar in blood (correlational).
- Uterus prolapsed increased Obstetric malpractice increase.

A well-thought-out and focused research question leads directly into your hypotheses. What predictions would you make about the phenomenon you are examining? This will be the foundation of your application.

Strong hypotheses:

- Give insight into a research question;
- Are testable and measurable by the proposed experiments;
- Spring logically from the experience of the staff;
- Build on the basis of theory

Normally, no more than three primary hypotheses should be proposed for a research study. A proposal that is hypothesis-driven is more likely to be funded than a "fishing expedition" or a primarily descriptive study.

Make sure you:

- Provide a rationale for your hypotheses—where did they come from, and why are they strong?
- Provide alternative possibilities for the hypotheses that could be tested—why did you choose the ones you did over others?

If you have good hypotheses, they will lead into your Specific Aims. *Specific aims* are the steps you are going to take to test your hypotheses and what you want to accomplish in the course of the grant period. Make sure:

- Your objectives are measurable and highly focused;
- Each hypothesis is matched with a specific aim.
- The aims are feasible, given the time and money you are requesting in the grant.

An example of a specific aim would be "Conduct a rigorous empirical evaluation of the online grant writing tutorial, comparing outcome and process measures from two groups—those with exposure to the tutorial and those without."

Based on your experience with the study problem, it might be possible to develop explanations for the problem, which can then be tested. If so, you can formulate hypotheses in addition to the study objectives.

A HYPOTHESIS is a prediction of a relationship between one or more factors and the problem under study that can be tested.

In our example concerning the cost and quality of HBC in Zimbabwe it would have been possible to formulate and test the following hypotheses:

1. The role of first-line relatives in the provision of care to AIDS patients is more substantial in rural than in urban areas.

2. The silence and stigma surrounding AIDS makes the formation of self-help groups of AIDS patients and their relatives next to impossible, which in turn maintains the high level of stigma on HIV/AIDS.

Note:

Policy makers and field staff usually feel the need for research because they do **NOT** have enough insight into the causes of a certain problem. Therefore, most HSR proposals present the specific objectives in the form of **open statements** (as given in the examples earlier) instead of focusing the study on a limited number of hypotheses.

III. Title of the Study

Now you can finalize the title of your study. The title should be in line with your general objective. Make sure that it is specific enough to tell the reader what your study is about and where it will be calculated.

NOT: 'A study on community home-based care'

BUT: 'A study on cost and quality of community home-based care for HIV/AIDS patients and their communities in Zimbabwe'

You might also consider fancier titles:

'Do We Care? A study on cost and quality of CHBC for HIV/AIDS patients in Zimbabwe'*

Another example could be:

'WORKSHOPS: Blessings or Burdens? A study of the workshops held in 1999 in Province Y - Their utility and consequences for daily working activities of health staff'
For details visit http://www.idrc.ca/en/ev-56596-201-1-DO_TOPIC.html

The Relationship between the Research Question and Hypotheses

Before you begin writing a grant proposal, take some time to map out your research strategy. A good first step is to formulate a research question.

A Research Question is a statement that identifies the phenomenon to be studied. For example,

What resources are helpful to drug resistance cases of TB?"

What are the social and cultural factors that facilitate or hinder the STDs case management?

Is there the relationship between sleeping hours and diabetes?

Does use of helmet reduce the death rate of road traffic accidents?

To develop a strong research question from your ideas, you should ask yourself these things:

- Do I know the field and its literature well?
- What are the important research questions in my field?
- What areas need further exploration?
- Does my research question fall in priority area?
- Could my study fill a gap? Lead to greater understanding?
- Has a great deal of research already been conducted in this topic area?
- Has this study been done before? If so, is there room for improvement?
- Is the timing right for this question to be answered? Is it a hot topic, or is it becoming obsolete?
- Would funding sources be interested?
- If you are proposing a service program, is the target community interested?
- Most importantly, will my study have a significant impact on the field?

A strong research idea should pass the "so what" test. Think about the potential impact of the research you are proposing. What is the benefit of answering your research question? Who will it help (and how)? If you cannot make a definitive statement about the purpose of your research, it is unlikely to be funded.

A research focus should be narrow, not broad-based. For example, "What can be done to prevent substance abuse?" is too large a question to answer. It would be better to begin with a more focused question such as "What is the relationship between specific early childhood experiences and subsequent substance-abusing behaviors?"

Now Write It Up...

Once you've thought through the key elements of your research questions, hypotheses, specific aims, and research design, you have the ingredients for a concept paper. This is an important tool to help you to organize your thoughts, as well as to promote, disseminate, or get feedback on your ideas. A concept paper is a succinct description of your research plan (3 to 5 pages) and can be particularly useful when trying to recruit collaborators or solicit letters of support. It is also useful to send a copy of the concept paper to a NIDA Program Official in the branch or office that covers your topic area.

Research topics

Overarching dimension of research

Previous analyses have revealed a complex heterogeneity along which researchers classify HPSR in developing countries, which is not surprising in an interdisciplinary field [5]. However, five overarching dimensions can be recognized:

- concepts reflecting the health system, such as policy and financial structures, regulatory functions, processes such as technology evaluation and quality monitoring, and results such as satisfaction and health gain
- concept reflecting the health care service delivery such as quality of care, equitable access to and utilization of health care.
- the levels of the health system, such as the households and the community, first level facilities and hospitals
- the issues or problems pertaining to the health system such as priorities, equity and the public private mix
- the populations addressed by the system, such as children, mothers and the elderly, or rural and urban populations, the health needs addressed, whether in terms of risks or disease.

While these dimensions can be useful to characterize the research portfolio, it is clear that there will be overlaps; for example, equity is both an issue and an attribute of the health system, particularly if it has been integrated in monitoring and regulation. In order to make use of these dimensions it is proposed to consider as the project topic the first dimension of concepts pertaining to the health system structures, functions, processes and results. The topic could then be classified following normative or theoretical frameworks or by using the categories researchers apply in their own research.

The other four dimensions can be used to qualify the research topic as to provide a more detailed description. These four dimensions could be selectively used or aggregated to facilitate description according to the needs at hand.

References:

1. Gonzalez-Block M. A(2004). Health policy and systems research agendas in developing countries. Health Res Policy Syst. 2004; 2: 6. Published online 2004 August 5. doi: 10.1186/1478-4505-2-6. Copyright © 2004 Gonzalez-Block; licensee BioMed Central Ltd.

2. Resources for behavioral researchers, http://www.theresearchassistant.com/tutorial/ index. asp

Annex 1:

The following topics and responded by the funding agencies, research institutes and policy makers.

A total of 19 research topics were identified when aggregating portfolio (project) and priority (voiced preferences) data into the reference list. Topics ranged in frequency from 2% to 11% and were ranked in 8 classes. The highest ranking topic is "Sector analysis" with 11% followed by "Disease burden" with 9% and "Management and organization" with 8%. From here three topics rank lower equally at 7%, two ranks at 6%, seven rank at 4% and then two each at 3% and 2%. Categories at the bottom of this ranking are "Equity", "Policy process",

"Economic policy and health" and "Information systems". The emphasis of topics at the top end is then about five times as greater as those at the bottom end of the range.

In global perspective “Equity" appears so low in the aggregated ranking could be partly attributable to the fact that this topic was defined to include only projects and priorities having equity as the central topic and measuring it through multi-dimensional approaches such as health conditions, access to services and financing. A subsidiary analysis was thus undertaken to include under "Equity" those projects or priorities addressing equity or poverty as a secondary, qualifying, role of research on other topics. This broadened topic "Equity" climbs to fourth rank, at the same level as "Accessibility", "Program evaluation" and "Research to policy".

Public and private institutions show no significant changes in topic ranking (corr = 0.70). "Community participation" and "Accessibility" are the only topics with major differences, ranking higher among private institutions.

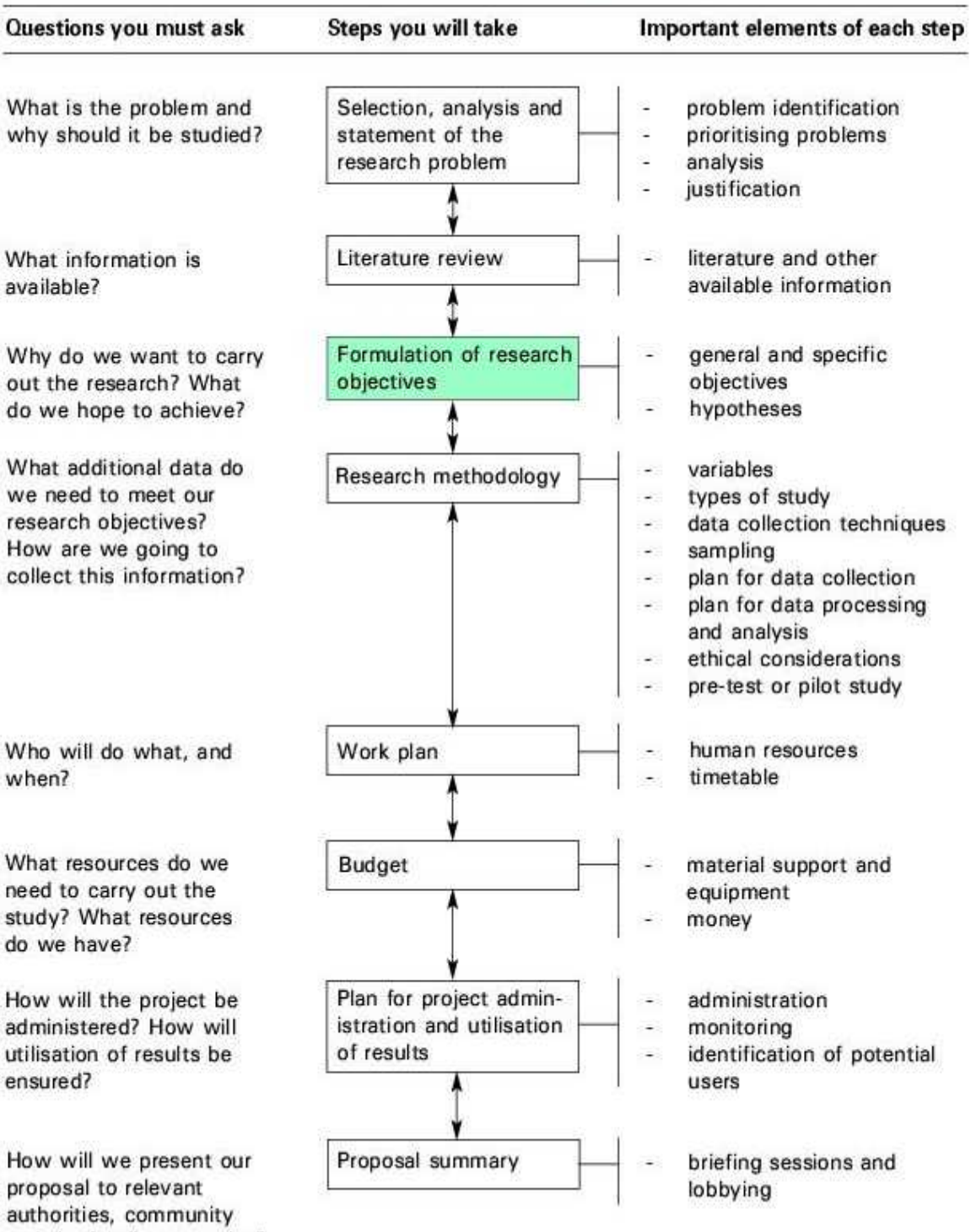
Glossary of Health Policy and Systems Terms Used for Content Analysis

TOPIC	**TERMS FOUND IN RESPONSES**
Accessibility	Health seeking behaviour, determinants of utilization, coverage, outreach, referral, barriers to care, willingness and capacity to pay, cost-sharing, price regulation, prices, equity in access, demand for health services.
Community participation	Community-based strategies, community participation in governance, empowerment, school health, family health strategies, social support networks.
Costing & cost effectiveness	Determination & evaluation of costs, cost-benefit of services, economic evaluation, cost-effectiveness of resource allocation, alternative uses for resources.
Decentralisation/local health systems	Decentralization policy and process, impact of decentralization on services and health outcomes, district health system development, healthy cities, municipal health services, local government, devolution, community participation in local health services.
Disease burden	Prevalence and incidence of diseases, mortality and morbidity, disease profiles, health status, health needs, burden of disease studies, risk factors, determinants of health and disease other than economic or social policy.
Economic policy and health	Free trade agreements and health, TRIPPS and health, economic crises and health, impact of poverty reduction and adjustment policies on health, debt reduction and health, social policy and health, social assistance and health issues, intersectoral co-ordination, labour policies and health.
Equity	Equity of health system, impact of health reforms on equity,

TOPIC	TERMS FOUND IN RESPONSES
	equity and poverty, poverty targeting of services, poverty and health, exclusion.
Financing	Financial mobilization, financial allocation, financing policies, national & district health accounts, financial equity, community health financing, financing of specific programmes.
Human resources	Personnel management, deployment, migration, motivation, knowledge, attitudes and practices of health personnel, satisfaction, quality of life, human resource policy, human resource performance, traditional healers, training and education of human resources, medical education curriculum assessment, evaluation of medical and nursing teaching programmes.
Information, education and communication (IEC)	Information and communication for the general public, health education strategies and impacts, knowledge attitudes and practices (KAP).
Information systems	Information needs, informatics, surveillance mechanisms and systems, strengthening of information systems, health monitoring systems, establishment of public domain databases, development of indicators for service management and policy.
Insurance	Risks and benefits covered by insurance schemes, community based health insurance, options for health insurance, insurance reform, impact of insurance on health and service outcomes.
Management & organization	Health service provider performance, delivery of services, administration, service management strengthening, contracting and provider payment mechanisms, impact of privatization on services, performance agreements, impact of hospital autonomy on service delivery, stakeholders in service management, community participation in management.
Pharmaceutical policy & management	Rational drug use, procurement, logistics, herbal medicine, dispensing practices, pharmaceutical regulation, national drug policy, essential lists.
Policy process	Stakeholder analysis, role and relationships of actors in the formulation and implementation of policy, role of government agencies in policy formulation, role of community and NGOs in policy formulation, factors influencing policy process, perceptions of policy, decision-making processes, policy negotiation.
Programme evaluation	Evaluation and assessment of impact of policies or programmes on specific diseases or services.
Quality	Clinical practice guidelines, evidence-based medicine, quality assurance, patient satisfaction.

TOPIC	TERMS FOUND IN RESPONSES
Research to evidence	Health systems research training, health systems research training, outcomes of research, research impact, policy utilization and impact of research, research methods, creation of national HPSR database, priority setting of health research, research ethics, essential national health research, dissemination of research.
Sector Analysis	Health sector reforms and implications, health systems development, private health service development, intersectoral collaboration and co-ordination, public/private mix health care, health care organization, regulation, policy formulation on specific diseases, on programmes or on aspects of the health system, sector-wide and system-wide performance.

Source: Gonzalez-Block M. A (2004).


Questions you must ask
Steps you will take
Important elements of each step
What is the problem and why should it be studied?
Selection, analysis and statement of the research problem
- problem identification
- prioritising problems
- analysis
- justification
What information is available?
Literature review
- literature and other available information
Why do we want to carry out the research? What do we hope to achieve?
Formulation of research objectives
- general and specific objectives
- hypotheses
What additional data do we need to meet our research objectives? How are we going to collect this information?
Research methodology
- variables
- types of study
- data collection techniques
- sampling
- plan for data collection
- plan for data processing and analysis
- ethical considerations
- pre-test or pilot study
Who will do what, and when?
Work plan
- human resources
- timetable
What resources do we need to carry out the study? What resources do we have?
Budget
- material support and equipment
- money
How will the project be administered? How will utilisation of results be ensured?
Plan for project administration and utilisation of results
- administration
- monitoring
- identification of potential users
How will we present our proposal to relevant authorities, community
Proposal summary
- briefing sessions and lobbying

Session 7: Accessing and Use Health Research Information, Literature Review and Referencing

Time frame: 5 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. To identify the detail of literature search via online and offline approach
2. To search Google, PubMed and HINARI more effectively
3. To analyze and use search material, more critically
4. To validate and authenticate the search literature
5. To use the referencing style more correctly

Teaching methods:

There will be 1hour mini-lecture session on Accessing and Use Health Research Information, Literature Review and Referencing and two hours will be given to online demonstration of literature search and literature review.

There will be 1 hour practical session on online search from pubmed, Hinari and google and 1 hour practical session on citation and referencing by using Endnote software.

Course content:

Accessing health information contains two larger components:

- **Literature Search**
- **Literature Review**

LITERATURE SEARCH

Literature search involves finding and read as many different references as possible to correlate the search query. It may be going through books/book chapters, journal articles, conference papers, web resources, government documents, standards, patents, etc. Just finding a few items on the web is not sufficient.

Develop a search strategy

Defining the search strategy should form part of the introduction to the literature review. It explains what limitations that have imposed on the review in terms of material read and dates

covered, as well as clarifying the terminology that is used to find the references. If you state clearly what the limitations of the literature review are, your reader cannot expect to read about alternative aspects.

- **What kind** of information? Decide what kinds of information you want to find.
  - Academic research only
  - Experimental results and data
  - An in depth report on a specific issue
  - A summary or overview of a topic
  - An official or government view
  - A popular or media view
  - Facts and figures

- **How much** information? Why are you writing the review/ This helps you to determine how much information you need.
  - Everything ever written
  - Just a few key references
  - Does language matter?
  - Your time constraints
  - LIMITS – define the topic and impose limits on the search? For example, limit by country, by an aspect of a topic, by views from a specific community, by specialty etc

- How **up to date** does the information need to be?
  - Make sure the time period the review covers.
  - Have you restricted it for pragmatic reasons (that's all that you had access to, or that's all you had time for) or because most literature on this topic was published within a specific time period?
  - Is it an update of an earlier review?
  - Does it need a historical underpinning?

- What **keywords and concepts** describe the topic?
  - Synonyms – alternative words and phrases
  - Broader and narrower terms
  - Alternative (and correct!) spellings

Gather information

Once you have a clear idea of what you need to find, you can search in the search engines like Google, Bing, Yahoo etc for general overview. Use PubMed and HINARI for specific

medical literature. You can use libraries (central library, national library), Nepal Health Research Council, Nepal Medical Association, Government offices, and concerned institutions and organizations for finding out local literatures.

There are various ways through which literature search can be done

1. Online
    a. PubMed
    b. HINARI
    c. Search Engines e.g. Google, Bing, Yahoo

2. Offline
    a. Library
    b. Institutions
    c. Government Offices

PubMed

Website: www.pubmed.com

Note: It is place where you search for the title and abstract of the articles.

PubMed is an on-line database developed by the National Library of Medicine that provides free access to MEDLINE records. MEDLINE is a subscription based bibliographic database that contains over 12 million citations and abstracts dating from the mid-nineteen sixties to present from more than 4,500 biomedical journals published in the United States and 70 additional countries. In addition to providing citations and abstracts from MEDLINE, PubMed also provides:

- Citations from Life Science journals not included in MEDLINE
- Access to full-text journal articles located at other web sites
- Access to the National Center for Biotechnology Information (NCBI) molecular biology databases

There are four medical journals being indexed in the MEDLINE from Nepal. They are; Journal of Nepal Medical Association, Journal of Nepal Health Research Council, Kathmandu University Medical Journal and Nepal Medical College Journal. You can find the article published in this Nepalese Medical Journal in the PubMed (www.pubmed.com).

HINARI

Website: www.who.int/hinari

Note: It is place where you search for the journal and then look for the full text article.

HINARI is the Health InterNetwork Access to Research Initiative. It was set up by the World Health Organization (WHO) and major publishers to enable developing countries to access collections of biomedical and health literature.

The Programme for Access to Health Research (HINARI) provides free or very low cost online access to the major journals in biomedical and related social sciences to local, not-for-profit institutions in developing countries.

HINARI was launched in January 2002, with some 1500 journals from 6 major publishers: Blackwell, Elsevier Science, the Harcourt Worldwide STM Group, Wolters Kluwer International Health & Science, Springer Verlag and John Wiley, following the principles in a Statement of Intent signed in July 2001. Since that time, the numbers of participating publishers and of journals and other full-text resources has grown continuously. Today more than 150 publishers are offering more than 7244 journals from HINARI as of August 14, 2010.

SEARCH ENGINES

There are various search engines for general search like Google, Bing, Yahoo etc.

- **GOOGLE**

Website: www.google.com Note: It is place where you search for the general information.

Today's web contains more than 10 BILLION web sites! There needs to be some way to catalog this information and search through it. That is what search engines attempt to do. You might get the information out of those billions of websites related to your research.

LITERATURE REVIEW

A literature review is summary of the findings of a literature search in terms of reliability, validity and applicability of the searched contents. It should provide clear justification for why the topic was searched should demonstrate that the latest relevant literature pertaining to topic of interest has been investigated well. It involves critical, constructive analysis of the searched literature. A good literature review will highlight any areas of controversy or

weakness and may also indicate possibilities for future research directions. The literature review should be able to gain an overview of the main issues surrounding the subject matter.

Beginning independent research for the first time can be a tricky task. Up until this point most of your work may have been guided by your lecturers, but now you have to select your own research topic and work out a plan for your work. It covers the information part of independent research.

It's likely that you will find far too much information and a key part of the literature review is knowing which references you should devote time to reading in full. You can't read everything you find; you will need to be selective and choose the key references by evaluating the results of your search. You probably do this instinctively, but read the guidelines below to help you to do it in a more structured way.

Evaluating your search results

Publisher

Who has published it

- Individual
- Organization
- Institute
- Researchers
- Scientist
- Authoritative

Authority

Authority is about whether the author of the article is an accepted expert in this field

- Who is the author? Have you heard of them?
- Do they have a reputation in this area of study?
- Can you tell if they an expert, a journalist, a student?
- Do they work at a recognized organization? E.g. a top class university or research institute.
- Are their credentials/ qualifications given?
- Have they been recommended by your lecturer?
- Websites – can you see who the author is?
- Does the URL give any indication of where the site is located?

Purpose

- What is the purpose of the article/book?

- Is it to inform, persuade, present opinions, report research, sell a product?
- Who is the intended audience?
- Does it show any bias? Be careful, skilled writers can make you think that their interpretations of facts are facts.
- Is the language objective (factual) or emotive?

Type of resource

The type of resource can also give an indication of it's usefulness to you.

- Is it a book, journal, web site, video, statistics, government document, letter, diary, manuscript, map, newspaper?
- If a journal, what type? (if you don't know about different journal types read the section on Journals types)
- Can you infer anything from the type of resource?

References

- Is there a list of references at the end of the article?
- Is it correctly placed?
- Is it extensive?
- Does it include all the details you would need to follow up the references?
- Does the website link to “quality” sites?

Suitability

- Is it at the right level for you?
- Can you understand it?
- Is there enough information? Too much? Too little?
- Does it support your initial point of view, or do you need to change it?

Moving from the results list to the full text of the references

- Check the Library’s Electronic Journals list to see if we have access to full-text
- Check the Library catalogue to see if we have the journal in print
- Use Inter Library loans to obtain material which is not available in print or electronically.

Use of Literature

The use of literature information is very important in your work. Many a times, it has been seen that ‘copy’ and ‘paste’ of the text. But, ideally, you have to use the gist of information in your own word.

THE REFERENCING

Referencing is a system, which has been used, in the scientific and academic community to indicate from where an idea, theories, quotes, facts and any other evidence and information have been taken to support your research, work and writing.

Referencing is important in the Academic Community for a number of reasons:

- To avoid Plagiarism, a form of Academic Theft
- Referencing your work correctly ensures that you give appropriate credit to the sources and authors that you have used to support your research.
- Referencing the sources that you have used for your work demonstrates the evidence and research that you have undertaken to complete and support your ideas.
- Referenced work enables the reader to independently consult the same materials that you have used.

There are various styles (methods) of citing evidences in your work. They have been developed by various organizations and institutes and popularly carry their name for reference style as;

- American chemical society ACS)
- American physical society (APS)
- American psychological society (APS)
- American psychological society (APS)
- British Standard Numeric
- Chicago
- Council of biology editors (CBA)
- Elsevier
- Harvard system
- IEEE
- Journal of American medical association (JAMA)
- Modern language association (MLA)
- Nature
- Oxford standard citation of legal authorities
- Plain
- Science
- Turabian
- Vancouver system and more

All the information that have been used in the research work and writing need to be acknowledged, which includes;

- Quotations: Using someone else's written or spoken words.
- Paraphrased text :Information converted from someone else's ideas into your own words

- Summaries: when you summarize someone else's work or ideas
- Theories and ideas
- Statistics and other forms of Data
- Images pictures, graphs, multimedia, tables
- Music, Designs or plans

This list is not exhaustive, therefore the simple rule is, if you use anything in your work authored by someone else, please acknowledge their work by referencing or citing them correctly.

There are 2 places in the scientific writing where you will need to acknowledge when you have used someone else's ideas, theories etc to support your research.

1. In the body of your work – called in-text referencing or citing. This is when you refer to known theories and ideas to support your own work.
2. At the end of your work in your Bibliography or Reference List. This is where you link the citations that you have used in the body of your work according to the referencing style used.

There are many instances where you do secondary referencing occurs for instances when you are reading a book or journal article whose author uses facts or information from research done by someone else, and you want to use this to support your own assignment.

There are 2 ways that you can approach a secondary reference:

1. You locate the original research so that you can read, use and cite directly from this original source. This is often the preferred method as this shows that you have exercised and increased your own research for your assignment.
2. In some instances this may not be possible as the original research may be difficult to find or gain access to. If you are confident that this secondary source is reliable and accurate you can refer to it in your own work using the rules for secondary referencing from the reference style.

In Nepal, mainly Vancouver (in journals) and Haward styles (in reports) are used. Beside this there are software which manages references, mostly used such software are:

1. EndNote
2. Reference Manager

Session 8: Concept of Variables and Scales of Measurements

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **Define** variables and describe its important in research.
2. **State** the difference between numerical and categorical variables and define the types of scales of measurement.
3. **Discuss** the difference between dependent and independent variables and their use in research designs.
4. **Identify** the variables that will be measured in the research project you are designing and develop operational definitions with indicators for those variables that cannot be measured directly.
5. **List** the variables that you hope to identify and describe during your planned study but that cannot be measured at this time (qualitative data).

Teaching methods:

Course content:

1. **Introduction**
2. **Formulating variables**
3. **Identifying indicators in qualitative studies**
4. **Causes and associations; confounders**

I. Introduction

A **VARIABLE** is a characteristic of a person, object or phenomenon which can take on different values. These may be in the form of numbers (e.g., age) or non-numerical characteristics (e.g., sex).

A simple example of a variable in the form of numbers is ‘a person’s age’. The variable ‘age’ can take on different values since a person can be 5 years old, 50 years old and so on. Other examples of variables are:

- weight (expressed in kilograms or in pounds);
- home – health facility distance (expressed in kilometres or in minutes walking distance);
- monthly income (expressed in dollars, NRS); and
- number of children (1, 2, etc.).

Because the values of all these variables are expressed in numbers, we call them NUMERICAL VARIABLES.

Some variables may also be expressed in categories. For example, the variable sex has three districts categories or groups, male, female and third gender. Other examples are:
Other examples are:

(i) Outcome of diseases: Recovery, Chronic illness, Death
(ii) Status of Disease Infection: Positive, Negative
(iii) Main type of staple food eaten: Maize, Rice, Wheat etc.
(iv) Living: Mountain, Hill, Terai
(v) Living: Rural, Urban
(vi) Availability of drugs: Yes, No
(vii) Birth weight: Low, High, Normal
(viii) Socioeconomic status: Low, High
(ix) Education status: Illiterate, Literate
(x) Age: Teenager, Adolescent, Old
(xi) Knowledge: Poor, Medium, Good
(xii) Field of study: Public Health, Sociology, Microbiology, Medicine, Nursing etc.

Since these variables are expressed in categories, we call them CATEGORICAL VARIABLES or QUALITATIVE VARIABLES.

