ETHIOPIAN PUBLIC HEALTH ASSOCIATION (EPHA)

RESEARCH METHODOLOGY & ETHICS TRAINING PROCEEDINGS

September 2009
Addis Ababa
Ethiopia

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Address:

Ethiopian Public Health Association
Dembel City center Building 11th floor
P.O.BOX 7117
Tel. +251-115-540391/92
+251-115-538924
Fax: +251-1-514870
E-mail: info@etpha.org
www.etpha.org

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Editors:

Berhanu Legesse (MPH)
Demeke Feyissa (MBA)
Mulugetta Betre (MD, MPH)
Wakgari Deressa (MPH, PhD)

Formatting:

Mikiyas Wakbush

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Acronyms

AAU	Addis Ababa University
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal Care
ANOVA	Analysis of Variance
ART	Anti Retroviral Treatment
ARV	Anti Retro Viral
CC	Community Conversation
CD	Compact Disk
CDC	US Centers for Disease Control and Prevention
CI	Confidence Interval
CIT	Community Intervention Trial
CMR	Child Mortality Rate
CSA	Central Statistical Authority
DHS	Demographic and Health Survey
DPT	Diphtheria, Pertusis and Tetanus
EHNRI	Ethiopian Health and Nutrition Research Institute
EJHD	Ethiopian Journal of Health Development
EMA	Ethiopian Medical Association
EPHA	Ethiopian Public Health Association
EPI	Expanded Program for Immunization
ESOG	Ethiopian Society of Obstetrics and Gynecology
ESTC	Ethiopian Science and Technology Commission
FDA	Food and Drug Administration
FGD	Focus Group Discussion
HAPCO	HIV/AIDS Prevention and Control Office
HEW	Health Extension Worker
HHs	Households
HIV	Human Immunodeficiency Virus
Ho	Null Hypothesis
ICU	Intensive Care Unit
ITNs	Insecticide Treated Nets
KAP	Knowledge, Attitude and Practice
M&E	Monitoring and Evaluation
MBA	Master of Business Administration
MCH	Maternal and Child Health
MoH	Ministry of Health
MoU	Memorandum of Understanding
MPH	Master of Public Health
Mphil	Master of Philosophy

NGO	Non governmental Organization
OR	Odds Ratio
PEPFAR	Presidents' Emergency Program for AIDS Relief
PI	Principal Investigator
PMTCT	Prevention of Mother-to-Child Transmission
POW	Prisoner of War
PSU	Primary Sampling Unit
RCT	Randomized Controlled Trial
RHB	Regional Health Bureau
RR	Relative Risk
SMART	Specific, Measurable, Achievable, Realistic and Time Bound
SNNPR	Southern Nations and Nationalities People's Region
SRS	Simple Random Sampling
SSU	Secondary Sampling Unit
STI	Sexually Transmitted Infection
SWOT	Strength, Weakness, Opportunity and Threats
TB	Tuberculosis
ToR	Terms of Reference
UN	United Nation
UNICEF	United Nations Children Fund
US	United States
WHO	World Health Organization

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Finally, EPHA wishes to extend its appreciation to the trainees for their active participation during the sessions; and to the EPHA staff who have been instrumental in making the training and this publication a reality, by putting their unreserved efforts towards that end.

With Best Regards,

Binyam Ayele (MD, MPH)

EPHA-Executive Director,

Disclaimer:

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EPHA

Preface

The Ethiopian Public Health Association (EPHA) recognizes the crucial gap regarding health research methodology skills in the country. Particularly, the mid-level health professionals engaged in hospitals, health centers and training institutions as well as in health management functions are in dire need of sound scientific knowledge and skills, i.e., acquisition of essential competence to be able to generate solid evidences towards improving service delivery in the health sector. Thus, EPHA is continuously working to upgrade professional knowledge in order to improve public health practice in Ethiopia.

As part of that, EPHA conducted several research/evaluation trainings for health professionals in collaboration with the US Centers for Disease Control and Prevention (CDC), Ministry of Science & Technology and Universities. So far, the Research Methodology and Ethics Training has been offered to more than 200 mid-level health professionals to improve their skills, and many more are eagerly looking towards such trainings to fulfill their requirements from different perspectives.

This Training Proceedings was developed particularly during the Health Research Methodology and Ethics Training organized by EPHA from 11th -20th Feb. 2009 for mid-level health professionals from the EPHA Regional Chapters, Regional Health Bureaus and Universities. The training was conducted using the modules developed by the Ministry of Science and Technology in collaboration with EPHA and Regional Health Bureaus. Through this training, the participants were able to understand better the role of health research for improved service delivery in general, and research proposal writing, methodology design, data processing and analysis, in particular. Moreover, the training also provided the essentials on health research communication, management and ethical values to protect study subjects.

Thus, the main objective of this Training Proceedings is to provide an opportunity for sharing research methodology know-how to health workers who did not benefit from such trainings. It aims at improving health research methodology and ethical skills targeting the mid-level health professionals who are working at the peripheries of the country, where access to information technology is limited. EPHA takes this opportunity to augment public health research and program evaluation skills as one of its main strategies, besides generating and disseminating the regular publications for improved strategic information for decision making and public health professionals' development purposes.

Therefore, this Training Proceedings is envisaged to have paramount importance, especially, to health workers assigned at health management and facility levels. It would help our target users to identify pressing health problems in working out pertinent solutions. EPHA also believes that such knowledge would also motivate

public health professionals working in health centers and hospitals towards research. It would also help to produce evidence based events and strategic facts to utilize for project formulation, strategic planning and day to day activity monitoring as well as to boost the professional capacity to accomplish informed decision making in the health sector.

Finally, the EPHA-CDC Project would like to call upon all our targets to exploit the entire Training Proceedings and apply them for program evaluation and study administration, in order to improve service delivery using facts to be generated at the respective levels. We would also like to take this opportunity to invite all health professionals to share research outcomes with EPHA, so that EPHA shares with the rest of the public health professionals through the Ethiopian Journal of Health Development (EJHD), Felege-tena and the Public Health Digest, which have been systematically disseminated throughout the country.

EPHA-CDC Project

HEALTH RESEARCH METHODOLOGY AND ETHICS TRAINING

TRAINING OVERVIEW

This training was conducted in Adama Mekonnen Hotel at Nazareth/Adama, according to the previously set program from February 11th – 20th 2009.

There were a total of 17 trainees from different regions and universities out of whom, four were females. A good number of the trainees were from universities. University of Gondar, Haromaya University, Makalle University and Arbaminch University were represented by one or two trainees. (The list of the trainees is annexed).
The training was begun with the welcoming address delivered by Ato Dereje Seyoum, a representative from the Ethiopian Public Health Association (the opening speech is annexed).

Following the welcoming address, Dr Wakgari Deressa, Assistant Professor and the Principal Trainer from the School of Public Health at Addis Ababa University took the floor and gave brief introductory remarks about the training.. Dr Wakgari mentioned that EPHA is on board to coordinate the health research methodology training for health professionals in different regions of the country. He mentioned that similar training has been recently given in other regions in the country which had included Gambella Regional State and Dire Dawa Administration Council. Continuing his introductory remarks, he told to the trainees that he has been involved in similar training in several places in the past. In this connection, he mentioned that such trainings help to cope up with the changing world. Apart from inspiring, it also helps the trainees to appreciate the importance of research in health development. Dr Wakgari also told the trainees that the training will be computer based in most of the cases. He said that the training will give an opportunity for getting exposed to the use of different computer applications like Epi-Info.

Dr Wakgari then moved to the specific training issues and mentioned that the training is a modular type which will be presented with power points in the process of the training. He said that the training is prepared in six modules and made available in the form of handouts by EPHA for all the trainees. He briefly presented them one by one as follows.

1. Health Research Proposal Writing – focuses on protocol development;
2. Health Research Methods – deals with techniques;
3. Data processing, analysis and interpretation – deals with application of data for inference;
4. Health research ethical issue – deals with the protection of human rights;
5. Health research project management– deals with how to implement and monitor research implementation;

6. Communication and dissemination of scientific findings. This module refers to the presentation and publication of the outcomes of research.

All the six modules were distributed to all the trainees for further reference and future preparation for the subsequent sessions. It will also serve as support document for similar future trainings at regional level. Dr Wakgari noted that the modules which were originally prepared by the Ethiopian Science and Technology Commission and the Ethiopian Public Health Association in 2005 have some rooms for modification and updates, as they were not revised since then. Nevertheless, they are still useful for individuals with first degree. It could be elementary for MPH, MBA holders who passed through the full process of research undertaking, even though they can serve them as revision tools. Following his brief introductory remarks, he then invited the trainees to introduce themselves to each other and which they duly had performed it.

PRETEST

The introduction of the trainees was followed by the pretest given to each participant. Dr. Wakgari said that pretest helps to examine the knowledge base of the trainees with regards to health research method before going through this training. It had aimed at gauging the outcome of the planned training by comparing the pretest result to the post test which as a standard offered to the trainees at the end of the Training. Pre-post test questions together with the outcome hereby are found annexed.

GROUP FORMATION

Following the completion of pretest, the trainees were grouped into different working groups on the basis of the regions they were representing to develop health research proposals as the training proceeds. Dr Wakgari spelt out the importance of grouping so early in time in order to start learning how to implement the lessons learnt as the training proceeds. Attempts were made to put adjacent regions together with those regions represented by only one participant. Accordingly, the groups formed were as follows.

Group One	Tigray
Group Two	Amhara
Group Three	Oromia
Group Four	SNNPR
Group Five	Somali, Harari and Haromaya University
Group Six	Addis Ababa
Group Seven	Gambella and Bneishangul

Dr Wakgari also brought to the attention of the trainees presentation requirements by the groups each morning as part of the training program. In this connection, he had stressed about the importance of late and long hours of efforts during the training. The importance of punctuality and time management in relation to the timely and proper coverage of the assigned modules to gain something relevant from the training was emphasized.

A take home assignment of drafting a study proposal was given to the formed groups. The proposal was scheduled for presentation in the morning by the group representatives immediately before the day's session begins. The need for thorough thinking and carefully examining the relevance of the problems on the ground was stressed. The groups were also informed that they should think about the sources of information, formulation of the questionnaires that are in line with the selected topics. The proper articulation and explanation of statement of the problem(s) and its strength to clarify and alleviate the problems at hand were also underscored. Awarding of certificate by EPHA for successfully completing trainees was also notified to the trainees.

As a reminder, sending the properly developed proposals to the Ministry of Science and Technology, the Ministry of Health (MOH), EPHA was also mentioned by Dr Wakgari, in order to be able to compete for funding. Trainees were informed about possibilities of interest for funding by organizations such as UNICEF and other organizations upon merit. The proposals that are scientifically sound are likely to be funded.

The trainees raised the difficulty of getting appropriate references in the regions as issues of concern. The possibility of looking for some alternative ways to get references was also brought to the attention of the organizers by the trainees.

TRAINING –IN-PROGRESS

DEFINITION AND RATIONALIZATION OF RESEARCH

By way of enhancing participation of the trainees, the trainer raised the issues of what research is. Different views were expressed by the trainees. The main views that somehow prevailed about research were stated by the trainees, as follows:

"Research is a means by which we can address the gaps."
"Research is a systematic collection, analysis and interpretation of data to address problems identified ahead of time, etc."

As the supplement to the views expressed by the trainees, the trainer had said that research is a very important work that needs a careful planning and cannot be done in haphazard manner. He emphasized that the word 'systematic' is a key word when one thinks about research. He also underscored that research should not be done just for the sake of doing it. He further explained that research is the basis for development: – all developments in the developed world are the products of research. Research also is the means to trigger further development. It helps to get evidences and good understanding about something which otherwise is not possible. Research always looks for new things as new problems occur and provides opportunities for advance in technology. So this makes research undertaking continuous. Those people who are involved in routine activities should observe carefully things around their environment. Evaluation and analysis of accomplishments against the stated plans is another important dimension of a research undertaking, i.e. hence, evaluative research may be one of the ways to trigger research undertaking to find solutions for the shortcomings, identified in evaluation exercises.

There are several issues of concern in the health of the community we are serving. This would mean that we need to undertake some sort of research to address health concerns. We should also bear in mind that all activities researched on may not be addressed. But there is a possibility of getting appropriate suggestions as to how to deal with the problems from researches or evaluations conducted to solve specific problems.

The trainer asked the trainees on how much the MOH is dependent on research findings and yet there was mixed responses. The majority agreed that MOH's reliance on research is low and mentioned some of the reasons why not. Some said that some researchers undertake their study without the consent of the policy makers

of the MOH. Others said that the communication between the universities and MOH is very poor. The studies done by the MOH are sometimes donor driven. The instructor also agreed that there is no culture of research in Ethiopia at present and emphasized that the documentation system in Ethiopia is also poor, in general.

The trainer suggested that all the concerned should think of the ways and means of linking the issues of research to the different sectors. He also mentioned that the different disciplines should come together in research undertaking to make the outcome complete, as research work in principle is multidisciplinary in nature.

The trainer explained that there are two major types of researches, namely **basic** and **applied**. Basic research is concerned with the study that leads to looking for new knowledge at the initial exploratory stage. However, some of the knowledge will ultimately fall in the applied category after sometime. Applied research is concerned with solving immediate problems. It is used to give solution to problems at hand. In a practical situation, it is very difficult to put a dividing line between the two types of research. Many times there could be overlaps of the two types.

As a summary to the section, the need for clear statement of the research problem, clear research objective(s), sound formulation of research methods and systematic plan, collection, analysis and interpretation of the data were mentioned as cardinal characteristics of research. The proper articulation of the research objective was also emphasized as a key feature of research.

RESEARCH PROPOSAL

A research proposal is defined as a systematically written document which contains the plan to undertake study or evaluation. The important components like; the abstract, statement of the problem, literature review, and method or design, data collection and analysis plans were explained as part of the essential requirements of any given research protocol. Also, the trainer had clearly stressed the fact that this very document, i.e., systematically developed in writing research proposal or protocol, is needed in order to duly convince the funding agencies to undertake the intended research was clearly stressed.

RESEARCH PROBLEMS AND STATEMENT OF THE PROBLEM

This portion of the training had looked in-to how the research problems are identified and on the specific steps of the problem statement. The responses from the trainees and complementary ideas from the trainer are reflected here below:

Research problems could be generated from the mind of individuals with some knowledge or life experience. The magnitude of a problem on the ground and situational analysis also give some clue as to how research problems are generated. The other sources of research questions are experience, literature review, experts in the areas of interest. For instance, the experience of antiretroviral therapy (ART) implementers could help to pose questions about research problems in the area of HIV/AIDS. The analysis of strengths, weaknesses, opportunities and threats (SWOT) of an organization or program also helps to generate questions as it is a good tool to assess the situations. Perceived discrepancy or gaps can also trigger a certain kind of question for research. However, generating research questions or inquiries is not simple as such. There could be two possible alternative answers regarding the discrepancy/problems to be investigated.

How and why the "X" factor causes the "Y" event and how much a certain amount of exposure to the factor "X" affects the outcome "Y" should be properly investigated in order to better understand the nature of the problem. The knowledge of 'cause and effect' relationship would help us to understand the impact of exposure to the subject. Such should be presented in chronological order, i.e., exposure to outcome. The related factors about the problems should also be seen. The following examples can also give some hint about cause and effect relationship.

E.g. Smoking $\longrightarrow$ can cause lung cancer

Parasitic Infection $\longrightarrow$ may lead to malnutrition

The ways problems are phrased also matter a lot. For instance, regarding a question like what are the main factors that lead to poor quality of laboratory service in a given hospital? A number of factors can be listed as follows: lack of laboratory reagent, laboratory facilities, lack of convenient rooms, workload, poor motivation of staff, poor quality control, etc. However, the main factors among those listed above can be sifted through research undertaking.

A number of discussions were entertained on research problem statement. Research problem statement reflects certain justification, main issues or ideas related to the main causes and importance of the research questions to be dealt with. The need to critically analyze the statement of problem was also stressed as the purpose is identification of truth or reality involved in the study. Problem statement is also a process, which helps to focus our attention to the clarification of potential factors and pull out knowledge from literatures and different sources. It highlights why the research is going to be undertaken. The statement of problem is one of the main parts of a research proposal which may actually determine the acceptance or rejection of the proposal. The content of problem statement include: A brief account about socio-economic conditions, overview of the health status and health care, succinct nature of the problem, purpose of data collection and utilization, had been carefully

articulated with clear language. As this is the part that the funding agents read first, attention must be given by any given potential researcher. It should not be more than one page, though there is no page limit to be set.

Training Session on Progress

LITERATURE REVIEW

Literature review is the act of searching for information in areas related to the subject of interest of the researcher. Literature review looks into what has been done, the gaps, the limitations, the controversies, etc. in the areas related to the subject desired to be studied. It also gives the updates of the relevant information. The updates need to be latest as much as possible. The trainer had duly highlighted the importance of literature review for formulation of the hypothesis, giving some light of the

accumulated knowledge and gets some ideas about the research to be undertaken. It was also noted that it is the basis for further evaluation of the proposal and the people at the back of the proposal. Literature review helps to consolidating knowledge to justify the importance of research proposal. Reminder was given that citation of pertinent information from any other source should be always acknowledged. The name of the publication and the author(s) of the publication should be mentioned as taking some body's idea without acknowledgement is illegal and considered as plagiarism. The funding agencies also scrutinize the project proposal in this particular respect.

How latest should the information from literature review be, was a question raised from the trainees. Taking literatures published earlier than five years is not acceptable by most researchers even though it is not possible to put time limit was the consensus reached by the trainees and the trainer. The number of references to be cited was also asked. In response to this question, it was said that there is no limit. However, citing up to twenty references is possible. However, some scientific journals limit number of references. Lack of access to literature review was also mentioned. It was noted that stating as "there is no document for literature review" has been a dilemma. However, the present time is considered better than the previous times due to the availability of the internet. Mention was made that citation from the famous persons can be put as personal communication. It was also brought forward that the quality and acceptability of the journals cited should be carefully assessed before they are considered for use. The possible sources for literature review were listed as follows:

- Computer based pertinent internet websites
- Journals
- Books - (has weakness as they lack frequent updating)
- Pertinent reports, some time
- Individuals (with expertise or persistent reference)

RESEARCH OBJECTIVE

Research objective is stated as "the clear aim of the study to be achieved at the end of the research undertaking". It, in a way, also gives a clear summary of the desired achievement after completion of the study. It was noted that the objective should be closely related to the statement of the problem to depict coherence. The objective should be written after development of problem statement. Objective is better stated with active or action verb form. It was noted that vague explanations like, appreciate, believe, etc… should be avoided. Having a clear objective can help to

organizing implementation of the research project. It also was noted that a clear objective helps to collect the information relevant for the desired study.

The characteristics of objective being SMART – (specific, measurable, achievable, realistic, time bound) should be derived from the problem statement; it should also be coherent, logical and relevant to the problem statement. Objectives could be stated in general and specific forms. The general objective should be linked to the problem statement and the specific objective should be linked to the topic of the research and emanated from the general objective, was highlighted.

Types of objectives:

General objective: It is stated as what is expected to be achieved by the study in general terms. It is also an overall summary of the problem statement. It is linked to the title of the research in most cases. The following examples better explain what it means.

Example:

- To identify the reasons for the low utilization of vaccination services in rural X District.

- To reduce infant mortality by 30% within a period of six years by improving access and use of insecticide treated nets (ITN) in Y District.

The difficulty of putting distinction between the two was mentioned. There was also the possibility of converting the general objective to the specific and vice versa.

Specific objective: It was stated the specific objectives are the tangible part of the general objective. Specific objectives are logically connected to the general objective and the findings of the research are measured through the specific objectives to conclude on the outcome of the research. In principle, it was noted that specific objectives should sort out the solutions for the problems mentioned in the statement of the problems. The importance of critical thinking and carefully selecting the appropriate language were clearly stressed in developing specific objectives.

RESEARCH HYPOTHESIS

It was stated that research hypothesis could be taken as an assumption to start with. It is also an intellectual guess related to the subject of interest for research. Study hypothesis has the tendency of guiding or directing the research process. The

hypothesis gives clue for the type of data to be collected and the method of data analysis to measure the relationship. The exactness of this guess can be found out using the study on the basis of a sample. Hypothesis can be stated in a null format – example: "There is no significant relationship between and among the variable of interest.'' It can also be stated in directional or alternative format – here, the direction of the relationship is clearly indicated. Hypothesis does not exist in descriptive type of study as descriptive study strives to explain occurrences and distribution of the study variables. The fact that hypothesis is not a mandatory item in all researches was also mentioned as a point of departure.

Examples of hypothetical statements:

- Teenage girls are better informed about the risks of HIV than teenage boys.
- Improved access and use of ITNs will reduce infant mortality by 30% in district X within 6 years.
- Utilization of expanded program for immunization (EPI) for children is lower in rural areas than those in the urban areas.

RESEARCH METHODS

Research methods were explained as the core parts of study undertaking which should answer the following basic questions with consideration to the different research aspects like research problems, literature review, research objectives, hypothesis, etc. covered earlier:

- What is to be measured and how? And why?
- What is the design and why?
- What is going to be done with the collected data?
- How good is the quality of the data (validity)?
- How is data collected? Who are the trainees? How do we select them? How big should the sample size be?
- Is bias anticipated? How to reduce bias?
- What are the statuses of logistics and other supports? Do we have adequate resource?
- What are the possible ethical problems and the necessary considerations?

RESEARCH DESIGN

Research design is a method basically concerned with the overall research implementing plan that the researcher prepares. It was also noted that designing strategies for collecting accurate information, relevant to the set objective is the main components of research design.

There are two main categories or types of research design, namely, observational and experimental or intervention. Observational research design has two parts. 1. Descriptive research design used for survey and other studies. 2. Analytic research design used for case-control and cohort studies.

***Research Design and Types*:** The design and the types are shown in the table below.

Types	**Methods**
1. Experimental/ interventional	I – Quantitative
2. Observational: - Descriptive (surveys and others) - Analytic: Case-control and Cohort designs	II – Qualitative
	III – Mixed

Types of Research Design:

1. Experimental/ interventional
   The researcher manipulates a situation and measures the effects of this manipulation. There are exposed and control groups.
2. Observational: which deals with –
   a. Survey
      - The whole population or sample is studied
   b. Cohort
      - Exposure status considered and followed-up
   c. Case-control
      - Selection based on case status with reference to those who are not affected.

Factors considered for choosing the type of research design are:

- The type of research problem;
- Statement of evidence and knowledge already available;
- Status of resources: That is expertise, personnel, finance, logistics, and time.

SAMPLING

Sampling is the selection of a finite number of elements from the population for the purpose of enquiry. Whereas sample is a small representative fraction of the population from which conclusion or inference can be drawn about the whole population.

Desired Features of Samples:

- Expected to possess the essential characteristics of source population;
- Should be representative of the reference population.

Why do we need sample? – Essential considerations:

- Cost (financial and human resource)
- Practicality
- Time

Types of Sampling: There are two types of sampling, namely:

1. Probability sampling
   - Random selection
   - Ensures representativeness
   - Clearly known or stipulated fair chance of selection

2. Non-probability
   - Non-random selection
   - Unknown chance of being selected
   - Lacks representativeness

Sample Size Determination:

- Different formula may be used for estimating sample size
- Sample size should be sufficient to represent the characteristics of interest of the study population. In homogenous population, smaller sample size can suffice.
- Important to make inferences about the population from which the sample is drawn, based on the findings from the sample.

PLANNING DATA COLLECTION

This is a new phase in the development of research methodology. It was noted that everything that is going to be included in the research undertaking should be planned in a concrete manner. The following are some among the many.

- Development of data collection instrument
- Study site selection
- Securing permission for the study
- Recruitment and training of data collectors
- Selection of study trainees
- Securing financial support
- Logistic arrangements

DATA ANALYSIS AND INTERPRETATION PLAN

Data analysis and interpretation has to be planned as part of prior planning process to remind and guide the researcher as a kind of check list to follow at the appropriate time. The following are the main components under this sub topic.

- Data coding
- Data entry to the computer
- Analysis – descriptive and advanced
- Significance testing
- Interpretation
- Preliminary findings, conclusions and recommendations
- Documentation and Reporting.

ETHICAL CONSIDERATIONS

Any research that involves human subject should fulfill the ethical issues relevant to a particular study in time. It helps to maximize the benefit of the study subjects. The proposal of such project must be reviewed by the appropriate ethical committee formed for this purpose. More details about this subject will be covered in module 4

WORK PLAN/IMPLEMENTATION PLAN

This part shows all components of a study in organized manner. It also helps as a guide to show what should be done when and by whom. The work plan should be simple and clearly understood by the implementers. It was also noted that the locally observed norms and traditions should be considered in the plan. The draft of the initial work plan can be developed at the time the proposal is prepared. Then, the refined one can be prepared after the pretest in the study area is done. It can also be revised when it is desired as the study is proceeding.

***Components of Research Proposal*:**

- Title page appears first on the proposal
- Abstract: prepared last but presented next to title page. It is a summary of the basic information contained in a proposal. Other parts include:
  1. Introduction
  2. Problem statement
  3. Literature review
  4. Objectives

5. Hypothesis
6. Methods
7. Work plan
8. Budget
9. Reference
10. Appendices

The trainees were asked to raise questions, give comments or suggestions at the end of each topic throughout the sessions. There were good interactions from the trainees.

SECOND DAY SESSION

GROUP WORKS PRESENTATION ON THE TITLES OF THE PROPOSALS

The second day of the training was started with the presentation of the group work by group representative or principal investigator (PI) as originally agreed.

Group one: Tigray Regional State
Selected topic by the group:

The role of health service extension program/ health extension workers in promoting adolescent reproductive health in a selected rural district in Tigray Regional State.

The presentation from group one was made by Ato Araya Abrha (PI). The group members are, Dr Tesfa Semane and Dr Endrias Lanchemo.
Group presenter from the region
Comments from the trainer:


He mentioned the need of introduction, problem statement, hypothesis, objective, feasibility, relevance and its contribution to the overall health service in the area. The trainer had emphasized that the comments may apply to all the groups from other region as well.

Comments from the trainees:

Other participants of the training said that the topic is good; however, it needed some kind of modification. They suggested that it is better to narrow the topic and focus on the health extension workers. The need for literature review was also mentioned.
When asked about the justification for selecting the topic, the group responded that the area of adolescent health is new and not documented in the region so far. It also was noted that adolescents are risk taking groups that are mostly exposed to reproductive health risks.

Group two: Amhara Regional State
Topic the group selected to study:

Assessment of Personal Hygiene and Latrine Utilization in Gondar Administrative Town.

The presentation from group two was made by Ato Melkamu Fenta (PI). The group members include: Ato Amsalu Feleke and W/ro Mahteme Haile

Group Presenter from the region

Comments from the trainer: complemented the comments stated above.

Comments from the Trainees: there was no much comment except on the necessity of specifying the study time.

Group three: Oromia Regional State

Topic the group suggested to study:
Assessment of Factors Affecting Community Conversation (CC) regarding HIV/AIDS control at community level in Oromia Region.

The presentation from this group was made by Ato Jeylan Kasim. The group members include: W/rt Bontu Fekade (PI) and Wro Seblework Tadesse.


Group Presenter from the region

Comments from the trainer:
The trainer mentioned that the previous comments were equally applicable here as well. He also noted that community conversation has become important in the endeavor of fighting HIV/AIDS. However, the methodology for the study of community conversation is difficult.

Group four: SNNPR State

Topic the groups suggested to study: *Assessment of magnitude and determinants of utilization of unmet needs of modern contraceptives among females in reproductive age group in SNNPR State.*

The presentation from the group was made by Ato Girma Temam (PI). The group members: Ato Asrat W/Meskal and W/ro Eskedar Solomon.

Group Presenter from the Regional States

Comments from the trainer:

He noted that the proposal needs some kind of rephrasing, giving emphasis to utilization.

Group five: Somali Regional State

Topic the groups suggested to study:

Assessment of factors affecting immunization service in drought affected areas in Somali Regional State.

The presentation from the group was made by Ato Hassen Ismael. The group members: Ato Tadesse Alemayehu (PI) and Ato Diriba G/yesus.

Group Presentation from the region

Justification: Focus of the government, RHB, low EPI performance (32%) in the whole region with the decreasing tendency when it comes to the drought affected areas, the displacement of the people in the area leading to low coverage. The health service coverage is also another factor which affects EPI coverage.


Comments from the trainer:
There was no much comment except he had mentioned that health service coverage as well may affect the EPI coverage.

Group six: Gambella Regional State

Topic the groups suggested to study:

Assessment of factors that affects/hinders PMTCT service utilization among ANC clients in Gambella Regional State.

The presentation from the group was made by Ato Jemes Bol (PI). The group member: Ato Lemma Adinew.
Group Presenter from the region


Justification: PMTCT is very low. There is need to know the reason for low coverage. The socio-cultural problems, prevalence of HIV is high in Gambella.

Comments from the Trainer:
The trainer mentioned that justification has been given. But it is still necessary to include the introduction, problem statement, etc. as commented for the first presenter to make the proposal complete.

The following general questions were raised from the trainees:
There was lack of relevant documents for literature review. The group expressed their desires to get some journals that are relevant to their topics from EPHA through post offices or other means. Attempts were made to give fast response to the questions from EPHA.

HEALTH RESEARCH METHODS (MODULE II)

This part of the training was started by asking what the trainees expect to know about health research methods. The trainees responded that they expect to get some knowledge about the types of study designs, advantages and disadvantages of different study methods, statistical calculations, and knowledge about sampling.

The training started by giving some highlight about the objectives of the lesson on health research methods in line with expectations of the trainees. This includes:

- Study the different types of epidemiological study designs, their uses and limitations,
- Be able to select the most appropriate study design for a particular research question,
- Sampling methods and sample size determination, and
- Study the application of qualitative and quantitative research methods in health research.

