# POSTGRADUATE DIPLOMA COURSE IN RESEARCH METHODOLOGY

## **OBJECTIVES OF COURSE**

The role of research in development of biomedical and social sciences is becoming increasingly important in this era of emerging disease epidemics, environmental pollution, scarcity of natural resources and the quest for economic development.

For quality and good research outcomes there is need to build capacity by increasing the number of researchers through appropriate training. The Research Methodology Course will meet the training needs of those involved or interested in quality biomedical and operational research. It will build on principles of epidemiology, biostatistics, health economics and social sciences.

The course targets graduates in biological disciplines, veterinary science, medicine, physical and social sciences who intend to pursue research activities at various levels including higher degree programmes (MSc. and PhD) in tertiary institutions.

The Objectives of the course are to:

- a) Enable participants design and implement research as well as translate research results into planning, policy, and implementation of evidence based programs.
- b) Organize, present, interpret and utilize research data for decision making and policy formulation.
- c) Utilize qualitative approaches in policy analysis and data gathering.
- d) Utilize operations research methods and study designs.
- e) Utilize concepts of economics and management in the health sector.
- d) Utilize the computer in communication, analysis of data and preparing reports and presentations.
- e) Conduct appropriate literature search and handle references.
- f) Demonstrate ability to read, write and make research presentations.

# DETAILS OF THE COURSE

# <u>WRM 601</u>

# **COMPUTER APPLICATIONS IN RESEARCH METHODS**

#### **Unit Objective**

Utilize the computer in communication, analysis of data and preparing reports and presentations;

#### Hardware and Software

#### **Objectives:**

At the end of the session students should be able to

- a. Identify the main components of computers and computer applications
- b. Describe the functional components of computer hardware, including peripheral devices.

- a. Didactic:
  - i. Computer hardware
  - ii. Computer Software
- b. Practical
  - i. Identifying different types of computers, (mainframe, personal computers and others)
  - ii. Identifying Components of a PC (connector Ports, Data Cables, The Power Supply, VDU, Mother board, Installing/Removing Adapter Cards, Drive Controllers, Hard Drives, Video Cards, Optical Drives, central processing unit)
  - iii. Installing Memory
  - iv. Formatting a Drive
  - v. Using Peripheral devices-printers, scanners, external hard disk, tapes, flash disks, external drives Digital Cameras, Modems (for communication)
  - vi. Using Input Devices e.g. Keyboard, Mouse, Scanners, etc
  - vii. Using Output Devices (Monitor, Printer, Speakers)
  - viii. Identify different types of software, the tasks for which each type of software is most suited, and the popular programs in each software category
  - ix. Identify Operating Systems, Program Codes, Applications, etc.

## **Computer Operating Systems**

#### **Objectives:**

At the end of the session students should be able to

- a. Use an Operating System
- b. Describe the common program functions
- c. Manage files using an operating system

- a. Didactic:
- i. Types of operating systems (stand alone, network)
- ii. Using an operating system
- iii. Common Program Functions
- iv. File management
- b. Practical
  - i. Manipulating and controlling the Windows desktop, files and disks
  - ii. Creating and managing folders and files
  - iii. Changing system settings and installing software
  - iv. Starting and exiting a Windows application and utilizing sources of online help
  - v. Changing Drives, and folders, Submitting Homework, Opening Files and Backing Up Files
  - vi. Identifying common on-screen elements of Windows applications, changing application settings and managing files within an application

- vii. Performing common editing and formatting functions
- viii. Performing common printing functions
- ix. Explaining the need for alertness on Computer Security-Virus Protection (Anti-Virus Software) alarms

#### Word Processing

#### **Objectives:**

At the end of the session students should be able to

- a. Use Word to create, edit, format, and print a document; apply different paragraph and character formatting; insert objects, such as tables, pictures, and charts
- b. Link Word to other data sources.

## Contents:

- a. Didactic:
  - i. Typing and editing
  - ii. Formatting a document
  - iii. Saving and retrieving a document
  - iv. Printing documents
  - v. Sharing documents

#### b. Practical

- i. Open an Existing Document, Delete Blocks of Text, Move and Copy Text, Copy Multiple Items
- ii. Type and edit a document Text Appearance, Spell Check, Thesaurus, Other Tools, Tables, Columns Footnotes & Endnotes, Importing Graphics,
- iii. Save a Document, Use Automatic Text Features and Obtain Online Help
- iv. Automatic formatting tools
- v. Insert, edit and format tables in a document
- vi. Use different styles, colors, sizes, orientation, etc.
- vii. Apply Character Formats, Change the Font and Font Size, Add Highlighting and Color to Text, Copy Text Formatting, Paste Options
- viii. Format paragraphs (Change Paragraph Alignment, Change Line Spacing Within a Paragraph, Add a Border and Shading to a Paragraph, Set a Custom Tab, Add Indents, Create Numbered and Bulleted Lists, Create an Outline Numbered List)
- ix. Add tables (Create a Table, Change Table Structure, Add Table Borders and Shading, AutoFormat a Table)
- x. Use Word Timesavers (Create a New Document Using a Template and a Wizard, Insert a Symbol, Insert the Date or Time, Find and Replace Text, Check Spelling and Grammar, Replace a Word Using the Thesaurus)
- xi. Use different types of printers and applications (Set Page Display and Printing Options, Preview a Document, Set the Page Orientation, Create Headers and

Footers, Change Margins, Insert a Page Break, Align Text on a Page, Print a document)

xii. Use computer applications to share documents

## **Common Data Base and Analysis Programs**

## Objectives:

At the end of the session students should be able to

- a. Use worksheet in database creation and manipulation
- b. Apply statistical and logical techniques to describe data
- c. Perform statistical analysis on data gathered in order to draw conclusions.