QUALITATIVE variables are usually unmeasurable. Hence, they are classified by some characteristics. People are categorized as to sex (male, female, third gender), eye color (blue, brown, green, etc), Political affiliation (democrat, communist, independent etc.).

Categorical variables, on the other hand, can either be ordinal or nominal.

1. ***Ordinal variables.*** These are grouped variables that are ordered or ranked in increasing or decreasing order:

   For example:

   High income (above $300 per month); Middle income ($100-$300 per month); and Low income (less than $100 per month).

   Other examples are:

Disability:	no disability, partial disability, serious or total disability
Seriousness of a disease:	severe, moderate, mild
Agreement with a statement:	fully agree, partially agree, neutral, partially disagree, fully disagree

NOMINAL variable: If the variable considered by name, referred as nominal variable. It may be of again two types: ***Dichotomous*** (e.g. *Infection:* +ve and –ve; *Availability of drugs:*

yes, no; *Outcome of disease:* Recovery, Death) and ***Polychotomous*** (e.g. *Nationality:* Nepali, Indian, American, Pakistani; *Eye Color:* blue, brown, green; *Main type of staple food eaten:* Rice, Millet, Maize, Wheat; *Outcome of disease:* Recovery, Chronic Illness, Death).
QUANTITATIVE variables are measurable and can be expressed numerically such as intelligence score, gestational age, birth weight, height, age, parity, distance, monthly income etc.

Because the values of all these variables are expressed in numbers, we call them *numerical variables*.

Other examples are:

(i) Age:
(ii) Weight:
(iii) Height:
(iv) Distance:
(v) Temperature;
(vi) Air pollution index:
(vii) Income:
(viii) Intelligence score or memory test:
(ix) Parity:
(x) Blood Pressure:
(xi) WBC or RBC count:
(xii) Number of microorganisms or infections:
(xiii) Quantity of rice eaten:
(xiv) Volume of water drinking:

Types of Quantitative Variables (Numerical Variable)
DISCRETE variable: This type of variable is usually thought of as being a whole unit, one that cannot be fractionated or divided up into smaller parts. Examples of discrete variables are intelligence score, WBC or RBC count, Parity, Number of microorganisms, Number of visits to a clinic, Number of sexual partners etc.

CONTINUOUS variable: This type of variable can be divided into fractional amounts in large or small degrees. Examples of continuous variable are height, weight, blood pressure, age, distance etc.

Quantifiable Qualitative Variable
Often categorical variables are disguised as quantitative variables. For example, one might record gender information coded as 1=Male, 2=Female, 3= Third gender. (Data is generally easier to manipulate in an analysis spreadsheet when it's coded quantitatively.) Still--the variable is categorical; it is not naturally measured as a number. Qualitative variables can be coded to appear numeric but their numbers are meaningless, as in male=1, female=2. In some cases it's together to make the distinction. A psychologist may collect survey data of the following nature.

How do you feel about the information on this page? (Circle one.)

1	2	3	4	5
Awful	Poor	OK	Good	Great

It's a tossup. Technically the numbers are artificial. But, the psychologist will work with these numbers as though they had meaning. For instance, two people might respond "Awful" and "OK." The psychologist would record 1 and 3 and, perhaps, compute an average of 2.0. However, it may be meaningless to have the average of Awful and OK being Poor! Nevertheless, this sort of scale (called a "**Likert Scale**") is often used in social science research. This variable is classified as categorical; it would not be entirely incorrect to classify it as quantitative.

You can see how any categorical variable may be coded to look like a quantitative variable -- simply by arbitrarily assigning numbers to categories.

Independent and Dependent Variable

Because in health systems research you often look for causal explanations, it is important to make a distinction between **dependent** and **independent variables**.

The variable that is used to describe or measure the problem under study is called the DEPENDENT variable.

The variables that are used to describe or measure the factors that are assumed to cause or at least to influence the problem are called the INDEPENDENT variables.

In research, particularly analytical and interventional study (research hypothesis testing study), the term independent and dependent variable are used.

The independent variable is referred to as the experimental treatment. The researcher controls what treatment will be selected and how much will be applied. The treatment, or independent, variable will not change during the research or as a result of the research. The dependent variable is the one that is expected to change as a result of the treatment. It is not under the control of the researcher. Said another way, the independent variable is expected to cause some effect on the dependent variable. The changed, or effected, variable is referred to as dependent because its value depends on the value of the independent variable. Actually, the independent variable forms or defines groups; the dependent variable generates data.

Following are some examples of independent and dependent variables:

Hypothesis: A vegetarian diet produces stronger and healthier people than does a non-vegetarian.
Independent variable: Type of diet (qualitative, nominal)
Dependent variable: Strength and health score (quantitative, discrete)

Hypothesis: There is a difference in self-confidence of female adults who exercise program and the female adults, who dropout of the exercise programs.
Independent variable: Exercise programs (qualitative, nominal)
Dependent variable: Self confidence score (quantitative, discrete)

Can blueberries slow down aging?

A study indicates that antioxidants found in blueberries may slow down the process of aging. In this study, 19-month old rats (equivalent to 60-year old humans) were fed either their standard diet or a diet supplemented by either blueberry, strawberry, or spinach powder. After eight weeks, the rats were given memory and motor tests. Although all supplemented rats showed improvement, those supplemented with blueberry powder showed the most notable improvement.
What is the *independent variable*? (Diet: blueberries or no blueberries)
What are the *dependent variables*? (Memory test and motor skills test)

Does β carotene protect against cancer?

β carotene supplements have been thought to protect against cancer. However, a study published in the Journal of the National Cancer Institute suggests this is false. The study was conducted with 39,000 women aged 45 and up. These women were randomly assigned to receive a beta-carotene supplement or a placebo, and their health was studied over their lifetime. Cancer rates for women taking the beta-carotene supplement did not differ systematically from the cancer rates of those women taking the placebo.
What is the *independent variable*? (supplements: beta-carotene or placebo)
What is the *dependent variable*? (occurrence of cancer)

*(**Note:** Dependent variable is also terms as predicted or response or outcome variable while independent variable is also referred as explanatory or predictor or input variable)*

EXAMPLE

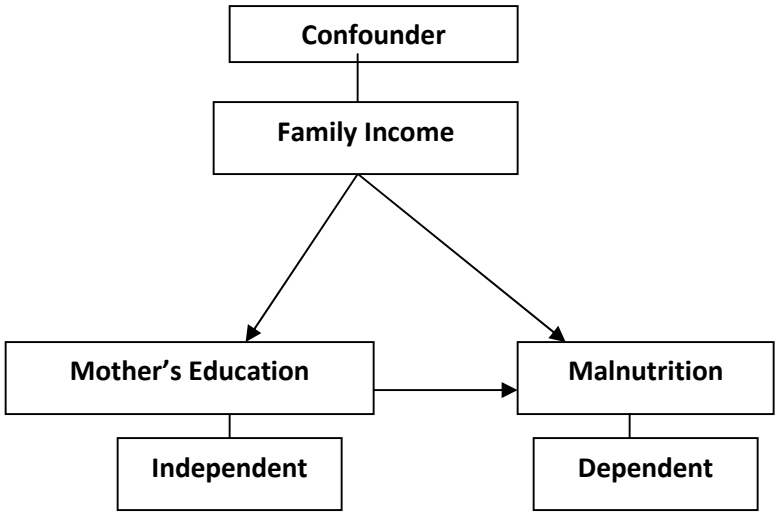
Consider a study performed by a medical center to determine which of two heart surgeries is most effective: angioplasty (running rubber tubes through the arteries) or bypass (rerouting arteries). The purpose of either procedure is to prolong the life of the patient. The study will certainly record the survival time of each patient (measured from the time of the surgery). This really is the outcome of the study; survival time is the response variable. Now, each patient will get one of the two types of operations; this is a second variable. Let's call it the "procedure" variable; it takes one of two possible values, Angioplasty and Bypass. The entire purpose of the study is to determine how, if at all, the procedure affects survival time. Type of surgery is an explanatory variable. We would use type of operation (explanatory variable or predictor) to predict survival time (response or predicted variable). Survival time may well *depend* on procedure; survival time is the dependent variable and procedure is the independent variable. Note that the response is measured after the explanatory. This is often---but not always---the case. The response variable is quantitative, the explanatory variable is categorical. In a true clinical trial many more explanatory variables would be recorded: gender, age at the time of surgery, state of health pre-surgery (how would this be measured?), numerous physiological indicators and so forth. There would be but one response variable,

survival time! (Actually, there would be others. Quality of life after the operation is important, as is an analysis of the side-effects attributable to the two procedures.)

Confounding Variable

A variable that is associated with the problem and with the possible cause of the problem is a confounding variable. It must be associated with the exposure and independent of that exposure be a factor. It interacts with the dependent variable to make the independent variable extremely effective or ineffective. e.g.

Mother's education (*Independent variable*)
Malnutrition (*Dependent variable*)
Family income (*Confounding variable*)



A relationship is shown between the low level of the mother's education and malnutrition in under fives. However, family income may be related to the mother's education as well as to malnutrition. Family income is therefore a potential confounding variable. To give a true picture of the relationship between mother's education and malnutrition, family income should also be considered and measured. This could be incorporated into the research design, for example by selecting only mothers with a specific level of family income, or it can be taken into account in the analysis of the findings, with mother's education and malnutrition among their children being analyzed for families with different categories of income.

*(**Note:** Confounding variable is also referred as extraneous variable, which come from outside of the research situation and interact with the dependent variable to make the independent variable extremely effective or ineffective. They correlate with, and affect, the dependent variable in a way that can invalidate the research conclusions)*

Background Variable

In almost every study, background variable appear, such as age, sex, educational level, socioeconomic status, marital status, and religion. These background variables are often related to a number of independent variables, so that they influence the problem indirectly.

(Hence they are called background variables). If the background variables are important to the study, they should be measured. However, try to keep the number of background variables measured as few as possible, in the interest of economy. Background variables are notorious "confounders".

*(**Note:** Background variables are some time referred as attributable or organismic variables which are the characteristics that are already determined and are unchangeable. Examples are sex, race, and age. If more than one sex, race, or age are included in an experiment, the researcher cannot manipulate the particular variable because it is already determined and already varies within the group to be studied. Thus, attribute variables either define the groups to be compared or must be equally distributed across all treatment groups).*

***(Note:** Sometime extraneous, attributable variables are referred as error-producing variables or intervening variables)*

Defining variables and indicators of variables:

To ensure that everyone (the researcher, the data collectors, and eventually, the reader of the research report) understands exactly what has been measured and to ensure that there will be consistency in the measurement, it is necessary to clearly define the variables (and indicators of variables). **For example**, to define the indicator 'waiting time', it is necessary to decide what will be considered the starting point of the 'waiting period' e.g., is it when the patient enters the front door, or when he has been registered and obtained his card?

Following example gives the common variables with different possible choices for indicators.

Occupation: Occupation for which subjects was trained (profession or trade), work actually per formed? If retired or unemployed, will previous occupation be used? Will women be classified by their own or by their husband's occupation or both?

Education: Number of years of education, or last grade attained, type of educational institution last attended?

Income: Personal income, family income, or average family income per member?

Crowding: (mean number of persons per room in housing unit which rooms are excluded from index (bathrooms showers, toilets, kitchens, storerooms, rooms used for business purposes, entrance hails)?

Social status: Based on occupation, education, crowding index, income, neighborhood or residence, home amenities, or subject's self perception? Based on one of these, or a combination?

Marital status: Expressed in terms of legal status (single, Married, widowed, divorced), or in terms of stability (e.g., stable union)?

Parity: Total number of previous pregnancies or total number of children delivered?

Date of onset of: Date when first symptoms were noticed date when first diagnosed or diseases date of notification?

Presence of chronic diseases: Based on duration since onset? If so, what duration makes it chronic: 3 months, 6 months, and a year? Or is chronic defined based on the presence of certain disease? If so, what diseases defined as chronic whatever their duration? If so, what diseases? What about conditions that come that come and go (e.g., recurrent store throats)?

Hospitalization: Is hospitalization for childbirth included or not? Is the hospital stay of a well newborn baby included? Is overnight stay essential? Is overnight stay in a casualty or emergency ward included?

Scales of Measurement

When we "measure" something, we are actually using a function that maps a property of the item being studied to a real number. Scales of measurement refer to ways in which variables/numbers are defined and categorized. Each scale of measurement has certain property which in turn determines the appropriateness for the use of certain statistical analyses. We generally consider four kinds of scales.

A measurement of a property of a unit has a (an) . . .

nominal scale if the measurements are data in name only; that is the data tells only what category to which a unit belongs.

ordinal scale if the measurement tells when one unit has more of the property being measured than does another unit. It is similar to the nominal scale in that the measurement tells to which category the unit belongs, but there is also an underlying ordering principle.

interval scale if the measurement tells us that one unit differs by a certain amount of the property being measured from another unit.

ratio scale if the measurement tell us that one unit has so many times as much of the property being measured as does another unit.

Measurements in the ***nominal scale*** simply place units into categories. Such properties as sex, race, ethnicity, eye color, hair color, employment status, etc are measured in the nominal scale.

Scale of Measurement and Framework for Defining Variables:

There are only four types of scales of measurement namely Nominal, Ordinal, Discrete and continuous scale.

Conceptual definition of variable	Operational definition i.e., indicator	Scale of measurement
Age	Age at last birthday	Continuous in months
Family size	Number of family members	Discrete
Use of clinic	Number of visits to clinic	Discrete
Hemoglobin	Hemoglobin concentration	Continuous: e.g., grams per 100ml.,

	in capillary blood, measured by haemoglobinometer	rounded off to nearest gram
Nutritional status	Weight in relation to age compared to a standard growth curve	Ordinal: e.g., 1. Well nourished = >80% of standard 2. moderately malnourished = 60% to 80% of standard 3. severely malnourished=<60% of standards
Patient's satisfaction	Response to a specific question about his/satisfaction with services obtained, put to patients on discharge	Ordinal: e.g., 1. very satisfied 2. somewhat satisfied 3. somewhat dissatisfied 4. very dissatisfied
Immunization coverage	Percentage of children immunized in a particular age group	Continuous: e.g., percentages: or ordinal, e.g., High> 80% Medium 60% -80% Low < 60%
Religion	As reported by informants	Nominal: Christian, Moslem, Hindu, Buddhist, etc.
Main source of carbohydrate in the diet	Main type of staple food eaten	Nominal: e.g., maize, millet, rice, cassava, etc.

Identifying Indicators in Qualitative Studies

Certain variables cannot be defined with indicators before the study, because the information to do this is lacking. The purpose of the study may be to find this information.

For example, policy makers in Nepal would like to eliminate leprosy. They have noticed that fewer women report for leprosy treatment than men and would like to know whether stigma keeps women from reporting for treatment and/or whether the services have to be more sensitive to the needs of women for privacy at diagnosis.

We define stigma as an undesirable differentness that disqualifies a person from full social acceptance. However, we cannot fill in more precisely in what way men and women are discriminated against, as that has still to be studied. Some indicators for stigma could be the divorce rate of male and female patients, or the degree of isolation of the patient by the healthy spouse or by the community, but how the severity of this isolation should be

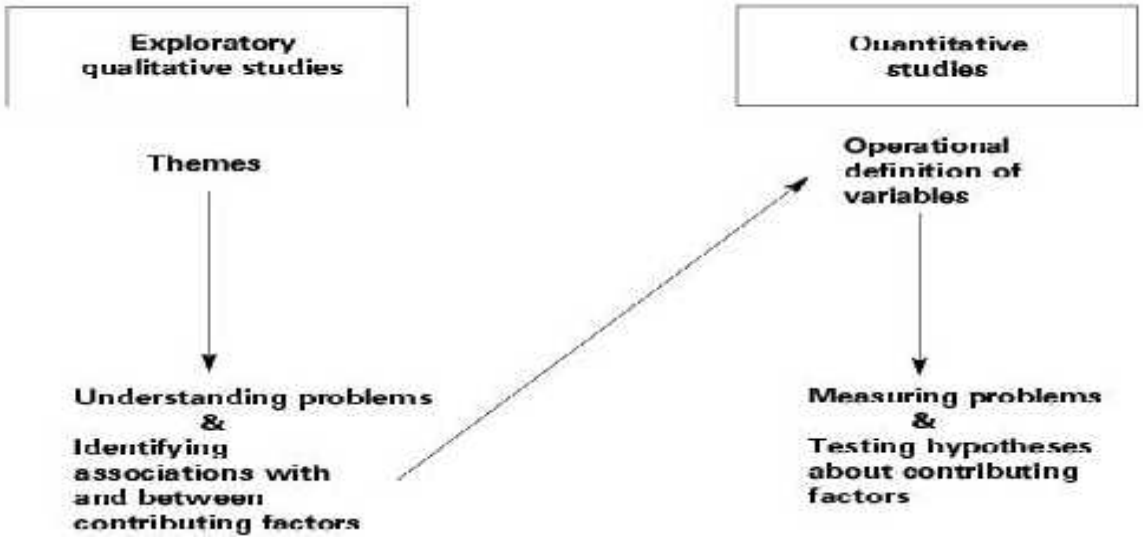
measured is still unknown. Possibilities included, for example, whether patients and spouses still share a house, share food, share one bed? Do community members still accept leprosy patients as village leaders, do they welcome patients to attend village meetings, and, if so, do they still drink beer or eat together, and do they ask patients to bring their own cups?

Note: that in many qualitative studies the researcher is not primarily interested in measuring variables, but rather in identifying variables or clusters of variables that help explain a problem or reasons for success. In that case, the researcher will often try to find indicators that make the variables measurable.

One could state that in exploratory, qualitative studies we study themes, such as stigma, to understand better how patients suffer from stigma and how they cope with it. We also discover contributing factors to stigma: in some societies women are more vulnerable to stigma than men; adolescents are more vulnerable than adults who have settled economically and socially; patients with deformities are always more vulnerable to stigma than those without visible signs.

By better understanding the problem of stigma we can now give an operational definition of the strength of stigma on a scale. This enables us to measure through a quantitative study the degree of stigma male and female patients suffer from, and the most important contributing factors to stigma. (See **Figure 1**)

Figure 1: Relationship between qualitative and quantitative studies in understanding and measuring problems



EXERCISE 3: Identification of variables in research (to be carried out in plenary, ½ hour)

Look at the following descriptions of research problems and then answer the questions that follow.

Problem 1

A health researcher believes that in certain region anaemia, malaria and malnutrition are serious problems among adult males and, in particular, among farmers. He therefore wishes to study the prevalence of these diseases among adult males of various ages, family size, occupations and educational backgrounds in order to determine how serious a problem these diseases are for this population.

Questions:

- What are the dependent and independent variables in the study?
- Which of these are categorical (ordinal and nominal) and which are numerical (continuous and discrete) variables?

Problem 2

A district medical officer (MO) receives a complaint from the community that village health workers (VHWs) often run out of chloroquine. In preliminary investigations this shortage of chloroquine is confirmed. VHWs get their drugs at monthly meetings at the health centre. The MO decides to investigate why the supply of drugs to VHWs is unsatisfactory.

Questions:

- What is the dependent variable in the study
- What would be a meaningful indicator for the dependent variable?
- How would you define ‘short of chloroquine’?
- Can you think of some independent variables?
- Which independent variables are ‘measurable’ as they are and which ones need indicators?

Session 9: An Overview of Research Design and Conceptual Framework

Time frame: 1hour 30 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Explain the concept of research design
2. Classify different types of study design used in health system research
3. Differentiate observational and experimental as well as descriptive and analytical study designs

Teaching methods:

- Mini- lecture followed by discussion 45 minutes (lecture 30 minutes and discussion 15 minutes)
- Questions and answer (15 minutes)
- Brain storming exercise for selecting the title (15 minutes)
- Group work and presentation (45 minutes)

Course content:

1. Concept of Research design
2. Concept on qualitative and quantitative methods
3. Differences between observational and experimental study
4. Differences between descriptive and analytical study

Concept of Research Design:

How is the term `research design' to be used in this training? An analogy might help. When constructing a building there is no point ordering materials or setting critical dates for completion of project stages until we know what sort of building is being constructed. The first decision is whether we need a high rise office building, a factory for manufacturing machinery, a school, a residential home or an apartment block. Until this is done we cannot sketch a plan, obtain permits, work out a work schedule or order materials.

Similarly, health research needs a design or a structure before data collection or analysis can commence. A research design is not just a work plan. A work plan details what has to be done to complete the project but the work plan will follow from the project's research design. ***The function of a research design is to ensure that the evidence obtained enables us to answer the initial question as unambiguously as possible***. Obtaining relevant evidence entails specifying the type of evidence needed to answer the research question, to test a theory, to evaluate a program or to accurately describe some phenomenon. In other words, when

designing research we need to ask: given this research question (or theory), what type of evidence is needed to answer the question (or test the theory) in a convincing way?

Research design "deals with a logical problem and not a logistical problem" (Yin, 1989: 29). Before a builder or architect can develop a work plan or order materials they must first establish the type of building required, its uses and the needs of the occupants. The work plan follows from this. Similarly, in health research the issues of sampling, method of data collection (e.g. questionnaire, observation, document analysis), design of questions are all subsidiary to the matter of "What evidence do I need to collect?"

Too often researchers design questionnaires or begin interviewing far too early - before thinking through what information they require to answer their research questions. Without attending to these research design matters at the beginning, the conclusions drawn will normally be weak and unconvincing and fail to answer the research question.

Specific:
Now to be more specific, research designs are generally categorized into qualitative and quantitative as given below:

Features of Qualitative & Quantitative Research

Qualitative	**Quantitative**
"All research ultimately has a qualitative grounding" - Donald Campbell	"There's no such thing as qualitative data. Everything is either 1 or 0" - Fred Kerlinger
The aim is a complete, detailed description.	The aim is to classify features, count them, and construct statistical models in an attempt to explain what is observed.
Researcher may only know roughly in advance what he/she is looking for.	Researcher knows clearly in advance what he/she is looking for.
Recommended during earlier phases of research projects.	Recommended during latter phases of research projects.
The design emerges as the study unfolds.	All aspects of the study are carefully designed before data is collected.

Researcher is the data gathering instrument.	Researcher uses tools, such as questionnaires or equipment to collect numerical data.
Data is in the form of words, pictures or objects.	Data is in the form of numbers and statistics.
Subjective - individuals' interpretation of events is important ,e.g., uses participant observation, in-depth interviews etc.	Objective – seeks precise measurement & analysis of target concepts, e.g., uses surveys, questionnaires etc.
Qualitative data is more 'rich', time consuming, and less able to be generalized.	Quantitative data is more efficient, able to test hypotheses, but may miss contextual detail.
Researcher tends to become subjectively immersed in the subject matter.	Researcher tends to remain objectively separated from the subject matter.

Main Points

- **Qualitative research** involves analysis of data such as words (e.g., from interviews), pictures (e.g., video), or objects (e.g., an artifact).
- **Quantitative research** involves analysis of numerical data.
- **The strengths and weaknesses** of qualitative and quantitative research are a perennial, hot debate, especially in the social sciences. The issues invoke classic 'paradigm war'.
- **The personality / thinking style** of the researcher and/or the culture of the organization is under-recognized as a key factor in preferred choice of methods.

- **Overly focusing on the debate** of "qualitative *versus* quantitative" frames the methods in opposition. It is important to focus also on how the techniques can be integrated, such as in mixed methods research. More good can come of social science researchers developing skills in both realms than debating which method is superior.

Differences between Observational and Experimental Study design

Observational and experimental study designs are used for quantitative type of research where the data collection are quantitative or in numerical form.
Studies aimed at quantifying relationships are of two types: **descriptive** and **experimental**. In a descriptive study, no attempt is made to change behavior or conditions--you measure things as they are. In an experimental study you take measurements, try some sort of intervention, then take measurements again to see what happened.

Types of research design
Descriptive or observational
• case • case series • cross-sectional • cohort or prospective or longitudinal • case-control or retrospective
Experimental or longitudinal or repeated-measures
• without a control group pre-experimental • with a control group quasi experimental true experimental

Observational Studies

Observational studies are also called descriptive, because you observe and describe the subjects without otherwise intervening. The simplest descriptive study is a case, which reports data on only one subject; examples are a study of a new disease like HIV/AIDS in USA during 1980s. Descriptive studies of a few cases are called **case series**. In **cross-sectional** studies variables of interest in a sample of subjects are assayed once and the

relationships between them are determined. In **prospective or cohort studies**, some variables are assayed at the start of a study (e.g., dietary habits), then after a period of time the outcomes are determined (e.g., incidence of heart disease). Another label for this kind of study is **longitudinal**, although this term also applies to experiments. **Case-control** studies compare cases (subjects with a particular attribute, such as an injury or ability) with controls (subjects without the attribute); comparison is made of the exposure to something suspected of causing the cases, for example volume of high intensity training, or number of alcoholic drinks consumed per day. Case-control studies are also called retrospective, because they focus on conditions in the past that might have caused subjects to become cases rather than controls.

Experimental Studies

Experimental studies are also known as longitudinal or repeated-measures studies, for obvious reasons. They are also referred to as interventions, because you do more than just observe the subjects.

In the simplest experiment, a time series, one or more measurements are taken on all subjects before and after a treatment. A special case of the time series is the so-called single-subject design, in which measurements are taken repeatedly (e.g., 10 times) before and after an intervention on one or a few subjects.

Time series suffer from a major problem: any change you see could be due to something other than the treatment. For example, subjects might do better on the second test because of their experience of the first test, or they might change their diet between tests because of a change in weather, and diet could affect their performance of the test. The crossover design is one solution to this problem. Normally the subjects are given two treatments, one being the real treatment, the other a control or reference treatment. Half the subjects receive the real treatment first, the other half the control first. After a period of time sufficient to allow any treatment effect to wash out, the treatments are crossed over. Any effect of retesting or of anything that happened between the tests can then be subtracted out by an appropriate analysis. Multiple crossover designs involving several treatments are also possible.

If the treatment effect is unlikely to wash out between measurements, a control group has to be used. In these designs, all subjects are measured, but only some of them--the experimental group--then receive the treatment. All subjects are then measured again, and the change in the experimental group is compared with the change in the control group.

If the subjects are assigned randomly to experimental and control groups or treatments, the design is known as a **randomized controlled trial**. Random assignment minimizes the chance that either group is not typical of the population.

Descriptive Vs. Analytical Research Designs

When choosing your study design the first decision is usually whether you wish to conduct a descriptive or an analytical research study. If your study aims to gain more information about a subject and use this to generate theories or hypotheses, then a descriptive study may be used. However, if your study aims to actually test preplanned hypotheses, based on existing knowledge or findings, then you will need to use an analytical research method.

For example, a psychologist may see a patient with a very unusual pattern of brain injury that has not been documented before. The psychologist could then conduct a single case study with the patient trying to ascertain whether he has any psychological impairment. This would be a descriptive study, as it is used to generate knowledge about a given situation, paving the way for future studies. Such studies are very useful in describing new diseases or side effects of treatment (Bowling, 2002). The psychological impairments seen in that single patient may then be used by other researchers to generate testable hypotheses regarding how particular areas of the brain may be involved in behavior. Further analytical research would be able to test these hypotheses regarding brain function. Therefore, descriptive studies are usually opportunistic and unplanned. Examples of descriptive studies include single case studies, case series, ecological studies, planned exploratory studies. All of these studies are useful for generating hypotheses, but do not test them.

Analytical research is usually pre-planned and tests one or more pre-stated hypothesis. Such studies are usually motivated by one or more hypothesis generating studies. Sometimes analytical research is called evaluative, as it determines the strength of a possible relationship between an exposure or intervention and outcome.

Observational Research

Cross sectional Study

Cross sectional studies are usually used to determine the prevalence of a condition, i.e. the number of cases in a given population at a given point in time and any associated factors (Mann, 2003). Such studies are often used to identify possible causative factors in disease by comparing respondents that report having a particular condition to participants who do not have the condition. Findings from cross sectional research can show associations between variables; however they do not establish causality. Therefore the findings may be used to identify associations that may be investigated further using a different experimental technique. They are relatively inexpensive as they often rely on questionnaires and no follow ups are required. The disadvantages are that response rates can be low and they are not suitable for studying rare conditions, as even very large samples may not identify anyone with the condition of interest.

