A Multi Campus University with ‘A’ Grade Accreditation by NAAC

AMRITA SCHOOL OF MEDICINE
Centre for Allied Health Sciences

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CURRICULUM
M.Sc Biostatistics

A Super Speciality Tertiary Care Hospital Accredited by ISO 9001-2008, NABL & NABH
SPIRITUAL PRINCIPLES IN EDUCATION

“In the gurukulas of ancient rishis, when the master spoke it was love that spoke; and at the receiving end disciple absorbed of nothing but love. Because of their love for their Master, the disciples’ hearts were like a fertile field, ready to receive the knowledge imparted by the Master. Love given and love received. Love made them open to each other. True giving and receiving take place where love is present. Real listening and ‘sraddha’ is possible only where there is love, otherwise the listener will be closed. If you are closed you will be easily dominated by anger and resentment, and nothing can enter into you”.

“Satguru Mata Amritanandamayi Devi”
Introducing AIMS

India is the second most populous nation on earth. This means that India’s health problems are the world’s health problems. And by the numbers, these problems are staggering 41 million cases of diabetes, nearly half the world’s blind population, and 60% of the world’s incidences of heart disease. But behind the numbers are human beings, and we believe that every human being has a right to high-quality healthcare.

Since opening its doors in 1998, AIMS, our 1,200 bed tertiary care hospital in Kochi, Kerala, has provided more than 4 billion rupees worth of charitable medical care; more than 3 million patients received completely free treatment. AIMS offers sophisticated and compassionate care in a serene and beautiful atmosphere, and is recognized as one of the premier hospitals in South Asia. Our commitment to serving the poor has attracted a dedicated team of highly qualified medical professionals from around the world.

The Amrita Institute of Medical Sciences is the adjunct to the term “New Universalism” coined by the World Health Organization. This massive healthcare infrastructure with over 3,330,000 sq. ft. of built-up area spread over 125 acres of land, supports a daily patient volume of about 3000 outpatients with 95 percent inpatient occupancy. Annual patient turnover touches an incredible figure of almost 800,000 outpatients and nearly 50,000 inpatients. There are 12 super specialty departments, 45 other departments, 4500 support staff and 670 faculty members.

With extensive facilities comprising 28 modern operating theatres, 230 equipped intensive-care beds, a fully computerized and networked Hospital Information System (HIS), a fully digital radiology department, 17 NABL accredited clinical laboratories and a 24/7 telemedicine service, AIMS offers a total and comprehensive healthcare solution comparable to the best hospitals in the world. The AIMS team comprises physicians, surgeons and other healthcare professionals of the highest caliber and experience.

AIMS features one of the most advanced hospital computer networks in India. The network supports more than 2000 computers and has computerized nearly every aspect of patient care including all patient information, lab testing and radiological imaging. A PET (Positron Emitting Tomography) CT scanner, the first of its kind in the state of Kerala and which is extremely useful for early detection of cancer, has been installed in AIMS and was inaugurated in July 2009 by Dr. A. P. J. Abdul Kalam, former President of India. The most recent addition is a 3 Tesla Silent MRI.

The educational institutions of Amrita Vishwa Vidyapeetham, a University established under section 3 of UGC Act 1956, has at its Health Sciences Campus in Kochi, the Amrita School of Medicine, the Amrita Centre for Nanosciences, the Amrita School of Dentistry, the Amrita College of Nursing, and the Amrita School of Pharmacy, committed to being centres of excellence providing value-based medical education, where the highest human qualities of compassion, dedication, purity and service are instilled in the youth. Amrita School of Ayurveda is located at Amritapuri, in the district of Kollam. Amrita University strives to help all students attain the competence and character to humbly serve humanity in accordance with the highest principles and standards of the healthcare profession.
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Part I
Rules and Regulations
I. Post Graduate Programmes (Master of Sciences)

1. Details of Post Graduate Courses:

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<td>Pass in B.Sc MLT (4 year regular courses only)</td>
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<td>Neuro-Electro Physiology</td>
<td>3 years + 6 months Internship</td>
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<td>Swallowing Disorders and Therapy</td>
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I.1. Medium of Instruction:

English shall be the medium of instruction for all subjects of study and for examinations.

I.2. Eligibility:

Eligibility details are mentioned under clause No.1 of this booklet.

II. General Rules:

Admissions to the courses will be governed by the conditions laid down by the University from time to time and as published in the Regulations for admissions each year.

II.1. Duration of the Course

Duration details are mentioned under clause No.1 of this booklet.