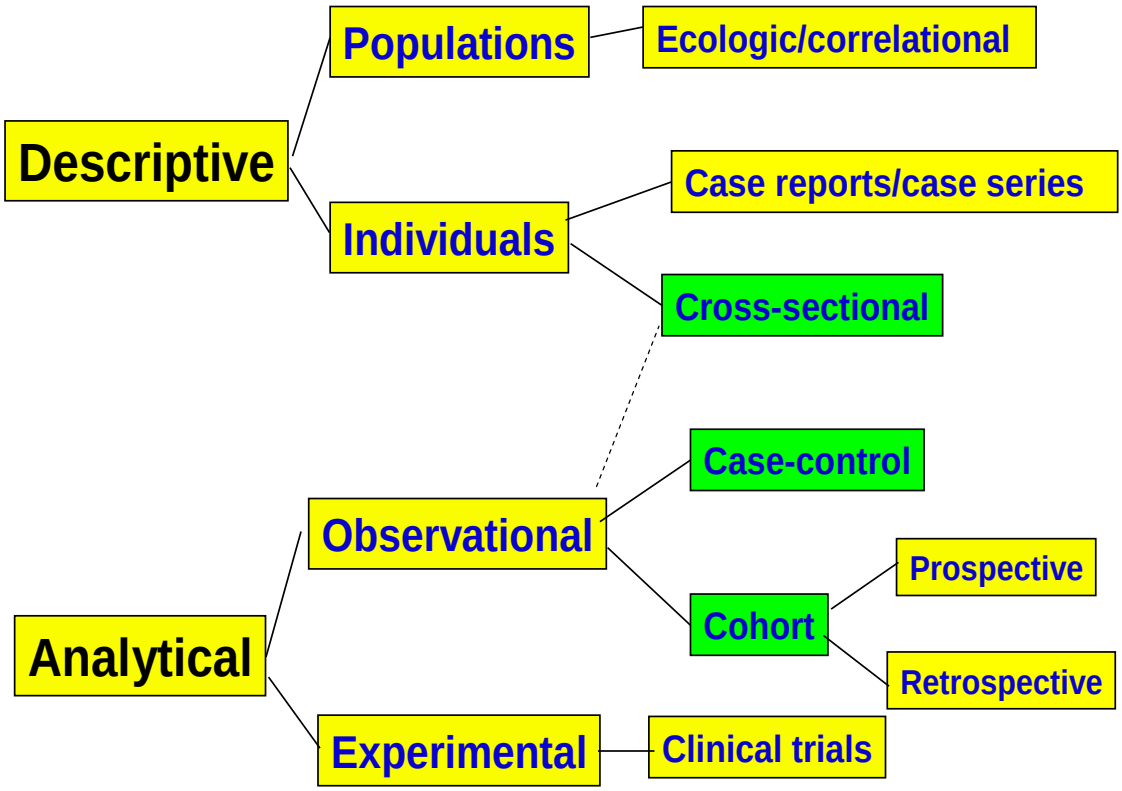
EPIDEMIOLOGICAL STUDY DESIGN

The trainer presented the lesson as follows. The general epidemiological study methods are classified into two:

1. **Observational (non-interventional)**
2. **Experimental / Interventional**

Schematic chart to show the different types of epidemiological studies is shown in the following diagram.

Schematic chart for different types of epidemiological studies



Observational study in return is classified into two, i.e. descriptive and analytical studies.

- *Descriptive study*: This type of study deals with describing the occurrence and distribution of the health problem or condition of study interest in terms of person, time and place. It responds to the questions: whom, when and where. It does not test hypothesis and the study is not structured as analytical study. The two targets of descriptive study are: population and individuals. Under population, **ecological or correlation** study is conducted to get information of a group of people from the village(s) or a country. Under individual study, **case report and case series** studies are carried out to get information on a

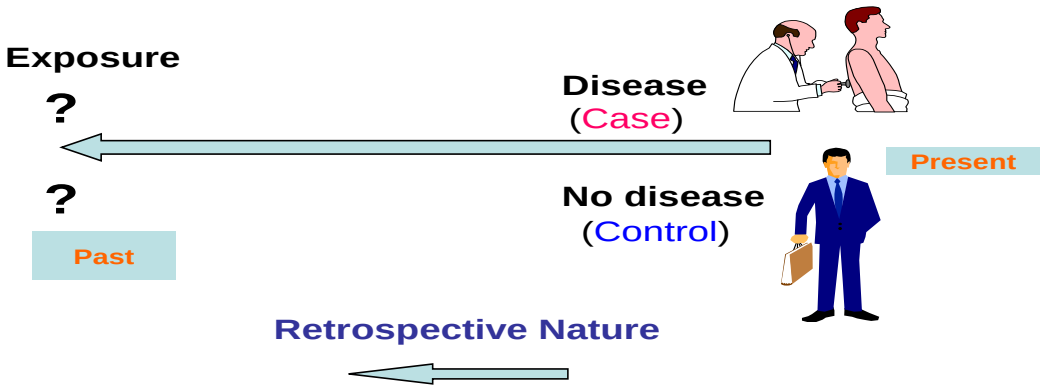
single individual. It was underscored that this type of study is useful in unusual cases or new health problems such as severe, acute respiratory syndrome (SARS), avian flu, etc. As it is important link between clinical medicine and epidemiology. The information about unusual cases is commonly found from specialized hospitals.

- Cross-sectional study was also covered as one sub section under descriptive study. In this connection, it was noted that this type of study is commonly used in developing countries like Ethiopia in order to determine the characteristics of health problems of the countries. The fact that this study assesses both exposure and diseases at the same time and gives 'snapshot' – showing only one part of the occurrence could be taken as the weakness of this type of study. In snapshot it is not possible to see what happened before and after the occurrence. Cross-sectional study also gives prevalence rate of a particular disease. Thus, the information obtained through this study is found to be useful for planning purpose.

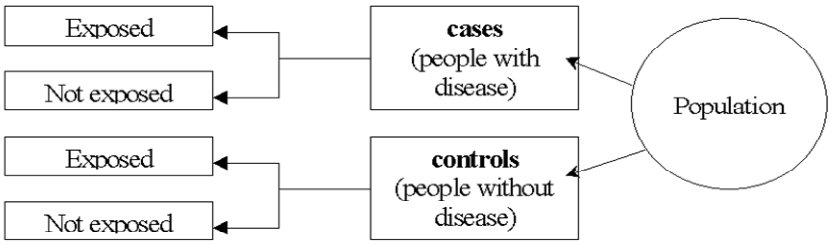
- *Analytic study*: deals with the study of cause and effect or exposure and outcome relationship. It finds answers for 'why' and 'how' questions. It compares determinants and looks whether there is an association or not. Determinants are investigated when comparative study is conducted, but not recommended for other studies. The case-control and cohort study designs are used here. In a case-control study design, the researcher(s) deal with the cases and controls looking back (retrospective nature) to the history of the exposure of cases and controls. The number of cases among exposed and non-exposed groups is compared to see magnitude of the problem. The cases among immunized and non-immunized groups were cited as example for case-control study. The following schematic drawing and the flow charts can be referred to for more explanations.

- *Case*-Control Study:
- In case-control study design, we deal with the cases and controls looking back (retrospective nature) to the history of the exposure of cases and controls. The number of cases among exposed and non-exposed groups is compared to see and compare the magnitude of the exposure in both groups. The immunization status of children can be investigated among cases and non-cases. This is an example for case-control study. The following schematic drawing and the flow charts can be referred to for more explanations.

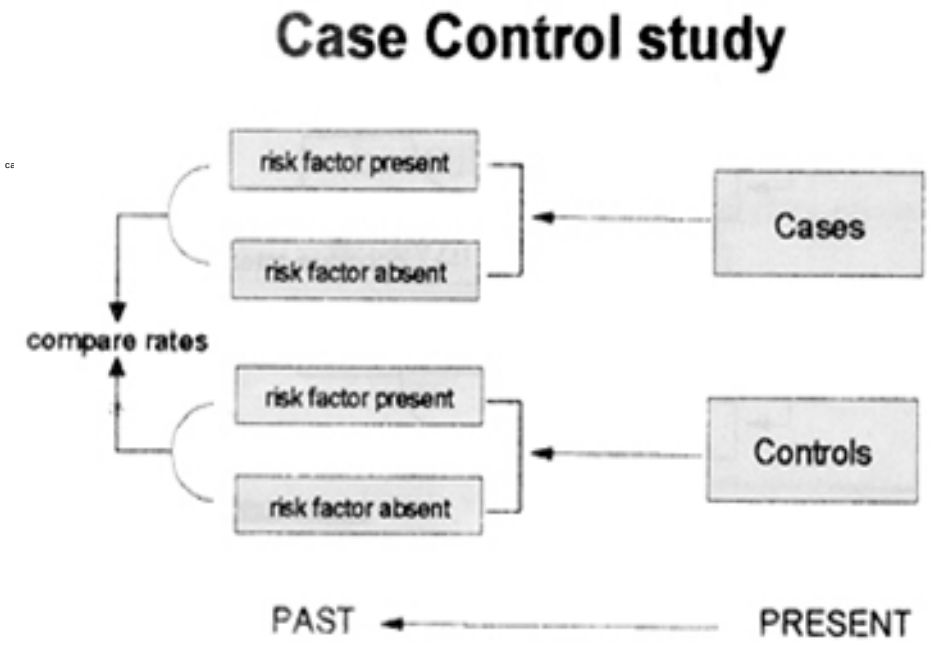
Case-Control Studies



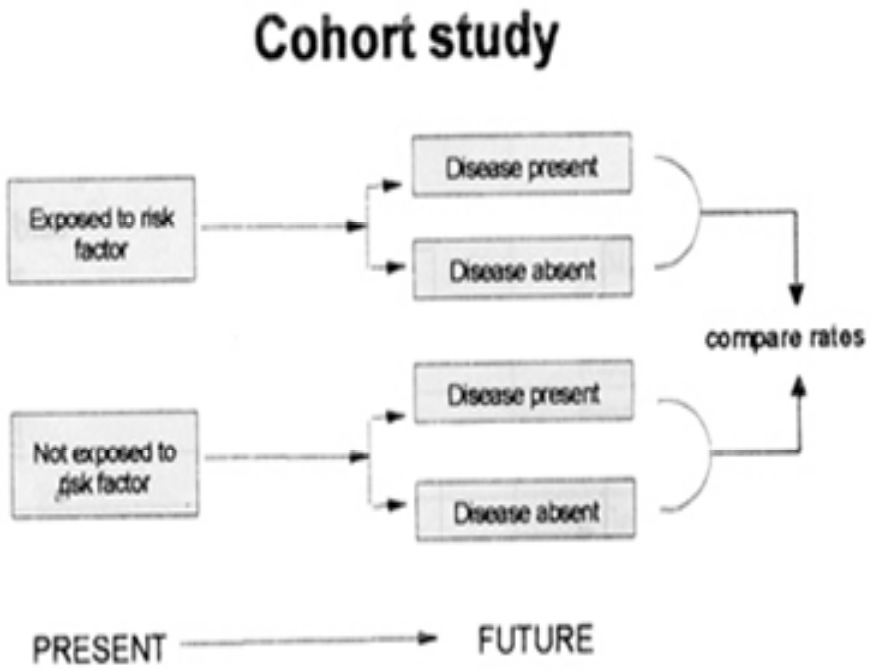
Design of a Case-Control Study



Source: partially adapted from WHO, 1993

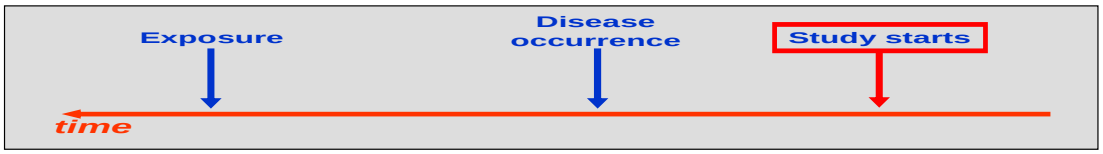


Cohort Study Design: This design starts with group of people (cohort) free from disease at the beginning, classifying under exposure and non exposure groups, and followed up over a period of time to find out and finally compare the outcome of disease or case of interest in both groups. There are two types of cohort study design; namely: prospective and retrospective study. Refer to schematic diagram shown below.



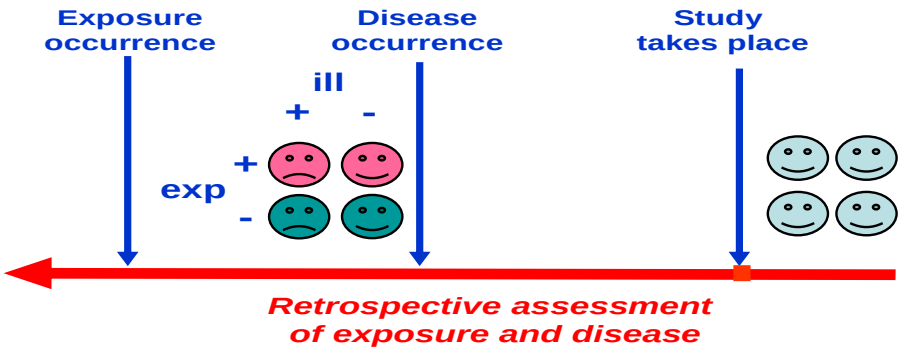
Retrospective cohort study design looks into the past occurrences. It identifies to the exposure and disease that had already happened in the past. The study in this case depends on availability of reliable records. These records are used to reconstruct what had happened in the past. The interest of the researcher here is to assess magnitude of the disease in already exposed people. The study on psychological problem among Dire Dawa people after the episode of the last flood disaster was mentioned as an example for this situation. The following schematic drawings explain the path of the process of the study. The trainer had drawn due attention to be able to observe, the difference between the following two drawings.

Retrospective cohort studies

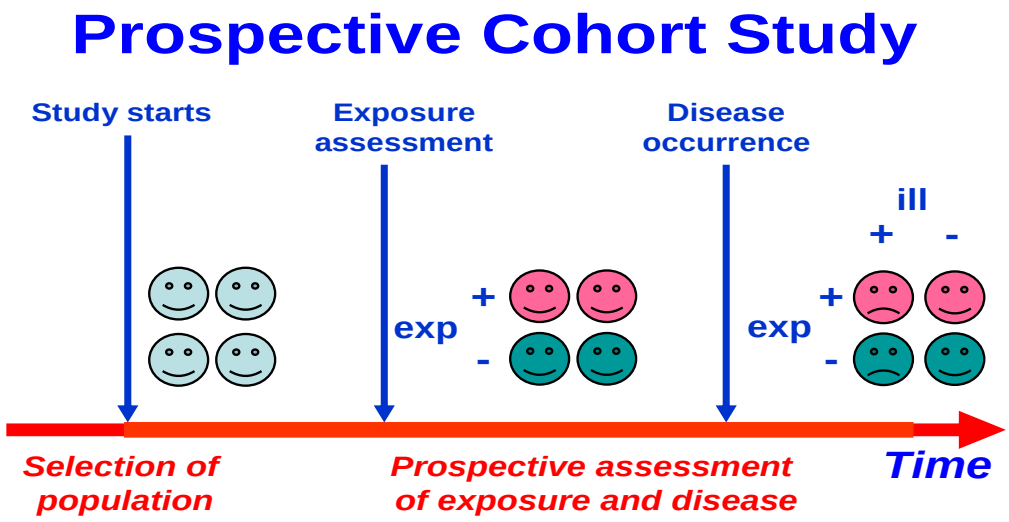


- Disease outbreak following a gathering
- Occupational exposure in mine workers

Retrospective Cohort Study



Again, a reference was made to the schematic explanation shown below for more information on prospective cohort study.



Analytic study also helps to test hypothesis. Determinants are real causes for a certain outcome. This type of study can identify the associated factors but not the determinants for sure. Analytical study is mostly based on individuals. It has two measurements, unlike the descriptive study type. It was noted, that the example of the study of EPI coverage in Ethiopia and in Kenya demonstrates its effect on the child and infant mortality and shows the pattern between the two countries over time.

Analytic study is also categorized as:

- **Observational studies where:**
  - The investigator simply observes the natural course of an event;
  - The investigator measures but does not intervene.
- **Interventional studies where:**
  - The investigator assigns study subjects to exposure and non-exposure, then follows to measure for disease occurrence;
  - The investigator manipulates the intervention or exposure.

  In this study, it was stressed that the difference lies in the role of the investigator.

Observational Studies

- Case-control – Both the exposure and disease have already occurred at the time of the study,

- Cohort – Disease free exposed and non-exposed people are followed up to measuring the outcome.

Direction

Temporal relationship between observations of Exposure (E) and Disease (D):

  - Forward: starts with Exposure
  - Backward: starts with Disease

Chronological relationship between onset of study and occurrence of disease:

Timing

  - Prospective: study onset -----> Disease
  - Retrospective: Disease <--------- study onset

It was noted that the whole purpose of the study is to identify the problems and alleviate them. Study undertaking is governed with the availability of knowledge, resource and time.

The objective and the nature of the problem statement determine the types of the study designs to be selected. Different objectives require different study designs. The selection of an appropriate study design for a particular study is the most important decision that has to be made by the investigator.

The limitations of the different study types were also duly noted. Accordingly, a descriptive study does not deal with comparison. It describes the cases and determinants in terms of person, place and time. In a case-control study, selection and recall bias are common problems compared to other designs. It is not possible to determine whether the exposure comes first or the disease or the other way round. In a cohort study, defaulting is common as the follow up period often is long.

An ecological study is just a study based on data gathering from the assessment results commonly at an aggregate level. It is relatively cheaper and accessible

Limitations of retrospective cohorts were shown as follows:

- All relevant variables may not be available in the original records
- It is difficult to ascertain that the study population was free from the disease at the start
- The data may be found incomplete due to loss of records.

Experimental/Interventional Study

This type of study was stated as a matured type of study that can be applied when all the other studies could not give answers to the problems. However, a lot need to be done before initiating an experimental study. This study is supposed to be conducted with the involvement of researchers' intervention where the investigators assign subjects randomly to exposure, non-exposure and makes follow up to measure occurrence of a disease(s). It is usually prospective study. The study has the ability to provide high quality data. Refer the flow chart below for the details.

Source: partially adapted from WHO, 1993

When does the investigator(s) choose an experimental study design? :

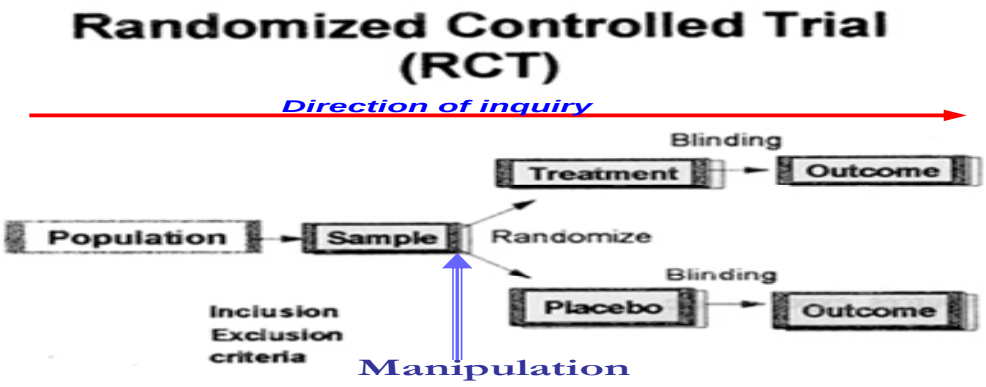
- When the research question cannot be answered by observational studies;
- If earlier observational studies have not answered the research question;
- If the existing knowledge is not sufficient to determine clinical or public health policy;
- If an experiment is likely to provide an important extension of the knowledge on the subject.

Types of experimental studies:

- Randomized Controlled Trial (RCT): It is individual patient based trial at health facilities. Single or double blinding is generally difficult.
- Community Intervention Trial (CIT: Randomization is done on the basis of community but not on individual bases; blinding is not possible.

Confounding is a common problem in this kind of study as information from the case goes to the control and vise versa. There is also a serious ethical problem as the exposed population is showing high disease occurrence before the study time is completed.

The following schematic explanation of shows the direction of inquiry for randomized controlled trial.



Co-intervention: - Intervention upon intervention: This would mean that one should carefully look into the environment in the desired study area.

Limitation of experimental studies:

There is ethical problem as people (cases) are deliberately exposed to risk factors or withheld treatment. There is also selection bias when the experiment is done in hospitals. Randomization of all risk factors outside of those examination variables is not possible. The samples cannot be representative as they are selected on voluntary basis or may be those picked with convenience to the investigator.

Advantages of intervention studies:

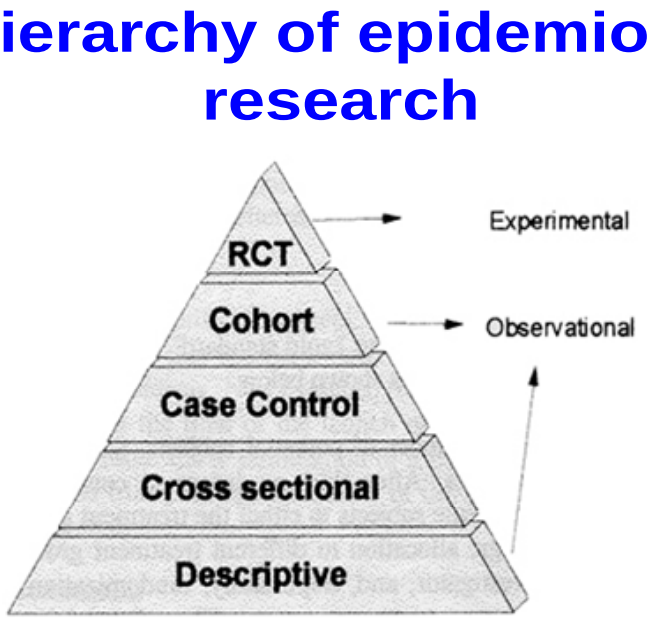
It is considered as ***gold standard*** as it is done with randomized, placebo controlled blinded clinical or community trials and has the following qualities.

- The ability to assign exposure
- The ability to control confounding
- Findings can be replicated and can be generalized

Summary

- Cohort studies allow measure of risk
- Case-control studies are rapid, but cannot measure risk; are only used to estimate Relative Risk
- In the ideal world: researchers prefer cohort to case-control study
- In the real world: case-control studies usually do the job

Hierarchy of Epidemiological Research: It starts with descriptive study, proceeds to cross-sectional study, case-control and cohort studies fall under the broad category of observational study. Experimental study comes at the pick of the triangle as it is opted when all others fail to give answer(s) to the question(s) of interest. Refer to the following hierarchy.



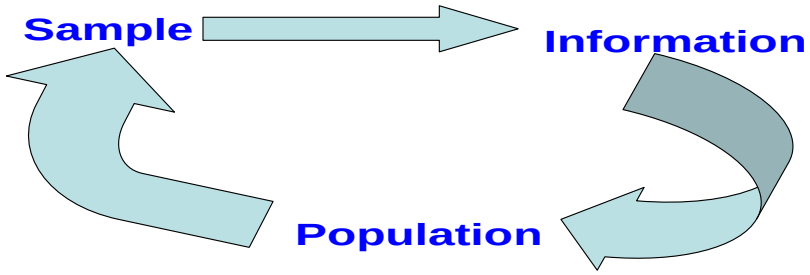
PRINCIPLES OF SAMPLING

During the training, it was noted that sampling is the selection of small number of people or subjects of interest from a particular study population in a manner it represents the population from which it was picked. Samples are subjects or objects in small number representing the characteristics of the entire population from which they are picked. There are a number of advantages when samples are used compared to applying census. Saving resources and time are few amongst many advantages. The sample size can give adequate information that could represent the entire population of the study, by applying correct sampling techniques

Determination of sample size: The correct sample size is determined based on the size of the population from which the sample is taken and based on the desired precision. When the prevalence is high, the sample becomes reasonable in size. For example, the prevalence of goiter in a community may be determined by the number of cases available in a given community. However, when the event of interest is

common, small sample size is enough for the study. But, when the cases are rare, small sample size may not show reality of the situation.

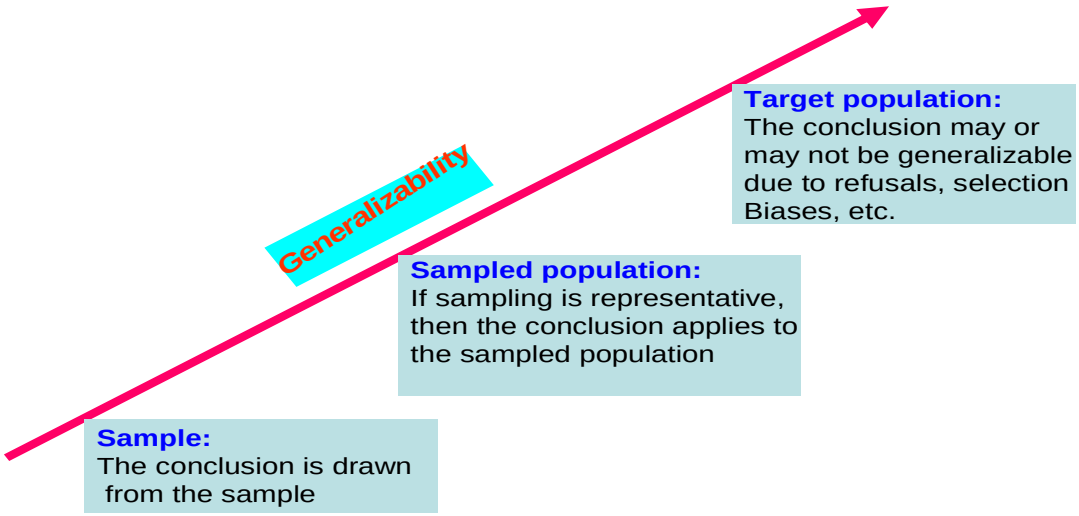
It was stated that the inference about a population is made based on the finding from the sample. Thus, the accuracy of conclusion is by and large be determined by the representativeness of the sample. However, it was also underscored that researchers are not interested in the sample alone, but they are also interested on what can be learnt from the study and how this information can be applied to the entire population. The schematic explanation given below shows the vicious cycle in the inter-feeding processes between the population and sample characteristics.



Certain decisions about the entire population from which the sample is taken are made on the basis of the information obtained from the samples. This is what is meant by making inference.
In the process of the training, it was stressed that the sampling process should soundly reflect the objective of the study. The main interest here is the reflection of the sample to the population from which the sample was taken and values drawn from the information to the researchers and stakeholders.

Sampling: It is a process of selecting representative subjects for observation from a population of interest. This process also involves quantitative, qualitative and probability issues. Homogeneity is considered as the main characteristic of representativeness during sampling. As a basic principle, the sample to be drawn should have the characteristics of the population from which it was selected. The two broad divisions of sampling are known as probability and non-probability sampling. In a probability sampling method, any study subject in a population has equal chance of being selected in the sample. Refer to the schematic explanation shown below.

Generalizability of the Sample's Information



Non-probability sampling is a sampling method where the chance of being selected in the sample is unknown. Such method is considered to be unfair and less strong. However, this method can give the first impression of the population in question, though it is not representative. Although there are limitations on non-probability sampling techniques, good results may be obtained in a particularly homogeneous population. The two main types of non-probability sampling are ***purposive sampling and quota sampling.***

Purposive sampling: It is the method used for qualitative research. This method helps us to get good information. However, the judgment to use purposive sampling should be based on certain assumptions. Different techniques are used to undertake purposive sampling. The following are some amongst many.

- *Snow balling or chain sampling*: This techniques starts with identifying an individual or a group of people who has rich information on the issue under study. Once the first person is identified, the rest of the informants will be easily picked by this person and/or the next person to be identified and so on. The group of informants gradually gets bigger and bigger the same way snow gets bigger as it rolls. This technique is useful when the researcher is new to the area and the subject matter of interest is very sensitive

enough and thus will have to be approached through the "in-house" contacts.

- *Convenience sampling*: This is a sampling technique where the researcher selects the study units that are available at the time of data collection. In this case, the researcher selects those people that are easily picked. Many clinic-based studies use this technique. It may save time, money and demands less effort. However, it is considered as weak sampling technique due to lack of representativeness which leads to low credibility.

Quota Sampling: In this sampling technique, the researcher takes the sample until a specific number of units or quotas for different categories of populations have been reached. This is the sampling technique which allows to using a certain quota for the sample to be involved in the study. Since there is no rule as to how these quotas are to be filled, ***quota sampling*** is a good means of satisfying sample size objectives of the researcher for certain sub-populations. Quota sampling is generally less expensive than random sampling. It is an effective sampling method when information is urgently required. The main argument against quota sampling is that it does not meet the basic requirement of randomness. Thus, the sample may be biased. However, this sampling technique is one of the most commonly applied forms of non-probability sampling techniques, as it is easy to administer as well as appropriate in certain circumstances.

It was re-emphasized that convenience sampling and quota sampling are the most common types of non-probability sampling.

Probability sampling: This is a sampling method where everyone in the population will have an equal chance of being selected in a sample. Probability sampling method requires similar approach in terms of, random selection and use of sampling frame. The selection approach is determined by the type of the proposed study. The characteristics of interest in the study may lead to the application of one or the other or even the use of combined approaches such as stratification, multi-stage, etc... Randomness is also ensured using lottery or other appropriate methods. There are five different sampling methods in probability sampling. These are:

1. Simple random sampling (SRS)
2. Systematic sampling
3. Stratified sampling
4. Cluster sampling
5. Multi-stage sampling

Simple random sampling (SRS): It is a sampling technique where random selection is involved. In simple random sampling method each member of a population has an equal chance of being included in a sample. *SRS technique uses:*

- Numbered list of all the units in the population under study;
- By numbering each unit from 1 to N (where N is the size of the population under study);
- Select the required number randomly according the sample size already determined.

The randomness of the sample is ensured by using "lottery' methods, or table of random numbers or a computer program prepared for the purpose.

Random number table is a table of random numbers constructed by a process in which

a) In any position in the table, each of the numbers from 0 through 9 has a probability of occurring 1/10

b) The occurrence of any number in one part of the table is independent of the occurrence of any number in any other part of the table.

The following are examples of random numbers which fulfil the above stated table of random number characteristics.

8094 2525 8247 1347 7433 3620 1897 ….
…. 3563 2198 8211 9045 2618 2751 2627 ….
…. 1330 6331 3753 9693 8738 6815 1538 ….
…. 3565 0016 2243 6432 4796 6095 5283 ….
…. 7850 5925 5588 7311 2192 4545 3530 ….
…. 4490 5417 9727 6153 5901 4878 9980 ….
…. 6545 9104 9318 8819 7537 2785 9373 ….
. . . .

Example
A school has student population of 500 students and there is a need to conduct a short survey on quality of the food served to students in the cafeteria. To conduct the survey, the researcher decided to take a sample of 10 students.

The researcher assigns numbers from 1 to 500 to each student in the school in order to get the desired sample. To select the sample, the researcher uses a table of randomly generated numbers through the following steps.

- Pick a starting point on the table (a row and column number) and look at the random numbers that appear there.

- In this case, since the data were run into three digits, the random numbers would need to contain three digits as well.
- Ignore all random numbers after 500 because they do not correspond to any of the students in the school.
- Remember that the sample is without replacement, so if a number recurs, skip over it and use the next random number.
- The first 10 different numbers between 001 and 500 make up the required sample.

As a general rule, a large sample is better than small sample, if and only if it s representative. However, a small unbiased sample is certainly more useful than a large biased sample because being representative is the most important characteristics but not the size alone.

Limitations of SRS: Simple random sampling has the following limitations.

- It requires a sampling frame.
- It, however, is difficult when the reference population is dispersed.
- Minority subgroups of interest may not be selected.

Systematic random sampling: Systematic random sampling is a sampling technique in which there is a gap, or interval, between each of the selected unit in a sample. The selection is systematic rather than being purely at random as every certain interval unit is sampled, i.e. the randomness was somehow systematically predetermined by the defined sampling interval. Systematic random sampling uses continuous and equal intervals between samples. The individuals at fixed intervals are picked (every *k*ith) based on the sampling fraction. For instance, if the sample includes 20%, then every fifth is taken as a sample. It is also important to arrange the reference population in some order: Like for instance, order of registration of patients; numerical number of house numbers; student's registration books, etc. to facilitate the systematic selection.