## Contents:

- a. Didactic:
  - ii. Data collection forms
  - iii. Data Base management
  - iv. Spreadsheets
  - v. Data analysis Programs
- b. Practical
- i. Design a data collection Form
- ii. Operate Epi-Info (Create a data base, design a simple query, create a report)
- iii. Create a Spreadsheet (edit cell contents, input formulas for calculations, copy formulas to blocks of cells, Print appropriate portions of the spreadsheet, save and retrieve spreadsheet files, Use Multiple Worksheets, Create a Chart, Use data sort)
- iv. Analyze data using Epi-Info, SPSS, STATA

## **Presentation Tools**

#### **Objectives:**

At the end of the session students should be able to

- a. Prepare and present a presentation
- b. Create a presentation using PowerPoint software

- a. Didactic:
  - i. Presentation Skills
  - ii. Preparing a presentation
- Types of presentation hardware (MS-PowerPoint, Harvard Graphics, Lotus Freelance)
  - iii. Power point presentations

- b. Practical
  - i. Identify components of a presentation
  - ii. Identify who the audience is and what they want
  - iii. conduct a needs analysis
  - iv. Create a power point Presentation (specified slide, use a template or wizard, move through different views, copy slides, insert headers and footers)
  - v. Modify a presentation (chage order of slides, find a replace text, modify the slide master, apply a design template, modify slide sequence in outline pane)
  - vi. Work with Text (Check spelling, Change and replace text fonts, Import text, Change the text alignment, Create a text boxes, Use the Wrap text in feature, Use the Office Clipboard, Use the Format Painter feature, Promote and demote text in slide and outline panes)
  - vii. Work with Visual Elements (Add a picture from the Clip Art Gallery, Add and group shapes using WordArt or the Drawing Toolbar, Apply formatting, Add text to a graphic object using a text box, Scale and size an object, Create tables within Microsoft PowerPoint)
  - viii. Customize a Presentation (Add AutoNumber bullets , Add speaker notes, Add graphical bullets, Add slide transitions, Animate text and objects)
  - ix. Create Output (Preview presentations in black and white, Print slides in a variety of formats, Print audience handouts, Deliver a Presentation, Start a slide show on any slide, Use on-screen navigation tools, Print a slide as an overhead transparency)
  - x. Manage Files (Save a file as a new presentation, Use the Microsoft Office Assistant)

#### Internet and E-mail

#### **Objectives:**

At the end of the session students should be able to

- a. Use Internet for communication
- b. Communicate using Electronic Mail:
- c. Use Networks and the Internet communication
- d. Discuss the Impact of Computing and the Internet on Kenyan Society

- a. Didactic:
  - i. Internet literature search
  - ii. Electronic Mail
  - iii. Use Networks and the Internet
  - iv. Impact of Computing and the Internet on Kenyan Society
- b. Practical

- i. Identify different types of information sources on the Internet
- ii. use a Web browsing application
- iii. Conduct Electronic internet literature search (relevant websites, data bases)
- iv. Sending and replying to E-mail
- v. Network computers

#### Website development and its application

## **Objectives:**

At the end of the session students should be able to

- a. Search the Web
- b. Create a Home Page

- a. Didactic:
  - i. Web applications
  - ii. Web design and hosting
  - iii. Address links
  - iv. Web images
- b. Practical
  - i. Create a home page (Background Colors and Images, Font Styles and Colors)
  - ii. Create web images (Table Basics, Data Tables)

# **OPERATIONAL HEALTH RESEARCH**

# Goal

The overall goal of this unit is to provide the learner with skills on the conduct of health system operational research to generate best practices and evidence for addressing priority health problems. This encompasses translation of knowledge and technologies to field utilization and clinic use; best implementation of existing and new prevention strategies, therapeutic tools and other interventions for broad-based field use; and the study of barriers to such translation and implementation that influence the effectiveness of interventions in "real world settings."

# Objectives

At the end of this unit the learners should be able to;

- 1. Describe the concepts and methods of health systems operational research;
- 2. Demonstrate knowledge and skills in problem identification and research priority setting;
- 3. Develop strategies for evaluating disease control programs;
- 4. Demonstrate skills in program performance evaluation;
- 5. Demonstrate knowledge and skills required for the translation of research finding into policy and practice.

# **Concepts And Methods For Health Systems Operational Research**

# **Objectives:**

By the end of this topic the participants will be able to;

- 1. Discuss the concepts of health systems operation research
- 2. Discuss philosophy of essential national health research (participation of community and policy makers)
- 3. Describe the methods of health systems operational research

# Contents

- Definition of operations research
- Identifying research problems
- Research design (exploratory/diagnostic studies, field intervention studies, evaluative studies, cost effectiveness studies)
- Current national and international health systems research

# **Research Priority Setting**

# **Objectives:**

By the end of this topic the participants will be able to;

- 1. Define principles of problem identification using existing literature, clinical and health systems data as well as other source of information ;
- 2. Demonstrate knowledge and skills in selecting strategies for problem resolution; and
- 3. Demonstrate an ability for research priority setting.

# Contents:

- Problem identification (reason for problems, unanswered questions)
- Determinants and risk factors (incidence/prevalence of disease, geographic distribution, affected populations,)
- Policies review of existing policies
- Problem justification (how current is it, magnitude, relationship to ongoing problems)
- Strategy selection to address identified problems quality of care framework (range of services, information for clients, technical competence of providers, client-provider inter-personal relationships, continuity of services), guidelines for strategy selection, justification of strategy, involvement of policy maker and community and other stake holder.