Duration of the course : 2 Years

Weeks available per year : 52 weeks
Vacation / holidays : 5 weeks (2 weeks vacation + 3 weeks calendar holidays)
Examination (including preparatory) : 6 weeks
Extra curricular activities : 2 weeks
Weeks available : 39 weeks
Hours per week : 40 hours
Hours available per academic year : 1560 (39 weeks x 40 hours)

II.2. Discontinuation of studies

Rules for discontinuation of studies during the course period will be those decided by the Chairman /Admissions, Centre for Allied Health Sciences, and Published in the “Terms and Conditions” every year.

II.3. Educational Methodology

Learning occurs by attending didactic lectures, as part of regular work, from coworkers and senior faculty, through training offered in the workplace, through reading or other forms of self-study, using materials available through work, using materials obtained through a professional association or union, using materials obtained on students own initiative, during working hours at no cost to the student.

II.4. Academic Calendar

Annual Scheme
FIRST YEAR
Commencement of classes - August
First sessional exam - 20 October - 30 October
Second sessional exam - 20 January - 30 January
Model Exam (with practical) - 15 May - 15 June (includes 10 days study leave)
University exam (with practical) - 15 June - 15 July (includes 10 days study leave)
Annual Vacation - After the exam
SECOND YEAR

Commencement of classes - August
First sessional exam - 20 October - 30 October
Second sessional exam - 20 January - 30 January
Model Exam (with practical) - 15 May - 15 June (includes 10 days study leave)
University exam (with practical) - 15 June - 15 July (includes 10 days study leave)

III. Examination Regulations:

III.1. Attendance:

80% of attendance (physical presence) is mandatory. Medical leave or other types of sanctioned leaves will not be counted as physical presence. For those who possess a minimum of 75% attendance, deficiency up to 5% may be condoned on medical or other genuine grounds by the Principal at his sole discretion and as per the recommendation of the Heads of Departments concerned. Students are allowed such condonation only once for entire course of study.

Condonation fee as decided by the Principal has to be paid. Attendance will be counted from the date of commencement of the session to the last day of the final examination in each subject.

III.2. Internal Assessment:

1) Regular periodic assessment shall be conducted throughout the course. At least two sessional examinations in theory and preferably two practical examinations should be conducted in each subject. The model examination should be of the same pattern of the University Examination. Average of the two examinations and the marks obtained in assignments / oral / viva / practicals also shall be taken to calculate the internal assessment.

2) A candidate should secure a minimum of 35% marks in the internal assessment in each subject (separately in theory and practical) to be eligible to appear for the University examination.

3) The internal assessment will be done by the department twice during the course period in a gap of not more than six months and final model exam which will be the same pattern of university examination as third sessional examination. The periods for sessional examinations of academic year are as follows:
4) First Sessional Exam: October
5) Second Sessional Exam: January
6) Model Exam: May / June
7) Each student should maintain a logbook and record the procedures they do and the work patterns they are undergoing. It shall be based on periodical assessment, evaluation of student assignment, preparation for seminar, clinical case presentation, journal club, assessment of candidate’s performance in the sessional examinations, routine clinical works, logbook and record keeping etc.
8) Day to day assessment will be given importance during internal assessment, Weightage for Internal assessment shall be 20% of the total marks in each subject.
9) Sessional examination as mentioned above and the marks will be conducted and secured by the students along with their attendance details shall be forwarded to the Principal
10) Third sessional examinations (model exam) shall be held three to four weeks prior to the University Examination and the report shall be made available to the Principal ten days prior to the commencement of the university examination.

III.3. University Examinations:
• University Examination shall be conducted at the end of every academic year.
• A candidate who satisfies the requirement of attendance, internal assessment marks, as stipulated by the University shall be eligible to appear for the University Examination.
• One academic year will be twelve months including the days of the University Examination. Year will be counted from the date of commencement of classes which will include the inauguration day.
• The minimum pass for internal assessment is 35% and for the University Examination is 45%. However the student should score a total of 50% (adding the internal and external examination) to pass in each subject (separately for theory and practical)
• If a candidate fails in either theory or practical paper, he/she has to reappear for both the papers (theory and practical)
• Maximum number of attempts permitted for each paper is five (5) including the first attempt.
• The maximum period to complete the course shall not exceed 6 years.
• All practical examinations will be conducted in the respective clinical areas.
• Number of candidates for practical examination should be maximum 12 to 15 per day
• One internal and external examiner should jointly conduct the theory evaluation and practical examination for each student during the final year.

III.4. Eligibility to appear university Examination:

A student who has secured 35% marks for Internal Assessment is qualified to appear for University Examination provided he/she satisfies percentage of attendance requirement as already mentioned at the III (1) of the clause.

III.5. Valuation of Theory - Revaluation Papers:

1. Valuation work will be undertaken by the examiners in the premises of the Examination Control Division in the Health Sciences Campus.
2. There will be Re-Valuation for all the University examinations. Fees for revaluation will be decided by the Principal from time to time.
3. Application for revaluation should be submitted within 5 days from date of result of examination declared and it should be submitted to the office with payment of fees as decided by the Principal.