Steps in systematic random sampling:

1. Number the units on your frame from 1 to **N** (where **N** is the total population size),
2. Determine the sampling interval (**K**) by dividing the number of units in the population by the desired sample size,
3. Select a number between one and **K** at random. This number is called *the random starting point* and would be the first number included in your sample,
4. Select every $\mathbf{K}^{\mathbf{ith}}$ unit after that first number.

Example

- To select a sample of 100 from a population of 400, you would need a sampling interval of 400 ÷ 100 = 4.
- Therefore, **K** = 4.
- One unit out of every four units is needed to select up to a total of 100 units in your sample.
- Select a number between 1 and 4 from a table of random numbers.
- Suppose, 3 is chosen, the third unit on the frame would be the first unit included in the sample;
- The sample might consist of the following units to make up a sample of 100: 3 is a randomly starting point and then proceeds to 7, 11, 15, 19...395, 399 (up to **N**, which is 400 in this case).
- Using the above example, one can see that with a systematic sample approach there are only four possible samples that can be selected, corresponding to the four possible random starting numbers of 1, 2, 3, and 4, as shown below;

  Either - 1, 5, 9, 13...393, 397
  Or - 2, 6, 10, 14...394, 398
  Or - 3, 7, 11, 15...395, 399
  Or - 4, 8, 12, 16...396, 400

- Each member of the population belongs to only one of the four samples and each sample has the same chance of being selected.
- The main difference with SRS is that any combination of 100 units would have a chance of making up the sample, while with systematic sampling there are only four possible samples.

The use of random in systematic sampling would mean that combinations of methods (random and systematic) are used for one study of interest. Systematic sampling is easier to perform and less time consuming compared to SRS. There is however, a problem of sampling errors and the risk of bias (E.g. The sampling interval may coincide with a sampling variation in a sampling frame) during the process of sampling. This is considered as weakness of the method.

Note: The trainer noted that systematic sampling should not be used when a cyclic repetition is inherent in the sampling frame.

Stratified Sampling: Selection of a predetermined sample by using any of the probabilistic sampling techniques from each stratum or group is called a stratified sampling. Heterogeneous groups are treated with this sampling method. The population is divided into homogeneous, mutually exclusive groups called *strata*. A population can also be stratified by any variable that is available for all units prior to sampling (e.g., age, sex, province of residence, income, etc.) Separate sample is

taken independently from the different homogeneous strata created ahead of time. Any of the sampling methods mentioned in this section (and others that exist) can be used to sample within each of the stratum. But same chosen probability sampling technique is required to be employed for drawing separate samples across all the given strata. It is difficult to use this method in cases of finding about income and wealth of people. It is done with the proportionate allocation.

Why are strata needed?

- Because a separate sample is taken independently from each stratum.
- This is the idea behind the efficiency gain obtained from using stratification techniques.
    - If strata are created within which units share similar characteristics (e.g., income) and are considerably different from units in other strata, then you would only need a small sample from each stratum to get a precise estimate of total income for that stratum.
    - Then, these estimates could be combined to get a precise estimate of total income for the whole population.

- When SRS approach is used in the whole population without stratification, the sample would need to be larger than the total of all stratum samples to get an estimate of total income with the same level of precision.
- Stratified sampling ensures an adequate sample size for sub-groups in the population of interest.
- When a population is stratified, each stratum becomes an independent population and one needs to decide the sample size for each stratum.

Equal allocation:

- Allocate equal sample size to each stratum

Explanation of proportionate allocation:

- j = 1, 2, ..., k where, k is the number of strata and
- nj is sample size of the jth stratum
- Nj is population size of the jth stratum
- n = n1 + n2 + ...+ nk is the total sample size
- N = N1 + N2 + ...+ Nk is the total population size

Example of Proportionate Allocation

Village	A	B	C	D	Total
HHs	100	150	120	130	500
Find Sample Size?	**?**	**?**	**?**	**?**	**100**

A =100X100/500 =20
B =150 X100/500 =30
C =120 X 100/500 =24
D =130 X 100/500 =26

Cluster Sampling: It is selection of the study groups (clusters) instead of selection of an individual study unit. Researchers may choose a ***cluster sampling*** **technique** to reduce the high costs required in other techniques. This technique is commonly used for geographically dispersed population. The clusters should be **homogeneous**, unlike stratified sampling where by the strata are heterogeneous. The sampling frame will be the cluster frame. School based studies can be done with cluster sampling because it is assumed that students of the same school are homogeneous. This sampling method helps to minimize the cost, shorten the time and give better accuracy.

Steps in cluster sampling:

- Divide the population into groups or clusters;
- Numbers of clusters are selected randomly to represent the total population, and then all units within selected clusters are included in the sample;
- The school sections (in the case of school-based study) are randomly selected by including all students of a selected sections only;

No study units from non-selected clusters are included in the sample.

Cluster sampling is considered to be appropriate for large surveys or population survey.

Multi stage sampling*:* It is a sampling technique whereby the samples of different groups are selected in several stages. It is similar to cluster sampling, except that it involves picking a sample from within each chosen cluster, rather than including all units in a cluster. This type of sampling requires at least two stages. In the first stage, large groups or clusters are identified and selected. Such clusters contain more population units than needed for the final sample. In the second stage, population units are picked from within the selected clusters (using any of the possible probability sampling methods) for a final sample. Primary sampling unit (PSU) is a sampling unit that is categorized in the first sampling stage. The secondary sampling unit (SSU) is the sampling unit grouped in the second sampling stage, etc. Such sampling is applied during national surveys or regional surveys.

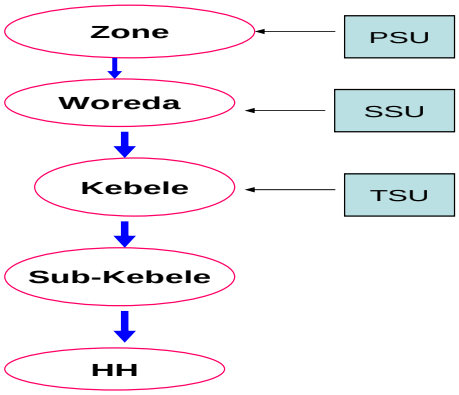
Advantages of multi-stage sampling:

- No need to have a list for all of the units in the population.
- What is needed is a list of clusters and list of units in the selected clusters.

- Multi-stage sampling saves a great amount of time and effort by avoiding list of all the units in a population.

The different stages of sampling in multi-stage sampling are shown in the following flow chart.

Flow Chart for Cluster and Multi-stage Sampling



Key: PSU –Primary sampling unit
SSU – Secondary sampling unit
TSU – Tertiary sampling unit
HH- Households

For example, the plan is to conduct a study on utilization and cleanliness of pit latrines in a district where 150 household members with latrines exist in a district by using interview and observation techniques. The district is composed of six sub districts and each sub-district has six to nine villages. The following four stage sampling procedure could be performed:

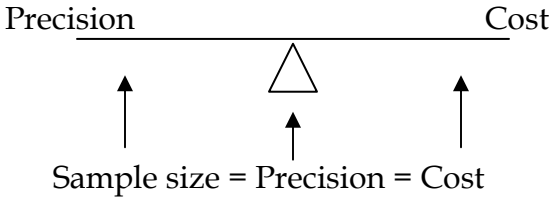
- Select three sub-districts out of the six sub districts, using simple random sampling method.
- From each sub-district, select five villages by simple random sampling (15 villages in total)
- From each village, select ten households.
- To avoid biased sample selection by simply choosing households from nearby center of the village, the following systematic sampling procedure are required:
    - Identify the center of the village;

- Choose a direction randomly either to one's left or right – spin a bottle on the ground and choose the direction where the bottleneck indicates.
- Walk towards the chosen direction and select every third or every fifth household depending upon the size of the village, until the ten households needed are achieved. When the boundary of the village is reached before getting the desired sample size from households, then, return to the center of the village and walk to the opposite direction and continue selecting the sample in the same way as previously done until the ten samples required is completed. The subject to be interviewed should be decided ahead of time. Then, conduct the interview with the person as per to the specification in the protocol.

Definition of the Study Population: A study population refers to the study subjects who comply with characteristics of the population from which the study sample is to be drawn. The inclusion and exclusion criteria should also be considered in this connection. In some cases, there is need to give a clear definition of the study population and other terms used in the study, as operational definition of the study.

SAMPLE SIZE CALCULATION

It was pointed out clearly that there should be an optimum sample size (not too small or too much sample) for every study in question. Having optimum sample size will help a lot in avoiding wastage of resources, and time, apart from reducing the errors. Care should be taken to the extent possible not to surpass the optimal level when sample size is increased. When deciding on sample size, it is necessary to balance between sample size, precision and cost; as shown in the schematic explanation below.



As it is shown in the above diagram, the increase in the sample size leads to the increase in the precision and that of the cost. So, we need to strike the balance between precision and cost.

***Sample size*:**

The number of study subjects selected represents a study population of interest. It is important to make inferences based on the findings from the sample. It should be sufficient to represent the characteristics of interest of the study population. In estimating a certain characteristic of a population, sample size calculations are important to ensure that estimates are obtained with required precision or confidence. The accuracy of the envisaged results determines the size of the sample.

For example, if the following prevalence rate & confidence level used:

- A prevalence of 10% of a certain case from a sample size of 20
  - would have a 95% CI of 3% to 23%,
  - This is not very precise or informative, because the CI is not too narrow.
- But, a prevalence of 10% of the same case as above from a sample size of 400
  - would have a 95% CI of 7% to 13%,
  - This may be considered sufficiently accurate, because the CI is narrower than the one mentioned above.

Sample size determination depends on the following factors:

- Objective of the study;
- Design of the study:
  - Descriptive/Analytical,
- Accuracy of the measurements to be made.

It was also noted that the degree of precision is required for generalization, planning for statistical analysis and degree of confidence to make the conclusion.

The feasible sample size is also determined by the availability of resources like:

- Time;
- human power or human resources;
- transport facilities or means;
- available facility; and
- Money.

Sample Size: Single sample mean (One group): This is to determine the mean of a sample or one group sample using the formula shown below.

n = sample size
s or σ = standard deviation
d = desired precision = half of the CI (w=2d)
e = Required size of standard error = $d/z\alpha/2 \approx d/2$ (at 95% Confidence level)

r = Rate

p = Percentage

Estimation of Single Mean: The formula is:

$$n = \frac{(z_{\alpha/2})^2 \cdot \sigma^2}{d^2}$$

It was stated that the above formula is derived from the confidence interval's formula developed earlier.

Observe the steps:

95 % CI = $\bar{x} \pm {}^{Z}\alpha/_{2} * \sigma^2/n$

D = ${}^{Z}\alpha/_{2} * \sigma/\sqrt{n}$

n = $\frac{{}^{Z}\alpha/_{2} * \sigma^2}{d^2}$

For exemple, suppose that certain group of cancer patients were studied. We were interested in estimating the mean age at the time diagnosis was made. We would like a 95% CI of 5 years wide. If the population SD is 12 years, how large should our sample be?

$$n = \frac{z^2 \cdot \sigma^2}{d^2} = \frac{(1.96)^2(144)}{(2.5)^2} = 88.5 \approx 89$$

The sample size would be about 89 as shown above. However, if larger sample is desired, we need to lower the size of 'd'.

Where do we get sd (standard deviation)? It is obtained from other similar studies. However, it is sometimes a challenge. Whenever not at all available, it can be obtained from a pilot study.

Estimation of Single Rate

n = $\frac{(Z\alpha/2)^2 * r}{d^2}$

The example shown below in this connection was meant to show the importance of the above formula for the estimation of single rate.

Example,
The maternal mortality rate in a country is expected to be 70 per 10,000 live births. A survey is planned to determine the maternal mortality rate with a 95% CI of 60 to 80 per 10,000 live births. The required n would be:

$$n = \frac{(Z\alpha/2)^2 * r}{d^2} = \frac{(1.96)^2\,(70/10000)}{(10/10000)^2} = 27{,}000 \text{ live births}$$

Estimate of single proportion

$$n = \frac{(z_{\alpha/2})^2 \cdot pq}{d^2}$$

The example which shows the importance of the above formula is shown as follows.

Example:

Suppose that you are interested to know the proportion of infants who breastfed >18 months of age in a rural area. Assuming a study revealed that in a similar area, the proportion (p) of breastfed infants was 20% or 0.20. What sample size is required to estimate the true proportion within ±3% precision at 95% confidence? Let p=0.20, d=0.03, α=5%

$$n = \frac{z^2 \cdot pq}{d^2} = \frac{(1.96)^2(0.2)(0.8)}{(0.03)^2} = 683$$

In situations where information about the proportion (p) on breastfeeding does not exist, we assume p=q=0.5 in most conservative way. Then, the required sample size increases to 1,068. Refer to the calculation for the details.

$$n = \frac{z^2 \cdot pq}{d^2} = \frac{(1.96)^2(0.5)(0.5)}{(0.03)^2} = 1{,}068$$

It is clearly seen that size of the sample increases when there is no prior information about the issue for the study. Most often, an estimate of p is not always available. Thus, the following formula may also be used for sample size calculation based on various assumptions for the values of prevalence (p).

- P = 0.1 → n = (1.96)2(0.1)(0.9)/(0.05)2 = 138
  P = 0.2 → n = (1.96)2(0.2)(0.8)/(0.05)2 = 246
  P = 0.3 → n = (1.96)2(0.3)(0.7)/(0.05)2 = 323
  P = 0.5 → n = (1.96)2(0.5)(0.5)/(0.05)2 = 384
  P = 0.7 → n = (1.96)2(0.7)(0.3)/(0.05)2 = 323

P = 0.8 → n = (1.96)2(0.8)(0.2)/(0.05)2 = 246

Comparison of sample size between two means: The following formula is used to compare the sample size between two means. The purpose of the comparison between two means is to find out the difference between the two population means within the precision of d i.e. (d=Zα/2* SE), with 95% confidence interval. This also has the variation width w = 2d. Sample size for estimating the difference between two means is summarized as follows.

- Aim: Estimate μ1-μ2
- Want within ± d units, where d = Zα/2*SE
  (95% CI of width= w =2d)

This would mean that d = Zα/2*SE

The formula for estimating the difference between two means is:

$$n = \frac{z^2 \cdot (\sigma_1^2 + \sigma_2^2)}{d^2}$$

The main purpose is:

Use σ_1^2, σ_2^2 or estimate using $s_1^2$and s_2^2

It was noted that equal sample size is required in both groups.

Comparison of the difference of the proportion between two means can be done using the following formula.

$$n = \frac{z^2 \cdot (p_1 q_1 + p_2 q_2)}{d^2}$$

Use estimates of p_1, p_2 or (or p_1=p_2 =0.5 if unknown)

It was also noted that equal sample size is required in both groups.

HYPOTHESIS TESTING

Significant Difference between Two Groups:

- Using power of a study to determine sample size = significant difference = Hypothesis testing

- Aim: Have large enough samples to detect a difference in population means (or in population proportions)
- We would like to maintain low probability of Type I error (α) and low probability of **Type II error (β) [high power = 1 - β].**

Level of significance (α) = Probability of making Type I error
1 – α = Confidence, 1 – β = Power
Ho = refers to that there is no difference, i.e., the null hypothesis
H_A = refers to that there is difference and is often labeled as the alternative hypothesis.

- **Type I Error (A)** = The Probability of Rejecting Ho When it is true
- **Type II Error (β)** = The Probability of Not Rejecting Ho When it is false
- **Power (1-β)** = The Probability *Ho* is Rejected given that it is false
  = P (Reject Ho/H_1 is true)

Types of errors in hypothesis testing are shown as follows.

Action (Conclusion)	**Reality**	
	Ho is true	**Ho is false**
Reject Ho	**Type I error (α)** (Prob. = α = Sign. level)	**Correct action** (Prob. = Power = 1-β)
Do not reject Ho	**Correct action** (Prob. = 1-α)	**Type II error (β)** (Prob. = β= 1-Power)

It was noted that Type I error is also called alpha (α) and Type II is beta (β) as shown in the table above. The null hypothesis wrongly rejected when it was actually true. In other words, it should not have been rejected and it is referred as Type I error. Type I error is defined as rejection of the true null hypothesis. In the other instance, we wrongly failed to reject the null hypothesis that was actually false; we should have rejected. Such error is termed as Type II error. So, Type II error is the failure to reject a false null hypothesis. The power of a test is the capacity to detect a false null hypothesis. A large sample size is usually attributed to greater power. However, there is a limit where increment of the sample size does not bring any more effect on the power. The power 80% is considered as having better detection power to accept or reject null hypothesis.

Using power of a study to determine sample size:

- Comparison between two means
- Δ = μ1-μ2

$$n = \frac{(z_\alpha + z_\beta)^2(\sigma_1^{\,2} + \sigma_2^{\,2})}{\Delta^2}$$

Using power of a study to determine sample size:

- Comparison between two rates

$$n = \frac{(Z\alpha/2 + Z\beta)^2\,(r1 + r2)}{(r1 - r2)^2}$$

Comparison between two proportions:

For calculation and comparison between two proportions, we use the following formula.

$$n_1 = n_2 = \frac{\left(z_{\alpha/2}\sqrt{2\overline{pq}} + z_\beta\sqrt{p_1q_1 + p_2q_2}\right)^2}{\Delta^2}$$

Δ = p1-p2

The interpretation of power (1-β): Power of a study is weak means the detection level of the study is low. Most studies recommend the minimum power size of 80% formula to have a better detection power.

The different power (1- β) =50%, when Z β changes are indicated as follows.

- Power (1 - β) = 50%, Zβ = 0.00
- Power (1 - β) = 75%, Zβ = 0.67
- Power (1 - β) = 80%, Zβ = 0.84
- Power (1 – β) = 90%, Zβ = 1.28

- Power is one-sided and Zβ is always one-sided

Like in the previous day, the trainees were encouraged to ask questions and give comments and/or suggestions at the end of each topic presentations or whenever they feel like to do throughout the sessions. There were good interactions from the trainees' side too.

A reminder was also given that there is more information in modules distributed in addition to what has been presented in this proceeding.

THIRD DAY SESSION

GROUP WORK PRESENTATION

The third day was dedicated to the second round of presentations of the group work. Presentations were made by the representatives of the respective groups on further development of their proposals. As previous time; questions, comments and suggestions were given by the trainees and trainers for each presentation. Accordingly, the following questions, suggestions and responses were forwarded on the presentations of the respective groups.

SNNPR: The following questions, comments and suggestions were first forwarded to the group from SNNPR region.

Questions: The topic for the study is about unmet needs of modern contraceptives among females in SNNPR. When the presenters say unmet need, there must already be certain knowledge about the level of unmet need in the SNNPR. The group was asked to explain on why they planned to study to get information already known.

Response from the group: The group responded saying that the already existing knowledge is just suggestive. The study aims to find out actual level of prevalence for unmet needs on the ground.

Comments: The fact that the group wanted to undertake the study on unmet needs in the area with large number of ethnic groups would make the study very difficult and unfeasible. So, the group was advised to know that it should consider this as a challenge and get prepared on how to handle it wisely. In a related discussion, particularly on the measurement of unmet needs, the group was reminded that there should be standard measurement that already had been used and validated by other agencies.

Tigray Region: The presenter reported that the topic has been revised based on the suggestion given during the previous presentation. Then relevant questions, comments and suggestions were forwarded to the group as here underneath:

Question: Why the study is limited to health extension workers and health service program? Why not include other service areas? Why not include school based questions?

Comments: Provision of operational definition for ambiguous terms and words can help to make clear the information for the readers. It was also suggested that type of

the study design should be qualitative for the part that deals with attitude & perception, while the others can be addressed by the quantitative method.

Amhara Region: Here also the presenter reported that the topic has been revised based on the suggestion given during the previous presentation. Then, comments and suggestions were forwarded to the group.

Comments: The comments from plenary stated that the sample size should be given some thought. The specific objectives and other parts of the proposal should be carefully reviewed and rephrased.

Oromia: The presenter reported that the topic has been revised based on the suggestion given during the previous presentation. Then, comments and suggestions were forwarded to the group from this region as presented below;
Comments: It was suggested to the group that the specific objectives with similar nature should be merged together. It was also suggested that the protocol should include only issues that are going to be studied. The flow should also show coherence and maintain sound flow of idea on the subject under the study.

Somali Region: The presenter reported that the topic has been revised based on the suggestion given during the previous presentation. To that effect, the group has limited the study to one wereda, specifically to Erer wereda. Then, comments and suggestions were forwarded to the group as follows.

Comments: The trainees said that socio-demographic characteristics do not need to be assessed as factors affecting immunization services. In addition the reason for linking drought and immunization should also be adequately explained.

Gambella Region: There was no question forwarded for this group. However, the following comment was forwarded to the Group.

Comments: The trainees and the trainer agreed that it should be clearly stated on whether the study is institution based or community based. Over all, the presentation of this group was considered fairly precise and informative.

DATA COLLECTION

Following the group presentations, the rest of the day was devoted to the lecture on data collection. It was noted that knowing how to deal with data collection is important for the project proposal as it helps for securing budget and decide on the human resource needed. To that effect, the two types of data collection were explained, as follows.

Observation: (It could be affected by bias)
There are two types of observations
Participatory
Non-participatory

Interview: Self administered
Face-to-face – is an in depth communication commonly used for community based survey.

The face-to-face data collection method is most common in addition to focus group discussion (FGD) used in qualitative survey. The different data collection techniques will allow to systematically collecting information. Data collected in haphazard manner does not help to answer the research question in a sensible way. The quality of the data collection method guarantees quality of the study. Thus, the different techniques of data collection and other relevant parts were also dealt with.

Data collection Techniques: There are different kinds of data collection techniques. These are:

- Using available information (record review)
- Observation
- Interview
- Administering written questionnaires
- Focus Group Discussions (FGDs)
- Other data collection methods

Using available data: The following are the most commonly available data used in health research.

- Morbidity reports
- Mortality reports
- Epidemic reports
- Epidemic investigations reports
- Laboratory data
- Special surveys – already done by others.
- Demographic data (census that has been already done)

However, the completeness and easy retrieval of these data most of the time remain challenging that need to be dealt with.

Source of the above mentioned data are:

- Health facilities
  - Health center, hospital
  - MCH clinics for childhood diseases
- Campaigns for Immunization and other illnesses
- CSA (Central Statistical Authority)

Advantage and Disadvantage

- Collection is inexpensive
- May not always be complete and precise

Observation: The following are the most important aspects of observation.

- Involves systematically selecting, watching, and recording behavior and characteristics.
- Give additional, more accurate information on behavior than interviews or questionnaires.
- Checklists or a list of question are usually used not to miss important issues.

Interviewing:

- Involves oral questioning of respondents, either individually or as a group.
- Answers are recorded by writing or tape recording the responses.
- When with high degree of flexibility:
  - Open-ended questions are used when the researcher has little understanding about the problem
- When with low degree of flexibility:
  - Closed-ended questions are used in a situation where the researcher is knowledgeable about the problem(s) in question and large numbers of study subjects are involved.

Interview can be conducted in two ways – face to face and telephone interview.

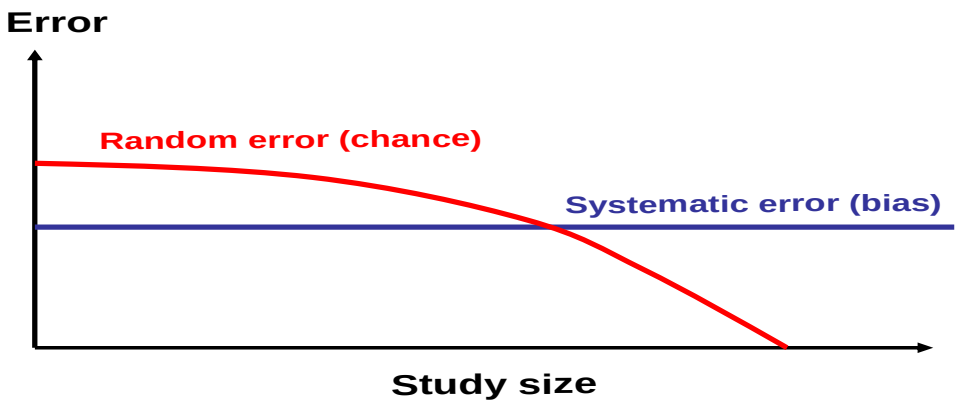
Administering Written Questionnaires:

- Written questions are presented to be answered by the respondents in written form. Also known as self-administered questionnaire.
- A written questionnaire can be administered in many ways, for example: - Sending questionnaires by mail with clear instructions, etc,
- Gathering all or part of the respondents in one place at one time, giving oral or written instructions, and let the respondents fill out the questionnaires; or
- Hand-delivering questionnaires to respondents and collecting them later.
- Focus Group Discussion (FGD) – the details are addressed under research methods.

Bias in data collection and its possible causes:

- BIAS is a distortion in an epidemiological study that results in incorrect information not representing the true situation.
- It is a systematic error that threatens the validity of epidemiologic information.

The figure below shows that small sample is likely to lead to random errors. This error can be minimized by increasing size of the sample. A systematic error would remain the same. A good example of systematic error is a scale that consistently adds 5 kilo gm to the true weight.



Source: Rothman, 2002

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The major types of bias are:

- Selection bias
- Information bias
- Confounding

Possible Sources of biases are:

1. *Selection bias were further explained as follows:*
   - High non-response (refusal) rate
   - Self-selection (volunteerism)
   - Loss to follow-up
   - Convenience sampling

2. *Defective instruments*
   - Poorly designed questionnaires

It was noted that it can be avoided by careful planning of the data collection process and pre-testing the data collection tools

3. *Information bias*
   - It arises from errors on how study information was collected
     - Poor recording, data extraction
     - Incomplete data
     - Recall (or memory) bias
     - Reporting bias
     - Interviewer (observer) bias

Effect of the interviewer on the informant
- Informant may mistrust the interviewer
- Misleading answers

MINIMIZING BIAS AND ENHANCING RELIABILITY

1. Combination of different data collection techniques:
- Can improve the quality of data
- Minimize the chance of bias
  - Example: the use of health facility records and household survey or FGDs

2. Data collection can be made more reliable by:

- Training the data collectors
- Using multiple sources of information (complementing)
- Questionnaire designed carefully by experts
- Direct measurements
- Observation
- Pre-testing
- Ensuring high participation rates
- Supervision

VARIABLE

- *A VARIABLE* is a characteristic of a person, object or phenomenon in which observation or measurement is made about or on. The examples of these include: weight, height, age, income, etc., all are variables;
- The variable assume to take any value;

- Categorical or qualitative and quantitative variables are: statistically summarized in different ways.

Types of variables

1. Qualitative (categorical)
2. Quantitative (numerical variables).

- **Qualitative variable**: It is a variable or characteristic which cannot be measured in quantitative form but can only be sorted by name or categories. Here, the notion of magnitude is absent or implicit. E.g. attitudes, knowledge, etc

- **Quantitative variable**: It is a variable that can be measured and expressed numerically. This variable has the notion of magnitude. E.g. height in meters, weight in kilograms, etc

Quantitative variable is divided into two:

- **Discrete variable**: It can only have a finite number of values in any given interval. It is characterized by gaps or interruptions in the values.

- **Continuous variable**: It can have an infinite number of possible values in any given interval. It does not possess the gaps or interruptions

Variables can also be classified based on the cause-effect relationships. These are:

- Dependent
- Independent

Dependent variables

- Known as outcome variables
- Are those which depend on the status or position of the other variables;
- Are the variables that a researcher is interested in understanding, explaining, or predicting;
- The presumed effect is the **dependent** variable.
  E.g. weight loss following TB infection

Independent variables

- Describe or measure the factors that are assumed to cause or at least influence the problem.

- Examples:
  - Does a drug cause improvement of a medical problem?
  - Does smoking cause lung cancer?
- The presumed cause is the **independent** variable
- Also known by various names: they are; exposure variable, explanatory variable, predictors, etc.

It was also noted that variability in the dependent variable may also depend on variability of the independent variable.

RESEARCH METHODS

There are two research methods –namely, qualitative and quantitative. The distinctions of the methods are shown as follows.

Qualitative Method	**Quantitative Methods**
Inductive	Deductive
Positivistic	Naturalistic
Non probability sampling	Probability sampling
Why?	How many?
How?	How much?
Non-numeric	How often?
Understanding behavior/insight	Quantification/Statistical analysis
Not generalizable	Generalizable
Small sample	Large sample
Non statistical analysis	Statistical analysis

Qualitative Research (QR) – QR is appropriate for understanding the experiences and behavior of individuals.

The four main categories of QR are:

1. Experience or behavior questions
   - How do adolescents experience the use of condom?

2. Opinion or value questions
   - What do you think about a child under 5 Years acquiring HIV/AIDS?

3. Feeling questions
   - How did you feel when you joined the field of medicine?

4. Knowledge questions
   - What are the different types of family planning methods?

Qualitative Methods: There are four major types

- Focus Group Discussions (FGDs)
- In-depth Interviews
- Key Informant Interviews
- Behavior Observations

1. Focus Group Discussion

This is a qualitative data collection technique in research where a group discussion on specific topic takes place with a specific group. In focus group discussions (FGD), individuals assembled by a researcher to give their opinion in, discussions from experience FGD take place and group interactions between the groups are observed.

Purpose of FGD:

- Assess respondents' attitudes, feelings, beliefs, experiences and reactions
- Used at the preliminary or exploratory stages of the study
- Used either as a method in their own or as a complement to other methods

The role of FGD moderator

- Ensures the discussion runs smoothly
- Ensures the discussion remains focused

- Stimulate the discussion and maintains group dynamics
- Ensures respect to individual ideas & personality is kept during group discussions

Advantage of FGD

- Inexpensive
- Gives results quickly
- Probing is possible
- Useful when quantitative data are not adequately available
- Generate hypothesis
- Useful for brainstorming and interaction
- Stimulating new ideas and concepts
- Could be conducted either at the beginning (explore) or at the end (explanation) of a large study

Composition of FGD

- Desirably 8-12 individuals
- Homogeneous nature
- Group composition influence group interaction
- Moderator/recorder
- The time should be one to two hours.

Discussion Guide

- FGD guides: unstructured or semi-structured
- Questions: General open-ended
- Discussion needs guiding and focusing
- The interview guide is modifiable (not fixed)
  The flow is from general to specific

Limitation of FGD

- Data not quantitative
- May not be representative
- Not appropriate for discussing private or sensitive issues
- Data analysis difficult

2. *In-depth interview*

- Should be done on one-to-one basis
- Detailed information obtained from individuals
- Reliable for highly personal, sensitive or confidential topics.

- Interviewee can be either "key informants" or "any other person".
- Valuable for searching busy people's opinion.
- It requires probing deeper into individual attitudes
- It lasts for 30-90 minutes
- Minimum sample size could be 10-30 individuals

3. *Key informants interviews*

- Key informant – actor in a social group (community leaders, etc)
- Links the researcher to the community
- Provides detailed data on specific areas

4. *Behavioral Observation*

- Direct observation
- Indirect observation
- Can be combined with other qualitative methods

Data Analysis: It was noted that data analysis can be done in the following ways.