# Approach To Disease Control

## Objective

By the end of this topic the participants will be able to describe appropriate strategies for evaluating disease control programs;

## Contents:

- Appropriate use of terms (control, elimination and eradication)
- Concepts of transmission infection and morbidity control
- Vertical versus horizontal approaches
- Outbreak investigations
- Program impact evaluation

# Project Implementation

# **Objective:**

By the end of this topic the participants will be able to demonstrate skills in program performance evaluation;

# Contents:

- Identification of research needs
- Formulation
- Administration
- Monitoring and evaluation (process evaluation,
- Budget, funding
- Report writing

# **Translation Of Research Finding Into Policy And Practice**

# **Objectives:**

By the end of the topic the participants will be able to demonstrate knowledge and skills required for the translation of research finding into policy and practice.

- Dissemination •
- Appropriate packaging of information for different audiences Utilization of results and further evaluation. •
- •

## SCIENTIFIC COMMUNICATION

### Goal:

Overall goal of this unit is to provide the learner with skills in searching for scientific materials, making oral and written presentation of scientific materials, and critical appraisal of published literature.

## **Objectives:**

At the end of this module the learner will be able to:

- Demonstrate the ability to do a literature search using manual and electronic sources;
- Write a scientific communication;
- Demonstrate skills in oral presentation of scientific materials; and
- Able to effectively carry out critical appraisal of published scientific material.

## Literature Search Using Manual And Electronic Sources Of Scientific Materials

#### **Objectives:**

At the end of this unit the learner will be able to;

- 1. List the common sources of scientific materials,
- 2. Compile a bibliography,
- 3. Use standard review techniques to develop a literature review.

#### Contents:

- Manual sources of data
- Electronic sources of data (use of key words, electronic search engines)
- Library and journal collections special data bases
- Interpretation and utilization of the literature, hierarchy of evidence and quality of data (case report, analytical studies, clinical trials)
- Compiling a bibliography, standard techniques of referencing literature, endnote

### Scientific Writing

#### **Objective:**

In this unit the learner will be able to;

- 1. List the different types of scientific communications;
- 2. Describe the critical contents of different types of scientific communications; and
- 3. Develop a scientific communication (abstract, poster, manuscript).

- Types of scientific communications (abstract, poster, manuscript)
- Structure of different types of scientific communications (Randomised controlled trials (RCT's), non-randomized evaluations, meta-analysis, observation studies, systematic reviews)
- Preparation and submission of manuscripts, abstracts and posters.

# **Oral Presentation Of Scientific Materials**

# **Objective:**

At the end of this unit the learner will be able to:

Demonstrate skills in making an oral scientific presentation including the appropriate use of multi-media to illustrate the presentation

# Contents:

- Structure of oral scientific presentation
- Use of multi-media in oral scientific presentation (slides, power point, flip charts, and overheads)
- Practice in developing and presenting oral scientific communications

# Appraisal Of Published Scientific Materials

# **Objective:**

At the end of this unit the learner will be able to conduct a critical evaluation of published literature for validity, generalizability, reproducibility and relevance.

- Criteria for scientific evaluation
- Valid and invalid criticism (chance, bias, confounding)
- Examples of critical appraisals Cochrane library
- Evidence based medicine Use of critical appraisal in medical practice.

## WRM 604 Health Economics, Policy and Planning

## Rationale

Developing countries have scarce resources. Health interventions therefore need to be both effective and cost effective.

## **Objectives**

At the end of this unit the participants will be to:

- 1. State key concepts in health economics
- 2. Specify how health care policy is formulated
- 3. Specify the processes in health planning
- 4. Request for cost effectiveness research and utilize the findings
- 5. Utilize planning & policy models to ensure that research findings are implemented

## Introduction to economics and health economics (15hrs)

#### **Objectives**

At the end of this topic the participant will be able to:

- 1. Describe the history of health economics
- 2. State the role of economics in our daily life
- 3. List the key concepts in health economics
- 4. Relate the development & role of health economics

#### Contents:

- History of Economics, overview of economics, definition& scope,
- Concepts in economics: Scarcity & choice, Opportunity choice, Supply & demand, consumer & producer surplus
- Economics in our daily life
- Development and role of health economics: Concepts of equity, efficiency & access, Welfare economics (organizing social services)

#### Introduction to Health Policy & Planning (15hrs)

#### **Objectives**

At the end of this topic, the participant will be able to:

- 1. Provide an overview of principles of planning
- 2. Describe policy formulation processes
- 3. Translate research into policy
- 4. Give examples of health policy success and failures and discuss why

- Principals of planning: introduction, personal planning, setting goals, time management, models of planning, levels of planning,
- Policy formulation & decision making

# **Health Management**

## **Objectives**

At the end of this topic, the participants will be able to:

- 1. Define the concepts of organization and management
- 2. Apply concepts of management & organization in the management of health services
- 3. Analyse the components of the health system and factors that influence the delivery of healthcare

## Contents:

- Over view of management, organization
- Management and organization concepts in health services management: setting objectives, directing/leadership, controlling, evaluating, & management by objectives,
- Organization of health services in Kenya, health information systems

## Financing Health Services

#### Objective

At the end of this topic, the participants will be able to:

Compare & contrast the different methods of healthcare financing

#### Contents:

- Trends in healthcare financing,
- Methods of financing health services,
- Public & private sector role in the provision of health services

#### Health Care Evaluation

#### **Objectives**

At the end of the topic, the participants will be able to:

- 1. Be able to undertake an economic evaluation of a health service
- 2. Be able to utilize the findings from health economic evaluation.