III.6. Supplementary Examinations:

Every main University examination will be followed by a supplementary examination which will normally be held within four to six months from the date of completion of the main examination.

As stipulated under clause No. 2 under Internal Assessment, HOD will hold an internal examination three to four weeks prior to the date of the University Examination. Marks secured in the said examination or the ones secured in the internal examination held prior to the earlier University Examination whichever is more only will be taken for the purpose of internal assessment. HODs will send such details to the Principal ten days prior to the date of commencement of University examination.
Students who have not passed / cleared all or any subjects in the first University examination will be permitted to attend the next year classes. However, he / she can appear for the final year university examination, only if he / she clears all the subjects in the first year examinations.

Same attendance and internal marks of the main examination will be considered for the supplementary examination, unless the HOD furnishes fresh internal marks and attendance after conducting fresh examination.

Students of supplementary batches are expected to prepare themselves for the University Examinations. No extra coaching is expected to be provided by the Institution. In case at any time the Institution has to provide extra coaching, students will be required to pay fees as fixed by the Principal for the said coaching.

**III.7. Rules regarding carryover subjects:**

A candidate will be permitted to continue the second year of the course even if he/she has failed in the first year university examinations.

A candidate must have passed in all subjects to become eligible to undergo compulsory internship.

**IV. Criteria for Pass in University Examination - Regulations:**

**IV.1. Eligibility criteria for pass in University Examination:**

In each of the subjects, a candidate must obtain 50% in aggregate for a pass and the details are as follows:

1) A separate minimum of 35% for Internal Assessment
2) 45% in Theory & 35% in Oral / Viva
3) A separate minimum of 50% in aggregate for Practicals / Clinics (University Examinations)
4) Overall 50% is the minimum pass in subject aggregate (University Theory + Viva / Oral + Practicals + Internal Assessment)

**IV.2. Evaluation and Grade:**

1. Minimum mark for pass shall be 50% in each of the theory and practical papers separately (including internal assessment) in all subjects.
2. A candidate who passes the examination in all subjects with an aggregate of 50% marks and above and less than 65% shall be declared to have passed the examination in the second class.

3. A candidate who passes the examination in all subjects in the first attempt obtaining not less than 65% of the aggregate marks for two years shall be declared to have passed the examination with First Class.

4. A candidate who secures an aggregate of 75% or above marks is awarded distinction. A candidate who secures not less than 75% marks in any subject will be deemed to have passed the subject with distinction in that subject provided he / she passes the whole examination in the first attempt.

5. A candidate who takes more than one attempt in any subject and pass subsequently shall be ranked only in pass class.

6. A Candidate passing the entire course is placed in Second class / First class / Distinction based on the cumulative percentage of the aggregate marks of all the subjects.

7. Rank in the examination: - Aggregate marks of I and II(final) year regular examinations will be considered for awarding rank for the M.Sc Graduate Examination. For the courses where the number of students are more than 15 rank will be calculated as under:

   I. Topmost score will be declared as First Rank
   II. Second to the topmost will be declared as Second Rank
   III Third to the topmost will be declared as Third Rank

V. General considerations and teaching / learning approach:

There must be enough experience to be provided for self learning. The methods and techniques that would ensure this must become a part of teaching learning process.

Proper records of the work should be maintained which will form the basis for the students assessment and should be available to any agency who is required to do statutory inspection of the school of the course.
Part II

Syllabus
1. INTRODUCTION:

The discipline of Biostatistics has contributed substantially to the development of health, medical and biological sciences and has emerged as an important tool for research. By applying various statistical methodologies a variety of easily applicable diagnosis, treatment and prognosis methods have been developed with scientific validity and many diseases and health conditions have been understood and dealt with appropriately. Statistical methodologies form the strength of any research study so as to make valid judgments and conclusions. Statistical design and analysis methods are very widely used in Clinical Trials, Pharmacology, Genetics, Biotechnology, Basic Sciences, Epidemiological studies, Demography, Quality Control of Medical & Biological equipments, Medical Diagnosis & Prognosis and Health Economics. Any research work is incomplete without treating the data statistically and interpreting the results with scientific and statistical reasoning and evidence. Its importance in Public Health administration in identifying causative factors of various diseases and identifying health priorities and proper allocation and utilization of the available budget appropriately and judiciously has also been well recognized now. There is an ever growing demand for this subject due to all these reasons.

2. EMPLOYMENT OPPORTUNITIES

Successful candidates of this course will get opportunities to work as Faculty / Statisticians and Research assistants and officers in medical colleges, research institutions, Health Ministries and Departments, Pharmaceutical companies and Universities.

