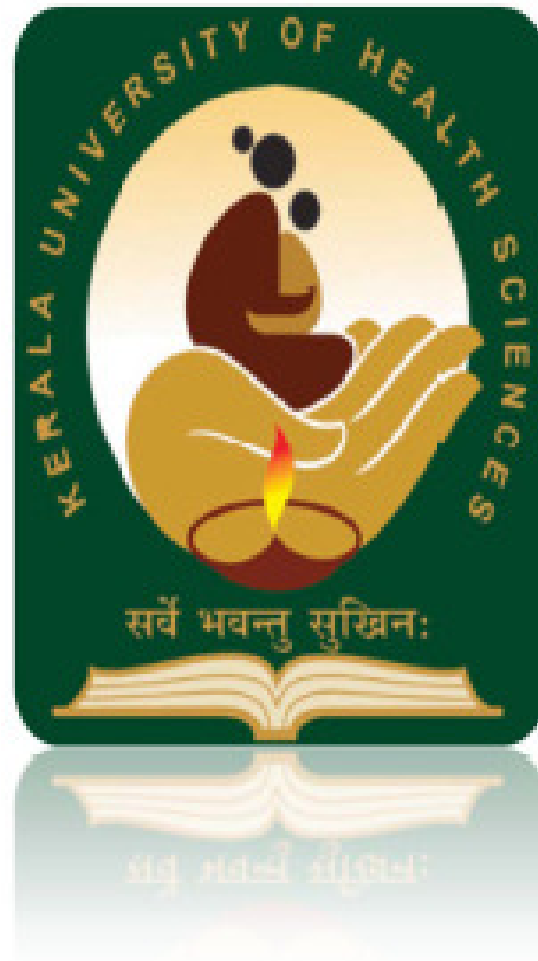


KERALA UNIVERSITY OF HEALTH SCIENCES

THRISSUR – 680 596, KERALA



REGULATIONS GOVERNING THE MASTER OF PHILOSOPHY

(M.Phil) PROGRAMME IN CLINICAL EPIDEMIOLOGY

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1. Description of the course

The M.Phil Course in Clinical Epidemiology is a regular course. This is a post MD course identical to the super-specialty degree in research methodology and also other similar epidemiology courses in international schools like that in Macmaster, UPENN, Harward etc. The goal of the course is to transform the clinician community to researchers and rational practitioners through evidence based medicine practice, adherence to high standards of professionalism and clinical governance. The successful candidates after the course are expected to be primary researchers of high quality in their respective clinical fields, expected to be placed in posts of research planners and managers, and to provide consultancy in health science research. They are also expected to play key roles in advocacy for public health and good quality research including clinical trials The course was conducted under the university of Kerala and as per the recent Govt. orders (GO (Rt) No. 996/2012/H&FWD dated 23-3-2012) is now getting affiliated to KUHAS. There are 10 already approved seats for the course and the course is currently envisaged as an in-service course, The selection and conduct of the course is by Director of Medical Education of Kerala through CERTC and the examination is conducted by the Kerala University of Health Sciences. .

2. The objectives of the course are :

- To equip clinical faculty with methods in health science research ·
- To popularize the concept of quality in health science research ·
- To generate a team of professionals capable of providing consultancy in health science research methodology.

Who shall be benefited from the course? ·

- Medical teachers, clinicians & faculty in allied disciplines, who have aptitude & commitment to medical research. ·
- Faculty members who wish to become investigators of research projects
- Faculty members who want to become investigators of clinical trials ·
- Clinicians who want to become health care managers

3. Eligibility for Admission:

Those who have passed MS/MD in modern medicine, approved by the Kerala university of Health Sciences or identical post graduate degrees in nursing, pharmacy and dental sciences in modern medicine. The candidates should not be aged more than forty five years on the forthcoming date of December 31st. There is a system of reservation among the various departments of health like DME, DHS etc as follows.

1. From faculty of DME Medical departments: 3 seats

2. From faculty of DME Dental/Pharmacy/Nursing departments: 2

{To be decided based on rotation}

3. For doctors from DHS and other general services including RCC/MCC (For those who have opted clinical specialty cadre in health services): 2 seats

4. Open seats (for all including private medical institutions and also other states— 3 seats
In case sufficient no. of candidates are not available any category those seats will be considered in category 1; If candidates are not available in category, those seats will be considered in category 2; If candidates are not available in category 2 those seats will be

considered in category 3; I candidates are not available in category3 those seats will be considered in category 4.