- Descriptive: Analysis that is concerned with describing the data collected on the study subjects in terms of person, place and time.
- Transcript and tape records: It is a process of transforming the data collected in written form from audio record or on tape recorder.
- Summarization and interpretation: This is the part that deals with putting the whole study in short form and presenting what it means.

Example: *"In FGDs, women agreed that fever was a major health problem in the area. A variety of causes were identified, including the consumption of inappropriate food and working or sitting in the sun. A few agreed that mosquitoes caused fever... etc".*
The data can be analyzed as the study is conducted.

Verbatim transcription:

It is the process of transcribing or writing down what study subjects verbally tell to the researcher in words into written form exactly as told for processing and documentation purpose.

Example:

- "Compared with private laboratories, the price I paid here for X-ray, hematology and sputum analysis is very cheap." (35 year-old female patient expressed from Addis Ababa).
- No statistical analysis
- Not generalized

With these presentations the morning session was concluded.

The afternoon session of the day was assigned to the group work on data collection. The trainees were divided into their groups to develop methods of data collection for their respective proposals based on the lectures delivered.

Like with the previous sessions, the trainees were encouraged to ask questions, give comments and/or suggestion at the end of each topic presentation or whenever they feel like to do throughout the sessions. There were good interactions from the trainees' side too.

FOURTH DAY SESSION

DATA PROCESSING, ANALYSIS AND INTERPRETATION

The fourth day of the session started with the subtopic of data processing, analysis and interpretation which are parts of module three training manual. In this relation, it was mentioned that basic knowledge of biostatistics is essential to understand this part of the training. The part of the training introduced Epi-info, a package meant for this purpose.

The subject was adequately covered with the support of the power point presentation and using laptop computers which were brought by the trainees in most cases and few were provided by the training facilitators. Accordingly, data processing was defined as entering of data into computer, checking for errors, making corrections and cleaning data to be imported to a statistical package for further analysis and interpretation. It also was useful for transferring a row data from questionnaire to computer program or file. In such process, coding – giving numbers, (e.g. 1=male, 2=females) takes place.

Data entry is usually done by data entry clerk for speed. However, these clerks may be less careful due to lack of understanding about the study. Code book is another item that the researcher should know in this relation. Code book is a book or sheet of paper where the codes against the different variables are recorded.

Data cleaning: Entered data should be checked for errors, impossible or implausible values and inconsistencies as in most cases' errors are inevitable. Errors can result from incorrect reading, incorrect reporting, incorrect filling, incorrect coding, incorrect typing, etc.

It has also additional features of shaping data entry, error checking, coding, selecting records, creating new variables, recoding data, importing and exporting files from other systems**.**

Following the introduction on data processing, the training continued with brief introduction about Epi Info, loading of the soft ware on trainees' lap tops and started application of the program with examples given in module three.

Epi Info 2002 is a series of programs for use by public health professionals in conducting outbreak investigations, managing databases for public health surveillance and epidemiological data processing. "Epi Info" is a product and trademark of the Centers for Disease Control and Prevention (CDC). Epi Info 2002

software is in the public domain and freely available in the internet for use by copying, translating and distributing to all interested users.
Epi Info is usually used with a personal computer by physicians, epidemiologists, and other public health and medical workers. It is easy to develop questionnaire or form, customize the data entry process, enter and analyze them.

Running Epi Info was demonstrated to the trainees. The different steps to be followed during utilization of the program were explained with the support of examples applying computers being used by each trainee. Following the demonstration, trainees proceeded straight to the application of the program. Accordingly, trainees used Epi Info program loaded on their lap tops for entering, viewing and analyzing data. Trainees had exercised application of the soft ware in the class with the support of the trainer. The different functions of the program have been made clear both in terms of concepts and practical applications.

One of the main advantages of Epi Info is its flexibility for skipping data entry. It is important to have the possibility to use skipping. One has to make sure that all the works done have been saved at the end. Reminder was also given that some information about the program is also available on the module for further reference.

Types of data for processing and interpretation

- ***Qualitative (or categorical)***
  - Measures by assigning names or labels
    - Sex: Male and Female
    - Blood group: A, B, AB and O
- ***Quantitative (or numerical).***
  - Discrete
    - number of patients, number of students
  - Continuous
    - Age, weight, height of person or things

Descriptive Statistics
It is the statistics that deals with distribution of the different variables and the patterns of this distribution.

- Distribution or probability distribution refers to the way data are distributed, in order to draw conclusions about a set of data.
- Continuous variables = the aim is to determine whether or not normality may be assumed

- Categorical variables = the frequency distribution for each variable is obtained

***Distribution of Categorical Variables*:** It tells the probability that the variable will take place in certain situation.

Example: A total of 25 patients entering Intensive Care Unit (ICU) at a given hospital:

1. Medical
2. Surgical
3. Cardiac
4. Other

The distribution of ICU patients in different cases in the hospital

ICU Type	**Frequency (How often)**	**Relative Frequency (Proportionately often)**
Medical	12	0.48
Surgical	6	0.24
Cardiac	5	0.20
Other	2	0.08
Total	**25**	**1.00**

Note: The total of the probability is 1.

Application of the concept of probability

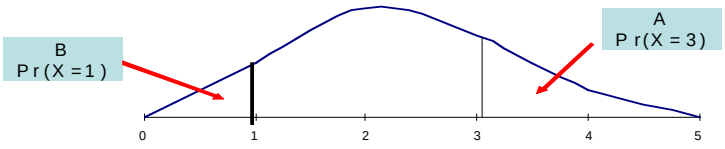
- The same principle can be applied to epidemiological studies such as estimating disease or the characteristics of interest.
- This involves the calculation of the probability of an event
- The prevalence of certain diseases – (malaria, TB, HIV/AIDS, diabetes, smoking, etc) or characteristics in the community can be estimated.

Distribution and characteristics of Continuous Variables

- The examples of continuous variables are: age, height, weight, etc
- Continuous variable is infinite
- The probability associated with any particular value is almost equal to Zero
- However, it will assume some value in the interval enclosed by two ranges: x1 and x2

- The probability distribution is visualized as a curve and probabilities are areas under the curve. Schematic explanation is shown in the following drawing

The total area under a probability distribution is always 1. The section marked "A" represents the probability of observing a value of 3 or greater, symbolically written as Pr(X = 3). If the area of "A" is say 0.2 units, then Pr(X = 3) = 0.2



Since the total probability area is 1, the probability of observing a value between 1 and 3 Pr ($1 \leq X \leq 3$) = 1- the two shaded areas = 1- [$Pr(X \leq 1) + Pr(X \geq 3)$]. Again refer to the above drawing.

During the whole session of the day, the trainees were encouraged to ask questions give comments and/or suggestion at the end of each topic presentation or whenever they feel like to do throughout the sessions like the previous days. The interaction from the trainees' side was impressive. The trainees were also reminded that there is adequate information in the modules provided.

FIFTH DAY SESSION

SAMPLE SIZE CALCULATION USING EPI-INFO

The fifth day of the session started with calculation of sample using Epi Info. The trainees were given hypothetical study problem in order to calculate the required sample with the help of Epi Info. Following the instruction and getting the support from the trainer, the trainees had managed to calculate the sample. It was also noted that there is no need to show the formula for sample size calculation as the computer program will handle everything. However, the margin of error, the confidence level, etc. should be mentioned.

The whole day was devoted to the exercise on Epi Info and preparation for group works' presentation for the next day.

SIXTH DAY SESSION

GROUP PRESENTATION

The sixth day started with the third round of group presentation from each group. This time, the presenters were those members who did not get the chance to present in the previous time. The main issue of the presentation this time was related to further development of the proposal that started earlier. The sample size determined has been included this time. The presentations were made in the following order.

Amhara Region.

In the presentation made this time, refinements were done on previously presented study protocol. However, the part which deals with sampling was a subject of hot discussion. Accordingly, the following, questions were asked and comments were

also made. The detail of the presentation is also available in a separate package.

Group Presentation from Amhara Region by Group's Presenter

Questions: The group was asked whether it has considered the feasibility of using the suggested sample size. The group was also asked whether they considered the data on drinking water from DHS (Demographic Health Survey) 2005. The main outcome variable was also asked.

Comments: As follow up to the questions asked, it was suggested that the group should revisit and look into the feasibility of using such a big sample size and also get the data from DHS 2005 as far as proportion of drinking water is concerned. The rest of the presentation was considered fairly impressive and had manifested that there is good progress over the last days. In a related discussion, it was noted that lesser sample size compared to the one suggested would improve quality of the study. It was also suggested that standard definition of what safe water and proper latrine utilization should be, for the purpose of this particular study.

Somali Region

The presenter from the group started his presentation by indicating the modifications made on the topic of the study proposal. He mentioned that the group discussed and decided to conduct the study only in one wereda rather than taking the entire region. To that effect, the group selected Erer wereda as study area. The detail of the presentation is available in a separate package.

Presentation from Somali Region by Group's Presenter

Question: The group was asked for justification why it has selected Erer. How is it possible to control the mobility of the people in pastoralist area like Somali Region? Why do you deviate from WHO standard cluster size of 30 to 7? In addition, what is going to be studied was not clearly explained.

In response to the questions the presenter responded that the wereda is selected with purposive sampling due to its accessibility and having relatively low measles immunization coverage (26%). The cluster size was reduced due to the highly scattered nature of Somali Region. He added that it is difficult to get all the people. As the modified study area i.e. Erer is not very much mobile. So, controlling the study will not be a problem.

Comments: The assessment of the health service in the wereda is not necessary as the objective of the study is basically EPI. It was advised to have been better to stick to the purpose of the study. It was commented that the age range of the children should be modified as 12- 23 months; the size of the sample should be revised as it is found to be a bit high and that the study should be clearly explained.

Gambella Region

This time, the presentation was made by a participant of the group who didn't present previously. Most of the materials presented were more or less similar to the previous one. There were some corrections and refinement. This time the sample size was determined using the new techniques learnt in the process. Detail of the proposal is available in a separate package.

Group Presentation from Gambella Region by Group's Presenter

Questions: Why do you use the international data as reference for the study that only concerns a small wereda in Gambella Region? Why not the general objective focuses on the study topic alone?

In response to the questions, the group had said that lack of reference from local source forced them to take the data from the international source.

Comments: There was a mix of literature review and statement of problems. These should be straightened and corrected. In a related discussion, it was mentioned that even the literature review should also be shortened and a more focus should be made on the topic to be dealt with. Specific objectives should also be sharpened focusing on the topic under the study. It was also noted that a part that deals with antenatal care should be included as one specific objective.

Tigray Region

In the outset of his presentation, the presenter stated that the topic was slightly modified. The modification was made on specification of the study area to one wereda. Sample size and the technique of sampling were included this time. The rest of the presentation was more or less similar to the previous one. The complete version of the presentation is available in a separate package.

Group Presentation from Tigray Region by Group's Presenter

Questions: How do you find the participants who are willing for the study? Why did you split the KAPs specific objectives into three different objectives?

Comments: The trainer started his comments that there is no scientific explanation for study village number limit. However, the issue of heterogeneity or homogeneity can be cited as the reason for deciding the size of the village or zone. Most of the time half is considered as preferred number. When one woreda is selected, it is considered as purposive selection with regard to logistics and resources. The specific objectives should be combined as KAPs. The association aspect seen during the process of the study should not be overlooked.

Comments by other facilitator were also made on the title being too long and needs to be shortened. The wording for specific objectives should be polished. The words like measure, describe, analyze can be used instead of repeatedly mentioning the word assess.

SNNP Region

The topic of the presentation was not changed. Presentation was made by the other member of the group who didn't present previously. The presentation made this time included the sample size and the technique used to determine the sample size. The complete version of the presentation is available in a separate package for the region.

Questions: No question was raised.

Comments: One of the facilitators pointed out that the study at zone level should be revised as attempting generalization could be difficult.

Group Presentation from the region by Group Presenter

Oromia Region

The topic of the presentation was not changed. But, the presenter was different from the previous presenter. The presentation made this time included the sample size and the technique used to determine the sample size. The complete version of the presentation is available in a separate package for the region.

Group Presentation by Group Presenter.

Questions: In what way are you going to see the outcome of the study at the end? How are you going to associate the role of the health extension workers with the outcome of the study?

In response to the outcome, the group said that the outcome cannot be seen directly. Its effect is felt on the result of the program at the end of the day.

Comments: Dr Wakgari, the trainer, noted that the use of the language in data collection is very important. It has to be converted to the local language, i.e. Afan Oromo. Data collectors should also be well versed in English language apart from the local language. This language issue should also get a proper focus on during the training for data collectors. He has also given the following general comment which applies to all groups. "Formulation of the objective, methodology and the sample size needs to be highly improved as they are cardinal points in study undertaking." The trainer also gave a general remark which stress on the difficulty of attempting to generalization. The group should revise this part. He said this comment also applies to the group from SNNP Region.

Following the conclusion of the presentations from the group, the training continued with another subject in module 3 during the remaining part of the day.

STATISTICAL INFERENCE

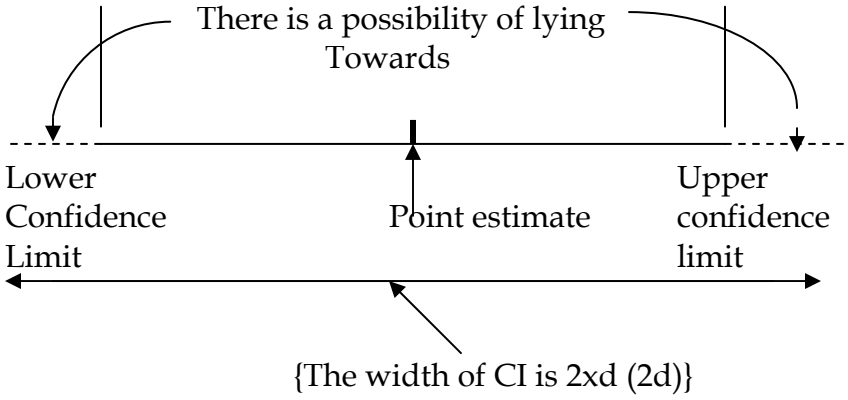
Statistical inference was defined as a process of making conclusion/inference about the population taking information from the sample. The statistical inference includes:
1. Parameter estimation. 2. Hypothesis testing using population values. Often the population parameter of interest is either mean or proportion.

It was noted that sample statistics are used to estimate the corresponding population proportion. Especially confidence interval is calculated by this system. Application of sample study estimation technique gives an answer about a population based on the sample data obtained from that particular population.

Parameter estimations and confidence intervals (CI) were explained as follows:

- Population parameter: shows the underlying (unknown) distribution of variables of interest for a population
- Sample parameter: estimates the population parameters obtained from a sample
- One needs CI level for estimating the true value of the population parameter
- CI tells how precise our estimate is likely to be
- CI expresses upper and lower bounds for anticipated true population parameter.
- A narrow CI implies high precision, while a wide CI implies low precision.
- 95% CI commonly used.
    - Sometimes 90% and 99% are also used depending upon the precision required for the outcome of the study.
- The 95% CI is calculated in such a way that, under the conditions assumed for underlying distribution, the interval will contain true population parameter in 95% of the time.
- Loosely speaking, you might interpret a 95% CI as one which makes you 95% confident that the interval contains the true parameter in average.

Point estimate: It is a single mean value in the sample. E.g. mean age of 35 years. *Interval estimate*: It was also noted that it has ranges expressed as lower and upper and provides more information about the population. E.g. mean age of 35-45 years can give more information. The calculation is done based on the point value.



The confidence level: Sample size can affect the CI. Sampling error decreases as the sample size increases. Standard normal distribution curve = 95% CI = 1.96.

CI for a population Mean:

a) **Known variance** (large sample size)

- A 100(1-α) %. C.I. for μ is:

$$\bar{x} \pm Z_{\frac{\alpha}{2}} \frac{\sigma}{\sqrt{n}} \quad \Rightarrow \quad \left(\bar{x} - Z_{\frac{\alpha}{2}} \frac{\sigma}{\sqrt{n}}, \bar{x} + Z_{\frac{\alpha}{2}} \frac{\sigma}{\sqrt{n}} \right)$$

- Where α is to be chosen by the researcher, most common values of α are 0.05, 0.01, 0.001 and 0.1, depending upon the presumed outcome of the trail but 0.05 is taken so commonly.

b) Unknown variance (small sample size n ≤ 30)

- A 100(1-α)% C.I. for μ is

$$\bar{x} \pm t_{\frac{\alpha}{2},n-1} \frac{S}{\sqrt{n}} \qquad \left(\bar{x} - t_{\frac{\alpha}{2},n-1} \frac{S}{\sqrt{n}}, \bar{x} + t_{\frac{\alpha}{2},n-1} \frac{\vec{S}}{\sqrt{n}} \right)$$

The t-distribution density curve is bell shaped and symmetrical about zero. Different curves for different df (i.e. sample sizes) and for very large df. very close to Z (Zero). CI also tells about the existence of association between the exposure and diseases or outcome of interest. CI = 0 (Zero) means that there is no association

> {df – degree of freedom: Was explained (as two values which can be any number, but the third one is fixed), the number that are free to vary after the sample mean has been calculated.}

The following formula can be used when the sample size is large.

CI for a population proportion

A 100(1-α)% C.I. for π is

$$P \pm Z_{\frac{\alpha}{2}} \sqrt{\frac{P(1-P)}{n}}$$

Example:

- A study on dental health practice: Of 300 adults interviewed, 123 said that they regularly had a dental check-up twice a year. What is the 95% C.I. for π?

P = 123/300 = 0.41 a point estimator of π.
$\alpha = 0.05 \Rightarrow Z_{0.025} = 1.96$

$$0.41 \pm 1.96 \sqrt{\frac{(0.41)(0.59)}{300}} \Rightarrow (0.36, 0.46).$$

HYPOTHESIS TESTING

- The majority of statistical analyses involve comparison, most obviously between treatments or procedures or between groups of subjects.
- Hypothesis: A statement about one or more population. It was also stated that it refers to the two population variable. Any analytical study needs testable hypothesis.

The study has noted that there are two types of hypothesis.

1. Null hypothesis – H_O –shows no difference. It is a statement claiming that there is no difference between the hypothesized value and the population value. **(The effect of interest is zero)**
2. Hypothesis – H_A – the alternative hypothesis, H_A, is a statement that disagrees with the null hypothesis. **(The effect of interest is not zero)**

Another way to state conclusion was also given:

- Reject the H_0 if *P-value* < α,
- Accept the H_0 if *P-value* ≥ α.

P- Value

- The *P value* is the probability that a difference has been observed simply by chance.

- P- value also indicates the probability that the association between two variables might be due to chance

Error of Testing the Hypothesis

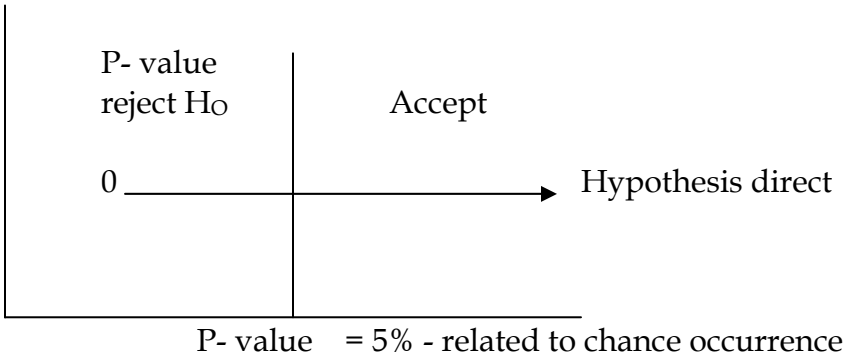
- The H_0 is either true or false.
- Then, it is either not rejected or accepted
- Type I error (α): the probability of rejecting H_0 when it is true.
- It is the probability of being wrong when H_0 is true.
    - Typical value for α (significance level is 5% when the CI taken by the researcher is 95%)
- Type II error (β): The probability of not rejecting H_0 when it is actually false.
- Failure to accept H_A when it is true
- Power: The probability of rejecting H_0 when it is false OR accepting H_A when it is true.
- Power = 1- β.
- Typical value for Power is 80%

Example

P = 0.40 = 40% Adult smokers in Addis Ababa.

Although most statistical figures are calculated by computers, the need to understand the principle behind was also emphasized.

The smaller the P-value the stronger the evidence is.



Observed difference is associated to chance, but not associated to exposure.

P-value = the observed difference

$\bar{X}_1 = 60\}$

$\bar{X}_2 = 55\}$ = the difference of 5 is due to chance.

Understanding P- value is very important although it can be produced by computer. However, it is up to the researcher to judge whether it is a reliable value or just jargon. P-value is important part to tell about the association or interpretation of a study.

Consider the hypothesis stated for mean birth weight Ho: $\mu = 3500$ grams for example. That is, when Ho holds as assumed the true underling birth weight distribution has a mean of 3500 grams. The mean birth weight in the sample was calculated as 3162 grams in the example given elsewhere. The probability of observing ones sample assuming Ho is true. This probability is called the p-value. Note that a large p-value implies that the probability of the value observed or the one or more extreme, occurring just by chance is low, when the null hypothesis is true. That is a small p-value suggests that there might be sufficient evidence to reject the null hypothesis. By convention, a p-value of 0.05 or smaller is considered sufficient evidence for rejecting the null hypothesis. Using p-value of 0.05 is considered as 5% chance of wrongly rejecting the null hypothesis when it is in fact true.

Note the following points when interpreting the p-value:

a) Regarding the 5% level: it is stressed that there is nothing magical about 5%. It is simply a convenient cutoff value adopted for 95% confidence internal. Therefore, values close to 0.05 (i.e. 0.04, 0.05) can be taken as moderate evidence against the null hypothesis. When the values are less than 0.01, it is regarded as considerable evidence against the null hypothesis. Hence, it is more practical to pay attention to the exact p- value than to $p < 0.05$.

b) Problems of multiplicity: When many independent tests are performed, the probability of one or more being statistically significant simply by chance increases to more than 5%. With two tests, the probability of one or the other or both being statistically significant by chance is 9.75%. With 20 and 50 tests, the probabilities are 64% and 92% respectively. In other words, it is very likely to observe one test being statistically significant, when in fact it is not.

c) Decisions based on p-value: The result of hypothesis test should not be equated with making a decision. P-values are a succinct way of reporting the result of statistical test. Decisions however depend on costs, risks, consequences and policy considerations. What hypothesis tests and p-values do is to give someone a valuable form of reporting because it can be standardized. The practical decision is a separate matter that uses p-value and other information, but not the p-value alone.

Student's test (for unpaired data)

- The ***Student's t-test*** or simply ***t-test*** is commonly used for comparison of the means of two groups.
- Null hypothesis is H_O: $\mu_1 = \mu_2$, where μ1 is the true mean of the first group and μ2 is the true mean of the second group.
- Assumption:
    - The data are independent & normally distributed. The term independent refers to the data value of each study subject arises independently. It is not influenced by the data values of the other subjects.

      Example
      - Comparing mean birth weight between the males and females
      - Comparing mean blood pressure between diabetic patients and non-diabetic patients.

The t-test (student's test) is easier and can be applied for larger sample. Eg. the mean birth weight of male and female babies born in a hospital can be tested using the t-test. The objective of the study is the guiding factor.

Student's t-test for (paired data):

Paired data can also be calculated.

- Study subjects from one population can be matched, or paired with particular subjects in the second population. Paired data arises from studies of twins and paired objects such as eyes or ears of the same individual.
  Example:
    - Comparing mean birth weight between twins
    - Comparison of the mean birth weights of newborns by time period and some demographic characteristics for newborns at Tikur Anbessa Hospital are shown in the table below.

Characteristics	*Mean*	*Test*	*P-value*
Period (years)			
1976-1979	3162		
1980-1989	3162		
1990-1996	3058	ANOVA	< 0.001
Sex of the baby			
Males	3168		
Females	3079	T-test	<0.001
Parity			

0	2982		
1	3120		
2 and above	3234	t-test	<0.001
ANC follow up			
Yes	3149		
No	3096	t-test	< 0.001
Gestational age			
28-37 weeks	2494		
3742	3166		
42 +	3183	t-test	< 0.001
Season			
Sept-Nov	3137		
Dec-Feb	3126		
Mar-May	3106	t-test	
Jun-Aug	3134	Not significant at 5%	0.116

Source: Enquselassie F, Menyilshewa A, Changes in birth weight of Ethiopian children in Addis Ababa. Eth. Journal of Health Dev. 2000: 14(2) 169-176.

There are differences of the means of babies with regard to some of the characteristics. For instance, the means of males and females are different, while their p-value remains the same and at the cutoff which indicates that the difference could have happened by chance as seen on the above table.

E.g.

- Comparing mean blood pressure of diabetic patients before and after some treatment
- Eyes or ears of the same individual

Notice that because members of a pair are inherently correlated, the t-test described above is not appropriate for analyzing such data.

Paired data can be analyzed by calculating the difference between each member of the pair, and testing to determine if the differences are significantly different from zero. In this case Ho: $\mu_d = 0$, where μ_d is the mean of the differences of the pairs. Student's t-test for paired data assumes that the differences are normally distributed.

ANOVA is also an extension of student's test. ANOVA is also suitable for deciding whether differences exist between the means of more than two groups. It is a generalization of the Student's t-test. It can be generated using Epi Info program. The Null Hypothesis is H_O: $\mu 1 = \mu 2 = \mu 3 = \mu 4 \ldots$, where μi is the true mean of the i^{th} group. ANOVA allows testing whether the mean of at least one of the groups differs

significantly from some other group. As with the t-test, ANOVA requires that the data be independent and normally distributed and the variances in the groups be approximately equal.

CORRELATION

Correlation was defined as a measure of the strength of relation for two continuous variables from a single population. The example of finding the relation between the outcome and the exposure was also mentioned. The examples given were on immunized children correlating with child mortality rate (CMR). It is necessary to display the data in scattered plot before carrying out any further analysis. One variable is plotted on the X-axis and the other on the Y-axis. The example should that increases in immunization lead to decrease in mortality. However, correlation does not show the cause and effects relationship. It models the relationship between a dependent variable (the variable to be predicted) and an independent variable (the predictor).

Simple Linear Regression: It measures the relationship between two continuous variables. It predicts the value of y variable from a linear relationship of x variable. It can also predict the outcome of one variable with independent variable.

This is modeled as:
Dependent ← Independent

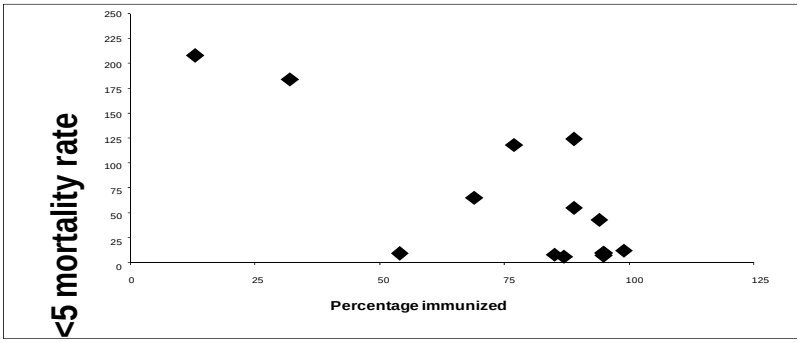
Dependent variable is expressed as y, where y:

Y = a+bx . Where:

- a is the intercept or constant;
- b is the gradient or slope;
- The parameters α (a) and β (b) are referred to as *regression coefficients*

The value of the slope tells us that a change in *x* (independent variable) of one unit will produce a change in *y* (dependent variable) of *b* units. When the slope is positive, the values of *y* will increase as *x* increases. When the slope is negative, the values of *y* will decrease as *x* increases. The relationship discussed above is shown in the graph below.

Percentage of children immunized against DPT and under-five mortality rate for 20 countries, 1992



The interest is also in whether *b* is significantly different from zero (Ho : *b*=0). If *b* is zero, it means that changes in *x* do not affect *y*. This is equivalent to saying that we cannot predict *y* from *x*, or that *x* does not explain *y*. This test of whether *b* is significantly different from zero uses the Student's t-test.

No change means Null hypothesis. y = under 5 child mortality in the example given previously.

Multiple Linear Regressions: There will be two or more independent variables meaning including more variables for prediction. E.g. Birth weight, maternal age, gestation, parity, etc

- Outcome is modeled as a function of variables x1, x2, …. xk by:
  $Y = \alpha + \beta 1x1 + \beta 2x2 + \ldots + \beta kxk$
  $y = a + b1x1 + b2x2 + \ldots + bnxn.$
- For two independent variables, the sample regression equation is:
  $y = a + b1x1 + b2x2$
  Birth weight = a + b1Maternal age + b2Sex + b3Gestational age + b4Parity

Correlation and Regression Using Epi Info 2002 was also demonstrated in the class.

Table 2. Birth weight in relation to some attributes, multiple regression analysis

Characteristics	Birth Weight		Low Birth Weight	
	β-coefficient	P-value	OR	95% CI
Maternal age	4.6	<0.05	0.99	0.97 – 1.01
Gestational age, for periods:				
1976-1979	92.0	<0.001	0.62	0.59 – 0.64
1980-1989	15.4	> 0.1	1.04	0.71 – 1.50
1990-1996	-81.4	<0.001	1.52	1.04 – 2.23
Sex of the baby				
Males				
Females	-88.9	<0.001	1.16	0.97 – 1.38

The birth weight of a baby is dependent on multiple factors. The attributes on the above mentioned table, like the maternal age, the gestational age, the period of birth would have influence on the birth weight of the babies. The variability in mothers' age, gestational age and the period of birth took place clearly explain the variability in the birth weight of the babies. Therefore, the explanatory functions of the variables have been observed.

STATISTICAL METHODS FOR CATEGORICAL VARIABLE

Statistical methods function with the involvement of collection, organization, analysis and interpretation of data. Categorical variable is the variable created in categories and expressed according to the issues. The issues of improvement of illness after treatment and no change seen on illness can be cited as example of two categories here. This is applied for non-continuous variables. The classified data is analyzed using the chi square being applied in the following manner.

Chi Square Test

Chi Square test shows only whether the association exists or not. It is also useful to know how strong the association is. Chi squared test is widely used in the analysis of contingency tables. It also allows testing for association between categorical variables.

The Hypothesis (Ho) for this test is "there is no association between the variables." Consequently a significant *p-value* implies association. The chi-squared test assumes that the numbers in each cell are not too small.

The problem with Chi Squared Test: It does not tell the magnitude and the direction of the study. But, it can tell whether the association exists or not. However, how strong the association is can be found out using relative risk and odds ratio as they are appropriate for this purpose.

Odds Ratio and Relative Risk: The *relative risk and the odds ratio* are appropriate measures of the strength of the association.

Odds Ratio (OR): It is the ratio of the presence of events to the absence of events. When the event for instance is exposure and non exposure to risk factor, the OR will be the ratio of exposure to non-exposure. When OR in this case is 1, there is no difference between exposure and non exposure. When OR is > 1 the risk of exposure has strong association with the proportion of the risk. When OR is < 1 the exposure has weak association with the proportion of the risk.

Relative Risk (RR): Relative risk is calculated using a 2x2 table.
Consider the 2 X 2 contingency table in which the outcome is the presence or absence of disease and the other variable is the presence or absence of a factor.