COURSE STRUCTURE

First year

Basic Medical Sciences: Important terms and Principles.
Paper -5: Sample size estimation and Sampling Methods.

Paper -6: Epidemiology- I (Epidemiology and Epidemiological Methods & Design and analysis of Case-Control studies).

Second year

Paper -7: Epidemiology -II (Design and analysis of Cohort studies & Survival analysis).

Paper -8: Demography & Health Statistics.

Paper -9: Design and Analysis of Experiments and Clinical Trials.

Paper -10: Multivariate Analysis Methods

Paper -11: Optional Subject (Any one subject)

OPTIONAL SUBJECTS

1. Statistical methods in the analysis of Biological Assays

2. Quantitative Genetics

3. Health Economics, Econometrics & Cost - benefit analysis methods

4. Statistical methods in Quality control

5. Bio-informatics
FIRST YEAR

During the first year the students will have didactic lecture from 8 am to 11am and from 2pm to 4pm.

**Internal Assessment**

Three sessional examinations will be conducted in this year. Average marks of these sessional examinations will be counted as internal marks.

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**I. Paper - 1 Essential Mathematics for Statistics**

**Unit - I**

Set theory, Vectors and Matrices: Set theory and vectors - introduction and basic concepts, Schwartz inequality, matrices - basic concepts, determinants, linear independence, orthogonality, addition and multiplication of matrices, inverse of a square matrix.

**Unit - II**

Solution of Simultaneous Equations: Linear equations - introduction, solution of simultaneous equations, matrix method, Crammer’s rule, rank of a matrix, matrix polynomials, characterized roots and vectors, Cayley Hamilton theorem, Reduction to Normal form, row equivalent canonical matrix.

**Unit - III**

Quadratic forms: Quadratic forms, real quadratic forms and its properties, matrix of a quadratic form, congruence of matrices and its properties, congruence of quadratic forms, rank of a quadratic form.

**Unit - IV**

Generalized inverses: Generalized inverses - basic concepts, necessary and sufficient condition for the existence of g-inverse, properties and its applications, algorithm for finding generalized inverses.
Text Books:

- **Linear Algebra**: Kennet Hoffman Ray Kunze; 2000; Prentice Hall.
- **Matrix Algebra from a Statistician’s Perspective**: David A Harville; 2000; Springer Verlag.

Reference Books:

a) **Matrix Algebra - Exercise and Solutions**: David A Harville; 2001; Springer Verlag.

b) **Calculus for Scientists and Engineers**: K. D. Joshi; 2002.

II Paper - 2: Descriptive Statistical Methods

Unit - I

**Introduction to Biostatistics**: Biostatistics - basic concepts, examples and applications of statistical methods in medicine, biology and public health, scale of measurements, statistical populations, sample from population, data collection - sampling methods.

Unit - II

**Descriptive Statistics**: Construction of statistical tables, frequency distribution, construction of frequency tables from raw data, cumulative frequency tables, diagrammatic and graphical representation of data, measures of central tendency, raw and central moments from grouped and ungrouped data, dispersion, skewness and kurtosis.

Unit - III

**Theory of attributes**: Attribute - definition and concepts, dichotomy, fundamental set of frequencies, consistency of data, conditions of consistency, independence and association of attributes.
Unit - IV

Correlation and regression: Basic concepts, Scatter diagram, line of regression, correlation coefficient, fitting of regression lines, definition of Spearman’s rank correlation coefficient, Kendall’s tau, partial and multiple correlation and regression, tests for correlation and regression coefficients, intra-class correlation coefficient, correlation ratio.

Text Books:


Reference Books:

- Basic Statistics and Pharmaceutical Statistical Applications: James E. De Muth; 1999; Marcel Dekker, Inc.

******************************************************************
III. Paper – 3 Probability Theory, Distributions and Stochastic Processes

Unit - I

**Probability Theory:** Discrete sample space - events, relation between events, random variables, probability on discrete and continuous sample space, probability of at least one out of many events, conditional probability, theorems on conditional probability, Bayes’ theorem.

Unit - II

**Discrete probability distributions:** Discrete random variables, expectation and conditional expectations, theorems on expectations, raw and central moments, moment generating function, probability generating function, independence of random variables, discrete probability distributions:- uniform, binomial, Poisson, geometric, negative binomial, and hypergeometric distributions.

Unit - III

**Continuous probability distributions:** Continuous random variables, expectation and conditional expectations, theorems on expectations, continuous probability distributions:- normal, beta, gamma, exponential, Weibull, Pareto, Chi-square, Student’s t and F- distributions, multivariate normal distribution.

