# Detailed Syllabus

# M. Phil- Clinical Epidemiology Course

# (Part time)

# by

# School of Public Health

# Thiruvananthapuram

# Kerala University of Health Sciences

Thrissur- 680596

**(2020 Admission onwards)**

**Syllabus of M Phil Clinical epidemiology**

**I.Module I Introduction to research methodology**

**Unit 1: Introduction to Research Methodology- 4 hours**

1.1: Introduction to health Research, Categories of research, Evidence Based Medicine practice

1.2: Selection of a research topic, Developing the title, Defining and refining the Research Question, Iterative loop

1.3: Objectives -general and specific, primary and secondary, Hypothesis -meaning and uses, types of variables, framing a hypothesis

1.4: Review of Literature**:** Steps in literature review, Sources of evidence, Elements in a review, Data bases in literature search

**Unit 2: Introduction to Research Designs- 4 hours**

2.1*:* Research strategies in general: Descriptive designs, Cross-sectional, Cohort, Case control

2.2: RCT, Diagnostic test evaluation, Systematic reviews and meta analysis, Hierarchy of research designs

2.3: Measurement in health research: Concept of validity and precision

**Unit 3: Introduction to Bio-Statistics - 4 hours**

3.1: Descriptive statistics (1): Introduction to Bio-statistics, Scales of measurement, Types of variables, Tabulation -frequency distribution tables, cross tabulation tables, Graphical presentation of data

3.2: Descriptive Statistics (2): Calculations using measures of central tendency, variability, percentages, proportions, rates and ratios

3.3: Inferential statistics: Descriptive Vs inferential, Sampling, Errors in sampling,

3.4: Standard Error, Forms of inference, interval estimation- confidence interval

**Unit 4: Descriptive Studies - 4 hours**

4.1: Descriptive studies, Case report, Case series, Ecological studies

4.2: Cross-Sectional studies (survey): characteristics of cross sectional design, steps in designing a cross-sectional study, Merits and Demerits of cross-sectional studies

4.3: Sampling and sample size calculation in Cross-sectional studies, Bias in survey research,

4.4: Data Analysis and interpretation

**Unit 5: Inferential Statistics-Testing the hypothesis - 4 hours**

5.1: Type 1 and Type 11 error, Probability, Statistical significance,

5.2: Statistical tests- Testing hypothesis about single mean, single proportion, difference between two means (Independent and paired samples), difference between two proportions

5.3: Non-parametric tests, Correlation and Regression, Principles of sample size calculation

**Unit 6**: **Questionnaire design- 4 hours**

6.1: Questionnaire as a data collection tool, Overview of questionnaire design, Types of questionnaires

6.2: Steps in designing a questionnaire: Source of items, wording, sequencing, Scoring & formatting questions, Translation and back translation

6.3: Pretest and pilot studies

6.4: Assessment of Reliability and Validity of questionnaire, Common problems in questionnaire construction and use

**Unit 7: Scale development - 4 hours**

7.1: Scale development: Importance of measuring subjective states in health, Types of measuring instruments (discriminative, evaluative and predictive)

7.2: Steps in scale development- conceptualization and operationalization, Item generation, item selection, wording, sequencing, response scales, scoring

7.3: Translation and back translation, pretesting and pilot study, sample size for final administration

**Unit 8**: A**ssessment of Psychometric properties - 4 hours**

8.1: Reliability - Test-retest reliability, inter-rater reliability and internal consistency reliability

8.2: Validity assessments- face and content validity, construct validity and criterion validity,

8.3: Statistical analyses for assessing the psychometric properties and interpretation of results

8.4: Practical Demonstration of item analysis on a data set

**Unit 9: Observational study designs: Case control and cohort designs - 6 hours**

9.1 Basic characteristics, Types of cohort studies, Advantages and disadvantages, comparison of case control and cohort designs, Design and conduct- Definition of case and control, Selection of cases and controls, Matching, Measurement of Exposure, Calculation of sample size,

9.2: Odds Ratio and confidence interval, Bias in case control studies, strength and weakness of case control design

9.3: Analysis and Interpretation of results

**Unit 10: Experimental studies: Randomised Controlled Trial- 4 hours**

10.1: Types of experimental designs, RCT- rationale, Design and conduct- Selection of study population Randomization, Blinding

10.2: Sample size calculation, Intervention, Follow up and Outcome assessment, Effect measures in RCT, Bias in RCT, Specific Ethical issues, Limitations of RCT