Longitudinal Studies

In a cross sectional study all observations occur at one time point, therefore the relationships of interest are not examined temporally and they are unable to distinguish cause and effect. In a longitudinal survey observations are typically taken at more than one time point and

relationships are considered temporally. They are usually prospective, but retrospective studies are possible. They are useful for studying the effects of new interventions or possible trends in behavior. They are analytical as they analyze events at more than one point in time, thus they can suggest the direction of cause and effect associations (Bowling, 2003).

Case Control Study

A case control study is an epidemiological study to assess the strengths of association between an exposure and outcome of interest. In a case control study groups are identified on the basis of the condition or outcome of interest (cases) and are then compared with a control group who do not have the condition. Such studies are retrospective as they ask whether the participants have ever had the exposure of interest. They are relatively quick and inexpensive and they may be the only feasible method for rare disorders as they usually require fewer subjects than prospective studies. However, they do rely on subject recall or past records to determine exposure, both of which may be unreliable. It may also be difficult to select and locate a suitable control group.

Cohort Study

Cohort studies involve looking at a population who all share a common feature of interest, for example, a group of people all born in the same year or a group of people who have all smoked cigarettes. They are very useful for describing the incidence & natural history of a condition. They can be either prospective or retrospective; however, the prospective study is most useful to investigate the causes of disease. For example, it is possible to identify a group of people who do not have the condition of interest and then over time see how many people in your group go on to develop the condition.

Cohort studies are often used when randomized control trials may be unethical, such as examining the effects of asbestos inhalation. Although it would be unethical to expose people to asbestos, it is possible to study people who have already been exposed. However, it is important that all confounding variables are measured, as missing one may lead to problems in analysis.

Experimental Research

Randomized Clinical Trial

In a clinical trial one group of participants is given a new drug/ treatment or intervention, whereas another group (i.e., the control group) is given either a standard treatment for the disease or a placebo. The main feature is that the allocation of participants to either the experimental or control group is randomized. This design can indicate the nature of any causal relationships. The main disadvantage is that ethical questions can arise regarding the use or non use of new treatments or interventions.

Quasi Experimental Designs

In a quasi experimental design there is no random allocation of participants into treatment or control groups. The experimenters control over participant selection and the administration of any interventions is more difficult, therefore it is more difficult to interpret causal hypotheses (Bowling, 2002). Examples of quasi experimental designs are time series studies, within subject designs and non controlled clinical trials.

Session 10: Study Types (Study Design)

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Explain the concept of three different research design particularly descriptive, analytical and experimental)
2. Differentiate the methods of different research design

Teaching methods:

- Mini- lecture followed by discussion 45 minutes (lecture 30 minutes and discussion 15 minutes)
- Questions and answer (15 minutes)
- Brain storming exercise for selecting the title (15 minutes)
- Group work and presentation (45 minutes) Scientific articles for each type of study will be given to participants for critical analysis

Course content:

- Concept of descriptive, analytical and experimental design
- Method to design descriptive, analytical and experimental design

<u>Descriptive study design</u>

Cross-sectional studies

Cross-sectional studies measure the prevalence of disease and thus are often called prevalence studies. In a cross-sectional study the measurements of exposure and effect are made at the same time. It is not easy to assess the reasons for associations shown in cross-sectional studies. The key question to be asked is whether the exposure precedes or follows the effect. If the exposure data are known to represent exposure before any effect occurred, the data from a cross-sectional study can be treated like data generated from a cohort study.

Cross-sectional studies are relatively easy and inexpensive to conduct and are useful for investigating exposures that are fixed characteristics of individuals, such as ethnicity or blood group. In sudden outbreaks of disease, a cross-sectional study to measure several exposures can be the most convenient first step in investigating the cause.

Data from cross-sectional studies are helpful in assessing the health care needs of populations. Data from repeated cross-sectional surveys using independent random samples with standardized definitions and survey methods provide useful indications of trends. Each survey should have a clear purpose. Valid surveys need well-designed questionnaires, an appropriate sample of sufficient size, and a good response rate.

Case-control studies

Case-control studies provide a relatively simple way to investigate causes of diseases, especially rare diseases. They include people with a disease (or other outcome variable) of interest and a suitable control (comparison or reference) group of people unaffected by the disease or outcome variable (Fig 1). The study compares the occurrence of the possible cause in cases and in controls. The investigators collect data on disease occurrence at one point in time and exposures at a previous point in time. Case-control studies are longitudinal, in contrast to cross-sectional studies. Case-control studies have been called retrospective studies since the investigator is looking backward from the disease to a possible cause. This can be confusing because the terms retrospective and prospective are also used to describe the timing of data collection in relation to the current date. In this sense a case-control study may be either retrospective, when all the data deal with the past, or prospective, in which data collection continues with the passage of time.

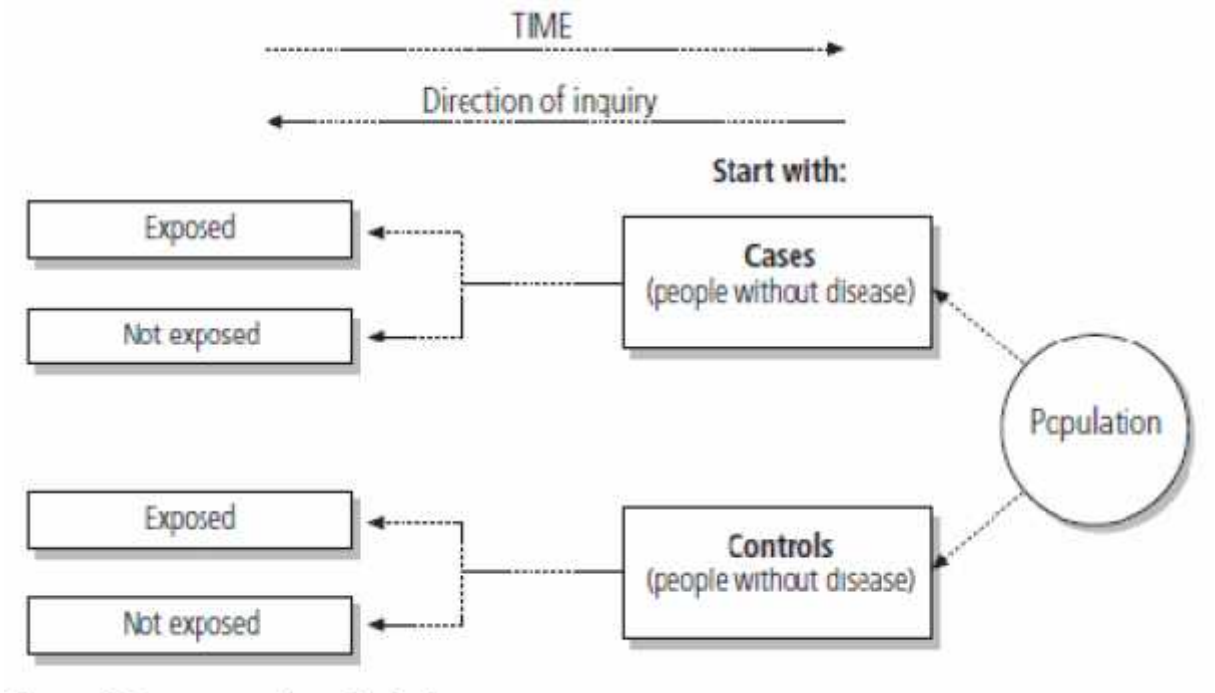


Figure 1 Case control study design

Selection of cases and controls

A case-control study begins with the selection of cases; these cases should represent all the cases in a specified population group. Cases are selected on the basis of disease, not exposure. Controls are people without the disease. A critical and challenging aspect of population-based case control studies is finding a cost-effective way to identify and enroll control subjects. The most difficult task is to select controls so as to sample the exposure prevalence in the population that generated the cases. Furthermore, the choice of controls and cases must not be influenced by exposure status, which should be determined in the same manner for both. It is not necessary for cases and controls to be all-inclusive; in fact they can be restricted to any specified subgroup, such as elderly people, males or females.

The controls should represent people who would have been designated study cases if they had developed the disease. Ideally, case-control studies use new (incident) cases to avoid the difficulty of separating factors related to causation and survival (or recovery), although studies have often been conducted using prevalence data (for example, case-control studies of congenital malformations). Case control studies can estimate relative risk of disease, but they cannot determine the absolute incidence of disease.

Exposure

An important aspect of case-control studies is the determination of the start and duration of exposure for cases and controls. In the case-control design, the exposure status of the cases is usually determined after the development of the disease (retrospective data) and usually by direct questioning of the affected person or a relative or friend. The informant's answers may

be influenced by knowledge about the hypothesis under investigation or the disease experience itself.

An example of the use of a case-control study design is shown in Table 1. Researchers in Papua New Guinea compared the history of meat consumption in people who had enteritis necroticans, with people who did not have the disease. Proportionately more people who had the disease (50 of 61 cases) reported prior meat consumption than those who were not affected (16 of 57). Exposure is sometimes determined by biochemical measurements (e.g. lead in blood or cadmium in urine), which may not accurately reflect the relevant past exposure. For example, lead in blood at age 6 years is not a good indicator of exposure at age 1 to 2 years, which is the age of greatest sensitivity to lead. This problem can be avoided if exposure can be estimated from an established recording system (e.g. stored results of routine blood testing or employment records) or if the case-control study is carried out prospectively so that exposure data are collected before the disease develops (Example 2).

Example 1

A classic example of a case-control study was the discovery of the relationship between thalidomide and limb defect in babies born in the Federal Republic of Germany in 1959 and 1960. The study, done in 1961, compared affected children with normal children. 41 had been given thalidomide between the fourth and ninth weeks of pregnancy, whereas none of the 300 control mothers, whose children were normal, had taken the drug during pregnancy. Accurate timing of the drug intake was crucial for determining relevant exposure.

The association of an exposure and a disease (relative risk) in a case-control study is measured by calculating the odds ratio (OR), which is the ratio of the odds of exposure among the cases to the odds of exposure among the controls.

For the data in Table 1, the odds ratio is given by:
OR = (50 / 11) ÷ (16 / 41) = 50 × 41/11 × 16 = 11.6
This indicates that the cases were 11.6 times more likely than the controls to have recently eaten meat. The odds ratio is very similar to the risk ratio, particularly if a disease is rare. For the odds ratio to be a good approximation, the cases and controls must be representative of the general population with respect to exposure. However, because the incidence of disease is unknown, the absolute risk cannot be calculated. An odds ratio should be accompanied by the confidence interval observed around the point estimate.

Table 1 Association between meat consumption and enteritis necroticans in Papua New Guinea

		Exposure (Recent meat ingestion)		
		Yes	No	Total
Disease (enteritis necroticans)	Yes	50	11	61
	No	16	41	57

	Total	66	52	118

Cohort studies

Cohort studies, also called follow-up or incidence studies, begin with a group of people who are free of disease, and who are classified into subgroups according to exposure to a potential cause of disease or outcome (Figure 2). Variables of interest are specified and measured and the whole cohort is followed up to see how the subsequent development of new cases of the disease (or other outcome) differs between the groups with and without exposure. Because the data on exposure and disease refer to different points in time, cohort studies are longitudinal, like case-control studies.

Cohort studies have been called prospective studies, but this terminology is confusing and should be avoided. As mentioned previously, the term "prospective" refers to the timing of data collection and not to the relationship between exposure and effect. Thus there can be both prospective and retrospective cohort studies.

Cohort studies provide the best information about the causation of disease and the most direct measurement of the risk of developing disease. Although conceptually simple, cohort studies are major undertakings and may require long periods of follow-up since disease may occur a long time after exposure. For example, the induction period for leukemia or thyroid cancer caused by radiation (i.e. the time required for the specific cause to produce an outcome) is many years and it is necessary to follow up study participants for a long time. Many exposures investigated are long-term in nature and accurate information about them requires data collection over long periods. However, in the case of tobacco use, many people have relatively stable habits and information about past and current exposure can be collected at the time the cohort is defined.

In situations with sudden acute exposures, the cause effect relationship for acute effects may be obvious, but cohort studies are also used to investigate late or chronic effects (Example 2). As cohort studies start with exposed and unexposed people, the difficulty of measuring or finding existing data on individual exposures largely determines the feasibility of doing one of these studies. If the disease is rare in the exposed group as well as the unexposed group there may also be problems in obtaining a large enough study group.

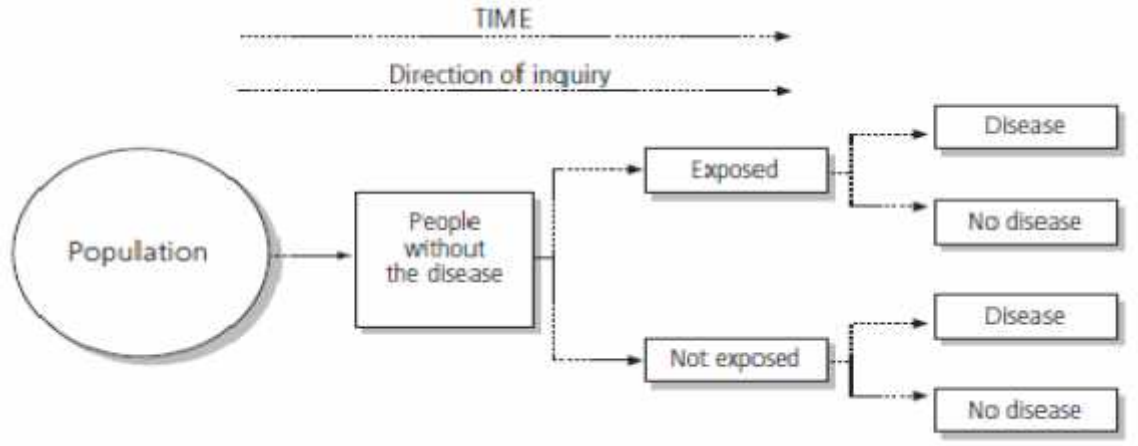


Figure 2 Cohort Study Design

Example 2 Late effects of poisoning: Bhopal

An example of measuring effects over a long time period is the catastrophic poisoning of residents around a pesticide factory in Bhopal, India, in 1984. An intermediate chemical in the production process, methyl isocyanine, leaked from a tank and the fumes drifted into surrounding residential areas, exposing half a million people to the gas. 20 000 people died as a result of this exposure. In addition, 120 000 people still suffer health effects caused by the accident and subsequent pollution. The acute effects were easily studied with a cross-sectional design. More subtle chronic effects and those developing only after a long latency period are still being studied using cohort study designs.

Example 3 Nurses' Health Study

Although cost is a major factor in large cohort studies, methods have been developed to make them less expensive to run. In 1976, 121 700 married female nurses aged 30-55 years completed the initial Nurses' Health Survey questionnaire. Every two years, self-administered questionnaires were sent to these nurses, who supplied information on their health behaviors and reproductive and medical histories. The initial cohort was enrolled with the objective of evaluating the health effects of oral contraceptive use. Investigators tested their methods on small sub groups of the larger cohort, and obtained information on disease outcomes from routine data sources. In addition to studying the relationship between oral contraceptive use and the risk of ovarian and breast cancer, they were also able to evaluate other diseases in this cohort – such as heart disease and stroke, and the relationship between smoking and the risk of stroke. Although stroke is a relatively common cause of death, it is a rare occurrence in younger women, and so a large cohort is necessary.

Example 4 Nested case-control study of gastric cancer

To determine of infection with *Helicobacter pylori* was associated with gastric cancer, investigators used a cohort of 128 992 people that had been established in the mid-1960s. By 1991, 186 people in the original cohort had developed gastric cancer. The investigators then did a nested case-control study by selecting the 186 people with gastric cancer as cases and another 186 cancer-free individuals from the same cohort as controls. *H. pylori* infection status was determined retrospectively from serum samples that had been stored sine the 1960s. 84% of people with gastric cancer – and only 61% of the controls – had been infected previously with *H. pylori*, suggesting a positive association between *H. pylori* infection and gastric cancer risk.

The expense of a cohort study can be reduced by using routine sources information about mortality or morbidity, such as disease registers or national registers of deaths as part of the follow-up. One example is the Nurses' Health Study (Example 3). Since cohort studies take healthy people as their starting- point, it is possible to examine a range of outcomes (in contrast to what can be achieved in case-control studies). For example, the Framingham study – a cohort study that began in 1948 – has investigated the risk factors for a wide range of diseases, including cardiovascular and respiratory diseases and musculoskeletal disorders. Similar large-scale cohort studies have been started in China. Baseline demographic characteristics, medical histories, and major cardiovascular risk factors including blood

pressure and body weight were obtained from a representative sample of 169 871 men and women 40 years of age and older in 1990. Researchers plan to follow this cohort on a regular basis.

A special type of cohort study is the study of identical twins, where the confounding factor of genetic variation – between people exposed and not exposed to a particular factor – can be eliminated. Such studies have provided strong evidence for a variety of cause-effect relationships for chronic diseases. The Swedish twin registry is a good example of the type of data source that can be used to answer many epidemiological questions.

Historical cohort studies

Costs can occasionally be reduced by using a historical cohort (identified on the basis of records of previous exposure). This type of investigation is called a historical cohort study, because all the exposure and effect (disease) data have been collected before the actual study begins. For example, records of military personnel exposure to radioactive fall-out at nuclear bomb testing sites have been used to examine the possible causal role of fall-out in the development of cancer over the past 30 years. This sort of design is relatively common for studies of cancer related to occupational exposures.

Nested case-control studies

The nested case-control design makes cohort studies less expensive. The cases and controls are both chosen from a defined cohort, for which some information on exposures and risk factors is already available (Figure 3). Additional information on new cases and controls, particularly selected for the study, is collected and analysed. This design is particularly useful when measurement of exposure is expensive. An example of a nested case control study is shown in Example 4.

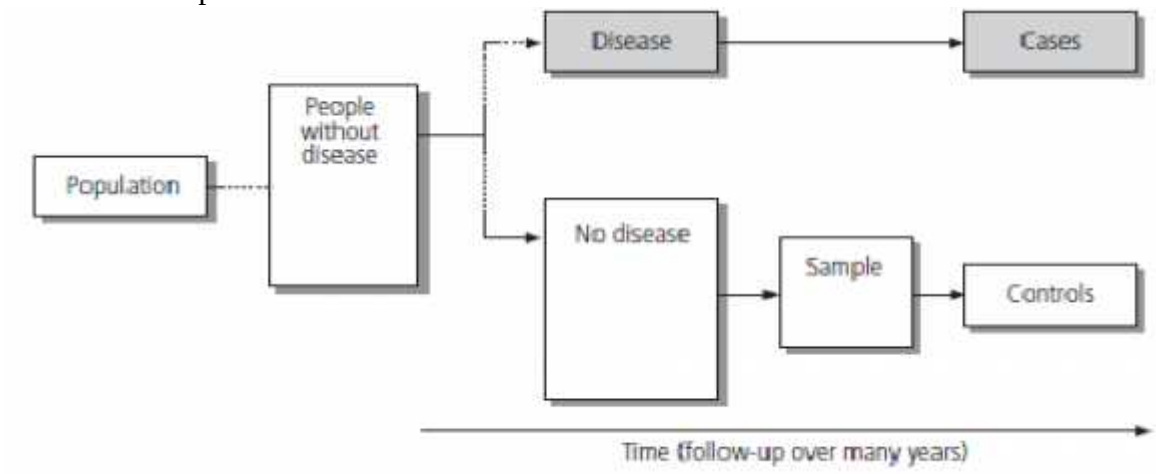


Figure 3 Nested case-control study design

Summary of epidemiological studies

Table 2 summarizes the applications of different observational studies and Table 3 outlines the advantages and disadvantages of the major types of observational study.

Table 2 Applications of different observational study design [a]

Objective	Ecological	Cross-sectional	Case-control	Cohort
Investigation of rare disease	++++	-	+++++	-
Investigation of rare causes	++	-	-	+++++
Testing multiple effects of causes	+	++	-	+++++
Study of multiple exposures and determinants	++	++	++++	+++
Measurements of time relationship	++	-	+[b]	+++++
Direct measurement of incidence	-	-	+[c]	+++++
Investigation of long latent periods	-	-	+++	-

a +..+++++ indicates the general degree of suitability; there are exceptions
Not suitable
b if prospective
c if population-based

Table 3 Advantages and disadvantages of different observational study design

Probability of:	Ecological	Cross-sectional	Case-control	Cohort
Selection bias	NA	Medium	High	Low
Recall bias	NA	High	High	Low
Loss to follow-up	NA	NA	Low	High
Confounding	High	Medium	Medium	Medium
Time required	Low	Medium	Medium	High
Cost	Low	Medium	Medium	High

NA: not applicable

Experimental epidemiology

Intervention or experimentation involves attempting to change a variable in one or more groups of people. This could mean the elimination of a dietary factor thought to cause allergy, or testing a new treatment on a selected group of patients. The effects of an intervention are measured by comparing the outcome in the experimental group with that in a control group. Since the interventions are strictly determined by the study protocol, ethical considerations are of paramount importance in the design of these studies. For example, no patient should be denied appropriate treatment as a result of participation in an experiment, and the treatment being tested must be acceptable in the light of current knowledge. Informed consent from study participants is required in almost all circumstances.

An interventional study is usually designed as a randomized controlled trial, a field trial, or a community trial.

Randomized controlled trials

A randomized controlled trial is an epidemiological experiment designed to study the effects of a particular intervention. Subjects in the study population are randomly allocated to intervention and control groups, and the results are assessed by comparing outcomes.
The design of a randomized controlled trial is shown in Figure 4. To ensure that the groups being compared are equivalent, patients are allocated to them randomly, i.e. by chance. If the initial selection and randomization is done properly, the control and treatment groups will be comparable at the start of the investigation; any differences between groups are chance occurrences unaffected by the conscious or unconscious biases of the investigators.

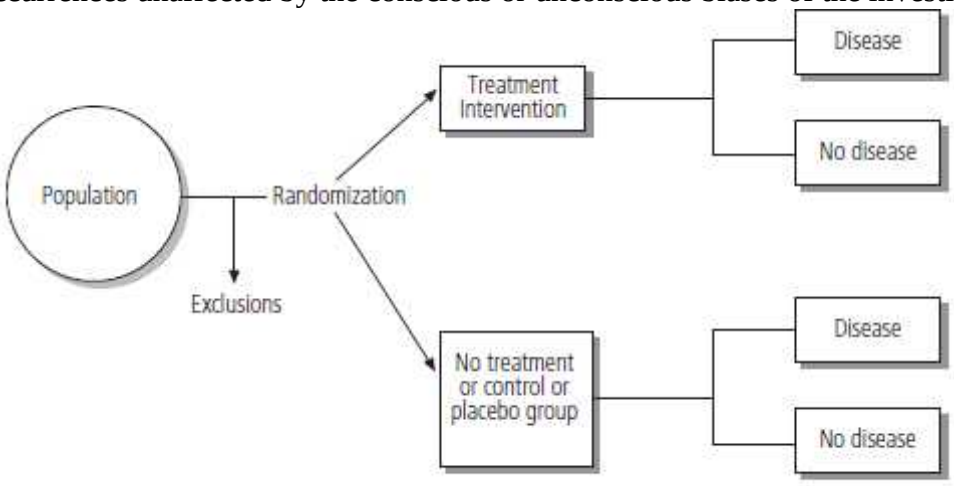


Figure 4 Randomized controlled trials design

Field trials
Field trials, in contrast to clinical trials, involve people who are healthy but presumed to be at risk; data collection takes place "in the field," usually among non-institutionalized people in the general population. Since the subjects are disease free and the purpose is to prevent diseases that may occur with relatively low frequency, field trials are often logistically complicated and expensive endeavors. One of the largest field trials was that testing the Salk vaccine for the prevention of poliomyelitis, which involved over one million children. Field trials can be used to evaluate interventions aimed at reducing exposure without necessarily measuring the occurrence of health effects. For instance, different protective methods for pesticide exposure have been tested in this way and measurement of blood lead levels in children has shown the protection provided by elimination of lead paint in the home environment. Such intervention studies can be done on a smaller scale, and at lower cost, as they do not involve lengthy follow-up or measurement of disease outcomes.

Community trials
In this form of experiment, the treatment groups are communities rather than individuals. This is particularly appropriate for diseases that are influenced by social conditions, and for which prevention efforts target group behaviour. Cardiovascular disease is a good example of a condition appropriate for community trials although unanticipated methodological issues can arise in large community intervention trials (Example 5).
Limitations of community trials

A limitation of such studies is that only a small number of communities can be included and random allocation of communities is usually not practicable; other methods are required to ensure that any differences found at the end of the study can be attributed to the intervention rather than to inherent differences between communities. Furthermore, it is difficult to isolate the communities where intervention is taking place from general social changes that may be occurring. Design limitations, especially in the face of unexpectedly large, favorable risk factor changes in control sites, are difficult to overcome. As a result, definitive conclusions about the overall effectiveness of the community-wide efforts are not always possible. Figure 5 shows a community trial of a tuberculosis outreach programme in rural Ethiopia. 32 communities – with a combined population of 350 000 people – were randomly allocated to intervention and control groups. The study showed that community outreach improved the speed of case-finding for smear-positive tuberculosis.

Potential errors in epidemiological studies

Epidemiological investigations aim to provide accurate measures of disease occurrence (or other outcomes). However, there are many possibilities for errors in measurement. Epidemiologists devote much attention to minimizing errors and assessing the impact of errors that cannot be eliminated. Sources of error can be random or systematic.

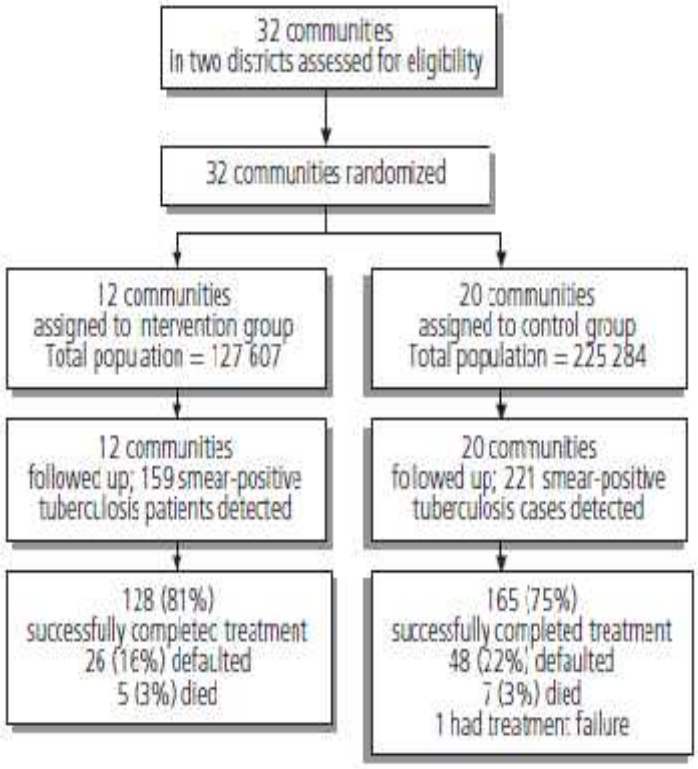


Figure 5 Community Trial Design

Example 5 Stanford Five-City Community Intervention Trial

The Stanford Five-City Project started in 1978 as one of several community intervention studies designed to lower population risk of cardiovascular disease. Researchers believed that the community approach was the best way to address the large compounded risk of mild elevations of multiple risk factors and the interrelation of several health behaviors. Although some components of the intervention proved effective when evaluated individually (for example, efficiency of the mass media and other community-wide programs), large, favorable changes in risk factor also occurred in the control sites. Part of the problem was related to design limitations. Internal validity was compromised by the fact that only a few intervention units could be studied in sufficient detail. Researchers also noted the need to improve educational interventions and expand the environmental and health policy components of health policy.