Unit - IV

**Stochastic Processes:** Definition and basic concepts, classification of stochastic processes, Markov chain, transition probability matrix and its properties, classification of states, periodicity, random walk, gambler’s ruin problem, Wiener process / Brownian motion processes.

Text Books:

- **An introduction to statistical methods:** Lyman ott; 1988; PWS-KENT publishing company.


**Reference Books:**

- Continuous univariate Distribution: Johnson L, Kotz and Balakrishnan; 1995; John Wiley.


******************************************************************

**IV. Paper - 4 Statistical Inference Methods**

**Unit - I**

**Estimation of population parameters:** Point estimation - properties of point estimation, maximum likelihood estimation, method of moments, Cramer-Rao lower bound, method of minimum chi-square, Fisher information, Rao-Blackwell theorem (statement only), UMVUEs, Interval Estimation - CI for mean and variance for normal distribution, CI for large samples.

**Unit - II**

**Tests of statistical significance of hypothesis I:** Concept of standard error, type I and type II errors, logic of statistical inference, CR, level of significance, power of a test, test of simple hypothesis against simple alternative hypothesis - composite alternative hypothesis, Neyman - Pearson Lemma, UMP test, likelihood
ratio test, tests: the mean of normal populations, the difference between means of two normal populations, the variance of normal population.

Unit - III

Tests of statistical significance of hypothesis II: Chi-square goodness of fit test and chi-square test for independence, tests for homogeneity and Barnett’s test of homogeneity of variance, test of proportion, tests of correlation coefficient, multiple comparison tests, sequential analysis and sequential probability ratio test.

Unit - IV

Non-parametric statistical tests of significance: Basic concepts and principles, median test, Mann-Whitney U test, Wilcoxon - Rank sum test, Wilcoxon signed rank test, Kolmogorov - Smirnov test, Run test, Kruskal-Wallis test, Friedman’s two-way analysis of variance test.

Text Books:


Reference Books:

- Principles of Statistical Inference: David Roxbee Cox; 2006; Cambridge University Press.
- Statistical Inference: George Casella & Roger. L. Berger; 2002; Duxbury.
V. Paper - 5 Sample size estimation and Sampling Methods

Unit - I

Sample size estimation: Importance of sample size in research design, methods of calculating minimum sample size: estimation of mean and proportion, comparison of two means and proportions, estimating an odds ratio and relative risk with specified relative precision, test of significance for odds ratio and relative risk, comparison of two survival rates, comparison of two median survival times and comparison of population proportion with a given proportion.

Unit - II

Sampling methods: Sampling and complete enumeration methods, probability and non-probability sampling, quota sampling, simple random sampling with and without replacement, sampling for proportions and percentages, stratified random sampling, allocation of sample size, construction of strata, number of strata, examples based on biostatistical experiments.

Unit - III

PPS sampling, PPS with and without replacement, cluster sampling, multistage and multiphase sampling, double sampling, sampling and non-sampling errors, randomized response technique, Warner’s method for randomized methods.

Unit - IV

Ratio and regression Estimation: Ratio and regression estimates, methods of estimation, systematic sampling, linear, circular and balanced, auxiliary information in sample surveys, general properties of sampling designs, specific estimators and unbiasedness, Hansen - Horvitz and Horvitz - Thomson estimators and their properties.

Text Books:

A. Sampling Theory: Des Raj and Chandhok; 1998; Narosa.
B. Sampling Techniques: Cochran W. G.; 2002; Wiley.
Reference Books:

- **Sample Survey**: Barnett V.; 2002; Arnold Publishers.

VI. Paper - 6 Epidemiology - I

(Epidemiology and Epidemiological methods & Design and analysis of Case-Control studies)

Unit - I

**Basic concepts**: Concepts of epidemiology, modern epidemiology, causation and causal inference, incidence time, incidence rate, other types of rates, incidence proportions and survival proportions, product limit and exponential formulae, prevalence, standardization of rates, study protocol, development of a study protocol, critical evaluation of reports.

Unit - II

**Measures of effect and association & Types of epidemiological studies**: Measures of effect and association, standardized measures, types of experimental and observational studies, bias, concept of chance, confounding, prevention of confounding, interaction, methods to deal with it, precision, validity, elements of data analysis, methods of significance testing and estimation, confidence intervals, ICD, National Health Policy, diagnostic tests, agreement analysis, likelihood ratio.

Unit - III

**Case - Control studies**: History of case-control studies, research question, definition of cases and controls, methods of selection, informed consent and
confidentiality, pilot tests, check list for protocol development, confounding, adjustments for confounding, sample size and power calculations, basic methods of analysis of grouped data, methods of analysis of matched data.