- Evaluation: Setting priorities, medical & clinical audit, Cost effectiveness analysis, cost benefits analysis,
- Societal values of life, health status QALY, DALY

- Measures of efficiency, common causes of inefficiency
  Concepts, tools in monitoring health care
  Policy formulation, program implementation

# QUALITATIVE RESEARCH METHODS

## **Objectives**

At the end of the course the learner will be able to:

- Describe the role of qualitative methods in research;
- Define the various types of qualitative methods;
- Apply appropriate qualitative methods in research;
- Demonstrate skills in development of qualitative research tools;
- Demonstrate skills in analysis of qualitative data and
- Discuss the use of qualitative research techniques in hypothesis generation and policy development.

- Role of qualitative methods in research
- Types of qualitative methods of research.
  - Key informant interview.
  - Focus group discussion.
  - o Narrative interview.
  - o In-depth interviews.
  - Key informant interviews
  - Participatory assessment.
  - o Participant observation.
  - Time analysis.
- Community mapping
- Application of qualitative methods in research
- Development of qualitative research tools.
- Analysis of qualitative research data.
- Utilisation of qualitative research techniques in hypothesis generation and policy development

## **PROPOSAL DEVELOPMENT**

## Introduction To Proposal Writing

## Objectives

At the end of the session students should be able to

- a. Describe why it is important to write a research proposal
- d. Describe various types of proposals and when they can be used
- e. Outline components of a proposal

#### Content

- a. Didactic:
  - x. Importance of proposals- work planning, standardization, role definition, budgeting, feasibility, peer review, social acceptability, and ethical review
  - xi. Types of proposals- program, operation research, and epidemiologic research proposals
  - xii. Components- background and literature review, question, hypothesis, justification, objectives, methods, analysis, ethics, dissemination and utilization and budgets
- c. Practical
  - i. Orientation to sample research proposals
  - ii. Development and group discussion of proposal outlines based on theoretical scenarios
  - iii. Develop and present own proposal outline

# **Developing A Research Question/Hypothesis:**

#### Objectives

At the end of the session students should be able to identify and write up research questions, hypothesis and problem statements

#### Contents:

- a. Didactic
  - i. Identifying research questions/hypothesis/problem statements
  - ii. Characteristics of research questions/hypothesis/problem statements (real, important, answerable)
  - iii. Writing of a research question/hypothesis/problem statement
- b. Practical
  - i. Identify research questions from hypothetical scenarios
  - ii. Development and group discussion of research questions
  - iii. Develop and present own research questions refined after brief literature review

#### Justification For A Proposal

#### **Objectives:**

At the end of the session students should be able to write a justification or rationale of their research questions.

# Contents:

- c. Didactic
  - i. Importance of justifications
  - ii. Strategies in justification
  - iii. Writing up justification
- d. Practical
  - i. Critique justifications from sample proposals
  - ii. Develop and present justifications of own research questions based on literature review

# **Developing Objectives For A Research Proposal**

# **Objectives:**

At the end of the session students should be able to

- a. Describe immediate/ultimate, broad/specific and primary/secondary objectives
- b. Write appropriate proposal objectives

# Contents:

- a. Didactic
  - i. What are objectives?
  - ii. Importance of objectives
  - iii. Characteristics and types of objectives
  - iv. Examples of objectives
- b. Practical
  - i. Develop objectives based on theoretical scenarios
  - ii. Critique objectives from sample proposals
  - iii. Develop and present own objectives based on own research questions and justification

# **Research Methodology**

# **Objectives:**

At the end of the session students should be able to

- f. Describe and select study designs to address specific questions and objectives
- g. Describe research populations and procedures used in their selection
- h. Describe study procedures and ethical issues in carrying them out
- i. Outcome measurements
- j. Develop budgets and justifications

# Contents:

a. Didactic

- i. Study designs
- ii. Selecting study designs (ethical, practical, financial, administrative and technical issues)
- iii. Research populations
- iv. Ethics
- v. Sampling
- vi. Budgets and justification
- b. Practical
  - i. Identify and critique study designs, research populations, methods of study population selection, study procedures and ethical issues from sample proposals
  - ii. Select, describe and present own study design, research population and method of selecting participants
  - iii. Describe and discuss own study ethical issues, budgets and justification

#### **Design Of Instruments**

#### **Objectives:**

At the end of the session students should be able to

- a. Describe and select methods of collecting quantitative data and qualitative data
- b. Appreciate the process of health status measurement
- c. Describe ways to check quality of data
- d. Develop data collection instruments

## Contents:

- a. Didactic
  - i. Structured interviews, self administered questionnaires, services statistics, and secondary data sources
  - ii. Content analysis, unstructured interviews, focus group discussions and direct observations
  - iii. Item selection, item reduction, variable selection, validity and reliability
  - iv. Data quality at instrument, data collection, abstraction, and analysis levels
- b. Practical
  - i. Critique methods, variables, instruments, and data quality checks in sample proposals
  - ii. Develop methods, variables, instruments, and data quality checks for own proposal

#### Data Handling

#### **Objectives:**

At the end of the session students should be able to

- a. Describe and select variables measured in the proposed study
- b. Do data, checks, entry, coding, and transformation of variables
- c. Tabulate and summarize data
- d. Plan for data analysis

- a. Didactic
  - i. Variable selection
  - ii. Data checks, entry, coding, and transformation
  - iii. Data tabulation and summarization
  - iv. Data analysis
- b. Practical
  - i. Critique measured variables, data, checks, entry, coding, and transformations, tabulation and summarization of data and data analysis plans from sample proposals
  - ii. Develop and present data checks, entry, coding, and transformations, tabulation and summarization of data and data analysis plans for own proposal