Subjects: M.Phil Clinical Epidemiology including Health system Epidemiology and Health Systems Management, Health social science, Clinical health economics

Course plan: Distance Education for Two Years with four semesters:

4. Brief outline of the course

First three months of first semester: contact classes in core subjects Consolidation at the end of each month at the CERTC about the months learning activity and doubt clearing for one full day (Holidays for the parent department) Consolidation at the end of each semester at the CERTC about the semester's learning activity and doubt clearing for two full days (Holidays for the parent department second Saturday and Sunday preferably)

Protocol development during the first year after contact classes.

Protocol implementation and project work during the second year.

Details of module based learning activities

First year

First three months - Contact classes and lectures in the core subjects. (Please see detailed syllabus in the appendix) Bio Statistics, Epidemiology, Health Social Sciences, Bio computing, Bioethics, Clinical health economics.

This will be module based and there will be five modules

Module 1: Introduction to Research methodology

Module 2: Basic epidemiology and clinical epidemiology in detail

Module 3: Biostatistics

Module 4: Health social sciences and Clinical health economics

Module 5: Bioethics and Biocomputing

Second year: 4 Modules

Module 1 Evidence based medicine

Module 2 Health management

Module 3 Health systems epidemiology including clinical governance, rational drug use and

treatment guidelines, clinical audit, infection control, patient safety, health policy analysis for

clinicians

Module 4: Current topics in epidemiology, Genetic epidemiology, social epidemiology (Social determinants as relevant for clinician)

Structure of the module: Each module will begin with an introduction to the particular subject in relation to specific research methodologies in clinical fields and specialties' to provide a clear conceptual framework for doing research in their day today ward work. Participants will understand a variety of approaches to research (both quantitative and qualitative) and assess their advantages and disadvantages for particular research problems. Data collection and data analysis techniques will be introduced, with students conducting practical exercises to reinforce learning. The participant's' critical capacity to read and understand complex article and their attitude will be assessed during the interactive sessions. Finally, each student will be helped for development of a specific research proposal for the student's case study or dissertation or thesis work. There will be mentoring from the inception and individual level tutoring with delegation of each candidate to one faculty.

The brief plan of each module is

Introduction

Learning objectives

Content area (study unit) -Theoretical aspects (Definition, features, description, applications) followed by practical exercise and self-practice problems.

References

Similarly six units in each module.

Project (Thesis) work: The candidate will have to work on a specified research theme under an approved guide and submit a dissertation at the end of the course. This can be on the topic developed in the discipline of the candidate and the content expert will be the co-guide. The dissertation will be the major activity during the second year.

The planning of this will be started from the first year after the contact classes. The candidate will identify a suitable mentor from the parent department who will guide in the subject along with the methodology guide from CERTC. The topic will be identified by the candidate in consultation with both the guides. During the first year the topic will be developed in to a full protocol through series of interactions and consultations with the guides and other relevant faculty. This protocol need to be submitted during the year end examination of first year and presented before the faculty for approval.

During the second year the candidate will do the thesis work (six months data collection, three months analysis and three months research communication. The candidate should submit a structured abstract and the final degree will be awarded only after the acceptance of project work for publication in indexed journal.

Assessment (Examinations):

Formative evaluations: This is by periodic objective tests, periodic tests through web platforms, reports by the thesis guide and mentor, assessment of extra interest taken by candidate in matters of research or health policy and final opinion poll by the whole faculty on overall academic performance of the candidate.

Summative evaluations

There will be three examinations:

1) Internal examination at the end of first year along with presentation of protocol

- 2) Internal assessment at the end of second year and internal presentation of thesis
- 3) Final summative examination by KUHS after submission of the thesis

Authority Responsible for conducting the course: Director of Medical Education.

Course affiliation: Kerala University of Health Sciences (KUHS)

Study Centre for the course: Clinical Epidemiology Resource & Training Centre, 2nd Floor, Principal's Office Building, Medical College, Thiruvananthapuram.

Phone 0471-2448825 Fax 04712448825 email certc @vsnl.com website

Fee Structure:Total Fees Rs 30, 000/- per Candidate per year. Annual Fees Rs.30, 000/- to be remitted in three installments and first installment at the commencement of the course. Fees for examination is to be separately remitted to the university. The exam fees should be remitted to the University as per the rules of Kerala University of Health Sciences.