**Unit - IV**

**Logistic Regression analysis:** Multivariate analysis of data, introduction to the logistic model, general definition of the logistic model, logistic regression for case-control studies, estimation and interpretation of logistic parameters, indicator variables, matched analysis - estimation of logistic parameters, unmatched analysis of matched data, confounder score.

**Text Books:**


**Reference Books:**

- **Clinical epidemiology and biostatistics**: Knapp R. G., Miller M. C.; 1992; NMS from Williams & Wilkin, Baltimore.
- **Epidemiology - Health and Society**: Mervyn Susser; 1987; Oxford University Press.
- **Clinical Epidemiology - The Essentials**: Robert W. Fletcher, Suzanne W. Fletcher; 2005; Lippincott Williams.
- **Statistics for Epidemiology**: Nicholas P. Jewell; 2004; Chapman & Hall (CRC).
SECOND YEAR

VII. Paper - 7 Epidemiology - II (Design and analysis of Cohort studies & Survival analysis)

Unit - I

Cohort studies: Prospective cohort studies: planning and execution, types of cohort studies, retrospective cohort studies, nested case-control studies, case-cohort studies - planning & execution, household panel surveys, measures of disease frequency and association in cohort studies, current and historical cohort studies, cohort studies:- statistical analysis, advantages and disadvantages.

Unit - II

Survival analysis: Basic concepts, concepts of time, order and random censoring, types of censoring, life distributions - exponential, gamma, Weibull and lognormal, linear failure rate, parametric inference (point estimation, confidence intervals, scores, LR, MLE tests) for these distributions.

Unit - III

Life tables, current life tables, clinical life tables, failure rate, mean residual life and their elementary properties, bath tub failure rate, hazard models, probability density function, estimation of survival function - acturial estimator, Kaplan-Meier estimation, Deshpande test.

Unit - IV

Two sample problem - non-parametric methods for comparing survival distributions, Gehan’s test, Cox-Mantel test, log rank test, Mantel-Haenszel test, Peto and Peto’s generalized Wilcoxon test, Cox’s F test, semi-parametric regression for failure rate - Cox’s proportional hazards model with one and several covariates and its assumptions, competing risk model.
Text Books:


Reference Books:


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VIII. Paper - 8 Demography & Health Statistics

Unit - I

Demography - Basic concepts: Basic concepts, collection of demographic data, coverage and content errors, completeness of registration data, adjustment of age data - use of Whipple, Meyer and United Nations indices, population composition, dependency ratio.

Unit - II

Measures of fertility: Different measures of fertility, standardized measures, stochastic models for reproduction, distribution of time to first birth, inter-live birth intervals and number of births for both homogeneous and non-homogeneous groups for women, estimation of parameters, estimation of parity progression ratios from open birth interval data.
Unit - III

**Measures of mortality:** Mortality measures, construction of complete and abridged life tables, distribution of life table functions and their estimation, model life tables - Coale and Demeny, United Nations model life tables, morbidity indices, health statistics, hospital statistics.

Unit - IV

**Population dynamics:** Growth models, stable and stationary population, migration, factors affecting population - internal and international, stochastic models for social and occupational mobility based on Markov chains, methods of population projection, Leslie matrix.

**Text Books:**

- **Demography:** Cox P. R.; 1970; Cambridge University Press.
- **Demographic Analysis:** Benjamin B.; 1969; George, Allen and Unwin.

**Reference Books:**

- **Stochastic Models for Social Processes:** Bartholomew D. J.; 1982; John Wiley.
- **Introduction to Stochastic Processes in Biostatistics:** Chiang C. L.; 1968; John Wiley.
- **Applied Mathematical Demography:** Keyfitz N.; 1977; Springer Verlag.

IX. Paper – 9  Design and Analysis of Experiments and Clinical Trials

Unit - I

General linear models, Gauss - Markov theorem, estimability of parametric function, theorems relating to general linear models, testing of linear hypothesis, One-way classification, two-way classification.
Unit - II

Principle of design of experiments, Completely Randomized Design (CRD), Randomized (complete) Block Design (RBD), Latin Square Design (LSD), missing value analysis in RBD and LSD, analysis of variance in CRD, RBD, and LSD, analysis of covariance in CRD, RBD and LSD.

Unit - III

Factorial Design: $2^2$ factorial design, $2^3$ factorial design, $2^n$ factorial design, confounding and partial confounding in a $2^n$ factorial design, Balanced Incomplete Block Design (BIBD).

Unit - IV

Clinical Trials: The rationale of clinical trials, types of trials, preparation of protocol, selection of patients, methods of randomization, blinding and placebos, ethical issues and informed consent, size of the trial, protocol deviations, monitoring trial progress, statistical analysis, cross-over trials, CONSORT statement, statistical methods in evidence based medicine, number needed to treat, interim analysis, intention to treat analysis.