Session 11: Introduction of Sampling Techniques

Time frame:

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Define different terminology used in sampling procedure
2. Define best sampling method
3. Describe the process of choosing best sampling method

Teaching methods:

- Mini- lecture followed by discussion 45 minutes (lecture 30 minutes and discussion 15 minutes)

Course content:

Terms Used in Sampling:

Target population: The target population is the entire group a researcher is interested in; the group about which the researcher wishes to draw conclusions.

Example
Suppose we take a group of men aged 35-40 who have suffered an initial heart attack. The purpose of this study could be to compare the effectiveness of two drug regimes for preventing further attacks. The target population here would be all men meeting the same general conditions as those actually included in the study.

Parameter and Statistic: A **parameter** is a value, usually unknown (and which therefore has to be estimated), used to represent a certain population characteristic. For example, the population mean is a parameter that is often used to indicate the average value of a quantity.

A **statistic** is a quantity that is calculated from a sample of data. It is used to give information about unknown values in the corresponding population. For example, the average of the data in a sample is used to give information about the overall average in the population from which that sample was drawn.

It is possible to draw more than one sample from the same population and the value of a statistic will in general vary from sample to sample. For example, the average value in a sample is a statistic. The average values in more than one sample, drawn from the same population, will not necessarily be equal.

Statistics are often assigned Roman letters (e.g. m and s), whereas the equivalent unknown values in the population (parameters) are assigned Greek letters (e.g. μ and σ).

Sampling Units: A sampling unit is one of the units into which an aggregate is divided for the purpose of sampling, each unit being regarded as individual and indivisible when the selection is made. The definition of unit may be made on some natural basis, e.g., household, persons, units of product, bed numbers, etc., or upon some arbitrary basis, e.g., areas defined by grid co-ordinates on a map.

Ultimate sampling unit: It may be defined as the smallest unit which is the subject of sample selection. In a household survey the ultimate sampling unit might be the household.

Sampling Frame: The names of the component parts of the population from which the sample is to be collected. The frame should d be updated and exhaustive. The voter list is the examples of sampling frame for community survey.

Probability Sampling: With probability sampling methods, each population element has a known (non-zero) chance of being chosen for the sample.

Non Probability Sampling: With non-probability sampling methods, 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.

Non-probability sampling methods offer two potential advantages - convenience and cost. The main disadvantage is that non-probability sampling methods do not allow you to estimate the extent to which sample statistics are likely to differ from population parameters. Only probability sampling methods permit that kind of analysis.

Census: The complete enumeration of the population is known as census. The sampling technique has many advantages over census.

Objectives of Sampling:

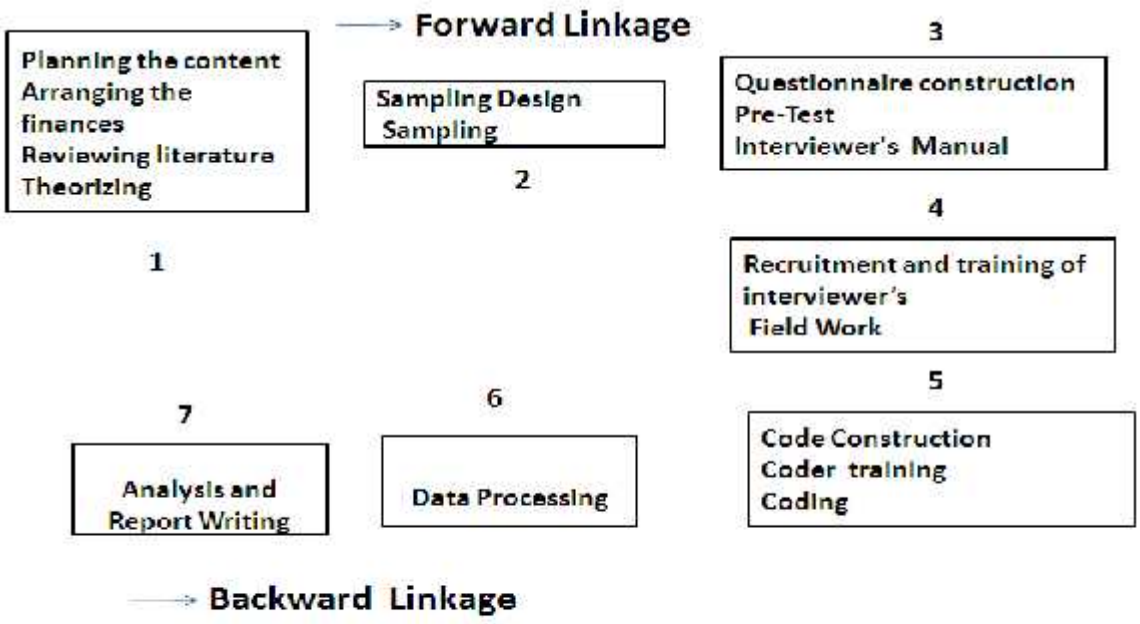
General Objective: The main objective of sampling is to get representative sample from study population characteristics **to minimize the cost, time and manpower** without losing the accuracy of the conclusion.

Specific Objective:
- obtain maximum information about population parameter based on the samples
- Testing Hypothesis
- To estimate the limits of population parameter.

Basic Steps of Sampling:
1. Define the population to be covered
2. Define the sampling unit
3. List of the population elements
4. Deciding about the size of Sampling
5. Decide about the types of sampling to be used

6. Testing the reliability of sampling

Planning the Sample Survey



What is the Best Sampling Method?

The best sampling method is the sampling method that most effectively meets the particular goals of the study in question. The effectiveness of a sampling method depends on many factors. Because these factors interact in complex ways, the "best" sampling method is seldom obvious. Good researchers use the following strategy to identify the best sampling method.

- List the research goals (usually some combination of accuracy, precision, and/or cost).
- Identify potential sampling methods that *might* effectively achieve those goals.
- Test the ability of each method to achieve each goal.
- Choose the method that does the best job of achieving the goals.

How to Choose the Best Sampling Method?

At the end of every school year, the state administers a reading test to a sample of third graders. The school system has 20,000 third graders, half boys and half girls. There are 1000 third-grade classes, each with 20 students.

The maximum budget for this research is $3600. The only expense is the cost to proctor each test session. This amounts to $100 per session.

The purpose of the study is to estimate the reading proficiency of third graders, based on sample data. School administrators want to maximize the precision of this estimate without exceeding the $3600 budget. What sampling method should they use? As noted earlier, finding the "best" sampling method is a four-step process. We work through each step below.

- List goals. This study has two main goals: (1) maximize precision and (2) stay within budget.
- Identify potential sampling methods. This tutorial has covered three basic sampling methods - simple random sampling, stratified sampling, and cluster sampling.
- Test methods. A key part of the analysis is to test the ability of each potential sampling method to satisfy the research goals. Specifically, we will want to know the level of precision and the cost associated with each potential method. For our test, we use the standard error to measure precision. The smaller the standard error, the greater the precision.

To avoid getting bogged down in the computational details of the analysis, we will use results from sample problems that have appeared in previous lessons. Those results are summarized in the table below:

Sampling method	Cost	Standard error	Sample size
Simple random sampling	Rs.3600	1.66	36
stratified sampling	Rs.3600	1.45	36
cluster sampling	Rs.3600	1.10	720

Because the budget is Rs.3600 and because each test session costs Rs.100 (for the proctor), there can be at most 36 test sessions. For the first three methods, students in the sample might come from 36 different schools, which would mean that each test session could have only one student. Thus, for simple random sampling and stratified sampling, the sample size might be only 36 students. For cluster sampling, in contrast, each of the 36 test sessions will have a full class of 20 students; so the sample size will be 36 * 20 = 720 students.

Choose best method. In this example, the cost of each sampling method is identical, so none of the methods has an advantage on cost. However, the methods do differ with respect to precision (as measured by standard error). Cluster sampling provides the most precision (i.e., the smallest standard error); so cluster sampling is the best method.

Although cluster sampling was "best" in this example, it may not be the best solution in other situations. Other sampling methods may be best in other situations. Use the four-step process described above to determine which method is best in any situation.

Types of Probability Sampling

Simple **random sample**

This is the most common and the simplest of the sampling methods. In this method, the subjects are chosen from the population with equal probability of selection. One may use a random number table, or use techniques such as putting the names of the people into a hat and selecting the appropriate number of names blindly. Recently, computer programs have been developed to draw simple random samples from a given population. The simple random sample has the advantages that it is easy to administer, is representative of the population in the long run, and the analysis of data using such a sampling scheme is straightforward. The disadvantage is that the selected sample may not be truly representative of the population, especially if the sample size is small.

Stratified sampling

When the size of the sample is small and we have some information about the distribution of a particular variable (e.g. gender:50% male/50% female), it may be advantageous to select simple random samples from within each of the subgroups defined by that variable. By choosing half the sample from males and half from females, we assure that the sample is representative of the population with respect to gender. When confounding is an important issue (such as in case-control studies), stratified sampling will reduce potential confounding by selecting homogeneous subgroups.

Systematic sampling

In this sampling, individuals are chosen at regular intervals (for example every fifth) from the sampling frame. Ideally we randomly select a number to tell us where to start selecting individuals from the list.

For example, a systematic sample is to be selected from 1200 students of a school. The sample size selected is 100. The sampling fraction is:

$$\frac{100\ (=\text{Sample size})}{1200\ (=\text{study population})} = \frac{1}{12}$$

The sampling interval is therefore 12.

The number of the first student to be included in the sample is chosen randomly, for example by blindly picking one out of twelve pieces of paper numbered 1 to 12. If number 6 is picked, then every twelfth student will be included in the sample, starting with student number 6, until 100 students are selected: the numbers selected would be 6, 18, 30, 42, etc.

Systematic sampling is usually less time consuming and easier to perform than simple random sampling. However, there is a risk of bias, as the sampling interval may coincide with a systematic variation in the sampling frame. For instance, if we want to select a random sample of days on which to count the clinic attendance, the systematic sampling with a sampling

interval of 7 days would be inappropriate, as all study days would fall on the same day of the week (e.g., Saturday only, which might be an off day every week).

Cluster sampling

In many administrative surveys, studies are done on large populations which may be geographically quite dispersed. To obtain the required number of subjects for the study by a simple random sample method will require large costs and will be inconvenient. In such cases, clusters may be identified (e.g. households) and random samples of clusters will be included in the study; then every member of the cluster will also be part of the study. This introduces two types of variations in the data – between clusters and within clusters – and this will have to be taken into account when analysing data.

Multistage Sampling

In very large and diverse populations selection of sample may be done in two or more stages till the sampling units (households, persons or health centers) are arrived at. In the first stage a list of large-sized sampling units are prepared. A sample of these is selected at a random with probability proportional to size. For each of the selected first stage units, a list of smaller sampling units is prepared. For example, if the first stage units are town, then in the second stage households are selected. A sample of these second stage units are selected at random and the study is carried out. The procedure may contain three or more stages. This type of sampling is frequently used in national level health research.

For example, if the researcher is interested to know drinking water system in rural area of Bagmati zone of Nepal. Then, at the first stage researcher can select the required districts (say two) out of eight districts randomly. In the second, stage researcher can select required VDCs (Say four each) by probability proportional to size. From the selected VDC, researcher can select households (say 300) by cluster sampling in the third stage where researcher interviews the household head.

Types of Non Probability Sampling

For quantitative surveys, probability sampling should be our preferred approach where possible. It allows randomness to drive the selection and allows estimates of the accuracy of survey findings to be obtained. The most likely situation for non-probability sampling to be needed is when there is either no sampling frame or the population is so widely dispersed that cluster sampling would be too inefficient. Non-probability techniques are cheaper than probability sampling, and are often used in exploratory studies e.g. for hypothesis generation. There are four main non-probability sampling techniques;

Purposive Sampling

Purposive sampling is a method where the participants are selected by the researcher subjectively. The researcher will pick a sample that he/she believes is representative to the

population of interest. Respondents are not selected randomly but by using the judgement of the interviewers. For example, the medical representative contracts to the popular and busy doctor purposively.

Quota Sampling

Quota Sampling is perhaps most commonly used in face-to-face interviewing. Interviewers on the street are usually looking for a specific type of respondent – age, gender are the most frequently used 'quota controls'. Quotas are given to interviewers and are organized so that the final sample is representative of the population. It is impossible to estimate the accuracy of the sample because it is not random.

Convenience Sampling

Similar to quota sampling, convenience sampling is a technique often used in face-to-face interviewing. A convenience sample is when the interviewer simply stops anyone in the street or knocks on doors asking anyone to participate and interviewing anyone willing to help. It is hard to draw any meaningful conclusions from the results obtained due to the lack of randomness, meaning the likelihood of bias is high.

Snowball Sampling

Snowball sampling is a well-known, non-probability method of survey sample selection that is commonly used to locate hidden populations. This method relies on referrals from initially sampled respondents to other persons believed to have the characteristic of interest. Limitations of this approach include non-random selection procedures, correlations between network size and selection probabilities, reliance on the subjective judgments of informants, and confidentiality concerns. Advantages include cost and efficiency. For example to study knowledge of HIV/AIDS of female prostitute snowball sampling is the appropriate method.

Reference :

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4. *Warwick DP , Lininger CA. The Sample Survey Theory and Practice.MCGraw –Hill ,Inc. (USA)*
5. *Star trek Teach you Statistics. Available on, www. stattrek.com/Lesson6/ Sampling Method.aspx [Accessed on :26/08/2009]*

Session 12: Types of Sampling

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Define probability and non-probability sampling
2. Differentiate probability and non-probability sampling
3. Explain different sampling techniques

Teaching methods:

- Mini- lecture followed by discussion 2 hours (lecture 1 hour 30 minutes and discussion 30 minutes)

Course content:

The technique of drawing a representative sample from the population of study is of fundamental importance in sampling theory; the different types of units enter a representative sample with nearly the same relative frequencies as they have in population. Note that the "units" can be defined as the objects to be surveyed, usually people, households, business (enterprises or geographic units), customers or activities (e.g. trips, phone calls, nights stayed). However, selecting a representative sample – a miniature of population, depends on many factors such as: (i) the nature of investigation, (ii) availability of suitable sampling frame, and (iii) amount of survey budget, etc. Although there are a number of different methods that might be used to create a sample, but these generally can be grouped into one of two categories: (i) probability sampling, and (ii) non-probability sampling.

1.1 Non-probability Sampling

An important issue influencing the choice of the most appropriate sampling method is availability of sampling frame, i.e., a listing of all units that compose the study population. If a sampling frame is not available, incomplete, unreliable and/or outdated, it is not possible to sample the study units in such a way that the probability for the different units to be selected in the sample is known. In such situation, the sample will be a non-probability sample and the sampling method based on such non-probability samples is known as non-probability sampling.

For example, if researcher want to conduct a study on homeless peoples' accessibility in primary health-care services. Then, neither there is a complete list of homeless peoples or individuals nor researcher likely to create such a list. However, researcher needs to get some kind of a sample of respondents in order to conduct his research. To gather such a sample, researcher would likely use some form of non-probability sampling such as purposive sampling.

There are many types of non-probability sampling methods. In this course, we will focus on six non-probability sampling methods: (i) purposive, (ii) convenience, (iii) judgement/ deliberate, (iv) quota, (v) haphazard, and (vi) snow-ball non-probability sampling methods.

1.1.1 Purposive Sampling

This method is based on purposely biased sample, which are drawn in such a way that the units in the sample provide the desired response. This may involve studying the entire population of some limited group or a sub-set of a population. Furthermore, it is good for exploratory or field research such as: (i) study of organization or community, which are especially informative – college coaches and championships, (ii) desired population for the study is rare or very difficult to locate (relatively limited group) – prostitutes, and (iii) case study analysis – find important individuals and study them in depth, etc.

Note that a purposive sampling does not produce a sample that is representative of a larger population. This method of sampling is often used by politicians, organizations such as labor unions. In this sampling, mainly, the judgement and deliberate effort is used to pick individuals who meet specific criteria.

1.1.2 Convenience Sampling

This method is based on convenience sample, which are drawn in such a way that the units in the sample are convenient to take without regard to representativeness of the population. In other words, convenience samples are obtained by choosing the easiest objects available. In this regard, many clinic-based studies use convenience samples. For example, a researcher wants to study the attitudes of villagers toward safe abortion services provided by listed sites. He decides to interview all women who have taken the safe abortion services in the site during one particular day. This is more convenient than talking a random sample of people in the village, and it gives a useful first impression.

A drawback of convenience sampling is that the sample may be quite unrepresentative of the population you want to study. Some units may be over-selected, other under-selected or missed altogether. It is impossible to adjust for such a distortion. If you need to be representative you have to use another sampling method.

1.1.3 Judgment Sampling

This method is based on judgment sample, which are drawn in such a way that the units in the sample are left to the judgment of the organizer of the survey, because the claim is that s/he "knows" the units in the population so s/he is "best" qualified to determine which units should be in the sample to "best" represent the population. In other words, the judgment sampling involves choosing objects that it is believed will give accurate results. For example, for representation of the service availability mapping, the three administrative types of broad areas (one large city, three municipalities, and fifteen Village Development Committees (VDCs)) may represent the entire nation.

1.1.4 Quota Sampling

This method is based on quota sample, which are drawn in such a way that the units in the sample are left to the interviewer to select units from the population so that s/he can meet his assigned quota. In other words, the researcher interviews as many people in each category of study unit as s/he can find until he has filled quota. The actual selection is usually done using purposive or convenience sampling. Therefore, quota sampling is a somewhat sophisticated form of purposive sampling, widely used in opinion and market surveys.

For example, the researcher of the family planning study just mentioned suspects that religion might have a strong effect on patients' attitudes toward the family-planning services. He is afraid to miss the Muslims, who are a minority in the area. He, therefore, decides to include in the study 20 patients to form each of the different religious groups (Hindus, Buddhists, Muslims, Christians, and Kirats, etc).

In summary, the total sample is allocated in proportion to the prevalence of characteristics of the study population for e.g., distribution of population by caste/ethnicity, religion or broad age groups and sex. The enumerators are given specified quota of sample. Within the quotas, the enumerators are supposed to obtain representative individuals. They are free to choose their samples as they like, provided the quota requirements are fulfilled. This method of sampling is preferred in public opinion surveys (especially for telephone surveys) because of the speed with which it can be conducted.

The primary problem with this form of sampling is that even when we know that a quota sample is representative of the particular characteristics for which quotas have been set, we have no way of knowing if sample is representative in terms of any other characteristics. If we set quotas for gender and age, we are likely to attain a sample with good representativeness on age and gender, but one that may not be very representative in terms of income and education or other factors. The underlying assumption is of course, that the sample reflects the same distribution of characteristics as the population and is well spread geographically. As is obvious, this method of sampling too lacks scientific validity as there is no element of randomization in the selection and one may expect serious biases too.

1.1.5 Haphazard Sampling

This method is based on haphazard sample, which are drawn without specifying rules for selection. For example, in many fields of research like medicine, anthropology, archaeology, a few items or specimens are inspected for findings, there being no specified rules for selection. Furthermore, it is also the practice to obtain data from whatever subjects come across their way. The samples are haphazard and hence no meaningful inference can be drawn about the population.

1.1.6 Snowball Sampling

This method is based on snowball sample, where a researcher identifies one member of some population of interest, then asks that person to identify others (samples) in the population and so on. In this method, an individual or group of individuals is sampled. In other words, when one member of the study population is sampled, then s/he provides other sources to be sampled, i.e., sampling snowballs into a large selection (chain sampling). In this method, sociogram, a map of individuals and their references is widely used tool. This method is useful for hard to identify groups or members of a special population that are difficult to locate such as: (i) study of criminal organizations, (ii) study of injecting drug users, (iii) study of female sex workers, etc.

The method creates a sample with questionable representativeness. A researcher is not sure who is in the sample. In effect snowball sampling often leads the researcher into a realm he/she knows little about. It can be difficult to determine how a sample compares to a larger population. Also, there's an issue of who respondents refer you to – friends refer to friends, less likely to refer to ones they don't like, fear, etc. which leads to biased sample.

In **summary**, we have discussed six types of non-probability sampling methods. Undoubtedly, there are many more in statistical practices. One common property underlying these methods is that they are all subjective in nature and hence are biased methods. The accuracy of sample estimates cannot be assessed because there is no probabilistic basis for estimating the sampling variability of the estimates from sample to sample. In conclusion, non-probability sampling findings are usually not qualified for any generalizations as they lack to be representative of the entire population.

1.2 Probability Sampling

When a sample is drawn from a population such that the probability of including any particular unit in the sample is known, then we speak of probability sampling. Such a sample provides a probabilistic basis for deriving sample estimates and estimates of accuracy. Probability sampling is characterized by the following:

(i) Every unit of the population has a known probability of being included in the sample,
(ii) The sample is drawn by a method of random selection, and
(iii) The estimates based on the sample take account of the probabilities of selection of the units.

Probability sampling – where representativeness is most important, requires that a listing of all study units exists or can be compiled. This listing is called the sampling frame. Note that, in probability sampling we do not require that the probability of selection be equal for all units of the population. All we need is that these probabilities are known. In other words, in probability sampling, each unit of selection has a known, non-zero probability of being selected. Furthermore, the probability sampling can produces unbiased results (if no non-response) and allows for calculation of sampling error (if pair-wise selection probabilities

known). There are several ways of drawing probability samples, the most common, which we are going to discuss in this course are as follows: (i) Simple Random Sampling, (ii) Stratified Random Sampling, (iii) Systematic Sampling, (iv) Cluster Sampling, (v) Multi-stage Sampling, and (vi) Probability Proportional to Size (PPS) Sampling.

1.2.1 Simple Random Sampling (SRS)

It is the simplest form of random sampling. The sample is drawn unit by unit, giving equal probability of selection to every unit in the population at each draw. There are two types of SRS such as: SRS with replacement (SRSWR) and SRS without Replacement (SRSWOR).

(i) In SRSWR, the unit selected is returned to the population before the next unit is drawn. Obviously, in SRSWR there is a possibility of some units getting selected more than once in the sample.
(ii) In SRSWOR, the unit selected at any draw is not returned to the population before the next unit is drawn. The sample so selected will consist of distinct units without any repetition.

In this sampling procedure, each element of the larger population is assigned a unique number, and a table of random numbers or a lottery technique is used to select elements, one at a time, until the desired sample size is reached. This procedure can be quite tedious in drawing large samples. However, the random sampling numbers can be obtained using: (i) a calculator, using RAN# function, (ii) a spreadsheet such as MS Excel, using RAN() function, (iii) statistical software packages like SPSS, SAS, SYSTAT, and STATA, etc., and (iv) random number tables – consist of a randomly generated series of digits (0-9).

Definition: a series of random sampling numbers is a linear arrangement where each place has been filled up by one of the ten digits 0, 1, 2, … …, 9, in such a manner that (i) each digit has probability 1/10 of occupying any place and (ii) the digits occupying different places are chosen independently of one another.

Note that, while using the random number tables you can begin anywhere (choose a number at random) but having once started you should continue to read across the line or down a column and NOT jump about.

Statistically, SRSWOR is more efficient than SRSWR, as the former gives estimates with smaller standard error (SE), though the computations of various statistics are easier in case of the latter. Note that, SRS is a basic sampling scheme but has not found wide application due to: (i) hard to achieve in practice, (ii) it requires an accurate list of the whole population, (iii) expensive to conduct as those sampled may be scattered over a wide area, and (iv) there are other more efficient sampling designs like systematic sampling, probability proportional to size which use other information about the population.

1.2.2 Stratified Random Sampling

When on the basis of past data a population is divided into groups such that the units in a group are more alike with respect to some characteristic of interest than are the units in the population as a whole and a basic sampling scheme (for e.g., Simple Random Sampling, Systematic Random Sampling, etc.) is drawn from each group, then this procedure is called stratified random sampling. The groups are referred to as strata and the process of dividing the population is called stratification. The variable used for forming the groups is known as stratification variable.

Let N denote the size (number of units) in the population which is split up into k strata numbered 1, 2, 3, … …, k. let the sizes (number of units) of these strata be denoted by N_1, N_2, … …, N_k, respectively. Then $\sum N_i = N$. Random samples of sizes n_1, n_2, … …, n_k are drawn independently from these strata by some method, say SRSWOR. The total sample size is then $\sum n_i = n$. However, one question arises in connection with stratified sampling is how should the total sample size n be allocated to the different strata? Several formulas are mentioned in the literature but two most popular methods of allocation of sample size are:

(i) Proportional allocation: here one uses the same sampling fraction for all the strata. For the over-all sample, the sampling fraction is $\frac{n}{N}$. The same fraction of units is drawn from every stratum. This means that → $n_i \propto N_i$ -- proportional allocation.

(ii) Optimum allocation: here the sampling fraction $\frac{n_i}{Ni}$ is higher for a stratum which has greater within stratum variability than for a stratum which is homogeneous. This is because the more variable strata contribute more to the SE of the over-all estimate. So one tries to reduce his contribution i.e., the SE of the estimate of mean of each heterogeneous stratum. This means that → $n_i \propto N_i\sigma_i$ -- optimum allocation. Where σ_i = standard deviation of study variable in the i^{th} stratum.

The basic idea behind stratification is to reduce unit-to-unit variability within a stratum to a minimum. The greater the variability between strata and the smaller the variability within the strata, the greater is the reduction of SE when stratified sampling is adopted. If a SRS is selected from the entire population consisting of several distinct groups of diverse sizes and divergent characteristics, we may fail to get adequate representation of each group. If the strata are made homogeneous within and heterogeneous between before sampling, estimates from such a technique will have increased precision relate to SRS. One or more variable, usually called stratification variables may be used for stratification. For example, geographically contiguity, population density and area under crops could be used together for stratification.

1.2.3 Systematic Random Sampling

Systematic random sampling is the most widely known selection procedure. It is very commonly used because of its simple procedure which consists of selecting the first unit with the help of random numbers, the remaining units getting selected without using random numbers. It provides an alternative for random and independent choice of sampling units and is sometimes called "pseudo-random" selection. The main application areas of systematic sampling are in agriculture, forestry, fisheries, and population studies.

Suppose that a population consists of N units and that these are numbered serially by some criteria from 1 to N. As before let n be the sample size and assume that N = kn, i.e., N is expressible as the product of k and n. if we draw a random number between 1 and k, say r and select the units corresponding to r, r+k, r+2k, … …, (n-1)k to be in the sample, then such a sample is called a systematic sample. The number k is known as the sampling interval. The above procedure of drawing every k^{th} unit with a random start is known as systematic sampling with a random start. Note that when $N \neq nk$, the sample size may differ from sample to sample when N is not exactly divisible by k.

Systematic sampling is usually less time consuming and easier to perform than simple random sampling. However, there is a risk of bias, as the sampling interval may coincide with a systematic variation in the sampling frame. For instance, if we want to select a random sample of days on which to count clinic attendance, systematic sampling with a sampling interval of 7 days would be inappropriate, as all study days would fall on the same day of the week, which might, for example, be a market day.

1.2.4 Cluster Sampling

Quite often the population under study consists of persons but the sampling design is such that one selects households and studies all the persons in each selected household. This is an example of cluster sampling. In cluster sampling, we form suitable clusters of ultimate units – the smallest unit which is the subject of sample selection, for e.g., households, take a sample of clusters and survey all the units in each sample cluster at the stage of data collection. In countrywide sample a survey, a direct random sample of units from the entire population is not possible as there would not be a frame from which to take a sample. For example, a frame of persons or even households is not available for the country as a whole. Moreover, from consideration of operational convenience and cost, larger units rather than elementary units are selected. For example, collection of data is easier, faster, cheaper and more convenient from all households in a village (cluster) or all persons in a household (cluster) than an independent sample of households/persons scattered all over.

In many cases, however, different units within a cluster give similar correlated observations. For example, similar spending patterns due to similar incomes, or a similar range of products being available locally. Thus for a given number of ultimate sampling units, SRS will give better results (with smaller SE's) than estimates based on cluster sampling. The sampling variance increases with cluster size and decreases with increase in number of clusters for a given total sample size in terms of units. The cost on the other hand decreases with increase in cluster size and increases with number of clusters. It is therefore, necessary to reconcile the

two opposite movements by finding the optimum values for the cluster size and the number of sample clusters which would minimize the sampling variance for a fixed cost or minimize the cost for a specified sampling variance.