## Proposal Formats Recommended By Institutions

#### **Objectives:**

At the end of the session students should be able to write proposals in the format recommended by various organizations

## Contents:

- a. Didactic
  - i. Recommended formats by WHO, UON/KNH ethics committee, NIH, NACC
  - ii. Adopting proposals into recommended formats
- b. Practical
  - i. Discuss proposal formats
  - ii. Adopt own proposal into a selected format

# **Dissemination And Translation Into Policy Strategies**

#### **Objectives:**

At the end of the session students should be able to

- a. Describe how study findings are disseminated and translated into health
- b. Action develop dissemination plans for their studies

#### Contents:

- a. Didactic
  - i. Reporting research findings (potential users, media channels)
  - ii. Dissemination strategy
  - iii. Utilization of research findings
- b. Practical
  - i. Develop and present dissemination strategies for own studies

# **Finalization Of Research Proposal**

#### **Objectives:**

At the end of the session students should be able to

- a. Write a complete research/program proposal
- b. Develop study management plans
- c. Critique a research proposal

- a. Didactic
  - i. Revision of components of research proposal
  - ii. Study management plans
- b. Practical
  - i. Oral/poster presentation of proposals
  - ii. Critique proposals

#### QUANTITATIVE RESEARCH METHODS

#### Rationale:

This unit provides an overview of the principles and methods of descriptive, analytic and experimental epidemiology, including measurement of population health status, measures of disease burden and occurrence, study designs in Epidemiology, measures of effect and association, errors in measurement and the application of screening and diagnostic test.

At the end of this unit the participants will be able to effectively carry our research using quantitative methods contained in this section.

#### Introduction To Epidemiology

#### Rationale

The purpose of this topic is for the student to understand the definition of epidemiology, its basic concepts and reasoning, its role in biomedical sciences and its application.

#### Objective

At the end of the course, the participants should accurately define epidemiology and adequately describe its basic concepts and application.

#### Contents

- i). Definition of epidemiology.
- ii). Basic concepts and reasoning in epidemiology.
- iii). The role of epidemiology in biomedical sciences.
- iv). The application of Epidemiology.

#### Disease Occurrence And Its Measurement

#### Rationale

The definition and description of Epidemiology encompasses both the description of the distribution of patterns of disease occurrence in human populations and the identification and control of disease determinants. Measurement of prevalence and/or incidence of a disease process or frequency of an outcome measure are vital components of epidemiological activities or studies.

#### Objective

At the end of this course, the students should be able to accurately describe demographic indices and determinants of disease outbreak and attack rate, and also be able to measure disease occurrence and disease effects and also disease association.

- i) Demographic indices.
- ii). Measures of disease occurrence and disease effects:
- Disease frequencies,
  - o Prevalence.
  - o Incidence
  - o Standardised rates
- Numerators and denominators,
- Transmission,
- Importance of reporting periods,
- Modes of transmission.
- iii). Determinants of disease outbreak,
- Incubation period,
- Attack rate.
- iv) Measures of disease association:
- Definition of risk and its interpretation and estimation,
- Definition of odds and its determination and interpretation.
- Measures of disease effect,
- Presentation of exposure/disease data,
- Interpretation of measures of association,
- Characteristics of measures of association,
- Measures of population impact.

## Sampling And Errors In Measurement

#### Rationale

In most situations, a researcher is not able to study all the subjects of a given target population, usually because of the large size of the population and the limited resources that are often available. However, a subset of this population, or a sample, and which is much smaller, is often studied instead of the target population. The method of obtaining such a sample is referred to as sampling. Consequently, every researcher must be familiar with sampling methods in order to be able to effectively carry out research since it is rare that they would be able to study the whole of their target populations.

Inherent in all observations and measurements is the element of error. Error is the degree to which the results of the study could be explained by factors other than the ones under study. An understanding of the various types of error and their effects provides avenues for appropriate elimination or reduction of error in the study.

#### Objective

At the end of the course, the students should be able to describe and discuss sampling and errors in measurement. The participants should understand the potential sources and types of error in epidemiological studies and the statistical methods used to measure and limit the role of error, especially with respect to various Epidemiological study designs.

- i). Types of Sampling:
  - random method,
  - non-random method.
- ii). Errors in measurement:

- Types I and II errors.
- Validity,
- Bias,
- Selection.
- Measurement.
- Information.
- Confounding,
- Random error.

# Diagnostic And Screening Tests

# Rationale

Establishing a diagnosis is an important, though imperfect, process resulting in a level of probability rather then certainty of being right. Clinicians spend a great deal of effort and time to determine a diagnosis on the basis of presenting complaints, physical signs of their patients and various appropriate diagnostic tests. However, very few of these physicians receive formal training in the interpretation of diagnostic tests. This unit will deal with the basic principles a clinician should be familiar with in choosing and interpreting the results of diagnostic tests. A diagnostic test is anything that serves as a tool for discriminating between those with a particular condition and those without and includes more than the traditional laboratory tests. It may include imaging results, physical findings, historical parameters, and clinical measurements, including clinical scoring systems.

# Objective

At the end of this course, the student should be able to accurately define screening and diagnostic tests and be able to use them, interpret them, and discuss their roles and applications appropriately.