Relative Risk

2x2 Tables

Factors	**Disease**	
	Present	Absent
Present	P_1	$1-P_1$
Absent	P_2	$1-P_2$

P = Probability. $P + (1- P_1) = 1$

Note: The above 2x2 table was explained as follows.

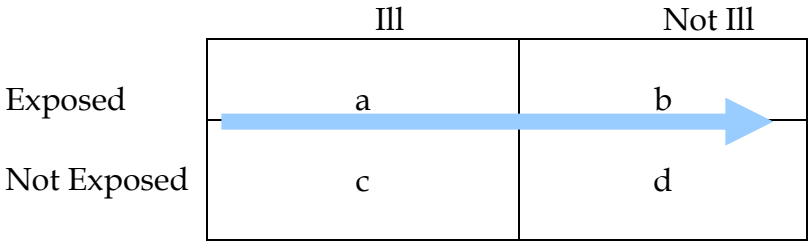
Suppose the probability of getting the disease when the factor is present *p1* and the probability of getting the disease when the factor is absent is *p2*. Thus, the probability of getting the disease when the factor is present is (1-*p2*) and the probability of not getting the disease when the factor is absent is (1-*p1*)

$$RR = P_1/P_2$$

***Relative risk* (RR)** is simply the risk of getting the disease when the factor is present relative to the risk of getting the disease when the factor is absent.

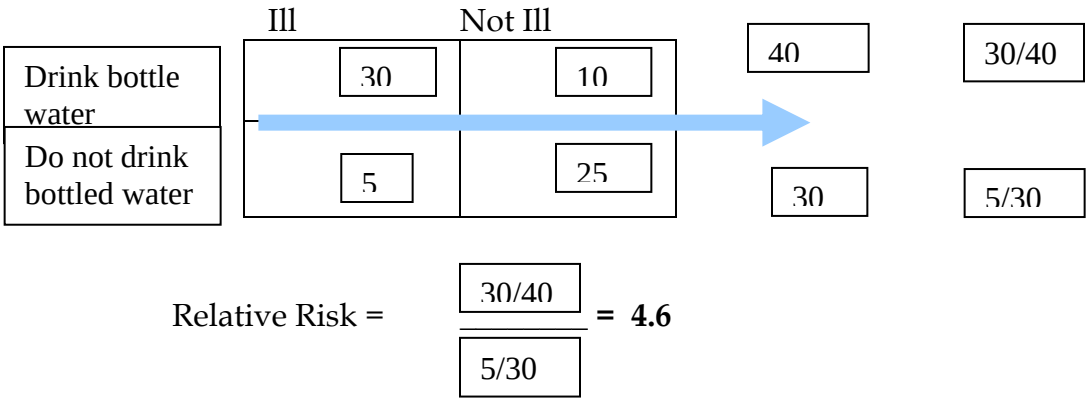
$$RR = \frac{\text{Probability of getting the disease when the factor is present}}{\text{Probability of getting the disease when the factor is absent}} = P1/P2$$

Cohort Experimental Design



Exposed = a/a+b Not exposed =b/c+d

Relative Risk = $\frac{a/a+b/}{b/\ c+d}$ $\frac{\text{Incidence exposed}}{\text{Incidence non-exposed}}$



Relative Risk = $\frac{30/40}{5/30}$ **= 4.6**

Interpretation of relative risk

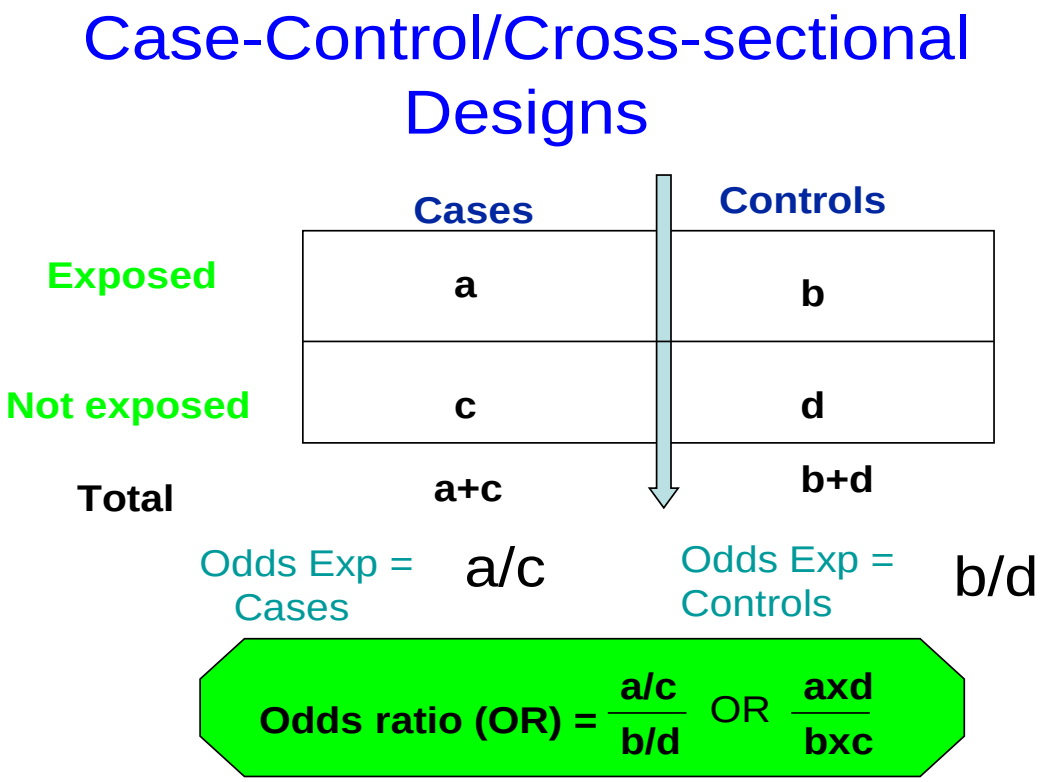
The risk of illness among those who drink bottled water is 4.6 times higher than among those who do not drink bottled water.

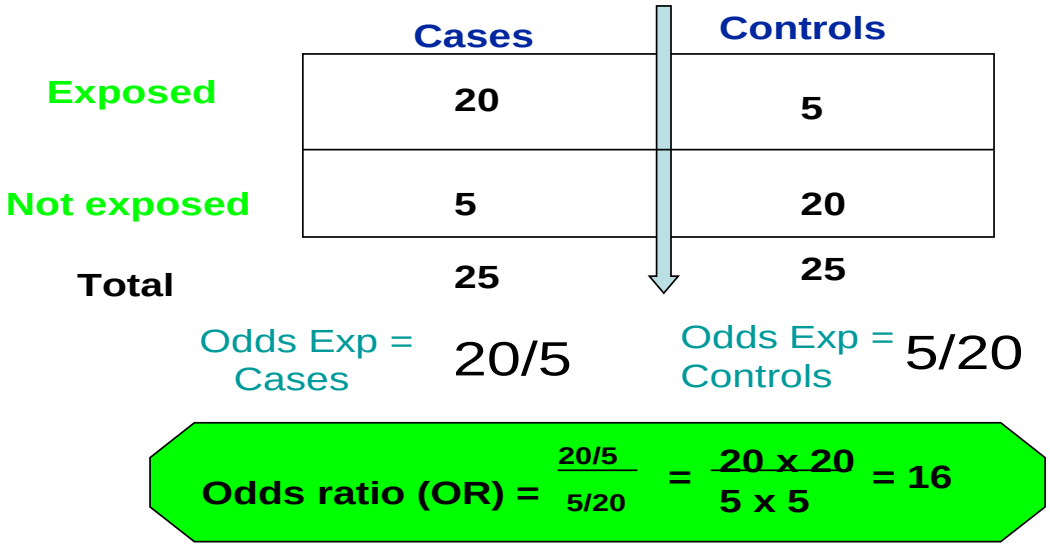
Odds Ratio (OR): Another commonly used measure of association is the odds ratio (OR). The odds in favor of an event happening (such as getting a disease), is the probability of the event happening relative to the probability of the event not happening. From the Table, the odds in favor of disease when factor is present, is

p2/1-*p2*. The odds in favor of disease when factor is absent, is *p1*/1-*p1*. It was noted that 2x2 table can be used to calculate Odds Ratio. OR is commonly used in many institutions. Addis Ababa School of Public Health is one of them.

$$OR = \frac{\text{odds in favor of disease when the factor is present}}{\text{Odds in favor of disease when the factor is absent}} = \frac{p2/1\text{-}p2}{p1/1\text{-}p1}$$

Example on 'OR' application





Interpretation of Odds Ratio (OR)

OR is defined as "the ratio of the odds of an event, occurring in one group to the odds an event occurring in another group". The ratio of the odds of exposure to the odds of the control group is shown as was depicted here above. OR in case-control studies is a good estimate of relative risk. The odds of exposure are 16 times higher among cases than controls. Therefore, the risk of getting the illness is 16 times higher among those exposed than those not exposed.

Logistic Regression:

It was underscored that in linear regression, the dependent variable is **continuous** and normally distributed. However, in logistic regression, the dependent variable is **categorical**; in particular, the dependent variable is **dichotomous**. Dichotomous refers to the presence of disease (yes) and absence of disease (no).

It was also clearly stated that in linear regression, estimates of the **regression coefficients** which tell us how the dependent variable changes relative to changes in the explanatory variable is obtained. However, in logistic regression, the estimates of regression coefficients are interpreted in terms of **odds ratios**.

Odds ratios calculated using probabilities are sometimes called ***crude odds ratios***, to distinguish from odds ratios estimated from logistic regression, which are called ***adjusted odds ratios***.

They are adjusted for the presence of other factors in the **regression equation** because the odds ratios are obtained simultaneously with all the factors together. **Adjusted ORs** are less affected by confounding between the factors. CIs and **p-values** can be derived for odds ratio estimated from logistic regression. The interpretation of these is the same as in the case of the crude odds ratios.

Trainees have been encouraged to ask questions, give comments and/or suggestion at the end of each topic presentation or whenever they feel like to do throughout the sessions as it has been done in the previous time. There were good interactions from the trainees' side too. It was also noted that it is worth referring to the specific module for more information.

SEVENTH DAY SESSION

RECAPS OF THE PREVIOUS MODULES

On the seventh day Dr Mulugetta Betre from Addis Ababa University, carried out the training. He started by summarizing, the topics covered in the previous days. Thus, by way of a revision attempts were made to see the process of the training walking on the pathway, on what research and what protocol or proposal are. Two major categories – experimental and observational study designs were also looked into. Furthermore, data, data processing and sampling were also covered. Regarding the modules, he said that the three modules that have been dealt with, so far, were the "hardware" portion of the training while the other modules to follow here forward may be identified as more of "software".

Following the explanation of the highlight of the areas to be covered, the trainer explained the terms in form of introduction of the new subjects by showing the link between the previous and the present lectures. The trainer also noted that there will be a substantial sharing of experience in the process of the training.

The trainer moved to the topics to be covered during the remaining days. He had mentioned that Ethics of the Module 4, Health Research Management of the Module 5 and Communication of the Module 6 were duly planned.

As the presentation proceeded, the trainer forwarded the following question to the trainees. "By taking some minutes, put forward your expectation from this training

putting yourselves in the place of researcher." It was made clear that expectations or concerns could be confidential or shared; it can be done on individual basis or in group.

The trainees seemed to make their expectations confidential as they did not share them to the plenary.

ETHICS

The training on the topic was started by asking question of what ethics is. The trainees gave different responses which actually reflected the same idea. Ethics is the study of code of human conduct. It is a philosophy which studies what is right and wrong. Some of the trainees also reflected it as the study of reasoning and it is about norms and laws.

After having listened to the responses from the trainees, the following explanation was given by the trainer. The study of conduct, rights and law have a lot to share in common. However, law is the basis for the study of ethics and rights. It was noted that a law is somewhat general and applies to every citizen while ethics applies to a certain category of people. For instance the religious codes of conduct which are considered as the supreme norms and values of conduct are observed by a certain category of people. Law is mandatory for every citizen while ethic may be practiced on voluntary basis. Law can be derived from ethics. But again law is also considered as a form of ethics. The explanation of different key terms and usage of terms in different context were also given as follows.

ETHICS: It is a branch of philosophy that deals with moral principles. Ethics can also be mode of implementation.

Moral: It is Just or Right or Appropriate Set of Norms. Moral is also the basis for code of conducts. It also is the inner most conscious perception used as a basis to develop code of conducts.

Principle: It is the general code or standard or guiding norms.

Right is the aspect that one has it as given. Rights are aspirations. The general conduct of biomedical studies is guided by internationally recognized human rights and resulting of ethical fulfillments.

Hippocratic Oath was also mentioned as code of conduct that the medical professionals commit themselves to follow and respect at the time they get into the

medical profession. The different institutions like EPHA, Ethiopian Medical Association EMA, and also other professional entities have their respective codes of conducts.

Eventually, the discussion had proceeded to specific area and had dealt with health research ethics following the explanation of the more general premises of ethics and law.

Aims of the Session on the Health Research Ethics were concisely highlighted as:

- Internalization of the concepts and rationale of bio-health (medical) ethics.
- Equip with the knowledge of the essential ethical principles.
- Enhancement of capacity on research proposal review for ethical merit.

***Health Research Ethics Concepts and Rationalization*:** The training has raised the following questions.

- What are the ETHICAL Issues of practical interest? Why?
- Real life (professional) encounters/experiences or incidents? Challenges?
- Lessons?

Health Research ETHICS (Code or Standard of Appropriate Set of Norms or Moral) was defined as:

- "Scientifically rationalized, substantiated and supported code of moral principles and practices with respect to design (formulation), implementation, and dissemination of any health research undertaking."
- It may be legally enforced or not.

Health Research Ethics Conceptualization and Law: The trainer explained the concept of health research ethics and law in the following manner.

- ETHICS: Morally accepted norm or standard of practice specific to a category of population. It primarily is about Humans and Animals!
- LAW: It is a local, national, international or universally bindings of legal system with rules and regulations. It could be about any aspects of life in any society.

- There is a two-way mutual interdependence between ethics and law.

It was noted that ethics is a moral obligation with regard to human and animals that a specific category of population is required to respect. However, law is everybody's not only concern but also obligation to be abided by. Respecting the given law is mandatory for everybody in a given society.

HEALTH RESEARCH ETHICS HISTORICAL PERSPECTIVES

Fundamental historical developments:

- Greek philosophy and practice: Greek philosophy formed the basis of all later philosophical speculations in the other part of the world. Ethics and other morality and even Christian or other religious ethics may have been developed from this philosophy.

- A historically closer example relates to the "Handling of Prisoners of War (POW)" – Nuremberg Code and War Crimes Trial: This refers to the disclosure of human experimentation in Nazi concentration camps during the World War II. The emanating thereof code's basic articulation are:
    - The need for voluntary consent of human subjects
    - The necessity for research proposal and meaningfulness
    - The need for prior animal experimentation
    - Avoidance of all unnecessary physical and mental sufferings and injures
- UN System and the "Codes of Rights": This was developed by the UN Commission for the protection of Human subjects of Biochemical and Behavioral Research in 1979. It is also known as Belmont Report. This report addressed the basic ethical principles – respect for persons, beneficence and justice that serve as foundation of ethics. The report also identified the three components of informed consent – information, comprehension and being voluntary. However, the report did not include family and community considering the important relationship of individual with family, in particular, and community, at large. Another historical example was the "Tuskegee experience": This refers to the experimenting of infecting the Black American in Alabama with syphilis without their knowledge for over 40 years. The infected were not given treatment throughout the study period. About 120 people died during the study time. This was a purely an unethical action.
- WHO Helsinki Declaration: This refers to the application of ethical principles to clinical research. The declaration includes:

- The need for review of experimental protocol by the independent committee
- Consideration of the participants in research being less than fully autonomous
- Assessment of risk/benefit ratio. The interest of the research participant must always prevail over the interest of science and the society.
- Description of information to research participants: It should be given prior to the consent. There should not be conflict of interest and pressure to give consent. The consent should be in written form
- Narrative sanction for investigators who violate the declaration should be included. The participant can reject the publication of the manuscript, if the researcher violates the basic principles of ethics

It was explained that ethics was derived from the philosophy of life that we have subscribed to. The practice of ethics was started with its application during World War II and continued to be used more and more as time passes. It has evolved to acceptable level since that time.

The relation between politics and ethics was also looked into. The political implication of the issue of Guantanamo Bay Prison was also seen in this connection. The prisoners were suspected as war criminals by the American Government and then put in Guantanamo Bay Prison without verdict for such a long time. This action was condemned by many people around the world. The act of imprisonment without verdict is considered as unethical action. The politics and ethics must have influenced or even complicated the due process of legal aspect and code of conducts.

The existence of controversies in the domain of health research was also discussed. The example of infant breast milk feeding from HIV mothers was looked into in this connection. The medical advice for HIV mothers state that the mothers can feed breast milk exclusively if she cannot afford formula milk. But the safest way is not to give breast milk to infants from HIV mothers. The ethical dilemma is pretty obvious.

Debates were held among the trainees in the class room on some issues which concerns ethics of the people involved in experimental studies. The debates were carried out on the basis of the exercise given in the module. The study conducted for example had revealed that one group of people was given Benzathine penicillin while the other group was given placebo. The control group developed rheumatic fever and acute nephritis. The question whether the study was ethical or not was raised for discussion. There was heated discussion on the issues. Thus, some said

the information given is not enough, some said the action is not ethical and others said it is ethical.

The concluding remarks given by the trainers had noted that the action taken was not ethical as the consent of the people involved was not asked. No information was given about the benefit and risks of the study. Those on control should have benefited from a standard of care.

Subsequently, by proceeding to the other sub topics, the basic principle of ethics was also seen.

Basic Principles

Components and Rationale:

Internalization of the need for:

- Respect of autonomy of health research participants: This is one of the ethical considerations that should be addressed as respect for persons. Respect of autonomy is giving attention to the opinion and choice of the individual, while refraining from obstructing his/her actions. E.g. Getting informed consent from participants prior to undertaking the study is compulsory.
- Protection of research participants with diminished or impaired autonomy: This is another ethical character that needs to be addressed as respect for persons. This refers to the people with decreased decision making capacity due to mental illness or being un-matured children. Parents or guardians should be consulted when children are involved in the study.
- Maximization of benefits and minimization of risks on research participants: These are the complementary of beneficence. The harm to research participants should be either minimized or avoided in the process of the study as harming them is violation of '*do no harm*' principle of medical ethics stated in Hippocratic Oath.
- Distributive justice: This refers to the distribution of burdens and benefits of participation in equitable manner. The widely accepted formulations include: i) an equal share to each person, ii) distribute according to the individual need, iii) according to individual effort, iv) according to the social contribution, and v) according to merit.

Cardinal Principles

These are very Basic Expectations towards the justification of ethical conduct/evaluation particularly in respect to clinical and health (or biomedical) research undertakings:

(1) ***Autonomy*** – respect to persons: The researcher should respect the choice of the participants. The participants should not be pressurized to decide to participate. Participation should be on voluntary basis. This would mean that the participants should be well informed and give consent.

(2) ***Beneficence*** – is doing good or protecting them from harm and making efforts to secure their well being. Study participants should not be harmed for the benefit of others. It has two components – benefits and risks. E.g. the issue of compensation was raised in this relation. This would mean that the participants should be compensated for the time taken during the study. It should also be clearly communicated to the participants. However, it has practical difficulties as it is delicate when money is involved. Sustainability is critical although it is justified. The question whether compensation distort the research product when people accepted the offer for compensation purpose was also raised. Compensation with money should focus on shoe shiners and beggars in order to minimize the distortion. Compensation should be considered after the context is carefully evaluated as precaution measure. Certain constraints may hinder to use compensation though it is in principle justified. It is necessary to be careful to prevent undue inducement.

(3) ***Justice*** – fairly distributing "goods" and "hazards" or "risks". There should be a fair balance of the goods and bad. The burden and benefits of participation should be distributed equitably as explained earlier.

(4) ***Non-maleficence*** – Doing no harm to the participants is one of the major requirements that the researchers should consider.

It was clearly explained by the trainer that ethical codes need to be clearly stated regarding investigators' (researchers) primary obligation which refers to the care of the human subjects in particular. Researchers should respect all the rights and benefits entitled for research participants. The researchers' accountability and duties were also stressed. Also, it was duly noted that researchers are going to be held responsible for any undesired acts on research participants in the process of the study.

1. Respect for Persons: TWO MAJOR Aspects are:

- Respect for autonomy.
- Protection of persons with diminished and impaired autonomy.

- Respect for Autonomy in turn would mean as:
  - *Voluntary participation*: Free, adequately informed and consented decision for participation or decline. It has to be free of any forms of force and, undue and unjustifiable influences.
  - *Confidentiality (and privacy)*: Protecting and safeguarding consented data or details, information, interest, etc. received from study participants is essential
- Protection of persons with diminished and impaired abilities:
  - Non matured or minors (children and adolescents);
  - Persons with disability (mental impairments);
  - Persons in confinement (e.g. prisoners).
- Special protection to avert undue subjection as well as having lawful guardians on behalf of children.

The question of patients rejecting the student's medical management in the medical school was taken up with regard to ethics. It was stated that there is a need to strike the balance between the importance of the training of the students and respecting the right of those patients that come to the teaching institutions with confidence on ethical issues. Making certain arrangements may clear the problems. It was noted that the patients should be taken as the final arbiters of the issues. Certain exceptions should also be accepted as long as the students are working under close supervision of the graduates.

The guardians of the miners (children) should be asked for consent when the issue involves clinical studies on such miners. The issues of mistreatments on the prisoners due to their lack of freedom were also mentioned as an example of violation of ethics of handling the prisoners.

2. Beneficence

- Ensuring maximal benefits and minimal risks.
- Appreciation of the longer term benefits against the short-term risks – contentious and delicate subject matter.
- Evaluation of the Benefits vis-a-vis Risks: by asking questions like;
  - Who/How/Why?
  - Form or type
  - Magnitude

- Duration

- Examples of special circumstances are research on vulnerable groups like non-dominant population, people with limited education, the poor, etc. The problem that is going to be studied is relevant to the health problems of the vulnerable groups
- Overall considerations for clearance – Making sure that there are:
    - No brutal or inhumane treatment of research participants.
    - Reduced risks to those who got enrolled in order to achieve research objectives.
    - Adequate description of benefits and risks on the informed consent form should be clearly written and given to the study participants to help them agree or disagree to the request of participation.

Reminder was also given to the trainees that this should also be considered during the development of their protocols.

3. Justice deals with:

- Treating each subject in accordance with what is morally proper and right.
- Ensuring equity: observance of equitable and fair distribution. Consider also individual vies- a- vis collective/community rights.
- Essential Set of "Criteria or Formula" will require observance on each prospective participant. The criteria include distribution of burden and benefits:
    - As an equal share
    - According to the need(s) of the individual
    - According to the effort of the individual
    - According to societal contribution
    - According to merit
- Ensuring local participation and community involvement
- Fair and sound selection of research trainees
- Justified use of placebo and randomization
- Provision of standard care for research trainees
- Compensation of research participants– See the details below under the sub topic of compensation.
- Clear dissemination procedure - clear memorandum of understanding and terms of reference in respect to: (a) authorship for publications; (b) Intellectual property right
- Specifications on post trial responsibilities
- Permission for sample handling, transport, storage, and use

Essential procedures:

(1) Passage through an Independent Ethical Review, Approval and Clearance system.
(2) Putting in place Progressive Monitoring about the Ethical Conduct.

The ethical dilemma in providing incentives in connection to justice was also seen. It was agreed that there should be fair and sound applications.

Compensation

In principle, time taken by the researcher should be compensated not only for the researcher but also for the research participant. It should be clearly communicated. The practical difficulty should also be considered. The delicacy of the aspect in terms of money and sustainability was also disclosed. However, it is justifiable. The question of distortion occurring due to compensation was also surfaced. However, care should be made to compensate the needy sectors like shoe shiners, beggars, etc. and, in general, for people with low economic income. Compensation should be considered after the context is carefully evaluated. The hindrance of constraints was also noted.

The development of protocol for research undertaking needs to be systematically reviewed at different stages. It is usually done at the beginning, in the middle and at the end. There should be a guideline prepared for this purpose. Certified researchers, those who are permitted to undertake research, should know these procedures.

The monitoring aspect as part of the ethical process in ethical clearance was also mentioned. The trainees mentioned that the ethical committee prevents the researchers from conducting the research as per the schedule set.

Health Research Ethical Guidelines

Health research is guided by internationally recognized ethical guidelines. The quality of the international standards for clinical research is evaluated against the specific goal, which such standards are expected to achieve. The following prominent international codes and ethical guidelines are the main sources of guidance for conducting clinical researches.

Review of Prominently International Codes of Ethics:

- **Nuremburg Code**: This code was promulgated by the allied nations in 1947 following the Second World War and disclosure of human experimentation in Nazi camps. It is used as reference for evaluation of other ethical guidelines.
- **Declaration of Helsinki**: This declaration was adopted in 1964 and modified in 1975, 1983, 1989, 1996 and 2000 by World Medical Association. It was required to develop more specific guidelines concerning the application of the ethical principles of the clinical research.
- **Belmont Report**: This report was issued by United States National Commission for Human Subjects of Biochemical and Behavioral Research in 1979. The report addressed the three ethical principles – respect for persons, beneficence and justice that serves as foundation for research ethics.
- **The International Ethical Guidelines for Biomedical Research involving Human Subjects**: This guideline was promulgated by the Council for International Organizations for Medical Science (CIOMS) with the collaboration of WHO in 1982. It was to broaden the applicability of standards observed in Nuremberg Code and Helsinki Declaration with the revision made in 1983. The guideline also had the task of amending the Helsinki Declaration so that it could be applied for special circumstances of developing countries.
- **Operational Guidelines for Ethics Committees that Review Biomedical Research and National Guidelines**: This is a guideline for national review committee of a given nation formed to accommodate the particularities and fit in the national needs. The guideline is developed on the basis and experience of international guidelines mentioned above. Ethiopia has formed a national health research review guidelines.

Nuremberg Code

Historical precedence: The cause for promulgation of the code.

- World War II – Nazi experimentation
- Promulgation 1947 by the then Allied Nations

Principles

- The need for voluntary consent of human subjects
- The necessity for the research proposal to be essential and meaningful
- The need for prior animal experimentation
- Avoidance of all forms of inhumane physical and mental suffering

Helsinki Declaration

Evolution: The progresses seen following the Declaration of Helsinki

- World Medical Association endorsed in 1964 with 1975, 1983, 1989, 1996, and 2000 revisions
- More emphasis, specifications and weight on clinical ethical fulfillment requirements
- US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which later, supplemented by the FDA (Food and Drug Administration) regulation and US National Bioethics Advisory Commission.
- Formation of the Council for International Organizations of Medical Sciences (CIOMS) to promulgate the International Ethical Guidelines for Biomedical Research in collaboration with WHO in 1982 with a revision later in 1993.
- Unique emphasis on the amendments and application aspects of the Declaration of Helsinki in light of the special circumstances of many developing countries.

Principles

- Independent review of experimental research protocols;
- Participation/consideration for the less than fully autonomous subjects;
- Assessment of the benefit/risk balance by participant, science and the society;
- Detailed description of critical information a priori consent fulfillment by the research participant; importance of written consent format;
- Disclosure of conflicts of interest; avoidance of coercion;
- Consents of minors and others;
- Inclusion of a narrative sanction for those investigators who violate the declaration.
- Respect for persons, beneficence, and justice.
- Informed consent: information, comprehension, and voluntariness inclusive
- Address the problem of research in developing countries sponsored by external agencies.
- Recognize the primacy of local concerns when evaluating the objective of the research protocol.
- Specific recommendations with respect to medical care for research participants and compensation in case of injury.
- Specifically addresses items such as information to be given, opportunity to ask questions, issues of deception, undue influence, intimidation, documentation and continuing consent.

- Proxy consent in recognition of the possibility not obtaining free and fair informed consent always.
- Independent review in addition to the informed consent.
- Recognition of cultural and legal variability by settings and thereof certain limitations of international guidelines.

International Guidelines for Biomedical Research Ethics Committee: The highlights of its involvement are shown as follows

Specifications / detailed description:

- The role of ethics review committees:
  - Establishment of an ethical review system
  - Prepare constitution of an ethical committee
- Application and submission for ethics review
- Review process
- Decision-making and communicating
- Follow up
- Documentation
- Serves as reference for respective National and International Guideline

The National Health Research Ethics Review Guideline of Ethiopia

The trainer had given the following highlight of the national health research review guideline. The health research review committee was established following the formation of the National Health Science and Technology Commission, presently converted to Ministry of Science and Technology. The review committees were established at three levels, i.e. national, regional and institutional levels. The roles of ethical review committee include ensuring and safeguarding the dignity, safety and wellbeing of the research participants. Trainees were advised to refer to the module for the details.

INFORMED CONSENT /DECISION

The trainer asked the trainees about their expectation(s) and/or concerns regarding informed consent. Accordingly the following concerns were raised.

- Time needed to get the informed consent
- Identification of data collectors
- On how is the subject identified?
- Know what the subject of interest (study) is
- Consideration of anonymity
- Consideration of compensation

In a related discussion, the trainer raised the issue of courtesy to the research participants. It was noted that the researcher should pay respect to non educated individuals as they are equally knowledgeable and important source of information. Trainees were given the exercise in the module, to work it out and give their views on informed consent connected to the exercise.

The exercise in the module refers to the determination of the effect of Vit. A supplementation in reduction of death and illness related to pregnancy. The study primarily involved the women in reproductive age. However, the family of these women, community leaders and the community were also involved.

The trainer noted that getting informed consent from every single woman involved in a community based study like the above ones is difficult. The better option the researcher has is to get the consent from community leaders. The community leaders, as get keepers of the community, may give decisions on behalf of mothers involved in a particulars study. However, the researcher should give the detailed information on the study for each and every study participant, the family (wives or husbands) of the participants and the community.

It was also noted that for a study to be conducted approval should be obtained from the concerned authorities. Researchers should take full responsibility to give information. It is preferable to use local language for better understanding. In studies that involve mothers, consent of husbands should also be consulted depending upon the specific culture. Parents should be asked for permission for under age (15-18) years. Decision from both the investigator and primary study unit is also needed. Husbands should also be informed; but the option of the wives should be taken seriously. The community should get awareness in this regards. The need for consent format was also brought forward. The two types of consent – verbal and written were also noted. Primary consent givers and proxy consent givers were also seen.

Potential risks: The need to envisage some of the risks that the subjects may encounter were also looked into.

Information content is case dependent. In academic world a certain standard should be followed. For instance, if the study is concerned with the provision of folic acid/iron, the consent giver can be the community. The investigator(s) need to go to the community get keeper (leader) first and then to mothers and husbands. It was stressed that the idea behind consent should be clearly explained in order for the subjects to get better understanding and avoid blames and risks that may come as a result at a later period. For instance, women in first trimester of pregnancy will

refrain from taking any drug when she gets clear information. The researchers also take care of every related issue.