10.3: Analysis Interpretation and reporting of results in RCT, Specific analytical issues Interpretation of results, CONSORT checklist for reporting

**Unit 11: Evaluation of screening /diagnostic test - 4hours**

11.1: Introduction and Rationale, Design and conduct of screening/diagnostic studies sample size calculation, Assessing the diagnostic utility

11.2: Problems in gold standard, Multiple tests- serial and parallel testing, Bias in Diagnostic test evaluation

11.3: Analysis in Diagnostic test Evaluation- Practical Demonstration

11.4: Interpreting studies of diagnostic tests, STARD criteria for reporting

**Unit 12: Qualitative Research (QR) - 4 hours**

12.1: Introduction to Qualitative research--Characteristics of QR, Quantitative Vs Qualitative Philosophical approaches to qualitative research,

12.2: Designing a qualitative study- framing research question, Study designs in QR

12.3 Sampling and sample size in QR

**Unit 13: Qualitative Data collection techniques- 4 hours**

13.1: In depth interviews,

13.2: Focus Group Discussions

13.3: Observation

13.4: Other techniques

**Unit 14**: **Analysis and interpretation of qualitative data - 4 hours**

14.1: Approaches to Qualitative data analysis, Inductive and deductive coding

14.2: Steps in analysis of Qualitative data

14.3: Ensuring rigour in qualitative research, Triangulation interpretation of findings, Reporting –COREQ criteria for reporting qualitative studies

**Unit 15: Ethics in Bio Medical Research- Introductory 4 hours**

15.1. ICMR guidelines-General principles of Ethics, Composition, Roles & Responsibilities of Institutional Ethics Committees (IEC), Ethical review procedures

15.2. Research protocol submission requirements for IEC

15.3. Informed Consent, Vulnerability

15.4. Guidelines for Epidemiological research, Clinical trials of drug and other interventions

**Unit 16: Introductory Health Economics and Health management - 2 hours**

16.1. Introduction to health economics, Economic analyses: cost effectiveness analysis, cost benefit analysis, cost utility analysis

16.2. Health Technology Assessment (HTA): Introduction to Health Technology Assessment, Quality and safety issues in health care, Process and outcome evaluation

16.3. Principles of health management

**Unit 17: Scientific appraisal of Journal article & Development of Research Protocol- 4 hours**

17.1Guidelines for Critical appraisal of journal article

17.2Critical appraisal of observational studies

17.3Critical appraisal of RCTs

17.4Steps in the development of a research protocol

**Unit 18: Publication of research results- 2 hours**

18.1: Publishing research results

18.2: Ethics in scientific publication

18.3: **P**recautions to prevent research misconduct and plagiarism

**Total 70 hours and 30 hours practical Cumulative Total 70 hours and 30 hours practical**

**Module II – Epidemiological methods in Clinical epidemiology 100 hours contact class including 20 hours practical and 20 hours distance learning**

1. Introduction, Historical aspects and Definition- Epidemiology and Clinical Epidemiology Principles of epidemiology, what is meant by epidemiological approach
2. Development of Clinical Epidemiology- The Schism of public health and clinical epidemiology Global Trends Clinical epidemiology in the global, national and local context and scenario
3. The patient as an epidemiologic unit Application of epidemiologic principles in the bedside
4. Concept of risk and risk measurement in clinical epidemiology
5. Observational studies for disease epidemiology Case control and cohort approach
6. Therapeutic effectiveness and intervention studies
7. Prevention effectiveness in clinical practice
8. Diagnostic test evaluation for choice of test in the bedside
9. Prognostic prediction and disease scoring systems
10. Translating research findings in to clinical practice

**Total 100 hours and 20 hours practical Cumulative Total 200 hours and 50 hours practical**

**Module III- Advanced epidemiology (Second level epidemiology) 100 hours contact class including 20 hours practical and 20 hours distance learning**

1. Power of comparison: Observational Vs experimental approach

The architecture of study designs and design intricacies in relation to study efficiency: How choice of design is made, detailed discussion on comparative efficiency in relation to evidence based medicine practice for descriptive designs, case control studies: Cohort studies and Clinical trials