1.2.5 Multi-stage Sampling

In many surveys, one does not have the sampling frame showing all the units in the population under study and the construction of this frame is very expensive. In such cases, one draws the sample in stages. An example will make the situation clear. Suppose one wants to draw a sample of 500 households from the rural areas of a country (or region) consisting of 100,000 villages, say. Even if the country (or region) is divided into strata, any particular stratum may have 500 villages, say. One cannot select the sample of households directly from any stratum by SRS or systematic sampling or PPS sampling, for the simple reason that the (up-to-date) list of all the households in all the villages in the stratum/ population is not available in the statistical office.

A reliable and up-to-date list of all households in any one village can only be prepared by a field worker going round the village, knocking at every door, in principle. Typically, a field worker can list 50 to 60 households per day. The preparation of such lists for all the villages in the stratum/ population would be too expensive. This problem can be overcome by two-stage sampling. In the first stage, we may use the list of villages to draw a sample of, say, 50 villages from the stratum/ population. We then send the field workers to these villages for the preparation of household lists for these 50 villages only. When these 50 lists are available, we may draw 5,000 households from them in a suitable manner.

For example, we can select 10 households from every village irrespective of its size. Alternatively, we may select the same percentage of households from every village, choosing this percentage in such a way that 500 (or nearly 500) households are drawn from the 50 villages taken together. In this procedure, the villages would be called the first stage units (fsu's) and the selection of villages, the first stage of sampling; and the households would be called the second stage units (ssu's) and the selection of households, the second stage of sampling. Note that each fsu consists of a certain number of ssu's.

In certain situations, one may have more than two stages in the selection of the sample -- hence the name multi-stage sampling. Thus, for a socio-economic enquiry in urban areas, one may first draw a sample of municipalities (fsu's). Then from each selected town, one may choose a sample of census enumeration areas (ssu's). Finally, from each sample area, one may select a suitable number of households (third stage units) after the process of listings. The method of selection can be different at the different stages, e.g., PPS for the first stage, SRSWOR for the second, and Systematic Sampling for the third.

Let us return to the above example – selection of 500 households from a 100,000 villages. Then there is the problem of choosing the number of sample villages and the number of sample households per selected village. If reduction of SE is the only consideration, the greater the number of sample villages the better, and the best plan is to choose 500 villages

and one household per village. But cost aspects are equally important in designing a sample survey. The cost of journeys and of listing of households goes up sharply with the number of sample villages. In practice, a balance is struck between these conflicting considerations. For most socio-economic enquiries, one takes 5 to 15 households per village, depending on the subject of enquiry.

1.2.6 Probability Proportional to Size (PPS) Sampling

In simple random sampling the selection probabilities are equal for all units in the population. Thus simple random sampling is an example of equal probability sampling. In many applications in agriculture simple random sampling is not proper, because it does not take account of the size of the unit. The same story also holds for systematic sampling.

To take account of the size of the units it is natural to assign different probabilities of selection to the units. When a sample is selected such that units have different selection probabilities, then we speak of unequal probability sampling. An important case of unequal probability sampling is sampling with Probability Proportional to Size (PPS). In PPS sampling, the units are selected with probabilities proportional to some measure of their size. The basic assumption here is that the variable under study is correlated with size. For example, the size may be the population of villages say, in a last census; number of manufacturing enterprises in village in the last manufacturing establishment census; cultivated area for a recent year for crop and livestock surveys, etc.

Finally, the principle merits of random sampling can be concluded as: (i) if the sample size n is large, then the law of large numbers of probability theory ensures that different types of units in the population enter the sample with nearly the same relative frequencies as they have in the population; or, in other words, the sample is representative of the population. The degree of representativeness increases as n increases. (ii) by making use of probability theory, one can assess the sampling error of any estimate based on the sample and hence the risk of using that figure as an estimate of the true value for the population. This is done through standard errors, or still better, through confidence intervals for population values.

Session 13: Study Based Sample Size Calculation

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **State** the sample size required for the study
2. **Describe** the factors affecting sample size determination for the study.
3. **Define** the different terms applied in determination of sample size.
4. **Sate** the steps of determination of sample size for the study.
5. **Apply** appropriate formula to determine the sample size for their study

Teaching methods:

- Class room lecture (50 minutes)
- Discussion , questions and answer (25 minutes)
- Individual practice work of sample size determination (45 minutes)

Course contents:

- **Sample Size & its determining factors-** What is Sample Size & Why?, Factor affecting the size of the sample (Nature of the population, Number of classes in analysis, Nature of the study, Types of sampling , Practical consideration)
- **Determination of sample size** - Sample size estimation for cross sectional studies, Sample size estimation for experimental studies

I. Sample size & its determining factors

What is Sample Size and Why?

- Sample size is an important factor to be considered in sampling
- The size has a direct bearing upon accuracy of estimation, cost and administration of the survey
- Though, large samples give smaller standard errors, they are, generally, difficult to manage and unfit for detail study

- On the other hand, small sample tend to give higher standard error but avoid unnecessary expenses

- Therefore, an optimum sample size is required

- An optimum sample size is one which fulfills the requirements of efficiency, representativeness, reliability and flexibility

- The criterion is that the sample should be small enough to avoid unnecessary cost and large enough to avoid intolerable sample errors

II. DETERMINATION OF SAMPLE SIZE

Most of the researchers are not sure of how many sample they need, to collect the information. Most the text books advocate using as large sample as possible. However that is impossible. On the other hand there is a approach including of one tenth of total population. The other methods for sample estimation are use of the formulas which depends on many factors. The first and foremost is the type of study to be undertaken, whether observational or experimental.

If it is an observational study, then the kind of observational study, whether crosses-sectional (survey), case-control or cohort will also determine the formula.

For cross-sectional studies, the formula for sample size estimation depends on the sampling design and on the parameter being estimated, i.e. whether the population mean, U, or the population proportion, P, is being estimated. For is session, we shall learn the estimation of sample size for simple random sampling and cluster sampling.

For case-control and cohort studies as well as for experimental studies, the design of the study, whether independent or matched, and the error rates; i.e., whether the population mean, U, or the population proportion, P, is being estimated. For this session, we shall learn the estimation of sample size for simple random sampling and cluster sampling.

Aside from these, there are other considerations specific for each type of study which shall be discussed in the following sections. The practical considerations for any type of study would be availability of resources (financial, time and manpower resources) and prospective subjects.

2.1 Sample size estimation for cross sectional studies

Considerations

a. Sampling design
b. Parameters being estimated (μ, p)

If simple random sampling is followed

Consideration

- Precision (maximum tolerable error) how close to the true value do we want our estimate to be.
- Reliability level: the degree of confidence that our estimated is within the maximum tolerable error set.
- Variability

The basic relationship is:

Maximum tolerable error = reliability X standard error

Estimation of sample size for the population mean, μ

$$n = \frac{Z\alpha^2 s^2}{d^2}$$

Where;
n = required sample size
Zα = z deviate corresponding to the reliability level
s^2 = variance
d = maximum tolerable error.

Example

A nutritionist wishes to conduct a survey among teenage girls to determine their average daily protein intake. If she would like her estimated to be within 5 units of the true value with a reliability level of 95%, how many girls should be taken into the study if the standard deviation of protein in 20?

$$n = \frac{Z\alpha^2 s^2}{d^2}$$

$$= \frac{(1.96)^2 (20)^2}{(5)^2}$$

$$= 61.47 = 62 \text{ subjects}$$

Estimation of sample size for the population proportion, P

$$n = \frac{Z\alpha^2 PQ}{d^2}$$

Where:

n = required sample size
Zα = z deviate corresponding to desired reliability level
P = estimated proportion in the population
Q = 1 – P
d = maximum tolerable error

Example:

A survey to determine the prevalence rate of TB is to be undertaken. How many subjects should be included in the study in the prevalence in the past is 35% and the desired precision and reliability are 3% and 95% respectively?

$$n = Z\alpha^2 \frac{PQ}{d^2}$$

$$n = \frac{(1.96)^2 (.35)(.65)}{(.03)^2}$$

n = 971.07 = 972 subjects

Sample size estimation for experimental studies

Consideration:

- Experimental design
- Magnitude of α error
- Magnitude of β error
- Minimum difference which has to be detected
- Difference being detected or difference on proportions

Test of hypothesis on the difference between means μ_1 and μ_2 (Ho: $\mu_1 = \mu_2$)

$$n = 2\frac{(Z\alpha + Z_\beta)^2 s^2}{d^2}$$

Where:

n = sample size required/ group
Zα = z deviate corresponding to the α error rate
Z_β = z deviate corresponding to the β error rate
s^2 = variance
d = difference to be detected

Example:

We wish to know whether a change in the structure of an analgesic drug increases the duration of pain relief. We specify a probability of 5% of failing to detect an increase of 15 min. with an error rate of 2 ½%. The standard deviation of the duration of pain relief, know for the old treatment from previous experience, is 1 hour and we assume that it is the same for the new treatment.

$$n = \frac{2\,(Z\alpha + Z_\beta)^2\, s^2}{d^2}$$

$$= \frac{2(1.96 + 1.645)^2\ 1^2}{(1/2)^2}$$

= 416 subjects/group

Test of hypothesis on the difference between two population proportions P_1 and P_2 (Ho: $P_1 = P_2$)

Example:

Suppose it has been estimated that the rate is 800 per 1000 school children in one district and 600 per 100 in another district. How large a sample of children form each district is required to determine whether this difference is significant the difference if it is real?

$$N = \frac{[Z(_1 - \alpha)\ \sqrt{\{2P\ (1 - P)\}} + Z(_1 - _\beta)\ \sqrt{\{P_1(1 - P_2)\}} + P_2\,(1 - P_2)]^2}{(P_1 - P_2)^2}$$

using formula with P = (0.60 + 0.80)/2 = 0.70 it follows that

$$n = \frac{[1.282\ \sqrt{\{2(0.70)\ (0.30)\}} + 0.842\ \sqrt{\{(0.80)\ (0.20)\}} + (0.60)\ (0.40)]^2}{(0.80 - 0.60)^2}$$

= 46.47

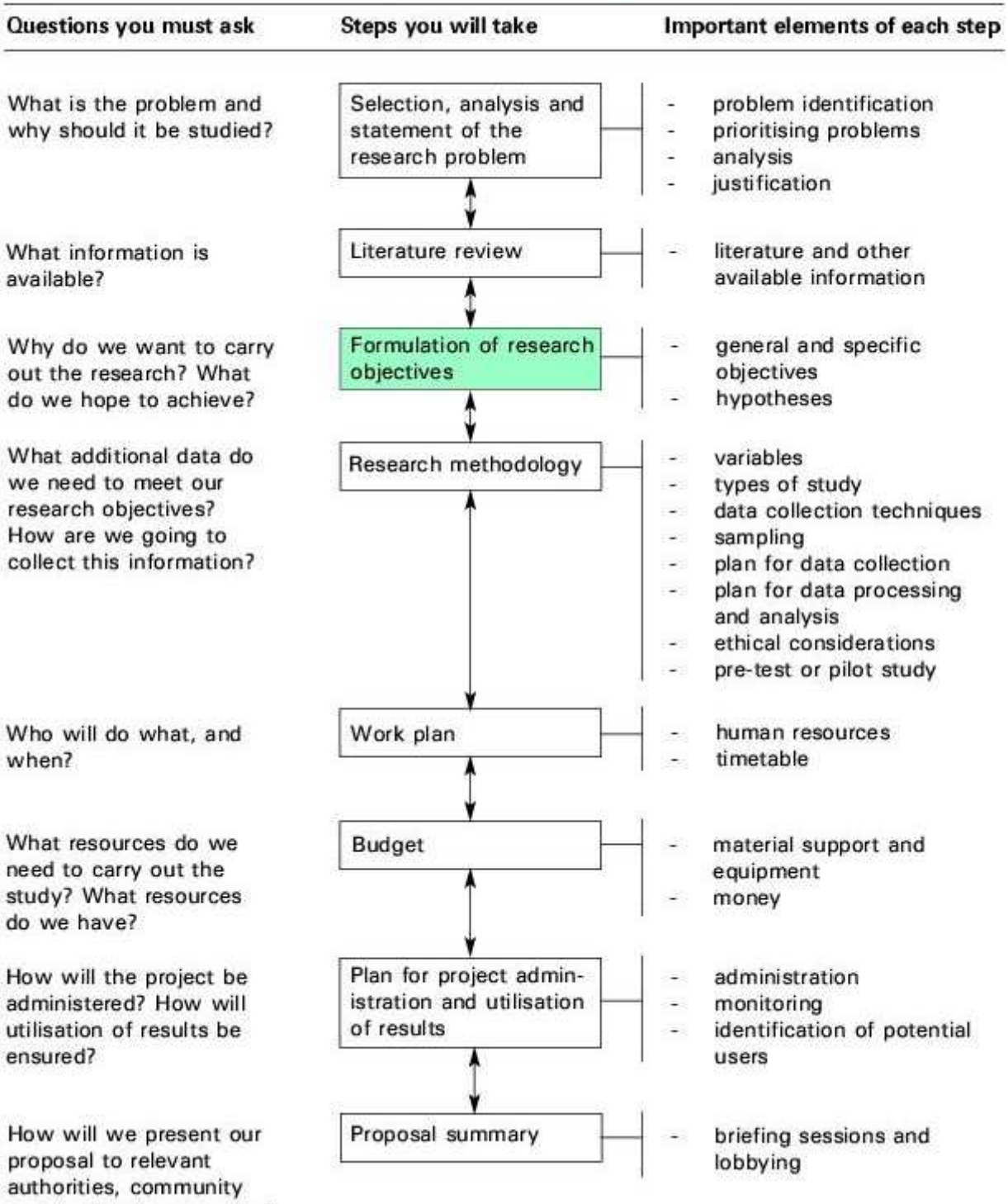
Hence, a sample of 47 children from each district would be required.

INDIVIDUAL PRACTICE WORK OF SAMPLE SIZE DETERMINATION (45 minutes)

1. A survey is planned to determine what proportion of the high school students in a
2. Metropolitan school systems have regularly smoked marijuana. If no estimate of p is
3. Available from previous studies, a pilot sample cannot be drawn, a confidence
4. Coefficient of 0 .95 is desired, and d=0 .04 is to be used, determine the appropriate
5. Sample size. What size sample would be required is 99 % confidence were desired?
6. A hospital administrator wishes to know what proportion of discharged patients are unhappy with the care received during hospitalization. How large sample should be drawn if we let d= 0 .05, the confidence is 0 .95, and no other information is available? How large should the sample be if p is approximated by 0.25?
7. A health planning agency wishes to know, for a certain geographic region, what proportion of patients admitted to hospitals for the treatment of trauma are discharged dead. A 95 percent confidence interval is desired, the width of the interval must be

0.06, and the population, from other evidence, is estimated to be 0.20. How large a sample is needed?

8. Mean pulse rate of a population is believed to be 70 per minute with a standard deviation of 8 beats. Calculate the minimum size of the sample to verify this, if allowable error L=± 1 beat at 5% risk.
9. Mean systolic blood pressure in one college students was found to be 120 with S.D. of 10. Calculate the minimum size of the sample to verify the result if allowable error is ± 2 at 5% risk.


Questions you must ask
Steps you will take
Important elements of each step
What is the problem and why should it be studied?
Selection, analysis and statement of the research problem
- problem identification
- prioritising problems
- analysis
- justification
What information is available?
Literature review
- literature and other available information
Why do we want to carry out the research? What do we hope to achieve?
Formulation of research objectives
- general and specific objectives
- hypotheses
What additional data do we need to meet our research objectives? How are we going to collect this information?
Research methodology
- variables
- types of study
- data collection techniques
- sampling
- plan for data collection
- plan for data processing and analysis
- ethical considerations
- pre-test or pilot study
Who will do what, and when?
Work plan
- human resources
- timetable
What resources do we need to carry out the study? What resources do we have?
Budget
- material support and equipment
- money
How will the project be administered? How will utilisation of results be ensured?
Plan for project administration and utilisation of results
- administration
- monitoring
- identification of potential users
How will we present our proposal to relevant authorities, community
Proposal summary
- briefing sessions and lobbying

Session 14: Data Collection Techniques

Time frame: 5 hours 30 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. List the various data collection techniques (both qualitative and quantitative)
2. Explain the various data collection techniques and their uses and limitations
3. Describe the purpose, process and limitations of interview techniques
4. Identify the purpose, uses and limitations of Focus Group Discussion as method of data collection in research
5. Mention the steps in conducting Focus Group Discussion
6. Identify the purpose, uses and limitations of observation techniques

Teaching methods:

- Class room lecture (50 minutes)
- Discussion , questions and answer (25 minutes)
- Individual practice work on Data Collection Techniques (4 hours 15 minutes)

Group Works

Group Exercise for designing questionnaire/interview schedule (one hour)

- Define the topics with details of information needed to answer research questions
- Prepare a list of variables
- Formulate one or more questions under each variable
- Decide form of questions (closed-end with two choices or multiple choices and open ended)
- Take care that you have mix between pre-categorized and open-ended questions
- Arrange questions in sequential orders.
- Prepare draft questionnaire
-

Group Exercise for preparing interview guide (semi-structure interview) (30 minutes)

- Decide the topics/sub-topics to be covered by interview. Topics of questions should cover knowledge, feeling, opinion/values, experience/behaviour.
- Write open ended questions under each topic/sub-topic.
- In-depth semi-structured interview is comprised of three kinds of questions: *main questions, follow-up questions and probes.*
- Main Question: Main questions should reflect the logical flow, moving from easy, broad and least threatening questions to more complex and interested issues as interviewer builds rapport.
- A follow-up question (Mini tour/specific questions) moves the interview or discussion to a deeper level by asking for more detail.

- A probe is a kind of follow-up question or example question that takes the discussion into still deeper territory, with or without specific reference to the topic.
- Sequence of Questions the main and follow up questions and probes

Exercise for preparing guidelines for FGD (30 minutes)

- Decide the subject matter and topic of FGD.
- Formulate one or more questions in each topic
- Develop 6-10 open ended questions.
- Questions should be ordered from easy, general questions to more specific ones
- Prepare a draft guideline containing following components
  Basic information: place, date, time, name of moderator and note-taker
  Background characteristics of the participants: Name, age, sex, ethnicity, occupation and education
  Step 1 Introduction and Rapport Building
  Step 2 Guiding Questions for discussion
  Step 3 Closing part of the FGD
  Step 4 Work to be done after Discussion

Exercise: FGD training (Role Play)

Conducting an FGD (60 minutes)

- Select a moderator and two note-takers from each group
- Prepare FGD guides
- Identify 6-10 participants from the group members
- Arrange the FGD participants in semi-circle
- Conduct discussion using FGD guide

Plenary (30 minutes)

- Recorder present the report of the FGD
- Recorders may then ask for comments and reactions from members of the group
- Plenary discussion should focus on process of FGD and strength and weakness

Course contents:

A. Interview
B. Focus Group Discussion
C. Observation

A. Interview Technique

An interview is data-collection technique that involves verbal questioning of respondents or informants. It is a conversation between the interviewer/researcher and respondent/informant for the purpose of obtaining research-relevant information.

Types of Interview

1. Structured interview

2. Semi-structured interviews
3. Unstructured interview

1. **Structured interview: t**he interview which is structured and controlled with a format, script or questionnaire with instruction that is followed exactly during the process of interview. It is like a interview schedule that is administered face to face with a respondent. The tight control over the wording of questions, the order in which the questions occur and the range of answer that are offered have the advantage of 'standardization'. Each respondent is asked the same questions in the same manner.
2. **Semi-structured interview:** In this type interview, the interviewer still has a clear list of issues to be addressed and questions to be answered. However, the interviewer has some freedom to reframe, add or clarify questions, develop ideas and speak widely on the issues. The answers are open-ended, and there is more emphasis on the interviewee elaborating points of interest. Semi-structured interview technique can be used in key informant interview and case interview.
3. **Unstructured interview:** In the unstructured interview, there are no specifications in the wording of the questions or the order of the question. The interviewer forms questions as and when required. The interviewer has freedom to ask questions as per her/his wishes considering context of interview and scope of the study. Qualitative/ethnographic interview is usually conducted in unstructured way.

Other types of interview

- Face to Face interview
- Telephone/Video interview
- In-depth Interview (IDI)
- Key Informant Interview (IDI)
- Case Interview
- Ethnographic interview
- Group Interview

Steps in conducting interview

Step 1: Planning interview process

- Define the objectives of interview.
- Identify the subject matter for interview.
- Determine the information /data (qualitative and quantitative) required for the study
- Choose the type of interviews: structured, semi-structured or unstructured
- Identify possible respondents or informants.

Step 2: Designing interview tool (schedule, format, guide)

- Determine the objectives of conducting interview
- Decide the contents and main points of interview.
- Formulate main questions
- Main question needs to be broken up into different parts.

- Arrange questions in logical order.
- Prepare interview schedule if interview is to be conducted in structured way.
- Prepare interview guide or checklist if qualitative information is required.

Step 3: Select respondents/informants and interview setting

- Select sample respondents or appropriate informants as per study objectives
- Seek appointment from the respondent before approaching for interview
- Select a comfortable and quiet setting.

Step 4: Conducting interview

A. Introduction and rapport building

- Approach to the respondents in their convenient time and place
- Greet your respondents and introduce yourself as soon as you meet them.
- respect the local language, culture and customs and dress up in simple clothing
- Start talking about aims of research, risk and benefits of the project.
- Try to break ice, build rapport and trust talking and asking most familiar things and reducing social distance/gap between interviewer and interviewee.
- Assure the informant of the confidentiality.
- Tell them how long the interview will last.

B. Start actual interview

- Follow instruction, schedule or guide/checklist.
- Ask previously formulated question in the schedule exactly and same manner to all respondents in structured interview.
- Ask open and probing questions following interview guidelines in semi-structured interview.
- Ask main questions, follow-up and probing questions or rephrase/formulate questions during the interview considering the context in unstructured interview.
- Emphasize the informant perspective: Consider yourself a student or learner/listener and tell the informant that s/he is the expert of interest of subject matter
- Ask simple, short and open-ended questions in qualitative interview
    - 'Would you please describe your hand washing behaviour?'
    - ‘What is your opinion on the services provided in this clinic’ (Explain why.)
    - ‘What do you think are the reasons some adolescents in this area start using drugs?’
- Ask one question at a time
- Avoid leading question. For example, do you wash your hand before eating? Don’t you?
- Do not ask hypothetical question. Where do you go for treatment when you suffer from malaria fever?
- Probe and prompt adequately in qualitative interview.
- Rephrase the questions using local terms when there is no answer.
- Ask sensitive questions in a socially acceptable way.
- Evaluate answers

C. After Interview

- Assemble all materials into one envelope. Double-check that you have completed all forms.
- All materials are appropriately labeled. Note and explain any missing materials on the archival information sheet.
- Transcribe the audio-tape and expand your scratch field notes within 24 hours if possible.

B. Focus Group Interview

Focus Group Discussion (FGD) is a data collection technique that brings six to ten people together by a moderator to discuss a specific topic of interest with a view to eliciting descriptive data and gaining an understanding of issues from the perspective of the group's participants. It is the use of group interaction to produce qualitative data and insights that would be less accessible without the interaction found group. FGD provide a rich and detailed set of data about perceptions, thoughts, feeling, impressions, beliefs and experiences of people in their own words.

When are focus groups appropriate?

Focus Groups are appropriate when you want to:

- When you are interested in understanding some issue from the perspective from some group.
- When your study's focus is on socio-cultural norms, expectation, values and beliefs.
- Explore the depth and nuances of opinions regarding an issue
- Testing ideas and reactions to actual or proposed health services
- When examining attitude or reactions of a group to some health issues.
- Explore certain topic areas in those areas where survey method is most difficult or where prior research is lacking
- Survey tools development
- Formative research: need assessment

Focus Groups are not appropriate when you:

- Need to ask participants sensitive information
- Need statistical information about an entire population
- Are working with emotionally or politically charged groups
- Can't ensure confidentiality
- Want people to come to a consensus
- Do not have the skills to analyze the data

Components of Focus Group Discussion

1. Moderator and note-taker
2. Participants (composition of focus group)
3. Environment

1. Role and responsibilities of moderator/facilitator in FGD

- Act as a guide or facilitator
- Politely and diplomatically enforce ground rules.

- Make participants feel at ease; facilitate open communication.
- Keep participants focused, engaged, attentive and interested.
- Stimulates group discussion; keeps it on course.
- Use the focus group guide effectively to ensure all topics are covered.
- Monitor time and use limited time effectively
- After the focus group, work with the note taker and transcribe FGD

2. Functions of Note-taker/recorder

- Arrange the room or site and equipments for discussion
- Welcome participants and sit them in designated location
- Record date, time and place
- Informally collect socio-demographic data before conducting FGD
- Take detailed notes throughout the discussion
- Run a tape recorder during the session.
- Observe carefully and note everything body language.
- Debrief with moderator

3. Composition of FGD participants

Participants should be relatively homogenous: people should be similar with respect to characteristics (age, gender, caste, occupation, resident etc.)

Participants should be familiar or grounded in the topic, either through personal experience, or vested interested arising from a particular role or position.

Select the participants who want to discuss in group and will not inhibit others' participation.

Five to nine participants are ideal for discussion (small vs. large)

4. Environment

Suitable environment is essential to conduct FGD successfully. It is important to choose or set up a physical space for the focus group that is going to feel welcoming and comfortable to the participants. It should be neutral and free from distractions and easily accessible.

Steps in organizing FGDs

I. Planning the FGD session

- Define objective and subject matter of discussions
- Determine the focus group composition (Homogenous or heterogeneous) and number of groups needed.
- Select supporting materials (tape recorder, cassette tapes, notebooks, pencils etc.)
- Develop discussion guide
- Select the participants
- Select sites, date and time.

II. Preparing the FGD guide

FGD guide or guidelines or checklist need to be developed to provide an overall direction for the discussion.

- Determine the purpose of FGD in data collection process
- Identify the issues and content of the discussion
- Develop 10-12 main questions and follow up/probing question on each question
- Topic and guiding questions should go general to specific.

- Pre-test or pilot the FGD guide that will help eliminate problems during FGD.

III. Conducting FGD

A. Introduction and rapport building (10-15 minutes)

- Introduction among participants and facilitators
- Determine the seating arrangement
- Brief the purposes of focus group
- Politely and diplomatically enforce ground rules
- Read consent sheet and obtain consent
- Build rapport and establish permissive/comfortable environment.
- Carry out the main agenda/topic for discussion

B. In-depth discussion (50-60 minutes)

- Enter the depth of discussion by asking open questions (WH questions) and follow-up questions in group. *Ask when, what, where, which, and how questions* – they provoke more detailed information.
- Ask only one question at a time.
- Encourage one person to speak at a time
- Encourage the participants to express their experience, thoughts and values.
- Listen carefully to participants and carry on probing.
- Give verbal and non-verbal clues to those who are reluctant to speak.
- Keep the discussion flowing.
- Be neutral and avoid judgments negative or positive
- Be comfortable with silence since it encourages elaboration.
- Use prompt probes and clarifying questions to stimulate discussions.
- Do not allow one person to dominate discussion

C. Closing down the discussion (5-10 minutes)

- Toward end of the sessions, the moderator summarizes the impressions or conclusions of the discussion
- Ask if anything has been missed.
- Ask how people have felt about taking part in the focus group.
- Thank them for coming and contribution.

After the FGD Session

- Verify if the tape recorder, if used worked throughout the session
- Review the notes taken for clarity and understanding.
- Discuss and record any insights or ideas that the discussion created while they are fresh in your mind.
- Transcribe audio-tape and combine it with notes.
- Prepare a one-page summary of the session for your team.