It was also noted that the interventional study requires to:

- Get written consent;
- Try to make clear total duration of the study;
- Get ethical clearance from the authorized body.

Conflict of Interest

Internalization of the: (a) problem and (b) ethical concerns of Conflict of Interest and, (c) rationale for regulatory requirements was explained as the main objectives. SCENARIO: Conscious or unconscious undue influence or distortion may occur due to conflict of interest.

The issues of primary and secondary conflict of interests were also looked into. The professional objectives may be compromised by a secondary interest which could be money or other things. The need of careful handling of such issues was also stressed.

A closer look was also made on the following aspects of conflict of interest:

- Severity of conflict of interest: It depends on the influence of professional judgment and the seriousness of the harm or wrong doing that may result from the influence.
- Regulating necessity for conflict of interest: It is needed for the maintenance of the integrity of judgment; it is necessary to minimize the influence of secondary interest for the benefit of the primary interest.
- Mechanisms for prevention of conflict of interest: The major mechanisms are:
    - Educating the researchers;
    - Supervising the research undertaking;
    - The need for disclosing conflict of interest by researchers.

The training on ethics, in a nut shell, is the expression of concerns for respects of persons, ensuring the beneficence and justice in the process with regard to research participants in any given research undertaking.

Ethical Review Board: It is a panel authorized to reviewing grant proposals with respect to ethical and scientific implications and deciding whether additional actions need to be taken to assure the safety and rights of participants. By reviewing proposals for research, the board gives ethical clearance to the researchers. The board also helps to protect researchers against potential legal implications of

neglecting to address important ethical issues of participants. Detailed explanation can be obtained from the Ministry of Science and Technology (MST) ethical guideline.

DAY EIGHT SESSIONS

HUMAN RESOURCE MANAGEMENT

The day's session was devoted to the module that deals with Human Resource Management. The subject was initiated with the statement of the trainer reflecting that the society is always in the state of trail process of life whether one is aware or not.

The question of human resource management was explored whether it is research conscious or not. A clear explanation was given that there is an element of management research too. Following this general introductory remark the trainer moved to the heart of the subject by asking 'what management is'. In response to the question, the trainees reflected the following. Management is getting the work done by people to achieve a certain objectives using the necessary resources, like money and materials. It was also disclosed that human being is the central element in the process of management undertaking.

Principle of Management

Definitions:

- Set of planned activities for effective and efficient resource utilization in pursuit of certain goal(s);
- Working with human, financial and physical resources to achieve organizational objectives as set by the people.

Management is also the ability to start, change and stop something as the situation requires:

- Management of organizational climate, people, resources, tasks and products (deliverables or results) were also discussed: a problem-solving process of effectively achieving organizational objectives; through the efficient use of scares resources in a dynamically changing environment;
- Improving organizational climate, enabling people to act, and ultimately achieving the set objectives;

Management/ Leadership

Management and leadership were explained in the following manner.

A blended function of:

- Science and Art
- Logic and intuition
- Rules and judgments

The difference between manager and leader was also seen. Thus, it was noted that "the manager is a person who thinks for today while a leader is a person who thinks for tomorrow". Leadership influences people to do things. It had surfaced that people usually like to lead easy life. But, leaders think beyond the common people. They ask the right question and inspire people. Leaders are always spearheading, engage in a thinking process and adopt analytical thinking. It was also noted that leadership and management should be able to operate in harmony.

The main functions of management, related competencies and environmental requirements were also discussed as follows.

Major Functions of Management:

- Planning
- Organizing
- Coordinating/Directing
- Controlling

Skills Competence of Leadership and Management Functions:

- Conceptual, Contextual and Visionary Skill
- Communication skills
- Diagnostic (forecast, analysis, prediction) skills
- Human relation (interpersonal and socialization) skills
- Political skills
- Technical (managerial performance) skills

The trainer noted that it is necessary to appreciate the existing reality, better to avoid dispute, be able to see the external and internal environment. The relationship of politics and other issues was shown using the following SWOT matrix.

The SWOT and PEST analysis was demonstrated and discussed in the class. Status of SWOT is entered in the matrix to do the analysis.

Matrix for Analysis

	PEST			
	Political	Economic	Social	Technical
S				
W				
O				
T				

Management Environment: TEAM building spirit covers;

Together,
Everyone,
Achieves,
More,

Hence, it was emphasized that there is **no single**, effective and lasting winner until we all do together!

The Decision Making Process:

- Making a thorough diagnosis
- Analyzing the problem
- Searching for alternative solutions
- Selecting the best possible solution
- Putting the decision into effect
- Following up
- Taking the responsibility/accountability
- Time required
- Timing and time management

Having good knowledge in the above areas was stated as an asset and critical for decision making.

HEALTH RESEARCH MANAGEMENT

The major types of Health Research – Basic Research which generates new knowledge and Applied Research which is meant to solve problems got overviewed in relation to management.

The following focus areas were discussed

- As diverse and as complex as the health field/ profession itself
- Comprehensive vs. Selective approaches
- Interconnectedness and Interdependence

There was a hot debate among the trainees on comprehensive vs. selective health services. Following the debate it was agreed that, nowadays, comprehensive seems to prevail. However, balancing is also considered at times. The example of target intervention when the situation demands was mentioned in this connection. The example mentioned to explain this was: The road map for HIV/AIDS prevention and control universal coverage by 2010 or the Health Extension Program could have been *'big, bold and bad' program, but we will need to do it*.

Participants/Partners

Participants/partners are considered to be useful for applied research and assessment undertaking. Thus, ensuring realistic participation and stakeholders is of paramount importance. There should also be clear definition of their roles and responsibilities. The implication of participants should be evaluated. It is also important to identify the stakeholders affecting and/or being affected by the research during research undertaking.

In relation to the issue of participants, there was a debate with regard to carrying out evaluation before or after. Following the heated discussion, the general consensus turned out that …undertaking evaluation both before and after the work proves critically essential.

(Applied) Health Research Management

Guideline and Principle

For "APPLIED" health research

- Need-based
- Problem-oriented
- Solution-driven (Action or Decision-geared)
- Priority!
- Pursuance of Research informed Action
- Participatory
- Realistically quick
- Cost-effective
- Multi-use format, at least, with key features
- Readily available/ accessible
- Resulting in desired change/improvement

The need to look into the funding situation as part of management was also discussed in connection to guiding principle.

Budget Request for the project

- Human, FINANCE, TIME and Other Resources
- Preparation: Format and Justifications
- PRACTICUM (taking note of the "Advices")

There was also discussion on whether budget is requested before or after ethical clearance among the trainees. It was finally agreed that the ethical clearance should precede the budget request. However, it was noted that the question of planning realistic budget should not be forgotten. And pledge can also be secured without commitment. It was mentioned that informal submission before approval is also possible. As a general principle, however, the budget should be approved first as part of the project proposal.

A question of the need for securing budget for proposal development was asked. In response to the question, it was said that this depends on the size of the project and also on the will of the funding agency. In general it is a challenge.

Health Service Research Management

Health service was defined as the provision of health and health related services /care to the people or a community. It was also noted that health care is somewhat broader than health service as it encompasses things like staffing, management, logistics, policy, strategy. Etc.

Concept and Focus
Research management should consider the following aspects:

- Scientific inquiry
- Produce knowledge (and result in action)In respect to policies, provisions, organization, resources, including financing
- Measured (viewed) at the population(s) level
- Multi-disciplinary professionals: biomedical, social, judicial, programmatic and others teamed up.

Management of Health Research Project:

It was stated that the major areas of management like, Administration, Budget, Work plan and evaluation should be considered here.

Administrative and Organizational Elements – Research TEAM composition may comprise:

- Lead or Principal Researchers Team

- The Research Team
- Collaborative Research Team

The need for clear definition of roles and accountabilities of research team, in addition to fulfilling agreement (MoU/ToR) right from the outset was stressed.

Requirements

It was noted that people involved in research undertaking should have the following knowledge and skills.

> SUBSTANTIVE Knowledge/Skills – refers to importance of statistics and expertise in areas of the study.
> METHODOLOGICAL Knowledge/Skills – reliability of the researcher on method and study design
> ANALYTICAL Knowledge/Skills – professional skills on ways the analysis is done, statistical analysis interpretations.

The requirement of putting in place the above mentioned skills was highly emphasized, among other.

Types of data and its quality

There are two types of data, namely, primary and secondary data. Primary data is considered to be the best, if it is not for the cost and the time it takes to collect.

The situation for dependency on secondary data with regard to cost, time, and etc constraints were also mentioned. Most of the time, secondary data are not complete and reliable, particularly in the case of our country and most developing counties unlike the developed countries.

It, however, stated that there are times when secondary data becomes more reliable than primary data though not frequent. The general situation is that both primary and secondary data have advantages and disadvantages, complementing each other might reduce their disadvantages and maximize the advantages.

Work plan

The work plans include the specification of the activities with time put in chronological order, time table, budget and responsible persons. It was noted that it is a guiding document for budget and administration of research projects. The purpose and three forms of planning were also put forward in the following manner.

The Work Plan

1. Clearly stats commitment details (who, what, when) Guide and Monitor
2. Narration – put the summary in word and linked to numbers
3. Illustratively Graphic detailed descriptions such as Gantt Chart (the task + time mentioned)
4.

Important Considerations during planning - The work plan needs to be:

- Realistically simple and understandable;
- Preparatory and implementation phases clearly shown;
- Administrative, training, and support aspects identified;
- Logistics factors considered;
- Local conditions and practical realities;
- Possibilities of seasonal and other variations.

The practical aspect of work plan:

1. GANTT CHART construction;
2. PERT scheme development;
3. Advantages and Limitations of each approach.

The need to see the advantages and limitations of each form was also reminded. The need for the three forms of work plan preparation for research grant application was also stated.

Trainees have been encouraged to ask questions give comments and/or suggestion at the end of each topic presentation or whenever they feel like to do throughout the sessions as has been done in the previous time. There were good interactions from the trainees' side. It was also noted that it is worth referring to the specific module for more information.

NINTH DAY SESSION

COMMUNICATION

The session of the day was to look into communication in health care. This session was conducted with the support of power point presentation and discussion on the practical examples in relation to the subject in question. Accordingly, three types of communication were covered. These are:

1. Basic Communication;
2. Scientific Paper Writing;
3. Oral Communication.

It was emphasized that the most important way to improve communication is by repeated practice and reading.

Abstract picture was projected and asked on what the trainees see and generate or interpret, i.e., understand from the depicted picture.
A number of messages were extracted from the picture as perceived by the trainees. To mention few: "Person, apparatus like mobile, darkness, transformation to light, technological transformation."

The two mode of communication – written or verbal between two persons or could be with animals too, was also noted. Communication is central in the life of human being. It was disclosed that particularly people in the northern hemisphere are sensitive about communication. Communication is not that easy, but can be learnt. So, it is extremely important.

Adequate explanation was given about the origin of the term communication which was derived from "Commune: is a Latin word. Communion is to have fellowship and it further developed to 'communication' through time. Human beings are commonly referred as 'social entity'. It was noted that communication is a never ending process in the form of interaction. People share their feelings and learn through communication. It is a dynamic process "as one always learns, learns and learns continuously". It was disclosed that one needs to repeatedly communicate to learn as the retention capacity of what had been heard and seen does not exceed 50%. It was also noted that the highest learning (83%) as told by psychologists is attained through seeing. But much more so learning becomes effective through the combined use of all the avenues of communication.

Communication Concept

- A process (dynamic; some kind of interaction)
- sharing (exchanging) of aspirations, attitudes, beliefs, commitments, desires, education, experiences, expertise, entertainments, feelings, ideas, information, intentions, instructions, knowledge, learning, opinions, plans, skills, views, wishes, etc. among people (primarily).
- An instrument of awareness, enlightenment, learning, action, innovation, transformation ...
- "Exchange of meanings" among the concerned parties.
- Communication gives "life" a meaning.

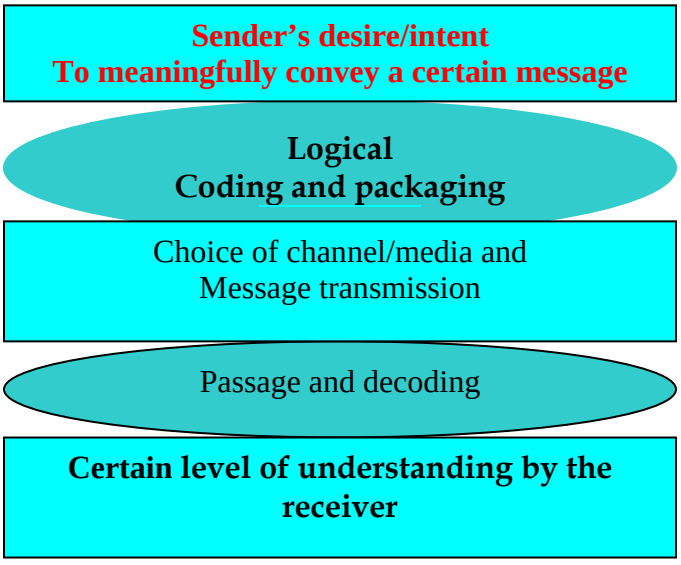
Process: It is the movement of message originated at a certain point, passing through a channel and reaching a destination.

Key Elements

- SENDER (SOURCE)
- MESSAGE
- CHANNEL
- RECEIVER

It was stated that there are numerous influencing factors and intermediary conditions at each level or phase.

Common form of the Communication Flow or Path way:



The above schematic explanation was given for better understanding of the flow of message from the source to its destination. But communication is never a one-way process. Essentially, it is a two way dynamics. The only difference is on how covertly or overtly the feedback gets manifested.

Approaches – Direction

The exercise from module 6 on communication was given to the trainees for brain storming. The exercise was intended to focus on the effectiveness of communication using the following concepts:

- One-way and two-way communication.
- The appropriateness (aims or purposes), characteristics, strength and limitations (shortcomings) of the two approaches or forms.
- Bringing in your own face-to-face communication example that went wrong and review on why so?
- Listing appropriate actions, measures and things that could have been done in order to avert or prevent the communication breakdown.

Important Attributes of Communication

- "Attitude" issue as part of the entertaining mathematics of life" projection was discussed – It was duly emphasized that attitude is the most important element in the human life, including in communication.
- Cultural and social system constructs and networks
- Level of audience orientation, analysis and targeting (tips of a priori analysis), including language choice
- Level of evidence and knowledge (content accuracy, clarity, consistence, credibility, up-to-date, etc.) This helps the people to trust us. The issue of HIV message sent to the people repeatedly without getting feedback from the people was discussed as good example in this connection. The need of adjustment of HIV message was also mentioned.
- Level of preparation (practice) and skills
- Media choice and others
- Physical and technological conditions/settings

Forms/Method/Ways of Communication

Forms

- Verbal,
- Non verbal,
- Mixed

Methods/ways

- Intra-personal
- Interpersonal
- Group
- Mass

Barriers to Effective Communication

The trainees were made to work on the identification, discussion and listing of common barriers to effective communication in the class. Discussion and exchange of views were made. The knowledge of a certain language, age difference, socio-economic gap and attitudes and beliefs were mentioned as common barriers to effective communication.

Appropriate grouping was also discussed. Generally, a group means two or more persons interacting together. Specifications may vary according to the prevailing practical contexts. Accordingly, the following grouping and the number of people in the group were also stated to be acceptable.

Small group	2-3 persons but may go as high as 50 and hundreds
Big group	20-25 persons but could be in several hundreds and thousands
FGD	8-12 persons

It was explained that this kind of grouping is believed to be good for effective and better interaction and communication. The need to use more than one sense (all the six senses) for better and effective productivity of communication was stressed.

Scientific Paper Writing/Written Communication

Principle, practice and other important aspect of the topic were discussed. Some are mentioned as follows.

At the outset, the necessity for a written proposal was explained, examined and reviewed as a scientific paper in respect to for better system communication. The need for maintaining the integrity of ethical process was also reiterated.

Scientific paper": Cardinal features and markers of "science":

- Ethically sound
- Scientifically generated (application of scientifically valid assessment methods);
- Rigorous investigation (research) and analysis;
- Systematic organization and synthesis;
- Peer review and edition; published for wider scientific knowledge building, reading, critics and improvement.
- "First" publication of original research results;
  - (i) in such a way that others may repeat;
  - (ii) In a peer reviewed publication, resource should be available to the scientific community.

The importance to remember the 3 Cs – conciseness, completeness and clarity from the outset as a rule of thumb was disclosed. The issue of the reliability and acceptability of journals/scientific papers was also raised. In the explanation given, it was said that in the commonly prevailing view, the journal having successfully published about six consecutive volumes or more survived for some years is considered to be more acceptable and credible. But, the journals that do not have volumes are becoming subjects for debate. Again, internationally recognized journals, more than the local ones, are often considered repeatable journals.

The aim of "*Scientific paper* "is to- Facilitate:

- Independent assessment about the observation;
- Repetition of the research when deemed necessary; determination of the justifications for the conclusions and recommendations in view of the given data.

Section/Structure of Scientific Paper Presentation

Commonly, the IMRaD principle has been applied:

- **Introduction** (what question was asked)

- **Methods** (how was it studied)
- **Results** (what was found)
- and
- **Discussion**

The above mentioned items were discussed as essential parts of a scientific paper. A defective out line for scientific paper was assessed in the class and defects were identified by the trainees. The main parts, like; introduction, methods, results and discussion were presented and thoroughly examined. A complete and comprehensive feature of a scientific paper design was projected.

The need for IMRaD in qualitative research was also discussed. It was explained that it can be used but, not a must.

The 'purpose' part is meant to describe the finding in relation to the objective. The flow that should make sense is the one in line with specific objectives.

The importance of editorial was also stressed. Considering editing as minor issue was considered as a big mistake.

The guideline for the assessment of scientific paper design was also highlighted.

An abstract as the image of the paper was adequately discussed. The need to critically see the abstract part was also stressed. Writing a total of 250 words was said to be an acceptable size for an abstract in common practice. But the practices do vary widely enough. It is advisable to properly consult to the respective specifications.

The style for reference: Harvard and Vancouver's styles are in a relatively broader common practice among the scientific community around the world. The availability of different styles was also mentioned. There are also soft ware's being progressively developed for standard reference citation purpose.

Oral Communication/Presentation Techniques

Oral presentation

Purpose:

Is the oral presentation for the sake of information dissemination?
Is it for Education?
or for Persuasion?

Planning

- **Understanding the context of presentation**: Concern, purpose, primary issue, focus and relationship, surrounding environment, type of presentation, time limit, etc.
- **Audience analysis:** Background, Thematic knowledge and expertise, concerns, questions, uncertainties, etc.
- **Preparation:** determine the purpose (instruction, information/education, persuasion) and start practicing early enough.

Effective oral presentation

- Important, but overlooked and under practiced.
- "Trait" vis a vis "learned"?
- Foresight, effort (hard work) and continuous practice.

Organization/Structure of an Oral Presentation

Introduction	Body	Conclusion
- Greetings - Introducing self - Main subject	- Excellent logical structure; - Main points of talk	- Reiteration and reinforcement; - Exhibit good coverage
- Topic and scope of the presentation; - Outline of the main points; - Specific historical account	- Transitional passage from a point to another - Offer evidences with examples; - Make an emphasis on important information (with why so).	- Offer a signal for an extra attention; - Restate the main points; - Re-answer the question.

Using Presentation with Visual Aid

Rationale and Resources:

- Helpfully important with a judicious application.
- Various forms, means and ways.

Important considerations and questions about visual aid:

- Appropriateness?
- Offer better clarity and quick communication?
- Add interesting flavor?
- Worthwhile investment of the effort, money, practice and time?

Designing Visuals

General Principles:

- Primarily for support and adding impact;
- Concise and simple message;
- Color variation for the sake of impact;
- Bold colors/fonts with proper spacing.

Four important design concepts:

- Big
- Simple
- Clear
- Consistent

It was made clear that visual aid plays a facilitation and supportive role but not replacing other forms of presentation. In this connection it was mentioned that pictorial presentations are very good but should neither be be unnecessarily destructive.

Prerequisites for making the presentation with visual aid are:

- Planning
- Organization
- Knowledge
- Preparation (practice/rehearsal)
- Trustworthiness

The need for repeated rehearsal was disclosed.

Delivery of verbal communication

Voice:

- Quality
- Intelligibility
- Variety: rate, volume, force and emphasis

Sincerity:

- In addition to adequate preparation and rehearsals!
- Honesty, truthful and faithfulness are important.

Delivery Non-verbal communication

- Eye contact
- Body movement
- Gestures

It was noted that sitting while presenting is not a good manner and not recommended with regards to the posture of the presenter.

Delivery: Handling Fear

Application of NINE (9) P's: The following should be considered when someone is planning for presentations.

"**P**rior **P**roper **P**reparation **P**revents **P**oor **P**erformance of the **P**erson **P**ut on **P**resentation"

The sentence with the nine Ps was read by each participant in the class. It was meant to fix in their minds.

Delivery: Large Volume

The need to focus on the main points was stressed when the presentation is of large volume.

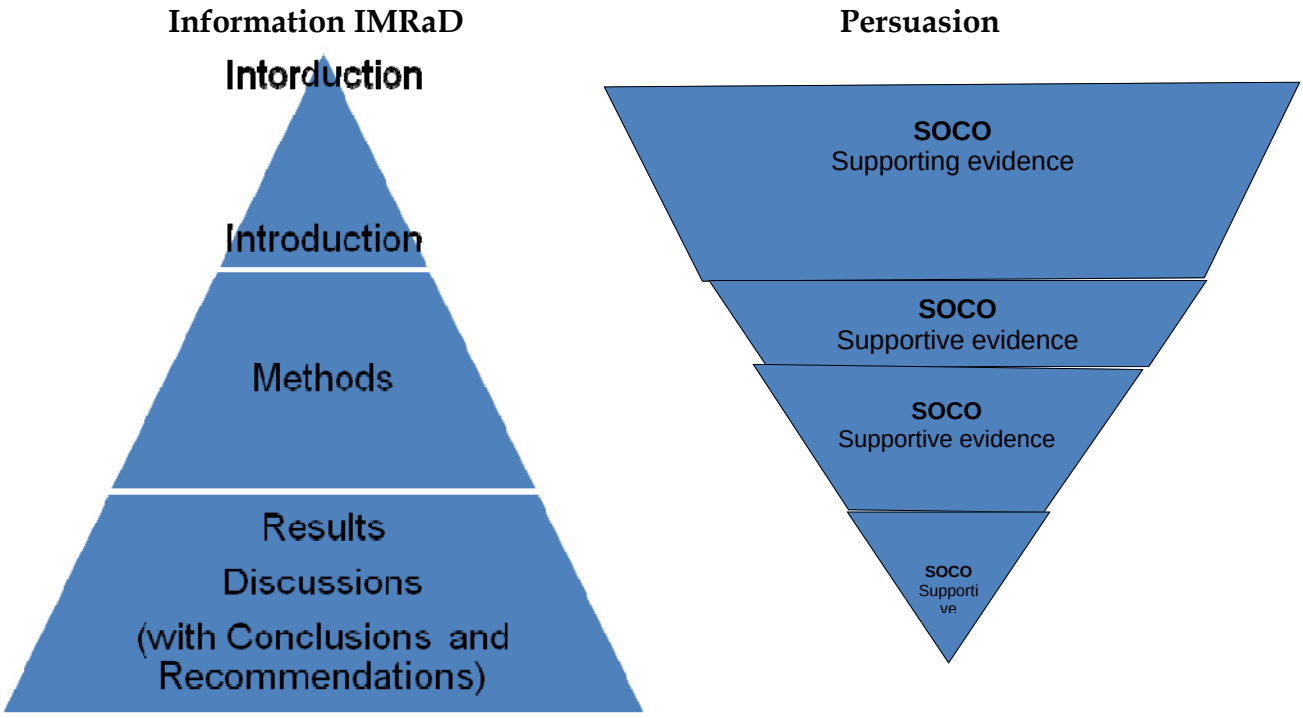
Delivery: Communicating policy

Information on IMRaD and SOCO – (**S**ingle **o**verriding **co**mmunication **o**bjective) was highlighted to the trainees. The schematic explanation of communication for policy makers is shown below.

- Simple language usage
- Short and attractive sentence
- SOCO
- Avoid unnecessary details
- GUAGE and SCAN "INEREST"

The importance of the above points were clearly explained

Delivery: Communicating Policy



Delivery – Communicating with Poster

Content:

- Title
- Background/Purpose
- Methods and Process
- Results
- Conclusions
- Acknowledgement

Important points to be considered on developing poster are:

- Colorfulness!
- Limit "Too much" Text
- Use active and to the point grammatical approach;
- Use Short sentences
- Use bulleted texts
- Make it clear and visible

Exercises for trainees group work

The trainees have carried out different exercises pertinent to the subjects studied during the sessions in their respective Research Working Groups.

At the end of lecture presentation a kind of educational entertainment with the title of 'Small truth to make life 100%' was projected and relaxed and relaxed the trainees.

TENTH DAY

GROUP WORK PRESENTATION

The last day of the training session was devoted to the final refined and completed proposal presentation by the entire group. The presentation was supposed to pass through the critics of the trainers, members of training facilitators and the trainees themselves as part of the training process. Accordingly, the presentations were implemented in accord with the arrangements made by the trainees and trainers to reflect the real situation.

Group Four, SNNPR

The topic of the presentation was the same as before. Presentation was made by the principal investigator. The presentation made this time was near complete as per standard proposal protocol. However, abstract, questionnaire for data collection, consent form, ethical clearance request forms were noted missing.

Following the presentation; questions, comments and suggestions were forwarded to the group.

Questions: Why did you select only married females as the study subjects? What is your justification for suggesting such a high budget? In response to the questions, the group said that married women are selected because the majority of family planning users in the rural areas are married females. Literature review indicates that married women are taken as main study subject. The married women being sexually active, was also mentioned as a reason for selection. Regarding the inflated budget, the group said it is subject to further refinement as the present one is very rough one.

Comments: It is expected that the study will also cover the urban areas. In such areas single and divorced women are the main users of the family planning service. The group was also advised to use the accepted tools like DHS. However, the group argues that DHS does not represent the region as such. So the group declined from taking it. In further comments from trainers it was stressed that the objective needs to be refined further. Putting health workers as data collectors in such a situation where there is shortage of health workers is not realistic. It needs to be revised. But the groups said that the health workers include the community health workers as well.

More Questions: Why didn't you show determination of prevalence of unmet need in the proposal? Why didn't you specify the types of the multivariate? In response to this question, the group said that issues about unmet needs will be included in the operational definition. The group also disclosed that it has intended to use logistic regression under the multivariate regression.

More comments: The time to submit the proposal is too short. The group was advised to push it to September 2009. The time to start the study should also be pushed to December 2009.

Group, Three Oromia Region

The topic of the presentation was not changed. The presentation made by one of the group members this time was somewhat complete. However, abstract, questionnaire for data collection, consent form, ethical clearance request forms were missing.

Comments: "In general, there is improvement in proposal development. However, there is still need for further improvement. Thus, some specific objectives can be put together. The design of sample size suggested in the proposal needs to be clearly indicated. Whether the HHs, individuals, and place of implementation in rural or both urban and rural should be clearly put. The sampling procedure should also be clearly stated. The terms 'good performance', 'poor performance' and 'No performance' need to be well defined and revisited. There is no doubt that health workers are important but, better not to include them in specific objectives as it will be very difficult during analysis."

Group Five, Somali Region

The topic of the presentation was not changed. But, the presenter was the principal investigator. The presentation made this time was almost complete. The only part missing was the table of contents.

Question: What is your justification for using design effect of 2 mentioned in the proposal? Why do you exclude <12 months when the policy states < 2 years? The group did not respond to the queries.

Comments: Trainers and trainees gave the following constructive comments. There must be sound justification for using 2 as design effect. Study areas should be stratified as urban and rural. The sampling procedures and the clustering part should be revisited and refined. The exclusion criteria should be in line with the existing policy. The problem statement should be revisited as it does not indicate about the study subject. It is good to mention about the importance of EPI. Care must be taken not to write about something that is known. It is better to focus on the fact and feasibilities of the study which can convince the donors and target stakeholders alike.

Group One, Tigray Region

The topic of presentation was not changed. The presenter was the principal investigator. The presentation made this time was almost complete. The table of contents, abstract and list of abbreviation were missing.

Questions: How are you going to get the 5% study subject for re-interview? Do we have enough information about the role of HEWs in reproductive health? What are you trying to convey with the picture on the front page of the proposal? In response to the questions the group said that doing the interview again in the 5% is possible, but, it is tiresome. The group had also felt that there is no ethical problem. Regarding the adolescent, reproductive health is one of the six components that the HEWs are supposed to take care of. The picture put on the front page was to make the proposal more attractive to the funding agencies/study sponsors and other readers.

Comments: The trainers gave the following comments. Giving definition for statement of problem is not necessary. The general objective does not include the influence that should have been included. The group was also advised to put more bullets on reproductive health under specific objectives. The need for making where the adolescent go when they face problems related to reproductive health was made clear to the group.

Group Six, Gambella Region

The topic of the presentation was not changed. The presenter was the principal investigator. The presentation made this time was improved. However, the table of contents, abstract and list of abbreviations were missing. The additional documents like questionnaires, consent form and request for ethical clearance were not enclosed too.

Comments: Trainers reported that there were progresses observed compared to the previous presentation. They had also disclosed that there are rooms for further improvement. Accordingly, they suggested that the inclusion and exclusion criteria should be put separately. The ethical consideration put in general form should be very specific as the ethical committee wants to see such documents clearly shown. The sampling that is destined to pick pregnant women has been found questionable. It appeared to be difficult to identify those women in the first trimester. The sample put in 2: 1 proportion ie. 534: 267 was found to be unclear. The group was advised to make it clear. The need to review the hindrance of PMTCT and the flow aspect was observed.

Group Two, Amhara Region.

The topic of the presentation was the same as before and the presentation was made by the principal investigator. The presentation made this time was complete as it had all the parts that standard proposal supposed to have. This includes: complete

protocol of the proposal, questionnaire for data collection (both English and Amharic version), consent form, request for ethical clearance.

Questions: Why did you select EPHA which is located at a very distant place for ethical clearance? Why is six month taken as a cutoff for exclusion criteria? Who will be taken as participant for FGD in such big town like Gondar? Have you considered the issue of condominium residence that is coming to the picture nowadays? Whom to consider among the HH members (owner or members) during the study?

Responding to the queries the group said that they selected EPHA for ethical clearance due to lack of ethical committee in the region. The six month cutoff point is based on information taken from DHS. Living in a certain place for more than six months enables someone to give better information. Kebele leaders, TBAs and influential people will be FGD members. The group appreciated the issue of condominium raised, and took it as a reminder to consider it in the proposal. In the HHs where there are other renters, only the household head will be considered. The group also stated that they use observation of personal hygiene of the study participants during data collection.

Comments: As a continuation to the above question linked to ethical clearance, trainers and EPHA facilitators have tried to make it clear to the group that ethical clearance is not a onetime issue as it needs to be followed for long time. They also made it clear that the ethical clearance should normally be in the region itself. The trainers have explained that the study subjects should be individuals but not the households when the nature of the study is carefully seen. In principle, the references cited in the document should be the ones that are properly read before they are cited. And, only published documents are accepted. Reports and unpublished documents are not accepted for scientific paper citations.