2. Sources of Data and Data Collection, use of secondary data in epidemiological studies
3. Measurement in epidemiology: Measures of effect and measures of effectiveness
4. Metrics of Morbidity and Mortality: DALY, QUALY and PYLL,
5. Measurement of burden of illness – Incidence, Prevalence, Cumulative incidence.
6. Risk and Causation, causality assessment in epidemiology
7. Precision and Validity in epidemiological studies: Clinical errors: Bias and Chance, Clinical agreement and disagreement.
8. Standardisation of Rates- Principles – and Methods, Methods of control of extraneous variables in detail confounder, bias and effect modification
9. Support tools for clinical decision making clinical decision support systems, online drug information data base use.
10. Evaluation of diagnostic tests – Normal range Screening in health and disease Likelihood ratios and ROC curve parallel and serial diagnostic tests
11. Diagnosis – Decision making – Decision analysis. Decision tree
12. Treatment – Clinical trials – Efficacy – Effectiveness. community trials cluster randomised trials
13. Meta- analysis and systematic reviews
14. Evidence based medicine and Knowledge management Treatment guidelines and protocols, precision medicine and personalized medicine
15. Prevention effectiveness and practice of prevention for the clinician
16. Critical appraisal – selecting and reading Medical literature.
17. Application for Grants and Grant review.
18. Abstracting and Editorial writing.

**Total 100 hours and 20 hours practical Cumulative Total 300 hours and 80 hours practical**

**Module IV Applied epidemiology and data analysis 100 hours including 20 hours practicals for statistical software and 20 hours distance learning**

1. Epidemiological data analysis in detail Software use SPSS,STATA,R EPIINFO
2. Further categorical data analysis, Multivariate analysis
3. Clinical prediction
4. Infectious disease epidemiology including surveillance
5. Health system epidemiology
6. Social epidemiology
7. Epidemiology of non-communicable diseases including Cancer Epidemiology
8. Environmental epidemiology
9. Reproductive epidemiology
10. Genetic epidemiology
11. Nutritional epidemiology
12. Injury epidemiology
13. Psychiatric epidemiology
14. Rare disease epidemiology and Neglected tropical diseases

**Total 100 hours and 20 hours practical Cumulative Total 400 hours and 100 hours practical**

**Module V Statistical methods for epidemiology** 80 hours with 20 hours practical and 10 hours distance learning

1. Inferential statistics: Estimation Point estimation – interval estimation – confidence intervals – Difference between means.

2.Hypothesis testing – power – sample size – Type I and Type II error – Testing in normal, binomial and "t' distributions.

3.Tests for normality of underlying distributions.

4.Frequency data – chi square. Statistical methods for rates and proportions

5.Regression and correlations.

6.Analysis of variance

7.Bayesian methods introduction

**Total 80 hours and 20 hours and 10 practical Cumulative Total 480 hours and 120 hours practical**

**Module VI: Advanced Biostatistics for epidemiology 40** hours including 10 hours practical and 10 hours distance learning

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. Logistic regression in different types of outcomes
9. Basics of survival analysis – life tables.
10. Agreement and kappa statistics
11. Bayesian methods in epidemiology
12. Non parametric methods.

**Total 40 hours and 10 hours practical Cumulative Total 520 hours and 130 hours practical**

**Module VII- Health Economics: 60 hours including 10 hours practicals**

1. What is 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 utilisation and Health expenditure. Out of pocket spending for health

5. Economic analysis in health care. – Cost minimisation, Cost effectiveness, Cost utility, Cost benefits.
6. Practical costing
7. Economic Evaluation. – Elements of sound economic evaluation, Detailed guides for efficiency studies, cost of illness methodology, preferences for health outcomes (comparison of assessment methods) Limitation of economic evaluation techniques.
8. Incorporating economic evaluation in research protocols.
9. Decision theory in Medicine and Decision analysis.
10. Critical appraisal of health economic article
11. Health related quality of life

**Total 60 hours and 10 hours practical  Cumulative Total 580 hours and 140 hours practical**

**Module VIII: Social and Behavioural Sciences Total 60 hours and 10 hours practicals**

1.Introduction to sociology and behavioural medicine.
2.Role of social aspects and patient behaviour in Medical research and clinical practice.
3.Family in health and disease.
4.Health seeking behavior and preferences for health systems.
5.Abnormal illness behavior. Health belief model and sickness behavior
6.Behavior change communication Knowledge attitude practice behavior model.
7.Social determinants of health and illness
8.Sociocultural aspects of pharmaceutical use/ illness behaviour/health programme evaluation
9.Principles and practice of Behavioural medicine, sickness behaviour