Total seats- 10 seats

Course of Study and Scheme of Examinations

The course of study, scheme of examination, pass criteria etc will be the same as that of other regular M.Philprogrammes. There will be three papers for the course.

Scheme of Examination

Internal assessment – There will be internal assessment for each module (1- Epidemiology,

2- Biostatistics, 3- Social and Behavioral science, Health Economics &Health policy)

Final exam

There will be three theory examinations, one at the end of first year and another at second year conducted by CERTC as internal exam. Final summative examination will be conducted by KUHS consisting of 3 theory papers (20% mark will be from internal exam and 80% from final KUHS exam). Each theory paper by KUHS carrying 80 marks will be of three hours duration. Thesis discussion and viva-voce will be conducted after the written examinations.

Exam pattern

Type	Papers	Topic	Hours	Marks
Theory	Paper I	Clinical Epidemiology	3 hours	80 marks
	Paper II	Bio statistics and Biocomputing	3 hours	80 marks
	Paper III	Health Social Sciences, Health economics, Health policy, Bioethics & Project management	3 hours	80 marks
Practical	Thesis discussion Viva Voce			100 marks

5. Criteria for Pass

A Candidate shall be declared as passed if he secures not less than 50% marks in aggregate, provided he/she shall obtain a separate minimum of 50% in each paper. He /She should also obtain 50% for the dissertation and viva voce examination.

6. Conferment of Degree

No candidate shall be eligible for conferment of the M.Phil degree unless he/ she is declared to have passed the full examination as per regulations laid down above.

7. Qualification of Teachers

All medical teachers eligible to be declared as a post graduate teacher and having formal training and degree in clinical epidemiology and having 5 years teaching experience after post graduation in clinical epidemiology are eligible to be guides for M.Phil Students.

8. Examiners

All medical teachers eligible to be declared as a post graduate teacher and having formal training and degree in clinical epidemiology and having 5 years teaching experience after post graduation in clinical epidemiology are eligible to be examiners. A list of qualified teachers in each field will be submitted to the university from the list of resource persons available with the Director, Clinical Epidemiology Research and Training Centre, Medical College, Thiruvananthapuram. List of experts from other INCLIN CEU's in India will also be submitted for selection of external examiners. The selection of examiners, question paper setting, conduct of examination etc will be done as per norms set for other M.Phil examinations of KUHS.

9. ACADEMIC TRANSCRIPT

No of Working Days	Total 250 days having 6hours per day for two years
No of Hours/Days	6
Thesis Preparation	2 days per week
Classes	5% distance learning and 50% contact classes
Total Academic Hours	250 x6 =1500

Sl.No	SUBJECTS	No of Hours
1.	Clinical Epidemiology	200
2.	Biostatistics	150
3.	Health Economics	70
4.	Health Policy	40
6.	Social Science	40
8.	Computer applications in medicine	30
9.	Project management Lecture	24
10.	Grand Round Lecture	12
	Total	656
	Thesis	500
	Training for teaching and attending	144

	conference and seminars	
	Miscellaneous	200
	Total	1500

10. Syllabus

I. CLINICAL EPIDEMIOLOGY- I

1. Introduction, Historical aspects and Definition- Epidemiology and Clinical Epidemiology
2. Development of Clinical Epidemiology- Global Trends INCLIN, IndiaCLIN
3. Type of Epidemiological studies – Introduction
4. Study Designs- in detail
Observational studies: Case control, cohort , case series, surveys,
Experimental studies: Clinical trials
5. Sources of Data and Data Collection
6. Morbidity and Mortality
7. Measurement of burden of illness – Incidence, Prevalence, Cumulative incidence.
8. Standardization of Rates- Principles – and Methods
9. Risk and Causation
10. Clinical errors: Bias and Chance, Clinical agreement and disagreement.
11. Evaluation of diagnostic tests – Normal range
12. Diagnosis – Decision making – Decision analysis.
13. Prognosis
14. Treatment – Clinical trials – Efficacy – Effectiveness.
15. Meta- analysis and systematic reviews
16. Evidence based medicine and Knowledge management
17. Prevention
18. Critical appraisal – selecting and reading Medical literature.
19. Application for Grants and Grant review.
20. Abstracting and Editorial writing.
21. Qualitative research: introduction

CLINICAL EPIDEMIOLOGY-II

1. Epidemiological data analysis in detail
2. Concept of validity and epidemiological inference in detail
3. Multivariate analysis