# Contents

- i). The Accuracy of a test result,
- ii). Sensitivity and Specificity (Establishing Sensitivity and Specificity)
- iii). Receiver Operator Curves (ROC).
- iv). Predictive Value (positive and negative)
- v). Likelihood Ratios,
- vi). Multiple tests

# **Epidemiological Study Designs**

# Rationale

Different conditions or outcomes and/or exposures require different approaches to investigate them. The method of investigation chosen depends on the problem to be studied and the type of data to be collected. Consequently, rese

Descriptive studies describe patterns of disease occurrence and association between exposure factors or risk factors and specified outcomes. Although these type of studies only reveal associations and risk factors, they often form a basis for more analytical studies that can investigate causal relationships between exposure factors and outcome measures.

Observational analytic studies enhance the level of investigation achieved by descriptive studies and are able to evaluate causal relationships between exposures and outcomes measures.

Experimental studies provide the highest level of investigations by a researcher and are able to address causal relationship between exposure factors and outcomes measures. The most rigorous experimental studies are randomised while those without this process are considered less rigorous and non-randomised.

## Objective

At the end of this course, the student should be able to adequately describe epidemiological study designs and also be able to effectively discuss their strengths, weaknesses, application and utility in medical research. The student should be able to identify the appropriate epidemiological study designs for various research questions.

## Contents

ii).

- i). Observational studies:
  - Descriptive Studies.
  - Cross-Section studies and Surveys,
  - Analytical Studies
  - Case Control Studies,
  - Cohort Studies.
  - Experimental studies:
    - experimental studies
    - quasi-experimental studies.

# DATA MANAGEMENT AND ANALYSIS

## Objectives

The objective of this unit is to enable the participants to prepare data for analysis, summarize and present of data and appropriately use statistical techniques for data analysis and interpretation. At the end of the course the participants will be able to organise and display relevant data to answer research questions, apply basic concepts of probability and select and use appropriate statistical methods to analyse data.

## Data Management

# **Objectives:**

At the end of this course the participants will be able to:

- a. Develop tools for data capture
  - code book
- b. Clean data
  - manual verification, apply double-entry, range checks, logical checks
- c. Transform data for analysis

# Data Capture

- Design and use various types of data collection tools

   questionnaire, structured and unstructured
- Conversion of data into appropriate codes for analysis
  - Guide book for coding

# **Data Cleaning**

Validation and Correction of data

- Manual for Verification,
- Double-entry,
- Range checks,
- Logical checks

#### **Data Transformation**

- Methodology, the process and the expected type of statistics produced.
- Purpose of a transformation;
- Principal value framework
- Transformation indices

#### **Descriptive Statistics**

#### Objective

At the end of this topic the participants will be able to demonstrate skills in:

• Categorizing of data;

- Display of data in graphical formats
- Summarizing of data using appropriate statistical techniques

## **Categorizing Of Data**

- One-variable descriptions
  - o Numerical variables,
  - o Categorical variables
- Two-variable descriptions
  - o Outcome versus predictor variables,
  - o Continuous outcome variable,
  - o categorical outcome variable
- Multivariables

## Graphical Displays Of Data

Creation, organising, and interpretation of data using:

- Frequency tables
- Histograms,
- Stem and leaf
- Box plot
- Line trends and

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• Pie charts

## Summarizing Data

- Selection and use of appropriate statistical methods to analyze data
- Interpretation of measures of central tendency and spread and
- Calculation of inter-quartile range
  - Mean, median, the mode and the inter-quartile range
  - o Difference between a population and a sample
    - Standard deviation for ungrouped and grouped data
      - Relation with variance
      - Advantages over range for spread.

#### Introduction To Inferential Statistics

#### **Objectives**

At the end of this unit the participants will be able to

- Describe probability distributions
- Describe the process of hypothesis testing

# Probability Distributions

Probability of an event with equally likely outcomes.

- An outcome, an event, and a sample space,
  - o use of tree diagrams.
- Addition rule and probability calculations
- Multiplication rule and probability calculations
- Mean and standard deviation and z-score and percentiles

## Hypothesis Testing

- Elements of a good hypothesis
- Logical process of hypothesis testing
- Appropriateness of test statistic, level of significance and power
- Study size and hypothesis testing
  - Confidence intervals for differences
    - means and proportions

#### **Univariate Analysis**

#### Objective

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At the end of the course the participant will be able to appropriately analyse data involving:

- Two population means and proportions
- One-way and two-way analysis of variance
- Regression analysis
- Analysing count data
- Non-parametric methods for data analysis

# Comparison Of Two Population Means And Proportions

- Assumptions needed to use the student t-and T distribution to test for differences between two means and proportion, paired and unpaired samples
- t-test for a designated set of data
- Kappa statistics for agreement
- Diagnostic tests for screening studies
- Testing the validity of a hypothesis.
- Probabilities in the T table.
- Confidence intervals for the differences of two means and proportions

#### Analysis Of Variance

- t-test and analysis of variance
- One- and two-sided hypothesis test and the F test statistic
- One-way analysis of variance (ANOVA)
- Multi-way ANOVA
- Robustness to violations of assumptions

# Regression Analysis

- Scatter plots
- Correlation coefficient
- Regression analysis

- Linear regression equation
  - o y and x concept, least squares, residuals and anova
- Estimate and interpret parameters of a multiple regression models
  - o standard deviation of the residuals and variable selection procedures

## Analysis Of Counted Data

- Contingency table
- Frequencies, observed and expected cell counts, and chi-square test statistics from a set of data
- Requirements for and rationale behind using the chi-square test
- Contingency table methods for binary outcomes
- Measures of risk and association for binary outcomes
- Tests of association in contingency tables
- Predictors with multiple categories
  - Interpretation of analysis

#### **Multivariable Analysis**

#### Objective

At the end of the sub-topic the participants will be able to demonstrate knowledge and skills to:

- Calculate and interpret the parameters for a logistic regression
- Estimate and interpret parameters of multiple regression model.
- Estimate and interpret the parameters for a multivariate model.