POST TEST AND OVER ALL EVALUATION OF THE TRAINING

Following completion of the presentation from the group, the trainees have done post test to see what is gained or levels of changes witnessed in the skills of the trainees as a result of this specific training given. The trainees have also evaluated the training activities conducted during the entire ten days, the venue and other things related to the training. The outcome of the post test and the evaluation are shown on annex 1.

Annex-I

References

The following Training Modules were Developed and Published By: The Ethiopian Science and Technology Commission/Ministry of Science and Technology in collaboration with the Ethiopian Public Health Association and Regional State Health Bureaus, June 2005, Addis Ababa-Ethiopia

1. Proposal writing for Health and Health-Related Research (Module 1)
2. Health Research Methods (Training Module 2)
3. Health Research Data Processing, analysis and Interpretation (Training Module 3)
4. Health Research Ethics (Training Module 4)
5. Health Research Management (Training Module 5)
6. Health Research Oral and Written Communication Techniques (Training Module 6)
7. Facilitators' Guides
8. National Health Research Ethics Review Guideline, 4th Edition-June 2005 Ethiopian Science & Technology Commission, NHS &TC-HD.

Note: You can also find the above Modules and the NHRE Review Guideline on the Ministry of Science and Technology Website: **www.estc.gov.et**

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Annex-II

EPHA Regional Chapters Training Workshop on Health Research Methods
Adama (11-20 Feb 2009)

Pretest (*Answers are in italics*)

1. One of the following is not true about the descriptive studies?
    a. Describe the characteristic of an interest in terms of place, person and time
    b. Can help to determine the magnitude of a given health problem in the population
    c. The investigator observes the occurrence of disease in people over a time
    d. Is used when the aim of the study is not to test a given hypothesis
2. When a group of initially disease free individuals are followed over a period of time to identify the occurrence of a particular disease, which type of study design is this?
    a. Case-control *b. Cohort* c. Experimental d. Retrospective
3. One of the following study designs is assumed to be a gold standard although it raises many ethical issues.
    a. *Interventional* b. Case-control c. Cohort e. Observational
4. One of the following sampling methods chooses subjects from the population with equal probability of selection.
    a. Cluster b. Stratified c. Systematic *d. Simple random sampling*
5. The number of cases of TB in a one-year period in Ethiopia would be:
    a. Nominal b. Ordinal *c. Discrete* d. Continuous
6. In a given study to test the association between vaccination and the occurrence of childhood illnesses, the associated p-value is 0.001 at $\alpha = 5\%$. The conclusion is:
    a. Vaccination is effective in reducing the occurrence of the disease
    b. There is no association between vaccination and the occurrence of childhood illnesses
    c. There is a very weak association between vaccination and childhood illnesses
    d. There is no difference between vaccinated and unvaccinated children in the incidence of the disease
7. A study was conducted to explore if there is a correlation between drinking alcohol and systolic blood pressure. If it was found that $r = 0.70$, it can be assumed that:
    a. Drinking alcohol causes high blood pressure
    b. There is a positive correlation between alcohol drinking and high blood pressure
    c. The relationship is assumed to be weak and inversely related
    d. a & b

Findings

Summary of the results of the pretest and Post tests for Research Methodology Part

Categories	Group Results (Out of 10%)	Number Trainees (%) Pretest	Number of Trainees (%) Posttest
1	< 5	8 (47%)	3(18)%
2	5-7	5(29%)	6(35%)
3	8-9	3(18%)	5(29%)
4	>9	1(6%)	3(18%)
Total …	**10%**	**17(100%)**	**17(100%)**

The pretest result showed that majority of the trainees scored higher grades. A total of nine (5+3+1) out of 17 trainees (53%) scored high i.e. 5 and above grades. This shows that most of the trainees did not lose much of the knowledge gained in the past. This could be because most of them are working in the environments which somehow involve research undertaking or research related works.

The result of post test taken following the conclusion of the training showed that the improvement made was tremendous. A total of 14 (6+5+3) 82% of the training trainees scored 5 and above grades as shown on the last column of the above table. A total of 47% of the trainees scored less than 5 grades in the pretest, which was only 18% in the test as shown in the above table.

Discussion

Obviously, the dynamics does not appear evenly uniform by trainees and by question. And still, improvements are evident all across both by trainees and by the questions. For majority of the trainees, the improvements are highly remarkable. This is clearly evident from the review of the corresponding SUMs and MEAN, respectively. Six of the trainees had scored significantly high (5.75 or above) whilst the two of these were on the maximally possible highest limit. Regardless of the overall positive dynamics, there, however, are still rooms for further improvement. Three of the trainees had fallen under 4.00 at the post-test out of the optimally possible 6.00 points; also, the post-test means of questions 3 through 5 exhibited less optimal as well as widely ranging scores (falling between 70%-80%). Key aspects are further, illustratively, highlighted on Figures 1 through 3 here under.

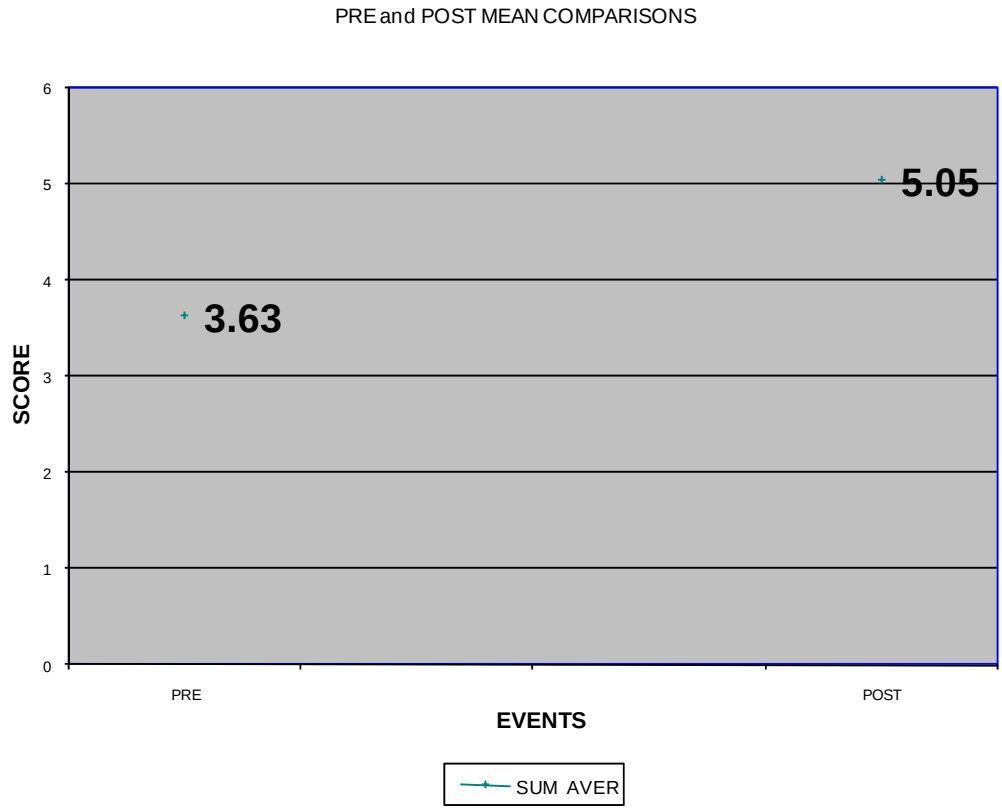


FIGURE 1: Trainees Performance Comparison by PRE and POST-Test Events

FIGURE 2: AGGREGATELY AVERAGED PRE and POST MEAN SCORE CHANGES

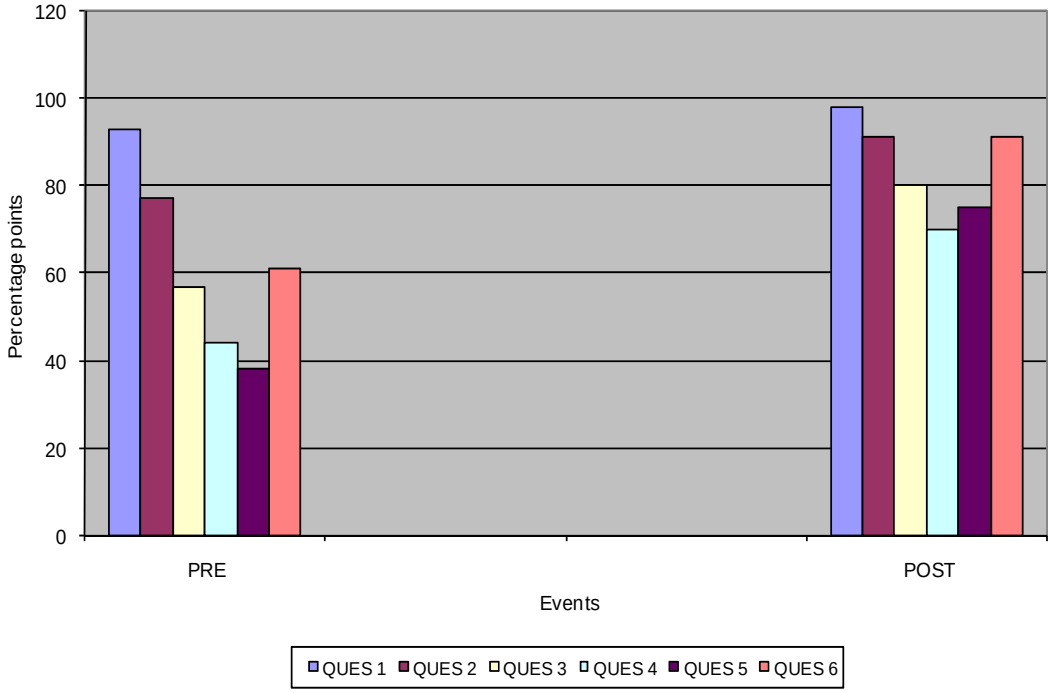
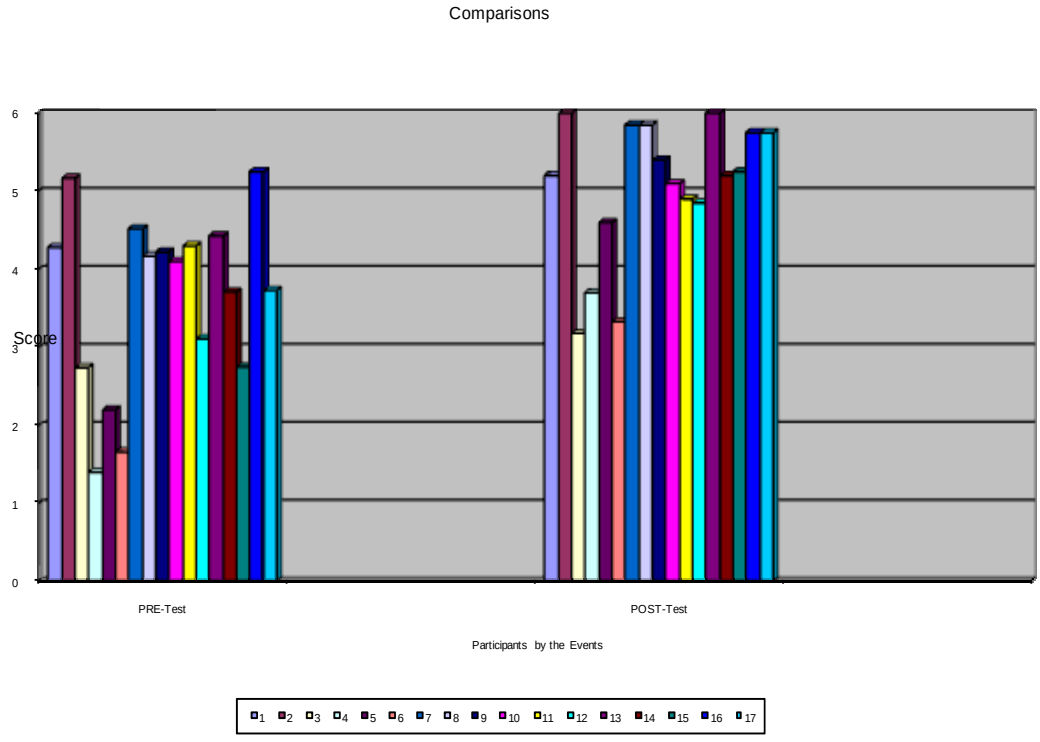


FIGURE 3: AGGREGATELY AVERAGED PRE and POST-TEST RESPONSE DYNAMICS by QUESTIONS



Annex -III

Evaluation of the training
Research Methodology and Ethics Training

Seventeen trainees completed the training successfully within the specified period of time. After the training was accomplished, the trainees had evaluated the training through filling the evaluation questionnaire prepared by EPHA**.**

The purpose of the evaluation was to:

- Assess the trainee's attitude towards their expectations, objectives, new learning, and fulfillment of instruments for the training.
- Assess the trainee's attitude towards the content, methodology, quality and skills of the overall session.
- Obtain trainee's attitude towards future important trainings, lacking and/or requiring improvement from the training and other specific suggestions and recommendations for the betterment of the trainings in the future.

Result

The evaluation result of the participants depicts that, from the total participants 64.7% of them strongly agree and the rest 35.3% agreed with the idea that ***their expectation has been realistically fulfilled*** with the idea of, ***the learning objectives***, as set out by the facilitators at the beginning of the course. Thus, 64.7% of them have strongly agreed that they have achieved their objective and 35.3% have agreed. But none of them has disagreed with the above objectives of the study. They thought that the course instruction has been ***instrumental towards fulfilling their performance objectives***. (See Part I).

Moreover the trainees were asked to list down important and new learning they have acquired from the particular course in the order of priority. Accordingly, the trainee's stated different ideas for the above two questions. But the majority of them stated the following as important learning:

1. Development of Research Proposal
2. Sampling Technique
3. Health Research Data Processing and Analysis
4. Health Research Ethics

As of new learning they stated:

1. Data processing and analysis using EPI-info Software.
2. Sample Size determination
3. Communication Skills

Regarding the overall sessions, the participants were asked to rate the characteristics found within each part of the course session to approximately 9-10, 7-8, 5-6, 3-4 and 1-2. The parts found for the overall sessions are course contents, including; course methodology, quality and skills of training, exercises and assignments. The evaluation done by the participants was summarized and the following results were found:

Under the course content part; the characteristics listed are relevance, accuracy/ thoroughness, new knowledge, new skills applicability, handouts or notes and power point slide materials. For these characteristics on average 64% of them rated approximately 9 to 10, 29 % of them have rated approximately 7-8, while 5.3% of them rated approximately 5-6 and the rest 2.6% of them rated approx 1-2.

Under the course methodology part, the characteristics listed are building on knowledge, building on experience, linkages between sessions, logical flow, meeting objectives and participation level. For these characteristics on average 81% of them rated approximately 9 to 10, while 17.8% of them rated approximately 7-8, and only 1% of them rated approximately 5-6.

Under the quality and skills of the training the characteristics listed are breadth and depth of knowledge, practical orientation, training time arrangement, time use, training time adequacy and subject matter coverage and clarity. For these characteristics on average 66.7% of them rated approximately 9 to 10, while 28.9% of them rated approximately 7-8, and the remaining 4.5% of them rated approximately 5-6 (See Part II).

The last question in the evaluation questionnaire was regarding the course they want to learn about in the future, lacking and/or requiring improvement and any other specific suggestions and recommendations in respect to the progressive betterment of the training workshop in the future. In response to this question, the trainees suggested different ideas. For instance, some of the participants stated the following:

1. The training was most relevant, crucial and need strong understanding, but the schedule (time arrangement) is totally unacceptable. How could a person sit 8 hours in a day for a particular course? So time arrangement should be improved so as adults could participate in the training actively.

2. Information has to be given for the participants in advance so as to prepare themselves in terms of material preparation and advance readings. For instance a group reported that it faced shortage of literatures while writing its proposal.

3. The time which was given for data analysis, interpretation and for the practical sessions should be increased.

4. For the future, it is better to arrange trainings which deal more with advanced statistical course and its applications for this group and others who took this methodology training.

Part I

Questions	Responses	Frequency	Percent
My expectation of the course has been realistically fulfilled	Strongly Agree	11	64.7
	Agree	6	35.3
	Somewhat	0	0
	Disagree	0	0
	Strongly disagree	0	0
The **learning objectives**, as set out by the Facilitators at the beginning of the Course, have been soundly achieved.	Strongly Agree	11	64.7
	Agree	6	35.3
	Somewhat	0	0.0
	Disagree	0	0.0
	Strongly disagree	0	0.0
Overall, the Course instruction has been **instrumental toward fulfilling the performance objectives.**	Strongly Agree	11	64.7
	Agree	6	35.3
	Somewhat	0	0
	Disagree	0	0
	Strongly disagree	0	0

Part II

Parts	Characteristics	Ratings									
		Approx 9 -10		Approx 7-8		Approx 5-6		Approx 3-4		Approx 1-2	
		N	%	N	%	N	%	N	%	N	%
Contents	Relevance	17	100.0	0	0	0	0	0	0	0	0
	Accuracy/thoroughness	12	75.0	4	25.0	0	0	0	0	0	0
	New Knowledge	8	47.1`	5	29.4	2	11.8	1	5.9	0	0
	New Skills	7	43.8	7	43.1	1	6.3	1	6.3	0	0
	Applicability	1	5.9	14	82.4	1	5.9	1	5.9	0	0
	Handouts or Notes	12	80.0	1	6.7	2	13.3	0	0	0	0
	PP slide materials	12	80.0	3	20.0	0	0	0	0	0	0
	Average		64.1		29.5		5.3		2.6		0.0
Methodology	Building Knowledge	12	80.0	3	20.0	0	0	0	0	0	0
	Building on Experience	13	86.7	2	13.3	0	0	0	0	0	0
	Linkages b/n sessions	13	86.7	2	13.3	0	0	0	0	0	0
	Logical Flow	12	80.0	2	13.3	1	6.7	0	0	0	0
	Meeting Objectives	13	86.7	2	13.3	0	0	0	0	0	0
	Participation Level	10	66.7	5	33.3	0	0	0	0	0	0
	Average		81.1		17.8		1.1		0.0		0.0
Quality and skills of the training	Breadth and depth of knowledge scope	8	53.3	7	46.7	0	0	0	0	0	0
	Practical Orientation	9	60.0	5	33.3	1	6.7	0	0	0	0
	Training Techniques	9	60.0	5	33.3	1	6.7	0	0	0	0
	Time arrangement	11	73.3	2	13.3	2	13.3	0	0	0	0
	Time use	10	66.7	4	26.7	1	6.7	0	0	0	0
	Training time adequacy	10	66.7	2	13.3	2	13.3	1	6.7	0	0
	Subject matter coverage and clarity	11	73.3	4	26.7	0	0	0	0	0	0
	Average		64.8		27.6		6.7		1.0		0.0
Exercises and Assignments	Individual and plenary	9	60.0	5	33.3	1	6.7	0	0	0	0
	TEAM Functions	9	60.0	5	33.3	1	6.7	0	0	0	0
	Practical relevance	12	80.0	3	20.0	0	0	0	0	0	0
	Average		**66.7**		**28.9**		**4.5**		**0.0**		**0.0**

Annex -IV

FACILITATORS' BRIEF REPORT OF HEALTH RESEARCH AND ETHICS TRAINING

Background: The Health Research/Evaluation and Ethics Training initiative was envisaged and hence designed with due recognition of the prevailing existing gaps in the training of health professionals. Therefore, it aims at contributing towards creating the necessary critical mass on improving the public health research standard of practice in the Ethiopian context in particular.

Observations and reflections: In the training program organized by EPHA from 11th-20th Feb. 2009 in Nazareth, 17 health professionals participated. First, it is very appropriate to note that the training workshop had progressed and completed in accordance with the designed plan. Accordingly, both the start-up and completion dates were duly observed. All the six Modules were covered most fairly and systematically enough. Equally, all the seventeen participants were able to fully as well as inspirationally fulfill their expectations. There neither were disruptions nor interruptions all throughout. To the extent of practical possibilities, all the sessions were considerably participatory and practical. All along the training endeavor, participants got organized in six different teams and then got practically guided through the phased Research Proposal (Protocol) development process entirety. Thus, by the end of the training, all of the groups had already laid up the fundamental research proposal provisions according to the respective priority health issues. As the way forward, the respective teams are going to proceed with further consolidating, polishing and refining the corresponding proposals by aiming at due application for grant potentially within and/or outside the organization per se, including the EPHA. The ultimate goal of the training indeed is: (a) the trained teams will implement the priority research agendas towards generating evidences and knowledge around the selected pertinent problems; and (b) the EPHA Regional Chapters get strengthened research capacities, including competencies in research proposals appraisal at their levels.

Overall, the Facilitation Team is deeply pleased to pronounce the training as a great success in all dimensions. The PRE and POST-TEST results as well as reflections of the Training evaluation are tangible testimonials in this respect. All the details of the training dynamics are to be found very well captured and consolidated within the complementing and accompanying proceeding document.

Conclusions and recommendations: The whole experience has been extremely fruitful. Evidently, such a very much targeted and a technically intensive training will remain at an ever growing demand. In view of the practical long-term benefits, therefore, EPHA in collaboration with the respective partners is encouraged to upkeep the momentum.

In an effort to pursue the initiative forward, the following may be among the essential considerations: (a) institutionalization of a sustainability continuity system; (b) revision and up-dating of the modules, including corresponding Facilitation Guides; (c) institutionalization of follow up, mentorship and feedback mechanism; and, (d) dynamically (progressively) and holistically targeting the regional and institutional health research review boards, in particular.

Acknowledgements: We extend our duly warm gratefulness to EPHA and, particularly, to Ato Berhanu Legesse with his Core Team for the unreserved all rounded support over the entire endeavor.

Facilitation/Trainers Team:

1. Wakgari Deressa (BSc, MPH, PhD), Assistant Professor, School of Public Health, FoM, AAU
2. Mulugetta Betre (MD, MPH), Assistant Professor, School of Public Health, FoM, AAU

Annex-V

OPENING SPEECH

The training was begun with the welcoming address delivered by Ato Dereje Seyoum, a representative from the Ethiopian Public Health Association (EPHA). In his speech, he welcomed all the trainees on behalf of the EPHA. He mentioned that EPHA is one of the most senior professional associations in Ethiopia. He also noted that it envisions the attainment of an optimal standard of health for all Ethiopians. He further stated that EPHA promotes better health services to the public and high professional standard through promotion of research undertaking in general and information dissemination, , in particular.

Ato Dereje mentioned that EPHA is committed to improve the health and living condition of the people in the country through dedicated and active involvement of its members and other stakeholders. He underscored that delivery of support would have not been possible without the support from partners and close working relationship with various government institutions, non-governmental organizations health institutions and universities.

Ato Dereje underlined that EPHA recognizes the existence of the different gaps in health service research skills among health professionals in the country. He said that changing and building the critical mass of health researchers through regular training and refresher courses are very essential to improve the delivery of health service in the health sector. He further mentioned that EPHA is continuously working to upgrade knowledge of the professionals in order to improve public health practice in the country. Continuing his speech, Ato Dereje said that health research is the process of getting systematic knowledge which can be used for improvement of health of the individual or group of people. He said that it also provides basic information on health and development tools to prevent and cure illnesses and mitigate its effects; it attempts to devise better approaches to health care for the individuals in particular and the community at large.

Finally, expressing his hope that the training will improve the health research undertaking of the trainees in the future, Ato Dereje concluded his welcoming address by wishing a pleasant stay in Adama and fruitful deliberations at the end of the training session.

Annex -VI

OVERVIEW OF THE TRAINING SESSION

The Training coordinator Ato Berhanu Legesse, introduced the expected roles and responsibilities of EPHA Focal-persons and distributed the related materials to the trainees. Ato Berhanu also wrapped up the training sessions of the ten days as follows, during the closing session.

Dear Participants, ladies and gentlemen;

EPHA recognizes the existing gaps in health research/evaluation skills among health professionals in Ethiopia. In this regard, creating and building the skills of health researchers' through regular training and refresher courses are very essential to improve service delivery. At the same time we know that there is no as such institution providing such an important training in the country after professionals went out of colleges. To alleviate such problems, EPHA worked closely with the Ministry of Science and Technology; formulated taskforces, developed six modules and provided training using the modules developed.

As you all know, EPHA takes training as one of the main strategies, in addition to generating and disseminating EPHA publications for improved strategic information development and applications.

Thus, this particular research methodology training was designed to help the EPHA Focal- persons understand the general role of health research, methodology design, data processing, research management and communication as well as applying evidence based information for decision making.

In addition to the methodology training, the trainees were familiarized with ethical considerations to protect human subjects from possible manipulations, during study applications. Consequently, the trainees acquired enhanced skills to identify pressing health problems and designed contextual research projects of local relevance. Hopefully, it would also motivate public health professionals in Regional Chapters to produce strategic facts and help them utilize evidence based events for policy formulation, strategic planning and day today activity monitoring as well as program evaluation, through informed and participatory decision making.

Training Participants: As far as trainees are concerned, 17 health professionals attended the training from the planned 20 professionals for the training. The trainees are composed of professionals working in regional health offices, hospitals and universities.

The Training Approach: EPHA contacted well experienced lecturers with the necessary academic competence to offer the course in order to attain the intended objectives. Dr. Wakgari Deressa and Dr. Mulugetta Betre from the Addis Ababa University (SPH) accepted our request to run the training program, in spite of their busy schedule in the university. Six health research training modules developed by EPHA and ESTA were used for the training.

Topics covered in the training were; health research proposal writing, research methods, data processing, analysis and interpretation as well as, research ethics, research management and communication.

These modules have already been tested for their feasibility during previous training sessions conducted in collaboration with the Ministry of Science and Technology (MSTA). The teaching-learning processes were participatory. Organizing 6 groups, the trainees developed research protocols through series of group discussions and presentations. The training was computer based; using **E**pi-info soft ware program. Moreover, each of the modules copied and distributed to all participants for the purposes of teaching aid and future references. The lecture note prepared in CD were also distributed to all the participants for future easy reference and cross fertilization of the training for other health professionals, who were not exposed to similar courses in their respective regions.

Participant Evaluation: We have also tried to evaluate the training. Events including conference setting and efforts of organizers were evaluated by the trainees, so that we should not repeat in the future the same mistakes we probably had committed during this training.

Documentation: In all these, every process has been documented from A to Z. We are lucky enough to get a well experienced, qualified and much disciplined health professional to document the training processes. Ato Demeke Feyissa engaged from day one up to the end of the training, developing the proceedings and documenting the entire processes. The participants have been given pre-test to see their level of confidence on the subject of the training and were finally given post test to gauge the benefits the trainees acquired from the course.

Organizers: As far as organizing is concerned, there are people who worked day and night behind the screen. W/t Meseret Fissehatsion, W/o Sisaynesh Bekele, Ato Kassaye Nebiyo and Ato Fikrewold Haddis from EPHA have energetically involved in organizing the course, preparing training materials and ensuring all the participants come for the training with the necessary information as well as facilitating funding.

Conclusion: From all the efforts made by all of you during and before the training, I am fully convinced that the training has successfully accomplished its objectives.

Therefore, I would like to thank the participants, organizers and the Proceeding Developer for all your contributions in the processes of this training. Particularly, I would also like to thank Dr. Wakgare and Dr. Mulugetta for your devoted and excellent contributions for the success of the training objectives.

Dear Participants, ladies and gentlemen,

At this moment, we are almost at our final stage of the training, therefore May I call Dr. Binyam, the EPHA Executive Director to hand over the certificate prepared by EPHA for the trainees and officially close the training processes lasted for ten days, by delivering the closing speech for this training. Thank You Very Much

The Training Coordinator

Annex -VII

CLOSING REMARK: RESEARCH/EVALUATION METHODOLOGY & ETHICS TRAINING

The Executive Director of EPHA made a closing speech and officially closed the Training session. The following is full speech delivered by Dr Binyam Ayele.

Dear public health professionals and EPHA Focal-persons,
Ladies and gentlemen,

As you all know, the Ethiopian public health association was established in August 1991 (G.C) in accordance to the Ethiopian civil code No. 404 of 1952 (E.C) registration. EPHA was established to achieve its mission of promoting better health services for the public and to maintain professional standards through advocacy, active involvement and networking with national and international organizations.

EPHA engaged in several activities in collaboration with universities. We are closely working with the School of Public Health (AAU) on leadership training in strategic information for regional HIV/AIDS program managers in cooperation with HAPCO and RHBs. EPHA also initiated the first monitoring and evaluation training at Jimma University, collaborating with the MoH and Tulane University.

Since 2007, EPHA has also started aids mortality surveillance project with Haramaya, Jimma, Gondar and Addis Ababa universities. Its purposes are for monitoring the ARV treatment effect in reducing AIDS mortality in particular, and generating health and demographic strategic information in general, using field training laboratories of the universities. We are also rigorously working with CDC to expand the AIDS mortality surveillance to Arbaminch and Tigray Universities to reflect nation-wide trends. In addition, EPHA is initiating field epidemiology training for the first time in Ethiopia; in collaboration with CDC, the Ministry of Health, and the School of Public Health (AAU).

Furthermore, EPHA is also working with regional health bureaus in the country. For instance, we have conducted the first most at risk population (MARP) study in collaboration with Amhara RHB and CDC. Using the Amhara MARPs study as an entry point, we are also proceeding with the necessary preparations to initiate the nation-wide MARP study together with the MOH-HAPCO, WHO, CDC and EHNRI. Moreover, we are also on the process of initiating intervention in Amhara Region based on the findings of the MARPs study in Amhara.

In all these efforts; the EPHA Focal-persons, universities, health bureaus, HAPCO and the ministry of health have been our main partners enabling EPHA to fulfill its missions and mandates. The Ethiopian Public Health Association has more than 2500 highly qualified members engaged in public health positions starting from the very district

health office to ministerial levels. EPHA has so many more plans in its future agenda to support the health delivery system. This plan can only be practical with the involvement of all the public health professionals coordinated by the EPHA Focal-persons and with your direct involvement in health service planning, organizing, and implementing the public health programs throughout the country. EPHA focal-persons are also expected to contribute to the EPHA publications by submitting research papers and abstracts for publication in the Ethiopian Journal of Health Development (EJHD), public health digest/Felegetena and may also involve themselves in the future to disseminate the EPHA publications in their respective regions. Some of the EPHA chapters are also in the process of managing MPH theses in collaboration with regional universities. However, all these activities cannot be effectively implemented without building capacity of the public health professionals in the country in general and the EPHA Focal-persons in particular.

Hence, the research methodology and ethical training is designed to enhance your understanding on health research in general, and research proposal writing, methodology design, data analysis, health research communication and ethical protection, in particular. Therefore, EPHA is very glad to invite you for this training, and hopes that you have benefited from the course and expects that the training inputs will be used to improve evidence based decision making for program planning and implementing in your own settings. It will also assist you to provide the necessary technical support to health sector managers and researchers in generating and applying strategic information to improve service delivery.