C. Observation

Observation is a technique that involves systematically, watching and recording behaviour and characteristics of living beings, objects or phenomena. It is based on the premise that, for certain purposes, it is best to observe what actually happens. One of the great assets of the observational techniques is that it is possible to record behavior as it occurs. It can be used as the primary method of data-collection in descriptive studies as well as, in the experimental studies designed for testing causal hypothesis.

Type of observation

1. Structured observation
2. Non-Participant Observation
3. Participant Observation

1. Structured observation

The observation which is carried out in organized, planned and systematic way employing formal procedure and format/checklist containing well defined observation categories is called structured observation. It is subjected to high levels of control and differentiation. It is used mostly in quantitative studies designed to provide systematic description or to test causal hypothesis.

2. Non-Participant Observation

In this type observation, the researcher/observer remains detached and does not participate or intervene in the activities of those subjects being studied. The researcher's role is to record what is seen and heard without taking part in any activities. It is also called direct observation. This type of observation includes both observations of small group activities and what is called 'the community walk'. Here, those being studied may have previously been informed about the research- the observation is overt or may not be covert observation. For example, you might want to study the functions carried out by nurses in a hospital. As an observer, you could watch, follow and record the activities as they are performed. This technique can be used in both qualitative and quantitative type of studies.

3. Participant observation

Participant observation is method in which the investigator becomes a part of the situation or social life being studied. A researcher participates in the activities of the group being observed in the same manner as its members, with or without their knowing that they are being observed. It always takes place in community settings. If you want to study the life of prisoners, you should pretend to be a prisoner in order to do this. It is supplemented by conversation and interview. It is used mainly in anthropological or qualitative study.

Methods of recording observation

Checklist and rating scale method: This method is used in structured observation that employs a pro-forma or check list or rating scale. Checklist is used in categorical recording in which observation items or categories have been already listed in the form. Researcher may develop a scale (positive, negative, neutral or bad, good, better or frequently, often, rarely etc.)

Note-taking and narrative recording: In non-participant observation or direct observation, a researcher observes people's behviour and situation and notes down the key points in note book. Immediately after observation prepare a detail observation notes in a diary. In participant observation, the researcher records the whole scenario of observation in narrative way. In narrative recording, the researcher observes the behavior and situation in unstructured manner, and soon after observation, makes detailed notes in narrative form.

Steps in observation

- Determine the purpose of observation related to the overall research objective
- Identify the scope of observation
- Determine the population or community or situation to be observed
- Select the possible sites for observation
- Plan for observation: prepare observation checklist or observation guide or format, or decide how you will record the observation, and determine date, time and duration
- Sampling Gain access in setting: Provide information and obtain consent from the concern person.
- Taking role of the observer
- Recording observation/jotting down field notes
- Analysis of data and writing report

Session 15: Data Collection Tools

Time frame: 2 hours 30 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Describe various data collection tools and their uses
2. Explain basic steps in developing questionnaire and observation checklist
3. Prepare questionnaire and observation checklist for research project

Teaching methods:

- Class room lecture (50 minutes)
- Discussion , questions and answer (25 minutes)
- Individual practice work on tools preparation (45 minutes)

Course contents:

A. Questionnaire
B. Interview schedule
C. Observation checklist

A. Questionnaire

Questionnaire is a data collection tool that contains a set of questions, the answers to which are to be provided by personally by the respondents. It is the structured set of questions usually sent by mail or through delivered by hand as well. Questionnaire is self-administered and there is no one to explain the meaning of questions to respondents. Questionnaires are an inexpensive way to gather data from a potentially large number of respondents. It is usually used to survey type of research to gather quantitative data.

Interview schedule

The set of structured questions in which answers are recorded by the interviewer himself is called interview schedule or simply schedule. The only difference between a questionnaire and interview schedule is that in the former responses or replies are recorded by the respondents themselves and in the later interviewer who asks the questions records the respondent's replies on interview schedule. Though the questionnaire is used as interview schedule when respondents are educated, the schedule can be used for the illiterate and the educated respondents.

Choosing between questionnaire and interview schedule

The questionnaire is used when the respondents are educated and scattered in large geographical area and the schedule is when respondents are illiterates or the respondents are located in a small area so that they can be personally contacted. If the study is about issues

such as sexuality, drug use, criminal activities that respondents may feel reluctant to discuss with an investigator, a questionnaire may be the better choice as it ensures anonymity. However, there are situations where better information about sensitive issues can be obtained by interviewing respondents. It depends on the type of study population and the skills of the interviewers.

Steps in questionnaire development

1. Define the objectives of the study
2. Make list of variables and define them
3. Formulate Questions
4. Sequencing and ordering the questions
5. Formatting the questionnaire
6. Translation
7. Pre-test/pilot the questionnaire
8. Revise and finalize the questionnaire

Steps 1: Define the objectives of the study

Objectives and research questions of the study are starting point for constructing questionnaire. A questionnaire that is written without a clear goal and purpose is inevitably going to overlook important issues and waste participants' time by asking useless questions. Therefore, a researcher must clearly define specific objectives , research questions or hypothesis that determine what sort of questions are required to collect data, answer the research questions and meet the objectives of the study.

Step 2: Make list of variables and define them

After defining the objectives of the study, a list of variables to be included in the study should be prepared. Variables usually include background, dependent, independent and intervening or other variables. A researcher can choose various variables and make list considering the objectives and nature of the study. Each variable needs to be defined and operationalized. Research objectives and list of variables will determine the content of the questionnaire.

Steps 3: Formulate questions

At this point the researcher should have decided what sort of data and information are required to meet the objectives of the study. The researcher can formulates a number of questions including closed and open ended considering the list of the variables. You should formulate one or more questions under each variable. Consider following points in formulating questions.

Decide the forms of question while writing questions

The form and wording of questions is extremely important in a research instrument as they have an effect on the type and quality of information obtained. In a questionnaire or interview schedule questions may be formulated as open-ended or closed-ended, single responses/multiple responses, pre-coded, etc.

Open-ended question: In an open-ended question the possible responses/answers are not given. In the case of a questionnaire, the respondent writes down the answers in his/her words, whereas in the case of an interview schedule the interviewer records the answers either verbatim or in a summary describing a respondent's answer.

Example of Open-ended questions

What is your opinion about the provided in the ANC?

What do you think are the reasons some pregnant women in this area do not visit health post for pregnancy check up?

Close-ended Question: In a closed-ended question the possible answers of each question are given in the questionnaire or schedule and the respondents or interviewer ticks the category that best describe the respondent's answer.

Example of closed ended questions

What is your current marital status?

Married ☐
Unmarried
Separated ☐
Divorced ☐
Widow ☐

Pre-coded questions

Closed ended questions, responses are usually precoded for easy data entry. The pre-coded questions ask respondents to indicate or tick the code which *one* category applies.

Types of closed questions

Two choice: Do you smoke cigarettes? Yes/No
Multiple choice and single response: Multiple-choice questions but single response: In this type of questions, all possible answers are predetermined and enumerator or respondent simply checks, ticks or circles only one of them.
Multiple choice and multiple answer questions: In multiple response/answer questions also have all possible answers and enumerator or respondent checks or ticks as many codes/category of response apply. It is better to replace such questions with multiple choice and single answer question because multiple response questions may create some confusion for the data tabulation.

Contingency Questions

Questions which depend on the responses to earlier questions are referred to as contingency questions. If you want to ask a person how many cigarettes he or she smokes a day, such a question should be contingent on an earlier question ("do you smoke cigarettes?")

101. Do you currently smoke cigarettes?
Yes _____ 1 No _____ 2 (Skip to Question 3)

102. How may cigarettes do you usually smoke each day?

1. Less than 5 ( )
2. About half packet ( )
3. A packet ( )
4. A packet and half ( )
5. Two packets ( )
6. More than two packets ( )

103 Have you ever smoked in the past?

1. No ( )
2. Yes ( )

Likert-type questions

Likert-type questions ask respondents to indicate how much they agree or disagree with a statement. Response options include strongly disagree, disagree, undecided or neutral, agree, strongly agree.

"I believe capital punishment represents the most effective deterrent to murder."

1. Strongly agree ( )
2. Agree ( )
3. Not sure ( )
4. Disagree ( )
5. Strongly disagree ( )

Some guidelines for formulating questions

- *Always use short, simple and clear questions:* Long questions containing technical jargon and difficult words are to be avoided. Take extra care to use simple words and make simple questions that respondents should be able to read quickly, understand its meaning and think of answer without difficulty.
- *Avoided leading questions*: A leading question is one which, by its contents, structure or wording, leads a respondent to answer in a certain direction. Such questions lead respondents to answer either positively or negatively.

  Smoking is bad for health, isn't it?

  In this question, respondents may feel that to disagree with them is to be in the wrong. The feeling that there is a right answer can force people to respond in a way that is contrary to their position.
- *Do not ask double-barreled questions:* A double-barreled question consists of two or more questions joined together. It makes a respondents' answer ambiguous. In this type of question, one does not know which particular question a respondent has answered. Some respondents answer both questions and others may answer only one of them.

  For example, "Does this company have pension and health insurance benefit?"

  "Do you like oral pills and DMPA injection?
- *Avoid negative questions*: The appearance of a negation in the question paves the way for easy misinterpretation. The use of negatives in questions- for example, "AIDS cannot be prevented through safer sex practice: agree or disagree/" is confusing. It is always better to

word questions positively and then give the respondents a chance to respond positively or negatively.

- *Do not use ambiguous questions*: An ambiguous question is the one that contains more than one meaning and that can be interpreted differently by different respondents.
  For example, “Is your work made difficult because you are expecting a baby? Yes ( ) No ( )
  Those women who were not pregnant ticked ‘no’ meaning no they were not pregnant, and those who were pregnant and ticked ‘no’ meant pregnancy had no made their work difficult.
- Question should not be biased: Leading questions encourage respondents to answer biased answer. For example, "When a child presents with ARI, do you prescribe an antibiotic?" Health worker obviously answers ‘yes’. Instead, you can ask this way. “What do you do when a child presents with ARI?"

Step 3: Sequencing and ordering of questions

- Questions should follow a logical sequence and be grouped by subject. Ideas should flow smoothly from one question to another, moving from more general questions to more specific ones within each topic. Questions should be preceded from the most familiar to the least.
- Put easy non controversial, non-threatening and interesting questions first. The limited number of questions concerning background variables such as age, sex, marital status, literacy may be put at the beginning.
- Place relatively easy-to-answer question first. When difficult questions are asked in the beginning the respondent may soon feel reluctant and may not answer seriously.
- Place sensitive questions in the middle. For example questions on income, social status and personal behaviour such as sex, drinking, gambling and illegal activities should be arranged gradually at the middle of the questionnaire.
- Place personal and less important/boring questions at the end

Step 4: Formatting questionnaire

After finalizing questionnaire, a series of decisions must be made about the formatting. The questionnaire must be pleasing to look at and easy to complete. The following guidelines may help in formatting the questionnaire.

- Begin with an introduction which includes the study purpose, who is conducting it, to what use the information will go, confidentiality and informed consent. In mailed questionnaires, a separate introductory page is attached to each questionnaire.
- Provide necessary headings and spaces for labeling and identifying all questionnaires, i.e., identifying information for respondent, date and place of interview, as well as name of interviewer.
- Try to keep all questions on one subject together. If the questionnaire is long, you may use subheading for groups of questions.
- Allow enough space to let the respondent feel it is not crowded and hard to read.
- Provide sufficient space for answers to open-ended questions.
- Be consistent with codes or boxes for pre-categorized answers.

Step 5: Translation
The questionnaire needs to be translated in local languages, if the respondents do not understand national language. After having it translated into local languages, the questionnaire should be translated into the original language by different persons.

Step 6: Pre-test or pilot study
A pre-test or pilot study is undertaken to examine flow of the questions, wording and the pattern of responses and assess the reliability, validity and practicability. The preliminary pretest might be with friends or acquaintances who will agree to take the questionnaire. You can conduct a formal pretest or pilot study by administering the questionnaires among the respondents who are similar to the actual respondents. Revise your questionnaire on the basis of preliminary and formal pretest.

C. Observation Checklist

Observation is a technique that involves systematically, watching and recording behaviour and characteristics of living beings, objects or phenomena. A checklist is a data collection tool that includes all the possible items or points that must be considering during an observation in the field or when extracting data from existing records. It is like an interview schedule used by researcher to systematically record observation. Observation checklist can be used to systematically observe human behaviour or social condition, physical facilities, equipment and so on.

General procedure for creating observation checklist

- Decide the objective of observation.
- Identify the possible features of situation to be observed through literature review.
- Identify the most significant and relevant items for inclusion in observation checklist.
- Prepare an appropriate format by including relevant items or questions based on these observation items.

Sample observation checklist of the main equipment and supplies available in the SHP

SN	Name of the equipments/supplies	Yes	No	Remarks
Equipments				
1	Stethoscope			
2	Fetoscope			
3	Weighing machine/scale			
4	Thermometer			
5	Sterile Gloves			
6	Height Measuring scale			
7	Syringe			
8	Examining table			
9	Table cloth			
10	Plastic bowl			
11	Vaccine carrier			
12	Equipment for repairing			

13	Stove			
14	Sutkeri Samagri/Clean Home Delivery Kit			
Displaying IEC materials				
1	Information on Inform choice			
2	Poster Danger signs during pregnancy			
3	Poster on HIV/AIDS			
4	Poster on contraception			
5	Poster on child health/nutrition			
6	Poster on pneumonia			

Session 16: Data Management and Analysis Plan

Time frame: 2 hours 30 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **State** the steps of data processing for management and analysis plan
2. **State** the data management and analysis plan
3. **Describe** the different components of data management and analysis plan for the study.
4. **Define** the different terms applied in data management and analysis.
5. **Apply** different techniques for data processing and summarizing data
6. **Select** appropriate formula to analyze the data

Teaching methods:

- Class room lecture (50 minutes)
- Discussion , questions and answer (25 minutes)
- Group work of data management and analysis with given questionnaire (45 minutes)

Course contents:

- Data processing as a components of data management
- Selection of appropriate data analysis methods

I. **DATA PROCESSING AS A COMPONENT OF DATA MANAGEMENT**

- **There are two components of data management process**

  A. Data Processing

  B. Data Analysis

Data Processing

- Generally is that survey component in which the data gathered in the survey are translated into a form of which would be suitable for statistical analysis**.**

Components of Data Processing

I. Editing of questionnaire

II. Coding of all data recorded into questionnaire

III. Entry of data into master table or computer

IV. Classification and tabulation

I. Editing of questionnaire

- Preliminary step in which the responses are inspected, corrected, and sometimes pre-coded according to a fixed set of rules.

Main Sets of Activities in Editing

- Checking of the questionnaires
- Procedures to facilitate subsequent coding

The checking procedure

- Completeness:

  - every questionnaire reviewed to determine

  if each question was answered

  - for items left blank, find reason for

  omission

- Logical Inconsistencies
- Comprehensibility

  e.g: illegible handwriting

Checking Procedure Usually Done by Three Persons

- Interviewer
- Field Supervisor
- Editors at the Main Office

Interviewer's Responsibilities

- Should review work after each completed interview, or at the latest by the end of the day
- Particular attention should be given to

* legibility of the information

* missing answers

* inconsistencies

* lack of uniformity

Field Supervisor's Responsibilities

- Done upon receipt of the questionnaire
- Purpose normally to detect obvious errors which can be corrected in the field

Editors' Responsibilities at the Main Office

- Purpose is to judge whether information is sufficiently complete to be coded
- Alternative for very incomplete questionnaires

* consider as non-interview

* return to the field

Some General Editing Rules

- Editors should be thoroughly familiar with the instructions to enumerators and to coders, as well as with their own instructions.
- In No CASE should the editor destroy, erase or make illegible the original entry filled in by the enumerator.
- All marks on the schedule by the editor should be made in a distinctive color.
- No answer should be changed without sufficient justification.
- Editor's initials and date of editing each schedule should be entered on each schedule when it is edited.
- The editors should be informed about sections of the schedule which may cross-checked for consistency with other sections.
- Errors which are apart to be most common and the means of detecting such errors should be pointed out.
- It is at most important to keep the number of changes in instructions and interpretation at a minimum

II. Coding of the Data

- Purpose of coding of the data is to have the data represented with numerical or other symbols permitting rapid and flexible storage, retrieval and tabulation.

Types of Codes

- **Field Codes** - *number are recorded as they are given by the respondent*
- **Bracket Codes** - *each category refers to a range of numbers*
- **Factual or listing code** - *type of coding use when the question is of the "multiple choice type". Code is allocated for each possible answer with 0 and 1 as the usual codes used, representing "mentioned" . This type of coding is advisable when several combinations of multiple responses are anticipated.*
- **Pattern codes** - *a single mutually exclusive or non-overllaping*
- ***Pattern codes*** - *a single code is allocated to each type of response, including multiple or combined responses*

Rules for Code Construction:

- The objectives behind the question and the use of the question ;in the analysis should be considered in devising codes for the responses.
- The code should not be any more detailed than necessary.
- Categories for free or open-ended questions might be determined from pre-test results or from a separate frequency tally of, say, the first 100 questionnaires to be processed.

  - if multiple reasons are given in an open-response format, codes

  - might need to accommodate combination of answers.

- Codes should be exhaustive and mutually exclusive

  - code entry should cover all of possible answers for any given question

  - they should not overlap

- It is good idea to adopt coding conventions for questions with similar answers.

III. Entry of Data

- Entry of data in numerical form (in code)

can be made into:

- Master table (old fashion but computer illiterate has to use this)

- Computer spread sheet eg Excel, SPSS, data editor, stata etc

- Computer data base software eg dbase, Epi-info, Access, Fox-Pro etc

IV. Classification and Tabulation

- For classification recode or group the numerical data in to the form suitable analysis
- Prepare dummy tables for cross-tabulation of according to need
- Produce the data according to dummy tables prepared

II. SELECTION OF APPROPRIATE DATA ANALYSIS TOOLS

Data analysis involves answering two basic questions:

- **What is the meaning of the data that I have collected?**

- The meaning of the data should be interpreted in relation to the objectives that were formulated at the start of the survey.

- **In order to determine the meaning of the data, what statistical tools can I correctly apply?**

  -Some criteria are used in selecting the appropriate analytical method:

Criteria in Selecting the Appropriate Analytical Method

- Objectives of the study
- Design of the study
- Scale by which the variables are measured
- Sample size
- Number of variables to be analyzed

Summarizing Data

- Statistical tables (*One way, two way, many fold tables etc)*
- Graphs/Charts (*Bar diagrams, Pie charts, Histogram, Frequency curve etc)*
- Measures of central tendency *(Mean, mode, median etc)*
- Measures of dispersion *(Range, Standard deviation, Variance etc)*
- Measures of location *(Quartiles, Deciles, Percentiles)*

Inferential Statistical Methods

- Estimating Parameters
- Testing of Hypothesis

Estimating Parameters

- For qualitative data:

  Point and interval estimates for proportions and its differences

- For quantitative data:

  Point and interval estimates for means and its differences

Testing of Hypothesis

- Comparison of means and proportions
- Association between different variables

Comparison of means and proportions

- Z-test corresponding non-parametric test
- t-test corresponding non-parametric test
- F-test : Analysis of variance (ANOVA) corresponding non-parametric test

Association between Different Variables

- χ^2 - test

  - used to determine the existence of a relationship between two qualitative variables

- Correlation coefficient

- used to determine the existence, magnitude and direction of the relationship between two quantitative variables.

Relationship between Dependent and Independent Variables

- Simple Regression Analysis
- Multiple Regression Analysis
- Analysis of Covariance
- Logistic Regression Analysis
- Discriminant Analysis
- Categorical Data Analysis
- Survival Analysis
- Factor Analysis

GROUP WORK (45 minutes)

Critically review in perspective of principles of editing, data entry , coding and prepare standard data processing plan and indicate suitable statistical tools for data analysis with following given questionnaire.

Tool/ questionnaire for exercise
Baseline Survey for School Health and Nutrition Project, JICA
Questionnaire for students

S. N.			Date	Month		
				Day		
Name of Enumerator				Signature		
Time started	:	Time finished	:	Total time In minutes		
District	1) Syangja 2) Sindhupalchok			VDC		
Ward no.				Village		
Name of Supervisor				Signature		

A. General Information

1. Name of School:
2. Full name of student:
3. Name of father:
4. Name of mother:
5. Ethnicity: 1) Brahmin 2) Chhetri 3) Newar 4) Gurung 5) Tamang 6) Magar 7) Damai/Kami/Sarki 8) Other (please specify) ……
6. Date of birth: Year ☐☐☐☐ Month ☐☐ Day ☐☐
7. Age:
8. Sex: 1) Male 2) Female
9. Grade:
10. Do you have
    1) Telephone 1. Yes 2. No
    2) TV 1. Yes 2. No
    3) Radio 1. Yes 2. No
    4) Motorbike 1. Yes 2. No
    5) Bicycle 1. Yes 2. No

11. How much walking time does it take for you to reach school from your residence?

…… minutes

B. Food Intake Pattern

12. What food items did you eat during past 24 hours

24– hour recall sheet

Meal	**Menu**	**Composition**	**Quantity**
Breakfast			
Lunch			
Mid day snacks			
Evening tea			
Dinner			
Others (mention)			

13. How much milk/curd do you drink in your home?

1) Two glass/day or more
2) 1 glass/day
3) 1/2 glass/day
4) Occasionally
5) Rarely
6) Never

14. How often do you eat meat/fish?

1) Once a week or more
2) 2 to 4 times a month
3) Once a month
4) 2-3 times a year
5) During festivals only
6) Rarely
7) Never

15. How often do you eat egg?

1) Daily
2) 2 to 4 times a week
3) Once a week
4) Once a month

5) Occasionally
6) Rarely
7) Never

16. How often do you eat fruits?
    1) Daily
    2) 2 to 4 times a week
    3) Once a week
    4) Once a month
    5) Occasionally
    6) Rarely
    7) Never
17. If you eat fruits, what do you usually eat?
    1) Banana
    2) Orange
    3) Apple
    4) Mango
    5) Papaya
    6) Pomegranate
    7) Others (specify all)…….
18. How often do you bring Tiffin?
    1) Daily *(go to Q.19)*
    2) 2 to 4 times a week *(go to Q.19)*
    3) Occasionally *(go to Q.20)*
    4) Never *(go to Q.20)*
19. What have you brought for today?
    1) Instant Noodles
    2) Biscuits
    3) Bread (roti) with vegetable/ pickles
    4) Fried rice
    5) Rice with vegetable/pickles
    6) Plain bread
    7) Beans

8) Pop corn
9) Fruits
10) Beaten rice (Chiura)
11) Other (please specify……..)

20. If you do not bring Tiffin from home what do you usually do?
    1) Tiffin is provided in the school
    2) Purchase snacks in the shop *(go to Q 25)*
    3) No Tiffin available
    4) Other (specify)……..

21. If Tiffin is provided in the school, how often?
    1) Daily
    2) 2 to 5 times a week
    3) Occasionally

22. If Tiffin is provided in school, what is provided?
    1) Instant noodles
    2) Chiura and tarkari
    3) Beans
    4) Bread/Dough nought
    5) MoMo/ meat products
    6) Tea
    7) Biscuit
    8) Ice cream
    9) Others (specify)

23. If Tiffin is provided in the school, do you pay for it?
    1) Yes
    2) No *(go to Q 27)*

24. If you pay for it, how much do you pay?

    Rs……per day

25. If you purchase Tiffin from shop, what items do you purchase?
    1) Instant Noodles
    2) Chiura and tarkari
    3) Beans

4) Bread/Dough nought
5) MoMo/ meat products
6) Tea
7) Biscuit
8) Ice cream
9) Others (specify)

26. If purchase, how much money do you spend a day for Tiffin/snacks?

Rs……. Per day

C. Knowledge on Nutrition (Ask Q.27~ 35 Question to student only Grade 4 and 5)

27. Do you know what food items contain vitamin A?

1) Yes
2) No *(go to Q 29)*

28. If yes, name the items

1)
2)

29. Do you know what is anaemia?

1) Yes
2) No *(go to Q 32)*

30. Do you know what food items prevent anaemia?

1) Yes
2) No *(go to Q 32)*

31. If yes, name the items

1)
2)

32. Do you know iodine deficiency?

1) Yes
2) No (*go to 34)*

33. If yes, how do you prevent?

1) Use iodized salt
2) Use rock salt
3) Drink plenty of water
4) Use sugar

5) Others

34. Do you know about worm infestation?

1) Yes
2) No (*go to 36)*

35. If yes, do you know how worm infest in your body?

1) Through mouth
2) Air
3) Blood
4) Others (Specify).....

D. Information on Toilets and Sanitation

36. Do you have toilet in your house?

1) Yes
2) No *(go to Q 41)*

37. If yes, do you regularly use toilet for defecation?

1) Yes
2) No/ not regularly

38. If yes, is there provision of water in your toilet?

1) Yes
2) No

39. Do you wash hands after defecation?

1) Yes
2) No *(go to Q. 44)*

40. If yes, what material do you use for washing?

1) Plain water
2) Soap
3) Ash
4) Soil
5) Others (specify)……

41. If you do not have a toilet, where do you go for defecation?

1) Jungle 2) Farmland
3) Dry stream 4) Other (specify)……..

42. Do you wash your hands before eating?

1) Yes
2) No *(go to Q. 44)*

43. If yes, what material do you use for washing hand?

1) Plain water 2)Soap
3) Ash 4)Soil
6) Others (specify)……..

44. Do you brush your teeth?

1) Yes
2) No *(go to Q.47)*

45. If yes, how frequently?

1) Twice a day
2) Once a day in the morning
3) Once a day in the evening/night
4) Not regularly

46. If yes, what material do you use for brushing teeth?

1) Tooth paste/powder
2) Charcoal
3) Plant branch (Neem, Sajiwan)
4) Others.....