## Logistic Regression Analysis

- Single predictor models
  - o Interpretation of regression coefficients, Categorical predictors
- Multiple predictor logistic models
- Likelihood ratio tests, Confounding, Interaction, Prediction and accuracy
- Risk measures for case-control studies
  - Matched case-control studies, Checking models assumptions and fit, Outlying and influential points, Linearity, Model adequacy, Technical issues in logistic model fitting

#### Multiple Regression Methods

- Parameters for multiple regression methods
- Tests of hypotheses for a multiple regression and assumptions for coded and uncoded predictors,
- ANOVA table

#### Multivariate Methods Of Data Analysis

- Parameters for multivariate analysis of variance
- Wilks and Rao parameters and criteria for significance of differences among groups including post hoc comparisons.
- Multivariate methods in data analysis
- o discriminant, canonical correlation, principal components analysis and factor analysis
- ANOVA, components and sources of variation.

#### Non-Parametric Methods

# Objective

At the end of this course, the participants will be able to determine conditions for which parametric and nonparametric tests should be used and also apply non-parametric tests of independence or association

# Conditions For Using Parametric And Non-Parametric Methods

- Parametric and nonparametric (distribution-free) tests.
- Expected frequencies and observed frequencies in chi-square tests of independence, the chi-square test of goodness of fit or independence
- The chi-square statistic for one or two variables with Yates' correction for continuity

# Tests Of Independence And Association

• Test of independence for two variables, using the chi-square statistic

# Conditions for using non-parametric methods

- Mann-Whitney test for small and large sample sizes and its application.
- Kruskal-Wallis test and its application
- Wilcoxon Signed-Ranks T-tests and its application.
- Significance testing using the Spearman rank-order correlation coefficient

## STRATEGIC PLANNING AND ETHICS IN RESEARCH

## **Objective:**

By the end of this unit, participants should:

- a. Be able to adequately describe the basic principles underlying a strategic plan
- b. Be able to design a simple strategic plan.

## Introduction To Strategic Planning

## **Objective:**

By the end of this session participants should:

- a. Adequately describe the context within which strategic planning is undertaken
- b. Adequately describe the basis of strategic planning
- c. Be able to design a simple strategic plan

## Contents:

- a. Definition and overview of strategic planning.
- b. Background and Introduction
- c. What Program Challenge is.
- d. External and Internal Environment
  - i. Understanding of the context within which the program will operate
  - ii. Appreciation of their abilities and weaknesses
  - iii. Understanding of existing opportunities that could be tapped to the advantage of the program
  - iv. View of program objectives and how they will be actualized
    - Insight on how monitoring and evaluation will be undertaken

# Situation And Stakeholders Analysis

#### **Objectives**

By the end of this session participants should:

- a. Should be able to adequately describe situation analysis entails and what it entails.
- b. Be able to undertake a situation analysis and stake holders analysis, taking cognizance of internal and external environments

# Contents:

- a. Situation analysis and what it entails.
- b. Stake holders analysis, taking cognizance of internal and external environments.

#### **SWOT Analysis**

# Objectives

By the end of this session participants should:

a. Be able to adequately describe how a SWOT analysis is undertaken within the prevailing political, economic, social and health environments.

b. Be able to adequately describe the importance of considering current and future trends in health field.

c. Be able to perform a SWOT Analysis

## Contents:

- a. Strengths,
- b. Weaknesses,
- c. Opportunities and
- d. Threats,

All within the context of political, economic and social trends.

## Vision And Mission Of Program

#### Objectives

By the end of this session participants should:

- a. Adequately describe what vision and mission are and their difference
- b. Be able to develop a vision and mission for a simple program

# Contents:

- a. Long term vision.
- b. Potentially attainable dream
- c. Not easily reachable dream.
- d. Dream that offers much challenge
- e. Focused dream.

# Core Values/Operating Principles

# **Objectives**

By the end of this session participants should:

- a. Adequately discuss the importance of defining core values and operating principles in a strategic plan
- b. Demonstrate ability to define core values and operating principles for a strategic plan

# **Development Of Strategic Objectives**

## **Objectives**

By the end of this session participants should:

- a. Adequately discuss the importance of defining strategic objectives.
- b. Demonstrate ability to develop and define strategic objectives for a strategic plan.

# Contents:

Characteristics of Strategic Objectives:

- Few in number but highly potent (3-4)
- Ability for each to address multiple constraints or obstacles
- Each requires a set of strategies to address

## **Strategies And Activities**

## **Objectives:**

By the end of this session participants should:

- a. Be able to adequately discuss the importance of defining Strategies and Activities
- b. Demonstrate ability to develop and define strategies and activities for a strategic plan

- Means to achievement of Objectives or Goals
  - o Demands a host of activities
  - May require constant revision

## Milestones, Action Plans And Summary Logistical Framework Matrices

By the end of this session participants should:

- a. Be able to adequately discuss the importance of defining milestones, action plans and logistical matrices in program design
- b. Be able to develop milestones, action plans and logistical matrices in a strategic plan

## Contents:

C.

- a. Tabulation of Work Plan
- b. Objectives
- b. Key Activities
  - Expected Progress Indicators
    - When to be Attained
- d. Person/s Responsible
  - e. Inputs and Outputs
    - o Usually for 1 year
    - o Includes more expected outputs than Milestones listing
    - o Indicates who responsible when and expected inputs

#### Monitoring and Evaluation plans.

#### **Objectives:**

By the end of this session, participants should adequately discuss the purpose and process of monitoring and evaluation of strategic plans

#### Contents:

- o Monitoring of strategic plans.
- o Evaluation of strategic plans.
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# ETHICS IN RESEARCH

#### Objectives

At the end of the unit the participant should be able

- a. Adequately describe the basic concepts of medical ethics
- b. Be able to determine the important ethical issues in research
- c. To adequately discuss the elements of informed consent
- d. To identify ethical issues emanating from a research study and incorporate the concerns in the research design.