4. Model building
5. Clinical prediction
6. Infectious disease epidemiology including surveillance
7. Health system epidemiology
8. Social epidemiology
9. Epidemiology of non-communicable diseases including Cancer Epidemiology
10. Environmental epidemiology including cancer
11. Reproductive epidemiology
12. Genetic epidemiology
13. Nutritional epidemiology
14. Injury epidemiology

II. BIOSTATISTICS - I

1. Definition of Statistics – Descriptive and inferential statistics – Population, sample, parameter, statistics – type of variables.
2. Central tendency and its measures – Measures of variability – Grouped data – percentiles, quintiles, ranks.
3. Probability – Factorial notation – Baye’s theorem.
4. Populations, samples – Random and Non Random samples – Random Number Table.
5. Distributions – Binomial, poisson, normal distributions – fitting a normal distribution to grouped data – central limit theorem.
6. Point estimation – interval estimation – confidence intervals – Difference between means.
7. Hypothesis testing – power – sample size – Type I and Type II error – Testing in normal, binomial and “t’ distributions.
8. Tests for normality of underlying distributions.
9. Frequency data – chi square.
10. Regression and correlations.
11. Analysis of variance
12. Bayesian methods introduction

BIOSTATISTICS - II

1. Multiple regression
2. Multiple correlations 2x2 table
3. Dummy Variables.
4. Analysis of variance – Two ways.
5. Analysis of co variables
6. Confounding and effect modification

7. Sample size calculation.
8. Basics of Logistic regression.
9. Basics of survival analysis – life tables.
10. Non parametric methods.

III. Computer applications for health science research

1. Introduction to personal computer.
2. Introduction to DOS.
3. Word Perfect and Typing exercise.
4. Questionnaire design.
5. Data editing, Data base management
6. Office software: Word, Excel, Power-point , other equivalent
7. Analysis of RCT data.
8. Data analysis for differential diagnosis, Risk factors, prognostic factors, prognostic review.
9. Computer graphics – Charts, diagrams.

IV.HEALTH ECONOMICS

1. What is economics: Microeconomics, welfare economics and health economics
2. Introduction to Health Economics, Efficacy, Effectiveness, availability, Efficiency Vs Effectiveness, Optimal allocation of scarce resources, Distribution of resource issues, Differing perspectives.
3. Health care market characteristics and functions, Risk pooling and insurance in private and public sector
4. Health care utilization and Health expenditure. Out of pocket spending for health
5. Health economics in India
6. Practical costing
7. Economic Evaluation. – Elements of sound economic evaluation, – Cost minimization, Cost effectiveness, Cost utility, Cost benefit analysis in detail.
8. Detailed guides for efficiency studies, cost of illness methodology, preferences for health outcomes (comparison of assessment methods) Limitation of economic evaluation techniques.
9. Incorporating economic evaluation in research protocols.
10. Decision theory in Medicine and Decision analysis.
11. Critical appraisal of health economic article
12. Health related quality of life

V. HEALTH POLICY

1. Introduction to Health Policy – What is health policy
2. Health policy templates and frameworks, determinants of health policy.
3. How to influence and implement – health policy
4. Translating research into health policy, economic analysis and health policy development.
5. Health for all – How? Right to health and provision of Universal health care

VI. MANAGEMENT

1. Project Management, management of an organization and management issues in multicentre studies including trials
2. Kerala and Indian Health Care System: role of research for policy change
3. Medical Education in Kerala and India , research career for teachers in medical education department
4. Fund seeking for research projects, conflicts of interest.

VII. Ethics in medical research

1. Introduction & History of science of ethics of medicine
2. Individual and societal rights.
3. Principles of ethics
4. Confidentiality
5. Informed consent
6. Functioning of IRB
7. Ethical guidelines for doing clinical research, field studies, social science research, genetic research, animal experiments
8. GCP ICH guidelines
9. Ethical principles of social science research
10. Trial regulation in India
11. Research mis-conduct and means to prevent it.

VIII. SOCIAL AND BEHAVIOURAL SCIENCES

1. Introduction to sociology and behavioral medicine.
2. Role of social aspects and patient behavior in medical research and clinical practice.

3. Questionnaire design and pretesting on behavioral and social aspects.
4. Qualitative research methodology: FGD, types of interviews.
5. Abnormal illness behavior and sick role.
6. Interviewing and Communication skills.
7. Social determinants of health and illness
8. Steps in developing a new instrument
9. Sociocultural aspects of pharmaceutical use/ illness behavior/health programme evaluation