Thus, I would like to thank the trainers; Dr Wakgarie and Dr. Mulugetta for their commitment and devotion in realizing the objectives of this training and I am also thankful to the training organizers particularly to Ato Berhanu (The Training Coordinator) and W/t Meseret (Facilitator of the Training) for their unreserved efforts to realize the objectives of this important training.

Lastly, I would like to bring to your attention that EPHA would like to take this opportunity to express its deepest assurance once again to continue working with all of you, and will do its best to involve the participants of this training in EPHA activities relevant to your specific institution.

Finally, I hereby declare that the training has been successfully accomplished and I thank you all very much for your active participation in the training and EPHA's activities.

Thank you all for your continued collaborations.

Annex- VIII

List of Trainees

Ethiopian Public Health Association Research Methodology and Ethics Training February 11 – 20 2009, Adama Mekonnen Hotel, Nazareth/Adama						
List of Trainees and their Addresses						
S.N	**Name**	**Region**	**Organization**	**Level of Education**	**Responsibility**	**Relation to EPHA**
1	Direba G/Yessus	Harar	HRHB(Harari Regional Health Bureau)	Bsc.	HHSC Director	Member
2	Lemma Adinew	Benishangul	TGPDA (Tikuret for Gumuz People Dev't Association)	Bsc	Executive Director	Focal Person
3	Eskedar Solomon	SNNPR	Hawassa University	Mphil	Lecturer	Member
4	Bontu Fekede	Oromia	Oromia Health Bureau	Bsc	-	Focal Person
5	Mahteme Haile	Amhara	Dessie H. Science College	MPH	Dean and Lecturer	Chapter Head
6	Tadesse Alemayehu	Oromia	Haramaya University	Mphil	Lecturer & CBE coordinator	Member
7	Asrat W/Meskel	SNNPR	RHB	MPH	Malaria Team Leader	Chapter Head
8	Endrias Lenchamo	A.A	ESOG (Ethiopian Society of Ob & Gyn.)	Gynecologist &Obstetrician	St. Paul's Hospital	-
9	Araya Abrha	Tigray	Mekele University	MPH	Lecturer, Research & Community Service Unit Coordinator	Chapter Head
10	Tesfa Semagne	Tigray	Mekele University	MD+ Radiologist	Head, School of Medicine	-
11	James Bol	Gambella	GRHB (Gambella Regional Health Bureau)	MPH	ART Coordinator	Chapter Head
12	Seblework Tadesse	A.A	AARHB	MPH	IDSR Team Leader	Member
13	Girma Temam	SNNPR	AMU(Arbaminch University)	MPH	DSS Coordinator	Member
14	Jeylan Kassim	Oromia	MWU	MPH	Public Health Dept Head	Chapter Head
15	Melkamu Fenta	Amhara	RHB	MPH	TB/HIV Program Officer	Chapter Head
16	Amsalu Feleke	Amhara	University of Gondar	MPH	Post Graduate Student Coordinator & Instructor	Chapter Head
17	Hassen Ismael	Somali	Regional Health Bureau	, Msc	Monitoring and Evaluation Team Leader	Member

Annex .IX
A research proposal developed by a group during the Training, and used here to demonstrate one of the purposes of the training

A STUDY PROPOSAL ON ASSESSMENT OF PERSONNAL HYGIENE AND LATRINE UTILIZATION IN GONDAR ADMINISTRATIVE TOWN, AMHARA NATIONAL REGIONAL STATE, NORTH WEST ETHIOPIA

PREPARED BY

1. Melkamu Fenta

2. Amsalu Feleke

3. Mahteme Haile

Introduction

Communicable diseases are considered as major causes of morbidity and mortality in Ethiopia. The high prevalence of communicable diseases in the country is linked to the poorly developed socio-economic and environmental factors that have been inherent for centuries. Seventy five to eighty percent of disease burdens in Ethiopia are assumed to be preventable using measures like improving environmental health and nutrition interventions (1-4).

The health and well being of a population is directly affected by the coverage of water supply and sanitation (5).The impact of poor environmental conditions on the transmission of communicable diseases is well established. High incidence of childhood diarrhea, helminthiasis, trachoma and high mortality rates are associated with poor sanitation and water supply (6). Excreta contains a wide variety of human pathogens and removal of these pathogens from the immediate environment has a dramatic impact on health (7).

Intestinal Helminthiasis infections cause hundreds of thousands of avoidable deaths each year and are among the world's most common infectious diseases. Intestinal Helminthiasis is more prevalent throughout the tropics, especially among poor communities. Records showed increasing trends in helminthiasis infection, particularly in developing nations (8). In Ethiopia, the prevalence and distribution of intestinal helminthiasis varies from place to place (9).

Ethiopia is among the few countries where such problems have been clearly manifested (10). Health is highly influenced by water and sanitation related diseases. Gondar Town has variety of landscapes, dominantly covered with ragged hills and plateau formation, imparts variable temperature largely favouring a wide range of illness. Gondar is also an older town which is not properly planned, zoned and has no sufficient sanitation facilities. There are also common traditional malpractices in the town, including; early marriage practice, rape, uvuloectomy and tonsillectomy (11).

Statement of the problem

Gondar is a historical Town established in the beginning of 17th century and severed as a Capital city for Ethiopia for more than 200 years. Currently because of decentralization, Gondar Administrative Town is one of the 151 Woredas in Amhara National Region State.

Despite the fact that Gondar Administrative Town has relatively good access of health institutions and health information, diseases related to personal hygiene and environmental sanitation as a whole are high.

The Annual Report of Gondar Administrative Town Woreda Health Office in 2000 E.C depicts that among the 20 top diseases related to personal hygiene and latrine utilization are:-

- Helminthiasis No.2=13.6%
- Infection of all skin and SC tissue No.8=4.3%
- Dental and gum diseases No.9=3.4%
- Other unspecified infection and parasitic disease No.11=2.9%
- Eye infection (other than Trachoma) No.13 =2.5%

Many factors are contributing to the above mentioned diseases, such as lack of access to adequate and safe water, poor health seeking behaviour, availability and utilization of latrines, etc.

The expectation of the urban residence is more privileged compared to the rural for adequate and safe water supply and latrine facilities. But still the diseases pattern are increasing and the health service coverage is low (the town health service coverage is 64.5%), compared to other towns in the country.

Studies had been conducted some ten years back in this area and the present study is intended to assess the changes made. This study will try to find the main contributing factors diseases for law performances in relation to personal hygiene and latrine utilization.

Literature Review

Globally at the beginning of 2000, about 1.1 billion (17%) people of the world's population were without access to improved water. The majority of these people live in Asia and Africa (12).

The physical characteristics, availability and accessibility of basic household facilities are important in accessing the general welfare and socioeconomic condition of the population. In 2005, Ethiopian Demographic Health Survey (EDHS) respondents to the household questionnaire were asked about household drinking water and sanitation facilities. These included questions on the source of water, time taken to the nearest source, and the person that usually collects drinking water, water treatment prior to drinking and questions on sanitation facilities.

The majority (61%) of household in Ethiopia have access to an improved source of drinking water with access in urban areas is much higher than in the rural areas (94% and 56%, respectively). The most common source of improved drinking water in urban areas is piped water with 90% of household having access to this source. On the other hand, only 13% of rural household have access to piped water. The majority source of improved drinking water in the rural areas is protected springs (39%).

The proportion of household with access to piped water has increased from about 14% in 1994 (CSA, 1999) to 18% in 2000 and 24% in 2005. Only 8% of household reported having water on their premises. Households not having access on their premises were asked for the time taken to fetch water, 44% of all households (36% urban and 46% rural) take less than 30 minutes to fetch drinking water.

In the majority (74%) of households adult females are usually collecting drinking water. Female children under age 15 are over three times more likely than male children of the same age to fetch drinking water. All households were asked whether they treat water prior to drinking. An overwhelming percent of households (92%) do not treat drinking water.

Rural households are somewhat more likely than urban household in getting treated drinking water and this is mostly done by straining water through cloth. Sixty two percent of the Ethiopian households do not have a toilet facility. Small proportion (7%) of household use

improved toilets that are not shared. Urban households are more than three times as likely as rural household to have access to improved toilet facility.

In urban areas, a pit latrine with a slab (12%) is the major type of improved toilet facility. The proportion of households with no toilet facilities declines in both urban and rural areas (from 30% to 12% in urban areas and from 92% to 70% in rural areas). Sixty five percent of households have earth or sand floors and 25% having dung floors, more in the rural areas. Urban houses more likely than rural houses to have floors made with cement/bricks. Slightly over 3/4th of household have no bedrooms or have only one room for sleeping. Nineteen percent of the households have two rooms and only 3% have three or more rooms for sleeping. Urban household is more likely than rural households to have two or more rooms for sleeping.

Objectives of the Study

General Objective

- The general objective of this study is to assess personal hygiene and latrine utilization in Gondar Administrative Town, North Gondar, ANRS, North West Ethiopia.

Specific Objectives

- To assess the KAP of the people with regard to personal hygiene, latrine utilization, and drinking water
- To investigate the health seeking behaviour of the people
- To assess the availability of adequate and safe water supplies
- To determine the availability & coverage of latrine and utilization pattern
- To identify contributing factors for low utilization of latrine and personal hygiene

Methods

Study area

Gondar Administrative town is located in the North Western part of Ethiopia and it is about 180 Km from Bahr Dar Town which is the Regional capital city and 748 km away from Addis Ababa. Administratively, the town is divided into 12 urban and 11 rural kebeles/localities.

The Population residing in this administrative town is 289,656 (M=144829 and F=144,829). In this town there are one government referral hospital, four health centres and 10 health posts. With regard to the private health institutions, there are four special, two higher, 19 medium, 20 Lower clinics and three diagnostic laboratories.

Study design

- Descriptive Cross-sectional quantitative study design will be used. This will be complemented by qualitative study whereby, FDGs and key formant interview will be carried out with the dwellers of Gondar Administrative Town.

Source population

- The total population of Gondar Administration Town which is 289,656 are the source population.

Study population

- The study population of this research involves people who are residing in Gondar Administration Town. Selected government, NGOs, Kebele leaders and individuals who have direct relation with water and sanitation will be included as study population.

Study Units

- The study units will be randomly selected households

Study participants

- The study participants will be either head of the households or mothers or caretakers. Randomly selected household will be utilized to find out the study units.

Sample size and Sampling procedures

A total of 1239 individuals residing in the randomly selected kebeles of the town will be interviewed using structured questionnaire. This sample size is determined using the formula for estimating single population proportion:

$$n = \frac{(z_{\alpha/2})2\ p\ (1-p)}{d^2}$$

The following assumption are taken to obtain the maximum sample size

- **P**= Taking DHS 2005 report on access to safe drinking water, the proportion of those household who have access to safe drinking water is 0.56
- **Z**=Standard score at level of significance of 0.05 is 1.96
- **d**= the margin of error taken as be 0.02
- **design effect** of 2
- **Sample size**=590
- **Non-response rate** 10% (118)
- Then the total sample size will be =(590*2)+118=**1298**

Based on the above calculation the sample size will be **1298**

Study variables

- **Dependent variables:**
  - ✓ Availability, source and utilization of drinking water.
  - ✓ Number, type and utilization of latrine.
  - ✓ Health seeking behavior

- **Independent Variables:**
  - ✓ Socio-demographic characteristics such as age, sex, marital status, occupation, educational status, ownership of house

Inclusion criteria

- ✓ Those individuals who reside in the selected kebeles for more than six months.

Exclusion criteria

- ✓ Those who cannot communicate due to different illnesses.
- ✓ If the randomly selected house is an Agent, Office, Institution, etc

Operational definitions

- **Access to safe water**:-the geographical proximity of safe source of drinking water points within 15 minutes walk or radius of 1km from user houses.
- **Adequate water**:-the amount of drinking water that is available to support an individual daily basic need required for drinking, cleaning, and other domestic purposes to satisfy personal hygiene. Recommended values are 20 and 50 liters per capita/day for rural and urban residents, respectively.
- **Safe water**:- Water that does not contain harmful chemical substances, or microorganisms in concentration that could cause illness in any form or impurities that interfere with color, taste, transparency, and odor (WHO).
- **Drinking water coverage:** - the proportions of populations or households who have access to safe drinking water sources that ensures and/or limits absence of pathogenic micro-organisms'.
- **Personal hygiene:-**
- **Latrine coverage**:- the proportion of population or households who have access to some kind of latrine

- **Health seeking behavior: -** Determined by the frequency of using health facilities for illnesses related to poor sanitation.

Data collection

The data collection for this study will be carried out using two approaches.

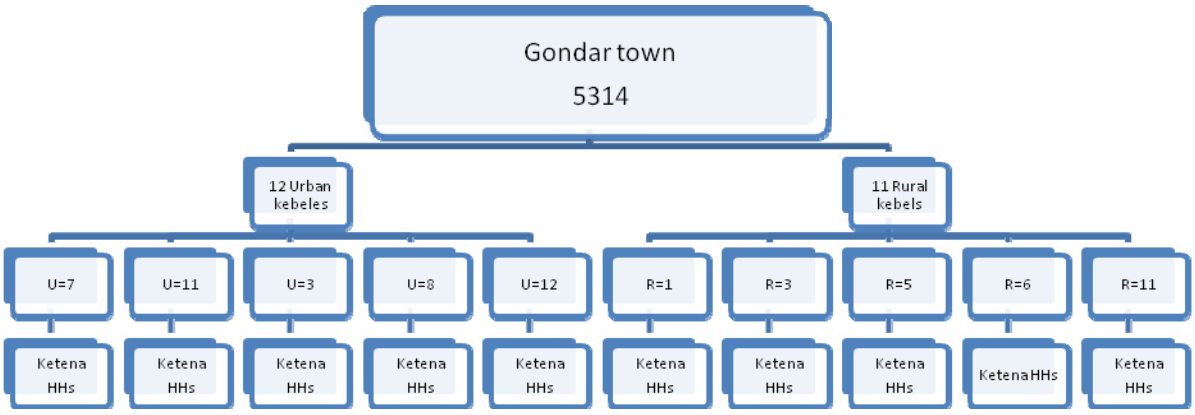
I. **The quantitative method** part will be carried out using pre-tested and standardized questionnaires. The questionnaires will be prepared in English and will be translated to Amharic and later on translated back to English.

Trained data collectors, 12th grade completed or college students will collect the data by moving house to house. Supervisors will follow the data collectors and the necessary correction will be made at the spot. The investigators also follow up the data collection process.

Based on the proportional allocation of households either the head of the house or mother or caretaker living in the selected houses will be interviewed. Prior to the interview consent will be obtained from the study subject.

II. **The qualitative study** will be conducted using FGDs and in-depth interview whereby semi-structured questionnaire will be designed. A total of --------FGDs will be carried out. The participants will be government officials, NGOs, kebele dwellers, who have direct involvement with water and sanitation. Tape recording will be utilized during the discussion, which will be transcribed later on. In-depth interview on key informants such as leaders, elderly mothers, heads of the relevant office etc, will be selected using the snowballing Method cont'dtechnique

Figure 1. Schematic presentation of sampling procedures



Data quality control

The questionnaires will be pre-tested in similar settings (kebeles) which are not part of the study. The necessary adjustments will be made after the pre-test.
Three days of training will be carried out for the data collectors and supervisors. During the training they will practice on how to complete the format/ questionnaires.
Close supervision will be carried out by the Principal investigators and supervisors during the data collection.
About 5% of the collected data will be assessed daily for the completeness that will help for correction in the coming days.

Data entry and analysis

The data collected using quantitative method will be entered to EPI info 2002 version 3.32 which will be transported to SPSS version 16.0 window soft ware computer programme for analysis. Frequencies, percentages, cross tabulation, odds ratio of different variables will be determined. Logistic regression will be used to control confounders.
The data collected using the qualitative method will be transcribed, coded, categorized and developed into themes for analysis.
The collected data will be presented using figures, tables and pictures.

Ethical Consideration

All the process will be started after securing permission from EPHA. A letter obtained from EPHA will be submitted to relevant and concern bodies at the Health Bureau ANRS, Regional Health Ethical Committee, Gondar Administrative Town such as City Administration, Health Office and kebeles, etc.
Informed consent will be obtained from individuals that are going to be involved in the study. Confidentiality of the information given and privacy of the interviewee will be kept throughout the data collection and the entire study period.

Dissemination of Results

This research is designed to assess personal hygiene and latrine utilization in the urban and rural kebeles of Gondar Administration town. The result f this study will be more beneficial for planners, health personnel's, City administration, NGOs, who are more engaged in the health care of the dwellers. Thus, the finding will be disseminated to the relevant body listed above and others directly or indirectly involved for the improvement of the health of the people.

Work Plan Schedule

Months	Description
February /2009	Proposal development
March /2009	Submission of proposal for Ethical Clearance & funding finalizing the preparation of data collection tools Securing, ethical clearance & fund
April	Identifying & mapping of the areas for data collection, Recruiting and selecting data collectors & supervisors, Training of data collectors & supervisors, Pre-testing and standardization of the questionnaires
May	Data collection
June	Data entry & clearance ,Data analysis
July	Write up
August	Submission of the final report

Budget break down needs to be included in details, using such formats

Items	Unit of measurement	Quantity	Unit price	Total	Remarks

Requisition for Ethical Clearance

Ethical clearance has been prepared with all details. Refer to Annex 1 for the details.

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Attachmt. 1

Ref. No_____

Date _____

To: EPHA Ethics Review Committee (EERCs)
Addis Ababa

Subject: Submission of Research Proposal for Review and Approval

We have planned to conduct a study on assessment of personal hygiene and latrine utilization in Gondar Administrative Town, from February to May -------.

Therefore, I kindly request your good office to review and approve the attached research proposal.

Please find the attached research proposal document.

With Best Regards

Melkamu Fenta (PI)

CC

- Gondar Administrative Town
- Gondar Woreda Health Office
- University of Gondar

Gondar

- Research and technology transfer core process
- Amhara Regional Health Bureau

Bahir Dar

Attachmt. 2

Questionnaires

CONSENT FORM

A study on assessment of personal hygiene and latrine utilization in Gondar Administrative Town, North Gondar, ANRS, North West Ethiopia.

Identification_____

Date of Interview_____

Time at the beginning of the interview_____

INTRODUCTION

Hello! Madam/Sir

My name is _____ and working for _____ organization. We are conducting a study on _____. The information collected will help the _____ to improve the _____.

CONFIDENTIALITY AND INFORMED CONSENT STATEMENT

I am going to ask you questions about the personal hygiene and latrine utilization. Your household number is randomly chosen using lottery method. Your name will not appear on this questionnaire and all the information you provide to me will be strictly confidential. You are not obliged to answer any questions that you don't wish to answer, and you can put an end to this interview at any time, if you wish to do so. Your participation in this study does not involve any direct risk or benefit for you but is very useful since your answers, as well as those of other participants/ clients, will help to improve the personal hygiene and latrine utilization in this area. Would you like to participate in the study?

1. Yes_____ 2. No_____

INTERVIEWER

If the answer is "Yes", please sign below to certify that the client gave his/her oral consent to take part voluntarily in the study. Otherwise, thank the client, conclude the conversation and file the questionnaire. _____

Signature

Result Code _____ (1=completed, 2=partially completed, 3=refused, 4=other)

Time at the end of the interview _____

Checked by Supervisor, Name & Signature _____

PART-1. SOCIO-DEMOGRAPHIC CHARACTERSTICES

S.no	QUESTION	Choice of response/circle the answer/	Code
1.	Sex	1.Male 2. Female	
2.	Religion	1. Orthodox Christian 2.protestant 3.catholic 4. Muslim 5 . other specify -------	
.3.	Age	----------years	
4.	Ethnicity	1.Amhara 2.Tigray 3. Oromo 4.Gurage 5.Other specify----------	
5.	Educational status	1. Unable to read and write 2. Read only 3. Only able to read and write 4.0 Grades: 4.1- six grade 4.2. 7 – 8 grades 4.3. 9-10 grades 4.4. 11-12 grades 5. Certificate holder 6. Diploma holder 7. Degree holder	
6.	Occupation	1. House wife 2. Merchant 3. Government employee 4.Daily laborer 5.Farmer 6.student 7.Local beer seller/ Tela ,Tej,Areki / 8.Other , specify ----------	
7.	Monthly income	1. ≤150 Eth. birr 2. 151-400 Eth. birr 3. 401-600 Eth. birr 4. 601-900 Eth. birr	

		5. 901-1500 Eth. birr 6. ≥ 1501 Eth. birr	

PART-2. HOUSING

8	House visited	1.Dwelling 2. business center 3. Others, specify ----------	
9	Ownership	1.Private 2.Kebele 3.Rented from individuals	
10	How many partition it has?	----------	
11.	How many people live in the house?	1. only one person 2. two persons 3. three persons 4.four persons 5. five persons 6.six and above	
12	How many window/s/ does/do the house has/have ?	1. one 2. two 3. three 4. four 5. more than five	
13.	In what way does the window constructed /situated?	1. on opposite direction 2. Side by side 3. parallel	
14	Is air flowing freely in the house?	1.V.good 2.Good 3.Bad	
15	Does the house have ceillings?	1.Yes 2.No	
16	How is the light?	1.Adequate 2.Moderate 3.Poor	
17	How is the House cleanliness /observe/	1.V.good 2.Good 3.Bad	
18	Does the house has a kitchen?	1.Yes / skip to ques. No 19/ 2.No /skip to ques. No 21/	
19	If your answer to ques.no.18 is yes where is it constructed?	1. separately from the house 2. attached to the house 3. together with animal cages	

20	What facilities does the kitchen have?	1.piped water 2.Improved stove/smoke free/ 3.Other specify	
21	If the answer to question ,no.18 is no Where do you prepare your food?	1.open filed 2.in side the house 3. Other specify ……	

PART-3. LATRINE

22	Do you have a latrine?	1 .Yes /Skip to ques.no 23/ 2.No/Skip to ques.no 31/	
23	If your answer to question no. 1 is yes, who is the owner	1. individual 2. communal 3.Public	
24	what type of latrine do you have	1. Ventilated improved privy (VIP) 2.Traditional pit latrine 3. Water flash 4.Public 5.Other specify----------	
25	Does the latrine has a hand washing facilities for use after toilet?	1. Yes / observe/ 2.No	
26	Does the latrine have super structure?	1. Yes / observe/ 2.No	
27	Where is your latrine located?	1.Inside the house 2.Inside the compound 3.Near the house 4.Far from the house	
28	Do you use your latrine?	1. Yes / observe/ skip to ques.no 28/ 2.No/skip to ques .no 30/	
29	If your answer to question no 28 is yes who are using the latrine?	1.children only 2.Elder only 3.all family	
30	If your answer to question. No 28 is no,		

	what is the reasons?		
31	If your answer to question no 22 is No, what is /are the reason /s/?	1.Lack of space 2.High cost to construct 3.Not needed by household 4.Other, specify----------	
32	Where do you defecate?	1. Open space 2. River 3. At your back yard 4.Other, specify----------	

PART-4. WATER

33	What is the source of your water?	1.Piped water in the premises 2. Piped water from the public distribution site 3.Protected spring water 4.unprotected spring water 5.Protected well water 6.unprotected well water 7. River 8.Other specify ----------	
34	Do you use home based water treatment before drinking ?	1.Yes/skip to ques.no 35/ 2. No/skip to ques.no 36/	
35	If your answer to question no.34 is yes What treatment do you use?	1.Boiling 2.Chlorination 3.filitering by cloth 4.Other ,specify----------	
36	If your answer to question no.34 is yes ,what is your reason		
37	How many minutes/hours does it take to fetch the water?	1.less than 30 minute 2.30 minute to one hours 3. One hour up to two hour. 4.More than two hour	
38	How much water do you use daily?	1. less than 20 liter 2. 21 -40 liter 3.41 - 60 liter 4. ≥ 61 liter	
39	How do you collect the water?	/Multiple answer possible/ 1.Jerikan of _____ liters 2.Pot of _____ liters 3.Baldi _____ liters 4.Other specify ----------	
40	How do you store water?	/Multiple answer possible/ 1.Barrel	

		2.Jerikan 2.Pot 3.Baldi 4.Other specify ----------	
41	How do you use water?	/Multiple answer possible/ 1.Dipping 2.Tilting 3.Other specify -------	
42	What problem/s/ do you face in relation to water?	/Multiple answer possible/ 1. Scarcity 2.Absence 3.Cleanness 4.Distance 5.Labour 6.Money 7.Time 8.Other specify	
43	How many liters of water do you use for all purpose per day?	---------- liters	

Part -5 . PERSONAL HYGEINE

44.	Do you wash your face?	1.Yes 2.No	
45.	If your answer to question No.44 is yes, How many times do you wash your face in day times?	1.One time 2.Two times 3.Three times 4.As needed 4. ≥ to four times	
46.	Do you brush your teeth?	1.Yes 2.No	
47	If your answer to question 46 is yes, how many times do you brush your teeth in day times?	1.One time 2.Two times 3.Three times 4.As needed 4. ≥ to four times	
48	At what time do you brush your teeth usually?	1.Early in the morning 2.After a meal 3.At bed time 4.Anytime	

49.	If your answer to question No 46 is No, what is the reason?		
50.	When do you wash your hands?	1.Only before eating 2.Only after eating 3.Before and after eating 4.After latrine utilization 5. After caring the child 6.Before preparing food 7.After preparing food 8.Other specify--------	
51.	If your answer to question No 50 is Yes, Do you use soap to wash your hands?	1.Yes 2. No	
52.	If your answer to question No 50 is Yes, how often do you use soap?	1.Always 2.Sometimes 3.Rarely	
53	How many times do you take bath?	1.Daily 2. Every other day 3. Once in a week 4.Every two weeks 5.Once in a month 6. others, specify ----------	
54	How many times do you wash your clothes?	1.Daily 2. Every other day 3. Once in a week 4.Every two weeks 5.Once in a month	

Part -5 WASTE DISPOSAL

55.	Where do you dispose your solid waste?	1. Open field 2.Private pit 3. Kebele selected site 4. Local collector usually take it 5. Municipal collection container 6.Throw it in the river 7.Burn it in your compound	
56.	What problem /s/ do you have in relation to solid waste disposal?		

57	Where do you dispose your liquid waste?	1.Open field 2. Private pit 3.Kebele selected site 4.Dispose it in once own compound 5.Other specify----------	
58.	What problem /s/ do you have in relation to liquid waste disposal?		

PART -6. HEALTH SEEKING BEHAVIOR

59	Is there a family member who has been ill during the last two weeks?	1.Yes 2.No	
60	If your answer for question No.59 is yes, what was sign and symptom?		
61	If your answer for question No.59 is yes, have you taken to treatment?	1.Yes 2.No	
62.	If your answer for question No.59 is yes, where did you take the sick?	1.Health institution 2.Brought drug from vendor 2.Holy water 3.Visit traditional healer 4.Go to local injector 5. Nothing ---------- 6.Other specify----------	
62	If your answer for question No.59 is No, what is the reason for not visiting the health institution?	1. The disease does not need visiting health institutions 2. No clinic nearby 3. Disease disappear by it self 4. No money 5. Other specify-----	

That is the end of the question .Thank you very much for your cooperation and sacrificing your time!!

Attachmt.3

In-depth Interview Questionnaire guide

Study on Personal Hygiene and Latrine Utilization

1. Name of the institution/private _____
2. Age ____
3. Sex _____
4. What is your field of graduation/training? _____
5. When did you graduate? (if so)
6. What is your work experience?
7. How long have you been lived in this area? _____
8. What is your job in the area? _____
9. What do you understand by personal hygiene and latrine utilization?

_____

_____

10. What do you think of the hygiene, latrine, waste disposal and water systems in this area?

    _____

    _____

11. How do you and others get water for consumption and other purposes?

    _____

12. What are the main problems related to getting safe and adequate water in the area?

    _____

    _____

13. What do you suggest to alleviate the above mentioned problems?

    _____

14. What is the practice of latrine usage in the area?

_____

15. Have you noticed any problems related to latrine and waste disposal systems?

_____

_____

16. How could you and others try to solve the above mentioned problems?

_____

_____

17. What are the main factors aggravating the above mentioned problems?

_____

_____

18. If you are assigned/requested to govern this area, what measures do you take to alleviate the above problems?

_____

_____

19. Do you think the responsible bodies (kebeles/city administration, health professionals, etc.) are trying to solve problems related with environmental sanitation?

If yes/no, how?

Attachmt.4

Question guide for focus group discussion

Greeting

Introduction

Here are some discussion points which we will discuss them together for the coming one and half hour.

1. What are the main environmental sanitation problems in your area?

2. What are the main causes for the above problems?

3. How do you tackle the above mentioned problems?

4. Is there any problem related to the health service provision in the area?

5. What do you think are the root causes of these problems?

6. As part of the community, how do you solve them?

7. is there collaborative work among the community, kebele leader, city administration, community health workers to solve the above problems and what do you propose?

Thank you!!!

EPHA Executive Board Members

Dr Mengistu Asnake	President
Dr Solomon Worku	Vice- President
Ato Mirgisa Kaba	Member
S/r. Tekebash Araya	Member
Dr Yared Mekonnen	Member
Dr Yelma Melkamu	Member
Dr Wakgari Deressa	Member
Dr Zewditu Kebede	Treasurer

Monographs Published by EPHA-CDC Project

1. Extract of MPH Theses works on HIV/AIDS/STI/TB (Extract No, 1 (September 2004);
2. Identifying HIV/AIDS, Sexually Transmitted Infections and Tuberculosis Research Gaps and Priority Setting Agenda in Ethiopia (December 2005);
3. Young People's HIV/AIDS & Reproductive Health Needs and Utilization of Services in Selected Regions of Ethiopia (December 2005) ;
4. The Role of Indigenous Practice in Assisting HIV/AIDS Orphans at Community Level in Selected Localities of Ethiopia (December 2005) ;
5. Determinants of Behavioral Change in HIV/AIDS and IEC-BCC Approach for Rural Ethiopia (December 2005);
6. Extracts from EPHA Research Awards and Master's Theses in HIV/AIDS (Extract No.2 (December 2005) ;
7. National HIV/AIDS Advocacy Framework and Guideline (In Collaboration with HAPCO (March 2005);
8. Research Training Modules (7) (In collaboration with ESTA-June 2005);
9. Factors Affecting Acceptance of VCT in North and South Gondar Administrative zones (June 2006);
10. Intention to Use Condoms and Remaining Faithful in Students at Gondar University (June 2006).
11. Masters Theses Extracts on HIV/AIDS- (Extract No.3 (Aug. 2007) ;
12. HIV/AIDS Sexually Transmitted Infections and Tuberculosis Training Needs Identification and Priority Agenda Setting Study (March 2008);
13. Masters Theses Extracts on HIV/AIDS- (Extract No.4 -May. 2008);
14. Masters Theses Extracts on HIV/AIDS- (Extract No.5 -Sept. 2008);
15. Master's Theses Extracts on HIV/AIDS (Extract No. 6-May 2009).

EPHA Standing Publications:

Ethiopian Journal of Health Development (EJHD) -3 Issues Annually;
Felege-Tena Newsletter (FTN) –Quarterly Issue
Public Health Digest (PHD)- Quarterly Issue