47. How often do you take bath?

1) Everyday 2) 2-4 times a week
3) Once a week 4) Twice a month
5) Not regular

48. How often do you cut your nails?

1) Once a week
2) Twice a month
3) Once a month
4) Not regular
5) Don not remember

49. Did you suffer from diarrhoea within past one month?

1) Yes
2) No *(go to Q. 51)*

3) Don't know *(go to Q. 51)*

4) Don't remember *(go to Q. 51)*

50. If yes, what did you do?

1) Home treatment (Specify_____)
2) Went to traditional healers
3) Went HP/SHP/PHCC for check-up
4) Went public hospital for check-up
5) Went private clinic/hospital for check-up
6) Other (specify)

51. Did you suffer from worm infestation within past one month?

1) Yes
2) No *(go to Q. 53)*
3) Don't remember *(go to Q. 53)*
4) Don't know *(go to Q. 53)*

52. If yes, what did you do?

1) Home treatment (Specify_____)
2) Went to traditional healers
3) Went to HP/SHP/PHCC for check-up
4) Went to public hospital for check-up
5) Went to private clinic/hospital for check-up
6) Other (specify)

53. What do you do when you get injury?

1) Apply mud
2) Apply leaves
3) Wash by water
4) Apply saliva
5) Keep it dry
6) Do nothing
7) Others

54. Have you used any tobacco product within past one month?

1) Yes
2) No

3) Don’t remember

4) Don’t know

55. How do you behave with following persons? (Ask this question to students of only grade 4 and 5 and tick accordingly)

S.N.	Type of people	1) I keep myself away from them	2) I am sympathetic but do not like them	3) I like do get mixed up with them and share their feelings	4) They should be given special facility	5) I have no feeling/ I do nothing	6) Don't know
1)	People living with HIV/ADIS (PLWHA)						
2)	Disabled						
3)	Visually impaired						
4)	Street children						
5)	Dalit Students						
6)	Ultra poor						

E. Observation

56. Length of nail

1) Normal

2) Long

57. Colour of nail:

1) Normal

2) Pale

58. State of nail:

1) Clean

2) Dirty

59. State of Hair

1) Tidy

2) Untidy

60. Dress

1) Clean
2) Dirty

61. Teeth

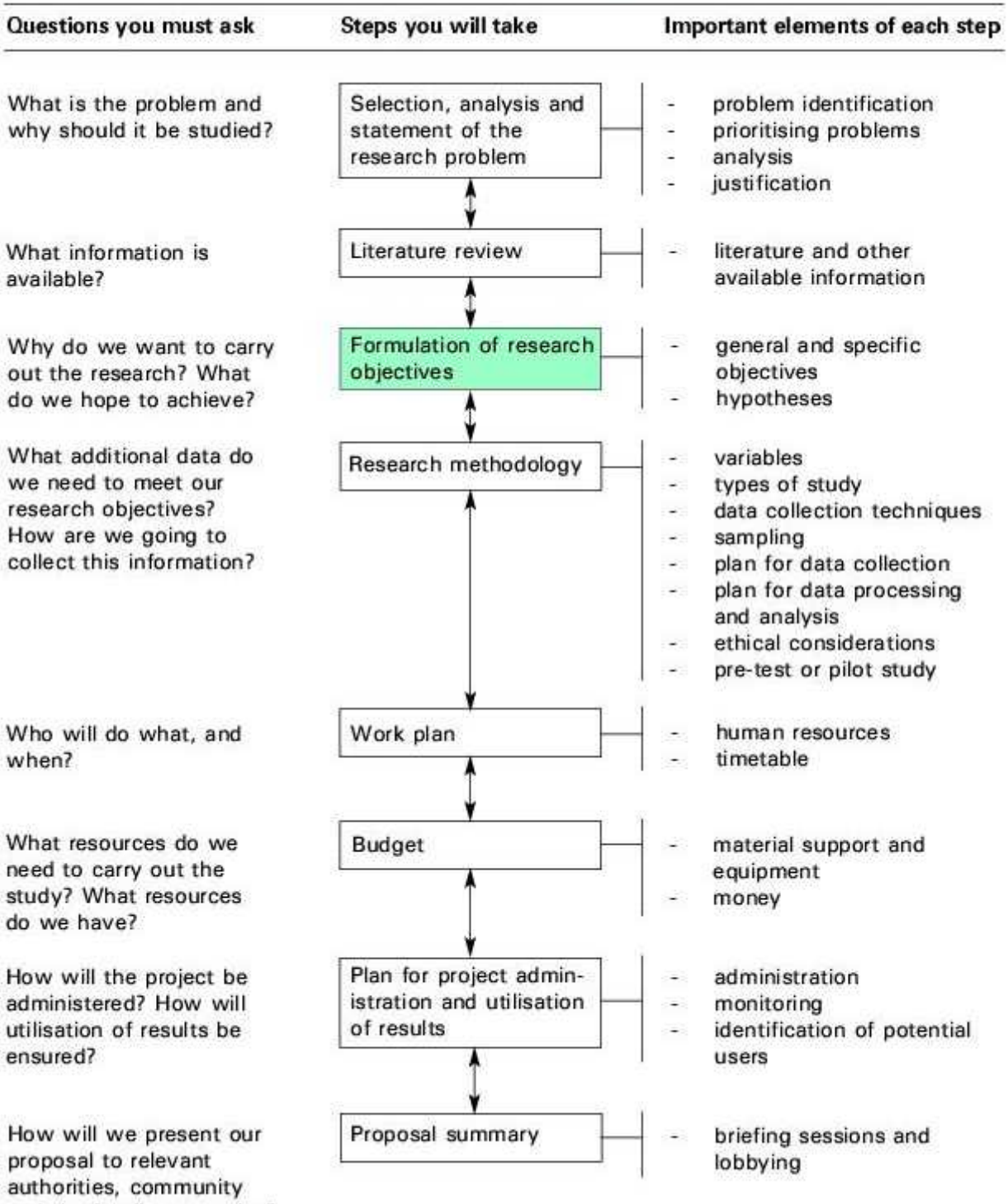
1) Clean
2) Dirty

F. Anthropometric Measurement

62. Height:..... cm

63. Weight: .....kg ..... gm

64. Mid upper arm circumference (MUAC):..... cm


Questions you must ask
Steps you will take
Important elements of each step
What is the problem and why should it be studied?
Selection, analysis and statement of the research problem
- problem identification
- prioritising problems
- analysis
- justification
What information is available?
Literature review
- literature and other available information
Why do we want to carry out the research? What do we hope to achieve?
Formulation of research objectives
- general and specific objectives
- hypotheses
What additional data do we need to meet our research objectives? How are we going to collect this information?
Research methodology
- variables
- types of study
- data collection techniques
- sampling
- plan for data collection
- plan for data processing and analysis
- ethical considerations
- pre-test or pilot study
Who will do what, and when?
Work plan
- human resources
- timetable
What resources do we need to carry out the study? What resources do we have?
Budget
- material support and equipment
- money
How will the project be administered? How will utilisation of results be ensured?
Plan for project administration and utilisation of results
- administration
- monitoring
- identification of potential users
How will we present our proposal to relevant authorities, community
Proposal summary
- briefing sessions and lobbying

Session 17: Work Plan and Planning of Budget

Time frame: 2 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. Define work plan and describe importance of work plan in research project
2. Describe the characteristics, purposes and methods of preparing a work plan of a research project.
3. Prepare a budget in a realistic approach and identify the major categories for a budget

Teaching methods:

- Class room lecture (50 minutes)
- Discussion , questions and answer (10 minutes)
- Group work (Work plan – 30 minutes)

Ask the participants to prepare work plans for their research proposals. Ask them to start by listing the tasks to be performed in the correct sequence. Then they should estimate the time involved for each task and assign the tasks to various staff members and consultants (if needed). Encourage each group to think seriously about what staffing pattern would be most cost-effective and efficient for its particular research project.

1. **For developing a work schedule:**

    - List all tasks to be carried out, completing and revising the list of tasks prepared for data collection.
    - Consider who will carry out each task, the number of working days required per person to complete each task, the number of staff need to complete each task in a given period of time
    - Note any public holidays or other important activities scheduled for the period in which you plan to conduct the fieldwork.
    - Include facilitator in stages of the fieldwork where and when required (e.g., during training of research assistants or during the initial period of data collection in the field).
    - Include support staff as per required (typists, drivers, for example)

2. **Prepare a GANTT Chart**

    - Similar as that of a work schedule.
    - Include activities and the duration of each activity.

3. Copy your work schedule and GANTT chart on flipcharts or overhead sheets, for use in the exercise below and in the plenary discussion.

- Group work (Budgeting – 30 minutes)

Ask the participants to prepare a budget for the research proposals. Ask them to start by looking at the prepared work plan where the activities timeline and the resources have been listed. Encourage each group to think seriously about the resources and allocate the cost in a realistic manner.

For developing budget of a research study consider the following points:

- Examine the work plan of the protocol and consider the expenses involved in each component. Rules of the donor agencies /government or any other format should be followed depending upon the type of the proposal.
- Indicate for each item the unit cost and the number of units.
- Justify large budget items, in one or two paragraphs attached to the budget.

Course contents:

Introduction (description, purpose)

A work plan is a document, which has a list of planned activities or a detailed timeline of the activities of a project or having a set of required activities in a stepwise order. It tells the initiation and completion date of the activity, the required resources to accomplish the activity, and the responsible person for carrying them out. It is a valuable tool for efficient and effective program implementation and should be used regularly and consistently as a monitoring tool at all levels.

Good work plans should be flexible. Work plan allows to compare the past ,present and future activities and examine the reasons for the difference and also to view the activity result helping to decide to make changes to the work plan as a result. Thus it can be used to monitor the progress of the activities.

Groups/ individual involved

It is for the project managers for working with their staffs or coworkers. It is also the useful tool to view the activities of the project for the planners, managers, and implementers, of governmental ministries, NGOs and private sector organizations. It also helps the involved staff in generating or designing a plan, to assist them in learning things needed to make management. It is a guide for the organization,

Rational for developing a Work Plan

It provides a framework for planning the work, and is a guide during the period implementing the activities. It also could be looked upon as a document for justifying the release of fund from various funding agencies. It provides a brief picture of the activities.

Duration

The optimum length for a work plan is either six months or twelve months. A three month work plan is too short, considering the amount of time and effort needed to prepare the plan. A twenty four month work plan might be too long, because many conditions change during a whole year, and by the end of the year the objectives and priorities may have all become different. They should follow annual reviews.

Roles and Responsibilities

In most projects the project manager is responsible for the work plan and updates it on a weekly or bi-weekly basis. In most projects the project manager is the only one that is allowed to update the plan. However, there are some options, especially for larger projects. In some cases, the project manager asks each team member to update the work plan with a current status and effort hours (if they are being tracked). In this scenario, the team members normally indicate whether their assigned work is completed. If not, they identify what percentage of the activity is complete, or adjust the end date to reflect when the activity will be complete. They can also plug in their actual effort hours per activity so far. In most cases, team members are not allowed to assign themselves to new work, add new activities or otherwise alter the work plan. After the team members update the plan with current status, the project manager can begin to evaluate the overall project status.

Purpose of a Work Plan

- to ensure that the work undertaken is relevant to the goals/objectives of the organization;
- to provide a basis for accountability and control over the work to be performed;
- to provide a basis for the appraisal of the manager; and
- to provide input to the evaluation process for the reporting on effectiveness, efficiency and economy of programs.

Process in developing a work plan

- Baseline Documents
- Create a Work Breakdown Structure
- Create a Network Diagram
- Assign Resources
- Plan Adjustment

Preparation of Work Plan

- Decide who will be involved in writing the new work plan.

- Schedule work planning meetings three months before the current work plan expires.
- Review the current work plan with the work planning group.
- Discuss with the work planning group whether the current activities need to be modified.
- If necessary, conduct a brainstorming exercise to come up with new activities.
- Write out each activity in detail.

Work plan Management

1. Review the work plan on a regular basis.
2. Capture and update actual hours.
3. Review your schedule situation.
4. Reschedule the project.
5. Run additional work plan management reports.
6. Review your budget situation.

Things Need to be Considered While Preparing Work Plan

- The activities need to be based on the stated program objectives
- The activity need to be stated clearly
- The activity need to be indicated when it is to be carried out & completed
- Determine who will be responsible for carrying out each activity.
- Decide what resources will be required to carry out the proposed activities.
- Check the budget to make sure that adequate funds are available to carry out the activities.
- It should be simple, realistic, and easily understood by those directly involved.
- It should cover from the preparatory upto the dissemination and utilisation of results.
- The realities of local customs (local holidays, festivals) and working hours should be considered.

Types of Work Plan

(a) Work Schedule
(b) Gantt Chart

(a) Work schedule

A WORK SCHEDULE is a table that summarizes the activities of a research project, including the time line and the responsible person of each activity. The work schedule includes the tasks, beginning and completion dates of each task and person involved in each task. It is calculated in person-days required by each individual.

(b) Gantt Chart

It is a work plan in a graphical form showing the activities and the duration of each activity.

Checklist for Work Plan

- The activities in the work plan are directly related to the goals, objectives, or short-term targets defined by the annual work plan.
- The activities are clearly presented.
- The activities are broken down into manageable tasks.
- The activities are presented in chronological sequence.
- The work plan shows which activities will be completed, by whom, and over what period of time (the period of time can be daily, weekly, or monthly depending on the management level for which the work plan is intended).
- The activities have been assigned to the appropriate staff members.
- The work plan indicates resource needs and resource allocations by activity.
- The plan and scope of activities are reasonable considering time limitations, human resources, and financial resources.

Budgeting

Introduction

Budgets are basically work plans translated into financial terms. Thus if work plans have been properly prepared, the budgeting process is greatly simplified. A good budget helps in utilizing scarce resources. There are a number of different approaches in preparing budgets depending upon the organisations or the funding agencies. In preparing a budget of a research study it needs to include personnel costs, operating expenses, subject costs, minor equipment, local travel, and other specified expenditure depending upon the study design.

Personnel costs

It is the cost for personnel time spent on the project by individuals not employed on a regular salary. This fund should reflect actual labour costs. In WHO-supported projects, the principal investigator's salary will not be supported.

Supplies

This cost relates chemicals, glassware, stationary, or other disposable items and other supplies to the number of procedures expected to be performed in the project.

Patient/subject costs

This cost relates to the time lost and/or actual transportation expenses. Costs for investigations and/or laboratory procedures may be included in the budget proposal if they are not a part of the routine medical care for the subjects and are performed only for the sake of the project. The costs should not exceed the local fees normally charged for such tests.

Minor equipment

Only requests for minor equipment are generally considered and must be fully justified.

Local travel of project personnel

This is the travel expenses (local per diem) of personnel involved in the study. Here vehicles cannot normally be provided as part of project support, although vehicle rental can be considered.

Other costs

If the study needs to have additional support such as investigators' meetings, training workshops and external consultant inputs, this should be under this budget item. Data analysis costs, costs of printing or photocopying forms, mail, telephone and telefax charges, etc., should also be specified and justified under this item.

It is necessary to justify the amounts stated under each budget item. It is important to relate the total budget to the scope of the project or number of subjects to be included in the study. Good justification of the budget, makes the donors difficult to reduce it.

Rational for budgeting in proposal development

It helps to identify which resources are already locally available and which additional resources may be required.

When to prepare a budget

Although a budget is considered complete only after the final stage of project planning however, cost needs to be kept in mind during the planning the proposal. Thus a tentative budget needs to be developed during developing a proposal.

Method of preparing a budget

- Use work plan for the starting point and for each activity in the work plan identify the required resources. Determine the unit cost and the total cost for each resource.

- Include a 5% contingency fund of the total budget. If contingency fund is not allowed, an alternative is to slightly over-budget in major categories.

- Do not too tightly with very detailed categories and amounts, especially if regulations do not allow adjustments afterwards.

- If the government or department has agreed to contribute a certain amount for the project, try to arrange that the contribution be administered separately, so that the administrators remain aware of the commitment. This may also ensure easier access to the funds.

- If the budget is for a period longer than a year, build in allowances for inflation before the project begins and in subsequent years by increasing costs by a set percentage. (If inflation is high in the local economy, you may have to build in allowances for even shorter projects.)

Budget justification

The budget justification follows the budget as an explanatory note justifying briefly, in the context of the proposal, why the various items in the budget are required. Make sure a clear explanations concerning why items that may seem questionable or that are particularly costly are needed and discuss how complicated expenses have been calculated. If a strong budget justification has been prepared, it is less likely that essential items will be cut during proposal review.

How can budget be reduced?

- Explore whether other health-related institutions are willing to temporarily assign or second personnel to the project.
- When possible, use local rather than outside personnel. If consultants are needed at the beginning, train local personnel as soon as possible to take over their work.
- Explore the use of students or community volunteers, where appropriate.
- Plan for strict control of project expenditures, such as those for vehicle use, supplies, etc.

Session 18: Logical Framework

Time frame: 1 hour 30 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to

1. Understand the concept of logical framework
2. Understand different components of logical framework

Teaching methods:

- Mini- lecture followed by discussion 45 minutes (lecture 30 minutes and discussion 15 minutes)
- Questions and answer (15 minutes)

Course content:

- Concept of logical framework
- different components of logical framework

Background

The Logical Framework Approach (Rosenberg & Posner, 1979) was developed by Practical Concepts Incorporated in 1969 for the United States Agency for International Development (USAID). Practical Concepts Incorporated then extended use of LFA to 35 countries. Logical Framework Approach (LFA) is widely used by bilateral and multilateral donor organizations like AECID, GTZ, SIDA, NORAD, DFID, UNDP, EC and the Inter-American Development Bank. It has also been widely adopted by NGOs, though not without reservations and concerns by some. In the 1990s it was often mandatory for aid organizations to use the LFA in their project proposals but its use in recent years has become more optional.

The logical framework or log frame is an analytical tool used to plan, monitor, and evaluate projects. It derives its name from the logical linkages set out by the planner(s) to connect a project's means with its ends. The log frame is only one monitoring and evaluation tool and its use does not pre-empt the use of other evaluation tools such as priority-setting or rate-of return analysis.

Purpose of Log Frame

The Log Frame will helps to:

- Organize thinking
- Relate activities and investment to expected results
- Set performance indicators
- Allocate responsibilities

- Communicate information on the project concisely and unambiguously

Use of Log Frame in elaborating strategic planning

- The architecture (goal, specific objective, outputs, activities)
- The managerial indicators
- The distribution of tasks
- The action plan with deadlines
- The articulation of the evaluation questions

The logical framework approach

- The logical framework is a tool designed to assist in planning a strategy or a policy
- It starts with a situation analysis and the results of the situation analysis are structured and articulated with the objectives of strategies so that the objectives are presented in a systematic and logical way
- Results are summarized in a matrix consisting of 4 columns and 4 rows (Figure 1)

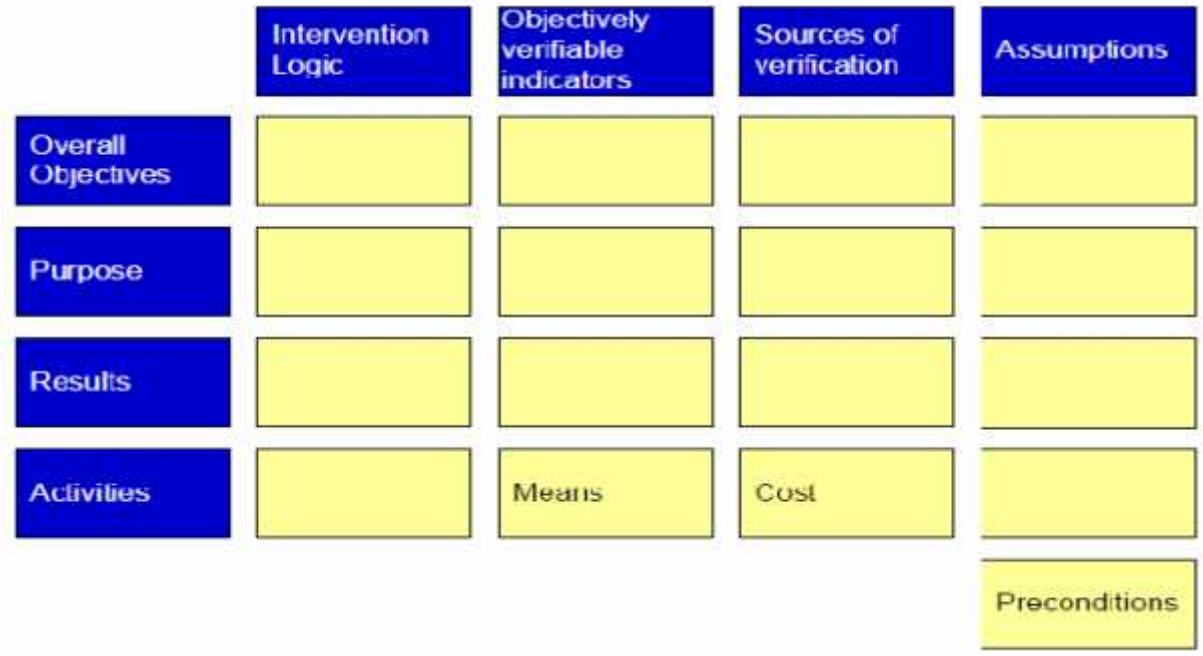


Figure 6: The Log Frame Matrix

- The Logical Framework is a tool. It has limitations. It is not enough to achieve the objectives
- The Log Frame consists of two main steps: analysis and planning
- The analysis comprises four domains: stakeholders, problems (the reality), objectives (the improved future), strategy (options to improve)
- Planning is the step by which one defines activities and resources required to reach the objectives.

Elaboration of Log Frame

There are two types of logic: vertical and horizontal. The vertical logic (column 1 of Figure 3) clarifies the reason for which the strategy was decided. It characterizes a strategy as a set of interrelated hypotheses:

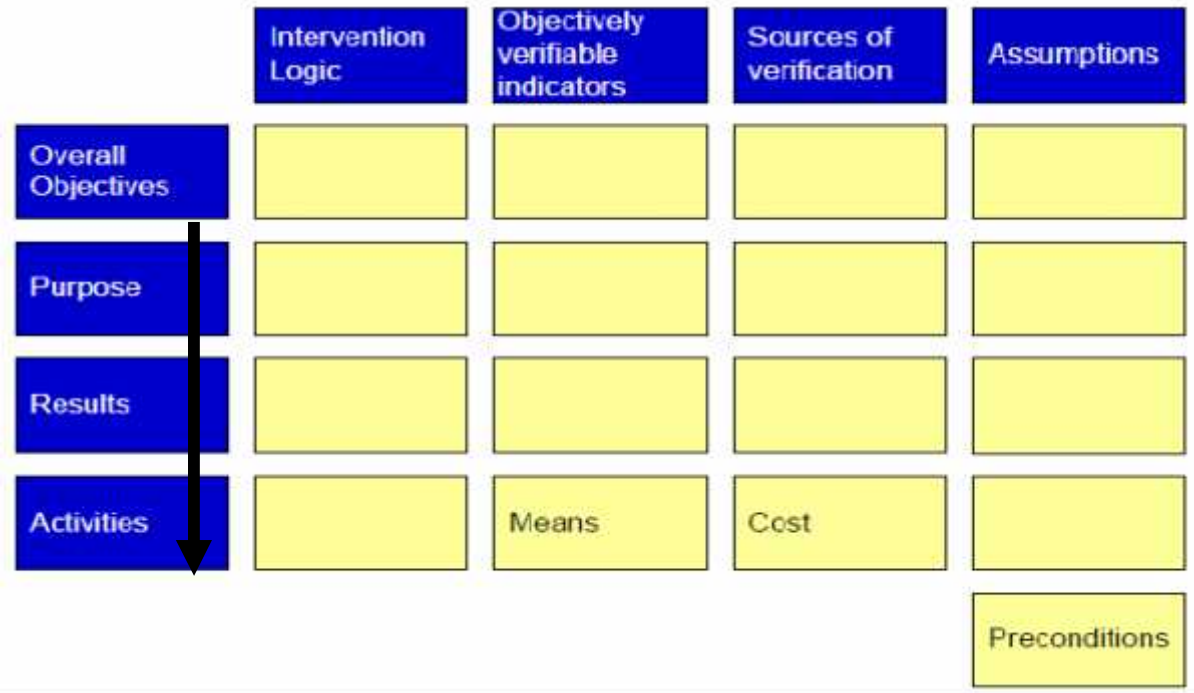
- *If we produce the following activities (inputs),*
- *Then we will produce the expected results (outputs)*
- *If we produce these results,*
- *Then the purpose will be met.*
- *If the purpose is met,*
- *Then the overall objective will be achieved*

The Vertical Logic

The **vertical intervention logic** (1st column) defines 4 levels (Figure 2):

- The **overall objective** (or goal): these are the long term benefits
- The **purpose** (it must be only one): what should be reached by the intervention
- **Outputs**: results of the activities implemented which contribute to the achievement of the purpose of the intervention
- **Activities**: actions and means required to achieve the outputs. Each activity will be split in tasks

Figure 7: The Vertical Logic



	Intervention Logic
Overall objectives	What is the overall broader objective to which the project will contribute?
Project	What are the specific objectives which the project shall achieve?

Purpose	
Expected Results	What are the concrete outputs envisaged to achieve the specific objectives? What are the envisaged effects and benefits of the project? What improvements and changes will be produced by the project?
Activities	What are the key activities to be carried out and in what sequence in order to produce the expected results?

In short, the vertical logic identifies what the intervention intends to do, clarifies causal relationships and specifies important assumptions and uncertainties beyond control.

The Assumptions: It will have become apparent during the Analysis Phase that the intervention alone cannot achieve all the objectives identified in the policy. Once a strategy has been selected, objectives not included in the intervention logic and other external factors remain. These will affect the intervention's implementation and long-term sustainability but lie outside its control. These conditions must be met if the intervention is to succeed, and are included as assumptions in the fourth column of the Log frame. So, Assumptions are the answer to the question: "What external factors are not influenced by the project, but may affect its implementation and long term sustainability?" (European Commission 2002).

These assumptions may be critical for the intervention. If they are not met, the intervention may be threatened. The probability and the importance of these assumptions should be analyzed and prioritized (SWOT analysis: strengths, weaknesses, opportunities and threats). If the assumption has a high probability to happen, then the intervention is not feasible. One should change the objective… or cancel the intervention.

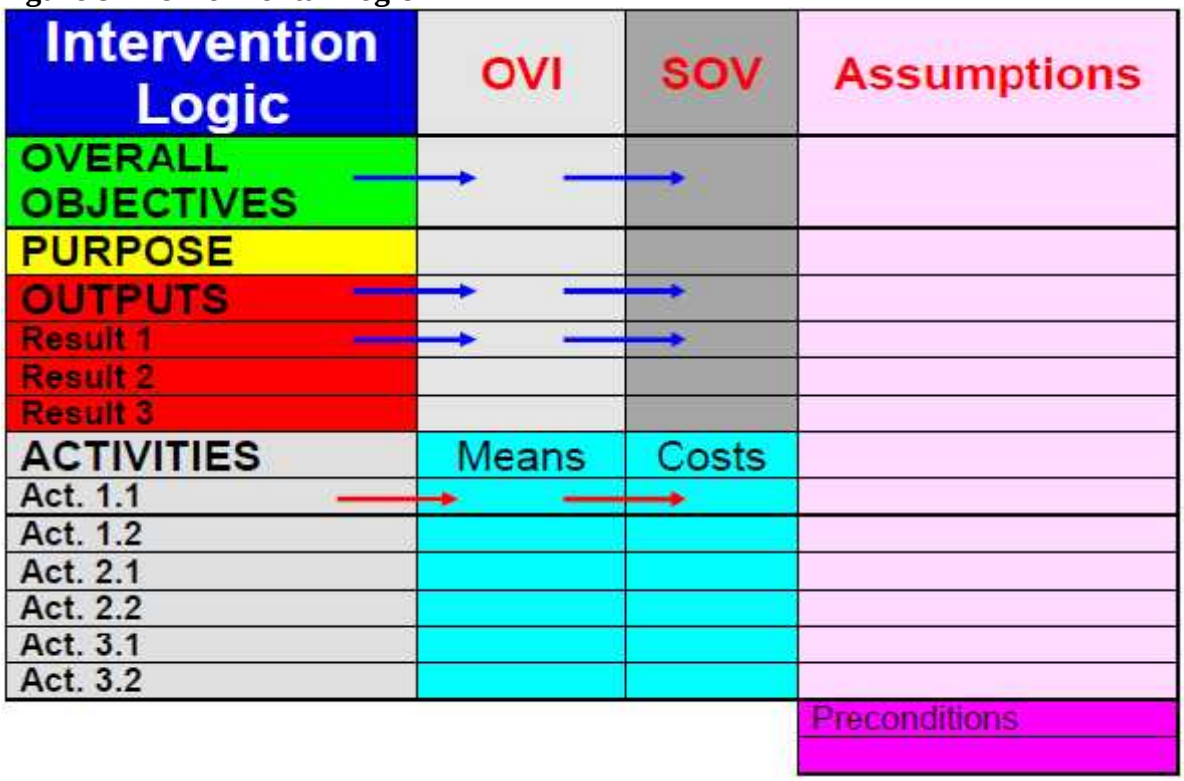
The vertical logic in the log frame, i.e. the relationship between the 1st and the 4th column, works as follows (and completes the previous reasoning shown above):

- Once the pre-conditions are met, the activities can start up;
- Once the activities have been carried out, and if the assumptions at this level hold true, results will be achieved;
- Once these results and the assumptions at this level are fulfilled, the project purpose will be achieved;
- Once the purpose has been achieved and the assumptions at this level are fulfilled, contribution to the achievement of the overall objectives will have been made by the project

The Horizontal Logic

The **horizontal logic** shows the relationship between the 1st and 2nd and 3rd column: it appraises the effects of the project and its resources: this means checking whether what we promised is being realized (Figure 3)

Figure 8 The Horizontal Logic



Objectively Verifiable Indicators (OVI)

The **Objectively Verifiable Indicators**: For each level of the vertical logic, one should define the quantity, the quality, the target, the localization and the deadline, i.e. define an indicator that will be specific, measurable, available, relevant and time-bound (SMART). How many indicators one has to define for each item? The fewer would be the better. Use only the number of indicators required to clarify what must be accomplished to satisfy the objective stated in the Intervention Logic.