**Total 60 hours and 10 hours practical Cumulative Total 640 hours and 150 hours practical**

**Module IX- Health Policy  20 hours and 5 hours practicals**

1. Introduction to Health Policy – What is health policy
2. Cash of 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
6. National health policy, state health policy
7. Methods of prioritisation for health policy
8. Epidemiologic methods for health policy development
9. Health policy analysis
10 Sub-policies in health sector: Fiscal policy, drug policy, nutritional policy, palliative care policy
11 Linkage with other policies :Population policy, environmental policy, Education policy, Nutrition policy and food securty

**Total 20 hours and 5 hours practical Cumulative Total 660 hours and 150 hours practical**

**Module X- Health system Management and project management 20 hours and 5 hours practicals**

1. Project Management, management of an organisation and management issues in multicentre studies
2. Mission and vision statement strategic plan
3. difference between leadership, management and administration
4. Principles of management POSDCORB, PERT, CPM MBO
5. Kerala and Indian Health Care System.
6. Medical Education in Kerala and India
7. Quality safety and accreditation in improving health system efficiency
8. International health and health of travellers

**Total 20 hours and 5 hours practical Cumulative Total 680 hours and 155 hours practical**

**Module XI- Ethics in Medical research 30 hours and 5 hours practicals**

1. Introductory, History of science of ethics of medicine
2. Individual and societal rights.

3. Principles of ethics
4. Confidentiality
5. Informed consent
6. GCP ICH guidelines

7.Ethical principles of social science research

8.Trial regulation in India ICMR Guidelines Other international guidelines

9.Research mis-conduct and means to prevent it

10.IRB and functioning

**Total 30 hours and 5 hours practical Cumulative Total 710 hours and 185 hours practical**

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**Module XII: Evidence based medicine and Knowledge Management 30 hours and 5 hours practicals**

1. Why EBM
2. Definition and evolution of Concept of EBM
3. Steps of EBM practice: The details
4. The hierarchy of evidence
5. Levels of recommendation and grading of evidence
6. GRADE and other evidence appraisal toolkits
7. Debates about practice of EBM
8. Knowledge management and translation research.

**Total 20 hours and 5 hours practical Cumulative Total 740 hours and 155 hours practical.**

**Conduct of Journal club, symposia seminar, debates and other innovative teaching learning methods 30 hours.**

**Special guest lectures and invited talks 10 hours.**

**Formative evaluations 20 hours Total 800 contact hours including practical sessions.**

## II.Examinations

Final summative examination by the University is as per examination scheme given below.

### a) Schedule of Examinations

| Group | Papers | Topics | Duration | Maximum Marks | Minimum for a pass. | Part Time | |
|---|---|---|---|---|---|---|---|
| Group A Theory | Paper I* | Basic Research Methodology, Bio-Statistics and Research Ethics and EBM. | 3 hours | 100 | 50 | University Written Examination **(End of 1st year)** | **Part I** |
| | Paper II | Health Economics, Health Policy, Health Social and behavioural Sciences, and project management | 3 hours | 100 | 50 | University Written Examination **(End of 1st year)** | |
| | Paper III | Advanced Clinical Epidemiology, Biostatics and Bio-Computing | 3 hours | 100 | 50 | University Written Examination **(End of 2nd year)** | **Part II** |
| | | | | **300** | **150** | | |
| Group B Thesis and problem solving exercises | Paper IV | Hard copy Evaluation of Thesis | | 100 | 50 | University **(End of 2nd year)** | **Part III** |
| | Paper V | Thesis Defence (*presentation and Viva-voce related to thesis*) | 1 hour (Presentation of 40 minutes and discussion for 20 minutes) | 100 | 50 | University examination. **(End of 2nd year)** | |

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|---|---|---|---|---|---|---|---|
| | Paper VI | 1.Log book Assessment<br>2.Interpretive and Problem solving exercises in<br>a. **Clinical Epidemiology** (1. Interpretation of a Statistical Software output. 2. Investigation of disease outbreak/ choice of study design including program evaluation appropriate to given objectives<br>3. Critical review of a structured abstract of a published article.)<br>b. **Biostatistics** (Should not be duplication of epidemiology and be on biostatistics, like calculation of confidence intervals, calculation of adjusted rates, SMR etc.)<br>c. **Health economics** (Calculation of ICER, micro-costing exercise, comments on an individual fiscal policy, results or methodology section of published economic evaluation article) | 1hour (30+15+ 15minutes) | 100 (including 25 marks for Logbook) | 50 | University examination **(End of 2nd year)** | **Part III** |
| | | **Total for Group B** | | 300 | 150 | | |
| | | **Grand Total** | | **600** | **300** | | |

b) **Scheme of examinations**

**b. 1. Valuation strategy**

***Group A***: Two Internal examiners and two External examiners will evaluate independently the three (3) papers in group A and give independent marks. Average of independent evaluations will be taken as the final marks to be uploaded to the University. Revaluation is not allowed, normally, as there are four independent

evaluations for each paper. Re-totaling is permitted, if the evaluation is other than digital evaluation.