Text Books:

- **Design and analysis of experiments**: Das M. N. & Giri N. G.; 1979; Wiley Eastern.

Reference Books:

X. Paper - 10 Multivariate Analysis Methods

Unit - I

Multivariate Analysis - Introduction: Multivariate data, multivariate analysis - basic concepts, multivariate normal distribution, random sampling from a multivariate normal distribution, maximum likelihood estimators of parameters, distribution of sample mean vector.

Unit - II

Tests of Significance: Hotelling’s $T^2$ and Mahalanobis $D^2$ statistics, applications in tests on mean vector for one and more multivariate normal populations and also on equality of the components of a mean vector in a multivariate normal population, Wishart distribution and applications.

Unit - III

Multivariate Linear Regression analysis and Classification Procedures: Multivariate linear regression model - estimation of parameters, tests of linear hypotheses about regression coefficients, likelihood ratio test criterion, multivariate analysis of variance (MANOVA) of one and two-way classified data, Classification and discrimination procedures for discrimination between two multivariate normal populations, tests associated with discriminant functions, classification into more than two multivariate normal populations.

Unit - IV

Cluster Analysis, Factor Analysis and Principle Component Analysis: Cluster analysis, hierarchical and agglomerative methods, Principal components, dimension
reduction, canonical variables and canonical correlation - definition, use, estimation and computation, factor analysis.

**Text Books:**


**Reference Books:**

- **Multivariate Observations:** Seber G. A. F.; 2001; Wiley.
- **Multivariate Statistical Inference with Applications:** Rencher A. C.; 1998; Springer.
- **Computer aided Multivariate Analysis:** Abdelonem Afifi, Susanne May & Virginia Clark; 2003; Chapman & Hall (CRC).
- **Applied Multivariate Data Analysis:** Brain S. Everett and Graham Dunn; 2001; Oxford University Press.

******************************************************************************

**XI. Paper - 11 OPTIONAL SUBJECTS**

**1. Statistical methods in the analysis of Biological Assays**

**Bioassay and it’s genesis:** Bioassay - objectives and structures, quantitative dose response relationship, various assays and their designs, incomplete block assays and multi-dose factorial assays, design of a balanced assay, multiple assays, Quantal response and tolerance distribution, adjustment technique for natural mortality, Abbot's formula.

**Reference Books:**

1. **Modeling Binary Data:** Collett D.; 2003; Chapman & Hall.
2. **Statistical Methods in Bioassay:** Finney D. J.; 1971; Griffin.
3. **Statistical Techniques in Bioassay:** Govindarajulu Z.; 2000; S. Kargar.
2. Quantitative Genetics

Basic concepts of inheritance, gene, genotype, phenotype, genetic constitution of a population, frequencies of gene and genotypes, Hardy-Weinberg law and its applications, changes in gene frequency, migration, mutation, selection, polymorphism, small population, inbreeding, continuous variation, genetic components of variation, correlation and interaction between genotype and environment, environmental variance, resemblance between relatives, heritability and its estimation

Reference Books:


3. Health Economics, Econometrics & Cost - benefit analysis methods

Concepts of general economics, definition of health economics, scope of health economics, cost and demand - concepts and principles, demand curve, macro and micro economics, health production and utility functions, supply and demand, principles of cost, benefit analysis, consumer behaviour, consumer expenditure, consumer price, index, cost allocation, cost effective analysis, decision making, economic effectiveness and efficiency, finance, finance utility and finance management in health, hospital economics, medical care economics, health care cost and benefits, health expenditure, health insurance, health services research, national health expenditure, pharmaco-economics, public health economics, quality of life and adjusted life year, evaluation and appraisal of health economics.
Reference Books:


2. **Health Economics**: Charles E. Phelps; 2002; Addison Wesley.

4. **Statistical methods in Quality control**

   Quality control and quality assurance, internal and external quality control, standardization, variation and coefficient of variation, correlation and regression - principles and methods, agreement analysis, kappa statistic, Control charts, control charts for mean and proportion, X-Y ratio plots, cumulative sum charts, analysis of duplicates of lab measurements, calibration principles and methods, reliability and reproducibility, validity assessment of lab parameters, sensitivity and specificity, international biologic standards, accuracy and precision.

Reference Books:


2. **Quality control and industrial Statistics**: Acheson J. Duncan; 1952; Irwin.

5. **Bio-informatics**

   Bioinformatics: concepts, objectives and applications, structural biology, challenges in Molecular biology, bioinformatics in India, macromolecules, protein structure and purification, visualization and prediction of protein structure, data mining, phylogenetic analysis, Gen BANK, genome assembly and annotation, gene mapping, exploration of databases like NCBI, DDBJ, PDB, annotation systems - DAS, Homology Tools - BLAST, FASTA, multiple alignment - CLUSTALW, molecular visualization software- Swiss pdb viewer, Rasmol gene prediction softwares - Genescan, McPromoter, protein modelling software - SWISSMODEL.