How to construct an OVI? The easiest way is to begin with the basic indicator. Then, make sure it is numerically quantifiable and then add the Quality and then the Time dimensions.

Steps		Example
Step 1:	Basic Indicator	Health strategic plans developed
Step 2:	Add Quantity	75% of health committees have documented strategic plans
Step 3:	Add Quality	75% of health committees have documented strategic plans approved by key stakeholders inc. community representatives
Step 4:	Add Time	75% of health committees have documented strategic plans approved by key stakeholders inc. community representatives by the end of Year 2

Source: Adapted from J. Coenen, The LogFrame, MDC, Antwerp

Example:
Expected Result: Maternity staff is trained in newborn resuscitation
(Number of doctors and nurses trained and meeting the standards topractice newborn resuscitation)

Steps		Example
Step 1:	Basic Indicator	Doctors and nurses have been trained on newborn resuscitation
Step 2:	Add Quantity	**All** doctors and nurses have been trained on newborn resuscitation
Step 3:	Add Quality	All doctors have been trained on newborn resuscitation **with standard equipment**
Step 4:	Add Time	All doctors have been trained on newborn resuscitation with standard equipment **by the end of 2008**

Source of Verification

The **Sources of Verification** are the place and the format under which the information will be available to obtain the indicator. The format may be a register or a report. The SOV should specify:

- The *format* in which the information should be made available (e.g. progress reports, project accounts, project records, official statistics etc.)
- *Who* should provide the information
- *How regularly* it should be provided. (e.g. monthly, quarterly, annually etc.)

Sources outside the project should be assessed for accessibility, reliability and relevance. The work and costs of collecting information to be produced by the project itself should also be estimated and adequate means provided. There is often a direct relationship between the complexity of the SOV (i.e. ease of data collection and analysis) and its cost. If an OVI is found too expensive or complicated to collect, it should be replaced by a simpler, cheaper and often indirect (proxy) OVI: e.g. instead of conducting a detailed survey on incomes of village households, the changes of household expenditure, e.g. fee for health care and pharmacies, or of tools or household goods (clothes, energy saving stoves, etc.) might be counted (European Commission 2002).

Means and cost of activities

The boxes “Means” and “Costs” replace OVIs and SOV at the level of Activities. OVIs and SOV are thus not specified for Activities in the Logframe, but may be specified later when preparing an Activity Schedule.
Means are *physical and non-physical resources* (often referred to as “Inputs”) that are necessary to carry out the planned activities and manage the project. A distinction can be drawn between:

- Human resources and
- Material resources

Costs are the translation into financial terms of all the identified resources (means). They should be presented in a standardized format, which will specify the contribution of the donors, the Government and any other party, such as target groups and beneficiaries. The Activities should therefore be worked out sufficiently to enable estimates of the necessary physical and non-physical means.

This will include the means and costs required for management support activities. An area for particular attention is the cost of collecting data on OVIs. This estimate should be completed at the end of the formulation phase (European Commission 2002).

Figure 9 The Means and Costs Item

INTERVENTION LOGIC	Objectively verifiable indicators	Source of verification	Assumptions
OVERALL OBJECTIVES			
PURPOSE			
OUPUTS			
Result 1			
Result 2			
Result 3			
Result 4			
ACTIVITIES	Means	Costs	
Act. 1.1	A. Investment costs	0,00	
Act. 1.2	B. Consumables	58.900,00	
Act. 1.3	C. Staff (excl. ITM)	4.000,00	
Act. 2.1	D. Training	29.200,00	
Act. 2.2	E. Travel	5.200,00	
Act. 3.1	F. Subsistence	6.700,00	
Act. 3.2	G. Shipping	2.000,00	
Act. 4.1	Total	106.000,00	
Act. 4.2			
			Preconditions

Means are summarized in a budget. The budget generally comprises the following lines:

- Personnel
- Heavy equipment/material (investments)
- Consumables (paper, printer ink, CDs, etc.)
- Working costs (fuel, books, meetings)
- Travel costs (transportation) and subsistence (per diem, hotels)
- Communication costs (telephone, DHL, mails)
- Shipping (transportation of the goods)
- Overheads

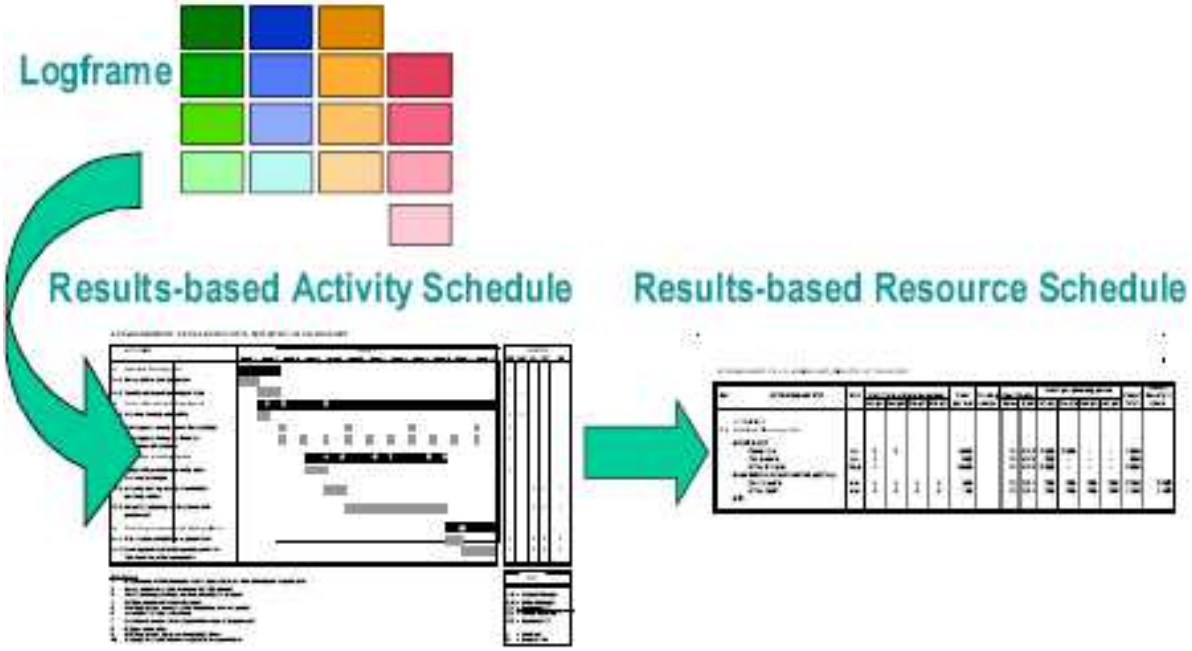
Developing Activity and Resource Schedules

The Logical Framework for a project describes often quite broadly, what activities are to be undertaken. After the logframe matrix has been completed, usually during the formulation phase, further planning can take place to add operational detail to the plan.

An activity schedule is a method of presenting the activities of a project, which identifies their logical sequence and any dependencies that exist between them, and provides a basis for allocating management responsibility for completing each activity. With the activity schedule prepared, further specification of means and scheduling costs can start. Both activity and resource schedules ought to be drafted during the feasibility study. Detailed information about net recurrent cost implications of the project may then lead to reformulation of the scope and ambition of the project.

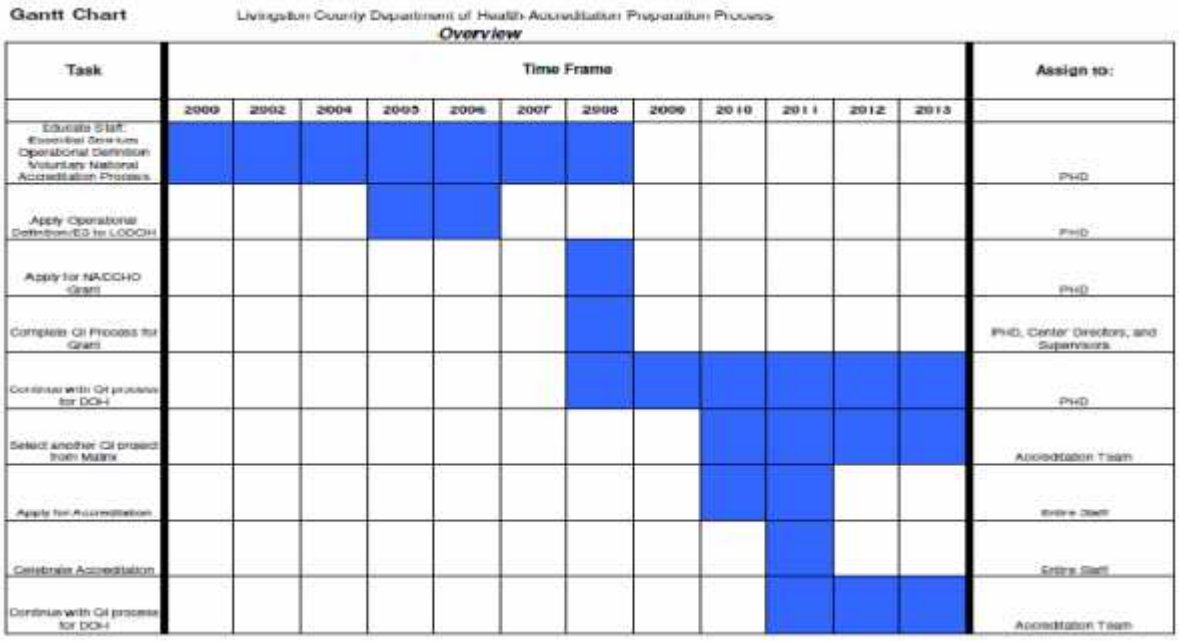
The overall activity schedule (sometimes also called “implementation schedule”) is updated and detailed activity and resource schedules are to be prepared during the first months of project implementation (inception phase).

Figure 10 Activity and Resource Schedule



Preparing Activity Schedule

All of the information in an activity schedule can be summarised in graphical format.



This is called a Gantt Chart. An example is shown above. The format can be adapted to fit with the expected duration of the project. An overall project schedule may only specify activities on a quarterly or monthly basis, while an individual's quarterly work plan may use a weekly format.

Preparing Resource Schedule

Cost estimates must be based on careful and thorough budgeting. They will have significant influence over the investment decision at project appraisal and subsequently on the smooth implementation of the project if the go-ahead is given. Again, the list of activities should be copied into an input and cost schedule proforma. Each activity should then be used as a checklist to ensure that all necessary means under that activity are provided for. This list may become very detailed. Then, the means necessary to undertake the activities must be specified. It will probably be necessary to aggregate or summarise the cost information. Intervention costings should allow the allocation of costs to the different funding sources so that each party is clear about their respective contributions.

Once Total Costs have been calculated, it is important to remember that the implementing agency will be required to meet any recurrent costs of maintaining service provision beyond the cooperation agreement. Recurrent Costs may be covered (fully or partly) through increased revenue that has been generated through other sources (MOH, cost recovery, other). Whether or not this is the case, it is important that the net recurrent cost implications of the project are clearly specified so that the future impact on the implementing agency's budget can be determined.

ESTABLISHMENT OF A PLANNING UNIT, MINISTRY OF TRANSPORT

Ref	ACTIVITIES/INPUTS	Unit	Quantity per planning period				Cost per unit	Funding source	Cost Codes		Costs per planning period				Project Total	Annual Recurrent Costs
			1st qtr	2nd qtr	3rd qtr	4th qtr			Donor	Govt	1st qtr	2nd qtr	3rd qtr	4th qtr		
	ACTIVITIES															
1.1	Establish Planning Unit															
	EQUIPMENT															
	Computers	no.	2	2			1.000		3,4	A/1.3	2.000	2.000	-	-	4.000	
	Fax modem	no.	1				500		3,4	A/1.3	500	-	-	-	500	
	Office furniture	lump	1				3.000		3,4	A/1.3	3.000	-	-	-	3.000	
	SALARIES & ALLOWANCES (LOCAL)															
	Counterparts	mm	4	4	4	4	200		5,2	B/2.1	800	800	800	800	3.200	3.200
	Office staff	mm	3	3	3	3	100		4,2	B/2.1	300	300	300	300	1.100	1.100
	ETC.															

Session 19: Basic Principles of Ethics in Health Research

Time frame: 3 hours

Objectives of the session: At the end of this session, participants (trainee) will be able to

1. Apply the knowledge of ethics learnt during the proposal development and during the conduct of the research
2. Describe basic principles of ethics in health research
3. Explain the ethical review procedures
4. Design the informed consent form and be familiar with consent taking procedures

Teaching methods:

- Mini- lecture followed by discussion 1 hour 30 minutes (lecture 60 minutes and discussion 30 minutes)
- Group work 1 hour
- Group presentations ½ hours

Course content:

- Introduction to Nepal health research council and its role in Health research management
- Introduction to basic principles of ethics and good clinical practice.
- Ethics committees and ethical review procedures.
- Introduction to National and International Ethical Guidelines
- Practical application of knowledge of ethics while designing and conducting the health research
- Designing the informed consent form
- Consent taking procedures
- Examples of ethical issues in health research.

Introduction to Nepal Health Research Council (NHRC) and National Ethical Guideline:

Nepal Health Research Council (NHRC) was established as an autonomous body by act of parliament in 1991 with the purpose of promoting scientific study and quality research in health in Nepal (National ethical guideline, NHRC, 2001).

There are established ethical and scientific standards to carry out the research as established by various International declarations and Guidelines. In the context of Nepal, National Ethical Guideline was published in July 2001 in a more concise and concrete way which serves as a national guideline to conduct the Health research in Nepal involving the human participants.

Similarly three other guidelines were published by NHRC in order to maintain the standards in doing the research involving animals, pharmaceutical products and clinical trials, and formation of Institutional Ethics committee.

The purpose of these guidelines is to assist NHRC /Ethical review Board and the researchers in Nepal to promote the research and to protect the dignity, rights, safety and wellbeing of all research and participants

Basic principles of Ethics in Health Research

Introduction:
The word Ethics is derived from Latin word Ethos, which means character, disposition or fundamental outlook which influences behavoiur related to moral values.

Codes of Medical ethics are found as far back as Babylon with hammurabis code of law (Babylon 1790 B.C) ,Charak samhita (Indian subcontinent ,800 B.C to 400 AD), and Hippocratic Oath (Greece 600 B.C)1.(national Ethical Guideline for health Research in Nepal, Nepal Health research Council,2001)

Concept of ethics in Modern era related to Health and Biomedical research started recently. Nuremberg Code on Experimentation on Human subjects, 1947 is the first international document related to health research involving human participants. This initiated series of other documents, international declarations and conventions. The prominent documents are Declaration of Helsinki (WMA), International Guidelines for Biomedical Research involving Human Subjects (CIOMS), WHO and ICH Good Clinical Practice.

Basic Principles of Ethics:
There are four basic principles of ethics which govern the conduct of Research involving human research .These are:

1. **Respect for Autonomy**:
   - Respect for autonomy requires that those who are capable of making their personal choices or decisions should be treated with respect for their capacity for self determination.
   - Protection of persons with impaired autonomy:
   - In every Health research there should be protection of persons with impaired autonomy if the research involves the participants with impaired autonomy or those who cannot make decisions for themselves or are vulnerable.

2. **Beneficence:**
Beneficence refers to the principle and obligation to maximize the possible benefits and minimize or avoid the harm. This necessitates that all health and biomedical research should be proceeded by a careful assessment of the potential risks and burdens in comparison with the potential risks.

Principle of beneficence also requires that the researchers are qualified and are capable of carrying out the research maximizing the benefits and not inflicting any harm by research to the participants, communities or those involved.

3. **Justice**:
Principle of justice explains that persons in similar condition or circumstances in health research must be treated alike. Justice requires equitable distribution of both burdens and benefits in research. Differences in distribution is justified only in those circumstances where morally relevant distinctions between persons or participants is present like vulnerability, age, susceptibility, or at risk or predisposed conditions like marginal population, genetic differences like race or genetic differences etc.

4. **Respect for the environment**:
Respect for the environment requires that health and biomedical research is conducted with respect in context to the social, cultural, and natural heritage of the society. This also includes that no damage or degradation of the environment is caused by conducting the research and there should be proper and safe disposal of bio hazardous and safe disposal of waste from laboratory, clinic, field or other areas used for the research.

Ethical Review procedures:
In order to undertake the Health research the research proposal needs to be reviewed and approved by the Ethics committee. Ethical review board is an autonomous body the purpose of which is to safeguard the rights, dignity, safety and the wellbeing of all research participants. The ethical review board ensures that the proposal is ethical and up to the standard and the review procedure is free from bias and influences.

The Ethics committee is constituted as a body having a team of multidisciplinary experts in various field, is gender and age balanced, one of the member is from the non clinical field such as social scientists, lawyer, or the statistician. The members should not have any conflict of interest during the review procedure and should maintain the principles of confidentiality. All the proposals undergo scientific and Ethical review before undertaking the research. Informed consent form is very closely reviewed by the ethics committee for the protection of rights, safety and dignity of the research.

Informed Consent:

In order to undertake the biomedical research involving human participants, all the investigators must obtain the informed consent from the prospective participants.

What is informed consent?
How it is obtained?

Informed consent is a process which involves various steps before the participant actually agrees and signs the consent form in writing to the researcher.
The following principles must be applied to get the informed consent from the participant.

(i) Information: The participant must be provided with the full information regarding the research by the researcher including the information regarding procedures, purpose of research, anticipated risks, benefits, alternative procedures, opportunity to ask questions and with draw any time without any fear or negative consequences.

(ii) Comprehension : It is the responsibility of the researcher that participant understands all the information provided, has understood and he is able to comprehend .If the research participant is not able to comprehend in case of vulnerable population, or incompetent ,researcher must obtain the proxy consent in presence of witness or authorized representatives.

(iii) Voluntariness: Informed consent is valid only if it is given voluntarily without any coercion. Biases, or influences and the participant understand all the consequences.

(iv) Obtaining the consent or signature and documentation of informed consent : Researcher must obtain from the participant the signature in writing or written consent and well documented and be provided one copy to the participant and keep one copy with him. The consent form includes the signature of the participant as well as signature of the researcher or his representative. In case the participant is not able to provide consent, proxy consent is obtained in writing from the legal representative /guardian.

SAMPLE INFORMED CONSENT FORM (Adopted from WHO IC sample form)

Informed Consent Form for (Research Title) _____

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor] if applicable
[Name of Proposal and version]

Informed Consent Form contains two parts:

- **Information Sheet (to share information about the research with participants)**
- **Certificate of Consent (for signatures after the participant agrees to participate)**

PART I: Information Sheet
(Example on how to write the Informed consent form and should state following points but the content may vary as per the research proposals)

Introduction of researcher and the research organisation
Briefly state your introduction who you are and explain that you are inviting them to participate in the research you are doing.

Example *I am Mr/Dr, working in (Institute). We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. Before you decide, you can discuss and ask the questions. Please go through the information and I will take time to explain.*

Purpose of doing the research

Explain in lay terms why you are doing the research.
Example X disease .. *is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with x are not as good as we would like them to be. In fact, only 40 out of every 100 people given drug A are completely cured. There is a new drug which may work better. The reason we are doing this resea ch is to find out if the new drug B is better than drug A which is currently being used.*

Type of Research Intervention
Example *This research will involve a taking the new drug as well as three follow-up visits to the clinic.*

Participant selection and the criteria
Example *We are inviting all adults with disease X who attend clinic Z to participate in the research on the new drug.*

Provision for Voluntary Participation

Explain that they can choose to participate or not to participate State, that they will still receive all the services they usually do whether they choose to participate or not.

Example *Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You can choose not to participate even if you agreed earlier*

Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.

Example*The drug we are testing in this research is called Drug B. It has been tested before with people who do not have disease X but in this research we want to test the drug B in this disease X……..*

.

2) explain the known experience with this drug

3) explain comprehensively all the known side-effects/toxicity of this drug, as well as the anticipated adverse events .

Procedures and Protocol

Explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain unfamiliar procedures that involve (placebo, randomization, biopsy, etc.) Indicate procedure which is experimental or research.

Example *The drug B which we want to test has to be taken by mouth, 500 mg, one tablet once .And first follow up visit will be after one week for check up .Check up will include interview for any side effects noted, testing the blood for following tests….. and 2 other such visits every 2 monthly ,3 times* .

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Example *The research takes place over ___ __(_days/ / months) in total. During that time, it will be necessary for you to come to the hospital*

In total, you will be asked to come 3 times to the clinic in 6 months including the first visit . At the end of six months, the research will be finished.

Side Effects

Explain any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Example. *It is possible that it may also cause some problems that we are not aware of. In case any problem please report to us in this address….*

Risks /Discomforts

Explain anticipated risks. Describe the level of care that will be available and how he will get the assistance .Mention what will be compensated and what will not be.

Benefits
Mention only those activities that will be actual benefits.
There maybe/ or may not be any benefit for you but your participation is likely to help us find the answer to the research question.

Incentives
State clearly what you will provide the participants with as a result of their participation.
Example *We will provide you [amount of money] to pay for your travel to the hospital/and the refreshment snacks/juice/tea.*

Confidentiality
Explain confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team.
Example *We will not be sharing the identity of yours in the research with anyone. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will not be identified by your name but by a number.*

Sharing the Results
Where it is relevant, explain plan for sharing the information with the participants.
EX. *we will publish the results in order that other interested people may learn from our research after the completion of research.*

Right to Refuse or Withdraw
Explain that participation is voluntary and includes the right to withdraw.
Example *You do not have to take part in this research if you do not wish to do* .

Whom to Contact and how
Provide the name and contact information of the person who is involved, informed and accessible
Example *If you have any questions you may ask: [name, address/telephone number/e-mail]*

PART II: Certificate of Consent
A researcher or the person going over the informed consent must sign consent form.
Example *I have been invited to participate in research (Research Title.) I have been informed about the new drug and this is a new research. I am aware that there may be benefit as well as some risk to me personally and that I will not be compensated beyond travel expenses and refreshments. I have been provided with the name of a researcher who can be easily contacted using the number and address I was given for that person.*

I have read the foregoing information, I have had the opportunity to ask questions and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research and understand that I have

the right to withdraw from the research at any time without in any way affecting my medical care.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

Proxy consent
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).
I have witnessed the accurate reading of the consent form to the participant, and he/she has had the opportunity to ask questions. I confirm that he/she has given consent freely.

Print name of witness*_____ *AND* *Thumb print of participant
Signature of witness **_____**
Date _____
Day/month/year

I have accurately read or witnessed the accurate reading of the consent form to the participant, and he/she had the opportunity to ask questions. I confirm that the he/she has given consent freely.

Print Name of Researcher_____

Signature of Researcher / (consent taken by)_____

Date _____
Day/month/year

A copy of this Informed Consent Form has been provided to participant _____ (initialed by the researcher/assistant)

Designing the Informed consent form (group work)
Exercises on the ethical issues: some examples

Session 20: Final Review of the Research Proposals

Time frame: 1 hour 15 minutes

Objectives of the session: At the end of this session, participants (trainee) will be able to:

1. **State** the major steps to be checked while developing/reviewing health system research proposal .

2. **Analyze** the different steps of research proposal development

Teaching methods: Mini- lecture followed by discussion 60 minutes (lecture 45 minutes and discussion 15 minutes) and 15 minutes will be allocated for questions and answers.

Content

Introduction:
Development of a research proposal is a very labor intensive activity. The researcher or research team would have gone through a rigorous process of identifying a problem, searched for the known solutions to the problem in the literature and identified the gaps in the knowledge in that area. They must have deliberated on the different solutions and thought of testing their hypothesis to solve a problem through a robust and scientifically valid study design. The research team then would have consulted a qualified statistician to estimate the sample size and the mechanisms for recruiting the study participants After this step has been reached, now would be the time to consider the ethical issues involved. The researchers will deliberate on the information to be provided to the potential research participants and ensuing that the prospective participants do understand the information provided and consent to participate in the study voluntarily without any elements of coercion. The researcher and team will have to consider the benefits and risks involved in the study and mention clearly the efforts to be taken to mitigate the risks and maximize the benefits.
In addition, the researcher and team will have to be aware of the requirements of the funding agency regarding the scientific and ethical issues involved in conducting a particular type of research and address that in the research proposal.

According to a WHO publication “A Practical Guide for Health Researchers” a written plan at the end of deliberations about different aspects of research is a necessary to guide the team members to be familiar with different aspects of research. This is also required to get approval from ethics review committees if the research requires participation of human participants and also for submission to sponsors or funders of research.

An appropriately finalized research proposal should be able to answer the following questions:

a. Is it adequately designed to answer the research questions and achieve the study objectives?
b. Is it feasible under the given circumstances?
c. Does the methodology section provide enough information for another researcher to conduct a similar study and arrive at comparable conclusions?

Headings of research proposal:
The proposal should start with an introductory section which clearly outlines the rationale of the study, its objectives, the methodology used, study design and sample size, the arrangement for data collection, analysis and management. In addition, it should clearly highlight the possible ethical issues involved in the study and how the research plans to handle them.
Research proposal should be checked for the following sections:

Title:
Project Summary:
Project Description:
a. Rationale
b. Objectives
c. Methodology
d. Data management and analysis
Ethical considerations:
a. Process of taking informed consent if the study requires human participation
b. Risk/Benefit ratio
c. Justifiable recruitment of study participants from different communities
References:

Title:
Title of the research proposal should be concise and descriptive. Many a times, the title is written down only after the writing of proposal has been completed in order to let the title precisely describe what the study intends to do.

Project Summary:
The summary should briefly summarize all the elements of the research paper and give a brief overview of the proposal without going into the other components of the proposal.
Project Description:

Rationale:
This section should answer the questions why the research is being conducted and what results are expected out of the study. The relevance of the study and the justification of the methodology to be employed should be supported with the relevant literature review findings.

Objectives of the study:
Specific objectives describe what the research plans to do and achieve. The objectives should be simple and specific (not vague) and this need to be started clearly in advance (not after the study is completed). After mentioning the primary objectives, secondary objectives may be

mentioned. It is advisable to be realistic in writing down the objectives and not try to be over enthusiastic and ambitious.

Methodology:
The methodology section is the most important part of the research proposal. It should be written after carefully considering all the aspects of research as stated in the objectives section. A detailed description of the different components need to be written in unequivocal terms so that other researchers interested in a similar study can carry out a similar study without any problem. The methodology section should provide information on research design, research participants planned interventions and the observations to be made.

Research design:
The research proposal should clearly explain the reasons for selecting a particular research design in view of the stated objectives.

Research participants:
This paragraph should clearly state the criteria for selecting the research participants and their inclusion and exclusion. If it is a intervention study, it should clearly mention the process of allocating an individual to intervention group or comparison group. Finally it should also mention the criteria for discontinuation of a particular participant or of the study as a whole.

Interventions:
If a drug or device is to be used as an intervention, a detail description about the chemical nature of the drug, its potential side or adverse effects, dosage from and mode of administration should be clearly mentioned. Similarly if a device is to be used, its manufacturer, lot number etc should be mentioned. If the drugs or devices are experimental additional information should be provided. The details should be provided even for the commercially available commonly used drugs if the intervention is for a new indication or for a different mode of administration. In such cases, approval of the drug regulatory authority is needed.

Observations:
Research proposal should clearly provide information about the observations to be made during the course of the study. It should mention what parameters will be observed and how frequently and also state the mechanism for ensuring the quality of observations. If the observations involved laboratory or other investigative methods, the details of the methods to be used need to be clearly described in unequivocal terms.

Sample size:
The research proposal should provide information and justification about the sample size. The basis on which the sample size is calculated explained in the methodology section of the proposal.

Data management and analysis:
The proposal should clearly describe the process of collecting data, methods adopted to maintain the quality of collected data and coding for computer analysis, monitoring and verification. The software for statistical analysis should also be mentioned.

Ethical Considerations:
All research which requires human participation needs approval from ethics review committee. Therefore, all research proposals must comply with the guidelines of ethics committees. The ethical guidelines of Nepal Health Research Council or Institutional Review Committees of different institutions should be followed while finalizing the research proposals.

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