***Group B***: Two Internal examiners and two External examiners will evaluate all the three (3) papers in group B independently and give separate independent marks. Average of independent evaluations will be taken as the final marks to be uploaded to the University. Revaluation is not allowed, normally, as there are four independent evaluations for each paper. Re-totaling is permitted, if the evaluation is other than digital evaluation.

**c) Obstruction in conduct of examinations**: Nil anticipated

**d) Clubbing of examination centres:** Not applicable now.

**e) Question paper pattern:** As appended (model question paper)

**f) Scrutiny of Question papers:** As per KUHS norms.

**g) Question paper setters from inside State / outside State**

As from approved panel by the KUHS

**h) Interdisciplinary observers:** As from approved panel by the KUHS

**i) Checking of Answer books before sending for valuation**

Same pattern for Postgraduate examinations of KUHS.

**j) Thesis/ Dissertation for the PG Courses**

The candidate will have to work on a specified research theme under an approved guide (From the approved panel of guides in clinical epidemiology program) and submit a thesis at the end of the second year, one month before the University examination. The thesis can be on the topic developed in the discipline of the candidate and the content expert can be the Co-guide. In collaborative research with external institutions, the mentor in that institution can be one of the Co-guides. The Biostatistics or Social Science faculty also can be the Co-guides. Details will be described in a separate module describing methodological issues of study conduct. Structured abstract of the Synopsis should be uploaded along with the final thesis. Only those students who submitted thesis to the University within the prescribed time limit will only be permitted to register for the final year examination.

**k) Regulations for the conduct of Practical and Viva voce**

Same pattern will be continued as described above

**l) Valuation Strategy:** KUHS pattern as above

**m) Conditions under which candidates are permitted to proceed to the next higher class**

- 80% attendance for all the papers for the first year examination and registered for first year University examination.
- The second year tuition fee shall be remitted within the period prescribed by the University.

**n) Meeting of Pass Board:** KUHS pattern

## Model Questions Papers Paper 1 and Paper 2

**Paper 1 – Basic Research Methodology including Epidemiology, Bio statistics and Research Ethics**

**Section A: Basic Research methodology including Epidemiology and Research Ethics**

**(All questions carry equal marks)**

**Time: $1^{1/2}$ hours** **Total Marks = 50 marks**

1. What is Incidence? What all are its differences from Prevalence?
2. What are the advantages and disadvantages of a cohort study over case control study?
3. What is Bias? What are the different types of biases?
4. What are the characteristics of a good research question?
5. What are the 4 cardinal principles in bio-ethics? Describe briefly about them.

**Section B: Biostatistics**

**Time: $1^{1/2}$ hours** **Total Marks = 50 marks**

1) What are the steps in Hypothesis testing? What are the errors associated with Hypothesis testing?

2) What is correlation? What are the different ways by which it can be measured or displayed?

3) What are the different type of data presentation suitable for a qualitative variable?

4) What is Confidence interval? How does it help in making statistical inference?

5) What is chi square test and what are the different variants of it?

## Paper 2- Health Economics, Health Policy, Health Social and behavioral sciences and Project management.

### Section A: Health Social and behavioral sciences

**(All questions carry equal marks)**

**Time: $1^{1/2}$ hours** **Total Marks = 50 marks**

1) What is Factor analysis? How do you interpret the results of a Factor analysis?

2) What is In-depth interview? What are the steps in conducting this?

3) Which is Triangulation? What are the different types and what is the importance of this in qualitative research?

4) How do we ensure the validity of results obtained in a qualitative research?

5) Write about Sampling strategies in Qualitative research.

### Section B: Health Economics, Health Policy and Project management.

**Time: $1^{1/2}$ hours** **Total Marks = 50 marks**

1) What is ICER? What are the different thresholds used for ICER values?

2) What are the different perspective used in economic evaluation? What are the differences between them?

3) What are the different types of costs?

4) What is health policy cycle?

5) Methods of outcome measurement in cost effectiveness analysis?