# History Of Ethics

# Objectives

By the end of this session participants should appreciate the evolution of ethics in health research from initial stages to date.

## Contents:

- a. Historical events,
- b. Development of codes of research ethics,
- c. Guiding principles for research ethics,
- d. Statutory frame work for research ethics.

## International Guidelines For Research Ethics

## **Objectives**

By the end of this session participants should adequately discuss international guidelines for research ethics.

## Contents:

- o Nuremberg code,
- o Declaration of Helsinki, CIOMS,
- o Belmont report

## **Principles In Research Ethics**

o Respect of persons, beneficence and justice.

## **Ethical Research Committees**

o Composition, regulation, requirement for research approval.

#### **Informed Consent**

o Elements of informed consent, privacy and confidentiality, balancing benefits and risks in research

# **Publication Ethics**

o Ownership of data and materials

## **RESEARCH PROJECT**

## Introduction:

The Research Project is an integral part of the Postgraduate Diploma in Biomedical Research Methodology Course. It is the practical demonstration of the students' capability to utilise what they have learnt by successfully carrying out a research activity. The Research Project will be carried out throughout the period of the Postgraduate Diploma Course, with 7.5 weeks allowed carrying out and writing up of the Research Project. The Research Project could be based on any of the topics covered during the course. Although the student will specifically be equipped adequately to carry out the Research Project during the various topics carried out during the course, specific important aspects of the Research Project will be covered during preparations before the Research Project is implemented.

## **Objectives:**

At the end of this course the student should have successfully carried out a research project of their choice and should have successfully written them up and be able to attain a good pass on their evaluation.

The Research Project will have practical sessions in terms of seminars and presentations by students:

Choice of Research Project and Opportunities for Research Projects: identification of research topics and prioritisation of research, retrospective and prospective research options, use of available data sets for research; Research Questions and Aims and Objectives: identifying research questions and setting aims and objectives for the project, identifying their justification in terms of feasibility and impact on answering the research question; background and literature review for the study topic: identifying sources of relevant literature, critical review of relevant literature; Choice of research design: the suitability of the various research designs for addressing various research questions, the limitation of the various research designs; population sampling and sample size calculations; data collection and data management; data analysis and data interpretation; write up and presentation of the study project.

The choice of supervisors and tutors for the students will be done at the beginning of the Postgraduate Diploma Course while the choice of the Research Project (identification of research topics and prioritisation of research, retrospective and prospective research options, use of available data sets for research) will be done during the course of the Postgraduate Diploma Course. The actual Research Project will be carried in accordance with the timetable below.

# **Timelines for the Research Project**

Serial No.		Activity	Time allocation: weeks/ days	Time allocation on the calendar
1.	Prep	aration for the Research Project	5 days	30/10/2006 to 3/11/2006
	а.	Developing Research Project	2 days	30/10/2006 to 31/10/2006

		i.	Research Question, Aims and Objectives.		30/10/2006
		ii.	Background and literature review, justification of study topic.		31/10/2006
	b.	Methodology		2 days	1/11/2006 to 2/11/2006
		i.	Research design, population sampling, sample size, research procedures, logistics,		1/11/2006
		ii.	Data collection and management		2/11/2006
	С.	Write up and presentation of research project:		1 day	3/11/2006
		i.	Analysis, presentation and interpretation of		Morning of
			study findings.		3/11/2006
		ii.	Discussion, conclusions, recommendations,		Afternoon of
			presentation of study findings.		3/11/2006
2.	Impl	Implementation of Research Project		4 weeks	6/11/2006 to 1/12/2006
3.	Ana	Analysis and write-up of the research project		5 days	4/12/2006 to 8/12/2006
4.		Presentation of the Research Project for Evaluation Including Poster Presentation.		3 days	11/12/2006 to 13/12/2006
5.	Write up of research project for publication		2 days	14/12/2006 to 15/12/2006	

# TIMETABLE FOR THE COURSE.

# Time Table for UNITID Post-Graduate Diploma in Biomedical Research Methodology Course for Year 2006/7

COURSE	WEEKS	No. of Working Days	DATES
Computer Applications I	1	5	
Quantitative Research	3.6	18	
Methods			
Qualitative Research	2.5	13	
Methods			
Proposal Development	2.5	13	
Data Management	3.6	18	
Computer Applications II	1.5	8	
Exams	Exams	3	
BREAK	BREAK	BREAK	
Operational Health	1.8	9	
Research			
Health Economics,	2.5	13	
Policy & Planning			
Strategic Planning &	1.8	9	
Ethics			
Scientific	1.8	9	
Communication			
Research Project	7.5	34	
Exams	Exams	5	
TOTAL	30	157	

## Starts in September 2006 (To fix the exact dates)

- 1 working week = 5 Days
- 8 working hours/day = 40 hours in a 5 day week
- Schedule shows 157 contact days but 8 days are examinations and 34 days for independent project work implies 115 actual teaching days @ 8 hours/day = 920 hours.
- A further 185 hours can be assumed to be of individual student study leaving the prescribed 735 Actual student/teacher contact hours as passed by senate.
- Research Project development and part of data collection will be ongoing during the course. Defense will take about 2-3 days.