Reference Books:

1. **Bioinformatics Computing**: Bergeron B.; 2003; Prentice Hall of India.

2. **Statistical Data Mining & Knowledge Discovery**: Bozdogan H.; 2003; CRC Press.

4. **Statistical analysis of gene expression and Micro array data**: Terry Speed; 2003; Chapman & Hall.

5. **Introduction to Computational Biology**: Waterman M. S.; 2000; CRC Press.

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**Time Table for M. Sc. course in Biostatistics**

<table>
<thead>
<tr>
<th>Day</th>
<th>9.30-10.30</th>
<th>10.45-11.45</th>
<th>12.00-1.00</th>
<th>2.00-3.00</th>
<th>3.15-4.15</th>
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<tr>
<td>Monday</td>
<td>DKS</td>
<td>AJ</td>
<td>SVS</td>
<td>Practicals</td>
<td>Practicals</td>
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<tr>
<td>Tuesday</td>
<td>AJ</td>
<td>SVS</td>
<td>DKS</td>
<td>Library</td>
<td>Library</td>
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<tr>
<td>Wednesday</td>
<td>KRS</td>
<td>DKS</td>
<td>AJ</td>
<td>Practicals</td>
<td>Practicals</td>
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<tr>
<td>Thursday</td>
<td>DKS</td>
<td>AJ</td>
<td>SVS</td>
<td>Project work</td>
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<tr>
<td>Friday</td>
<td>AJ</td>
<td>KRS</td>
<td>SVS</td>
<td>Seminar</td>
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<tr>
<td>Saturday</td>
<td>Library</td>
<td>KRS</td>
<td>KRS</td>
<td>Journal club</td>
<td>Journal club</td>
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**List of Topics in the Syllabus of the Course**

**TOPICS**

1. Basic Medical Sciences: Important terms and Principles.
7. Paper -6: Epidemiology- I (Epidemiology and Epidemiological methods & Design and analysis of Case-Control studies).

8. Paper -7: Epidemiology -II (Design and analysis of Cohort studies & Survival analysis).


10. Paper -9: Design and Analysis of Experiments and Clinical Trials

11. Paper -10: Multivariate Analysis Methods

12. Paper -11: Optional Subject (Any one subject)

**OPTIONAL SUBJECTS**

1. Statistical Methods in the analysis of Biological Assays

2. Quantitative Genetics

3. Health Economics, Econometrics & Cost - benefit analysis methods

4. Statistical methods in Quality control

5. Bio-informatics

**Semester I:** Topics 1 to 4

**Semester II:** Topics 5 to 7

**Semester III:** Topics 8 to 10 & Project work

**Semester IV:** Topics 11 and 12 & Project work

**Semesters-I & III:** July to December

**Semesters-II & IV:** January to June

********************************************************************
SCHEME OF EXAMINATION - FIRST YEAR M.Sc
BI STATISTICS DEGREE EXAMINATION

Distribution of Marks for each subject

<table>
<thead>
<tr>
<th>Subject</th>
<th>Theory</th>
<th>Practical</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Written (Max/ Min)</td>
<td>Internal (Max/ Min)</td>
<td>Subject Total</td>
</tr>
<tr>
<td>Paper1</td>
<td>100 / 50</td>
<td>50 / 25</td>
<td>150 / 75</td>
</tr>
<tr>
<td>Paper 2</td>
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<tr>
<td>Paper 3</td>
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<td>Paper 4</td>
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<tr>
<td>Paper 5</td>
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<td>TOTAL</td>
<td>600</td>
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TOTAL 1150
# Scheme of Examination Second Year M. Sc

## Degree Examination (Biostatistics)

<table>
<thead>
<tr>
<th>Subject</th>
<th>Theory</th>
<th>Practical</th>
<th>Project Work</th>
<th>Grand Total</th>
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<tr>
<td></td>
<td>Written</td>
<td>Internal</td>
<td>Oral</td>
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<tr>
<td></td>
<td>100/50</td>
<td>50/25</td>
<td>150/75</td>
<td>100</td>
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<tr>
<td>Paper-7</td>
<td>Epidemiology-II</td>
<td>100</td>
<td>50</td>
<td>150</td>
</tr>
<tr>
<td>Paper-8</td>
<td>Demography &amp; Health Statistics</td>
<td>100</td>
<td>50</td>
<td>150</td>
</tr>
<tr>
<td>Paper-9</td>
<td>Design and Analysis of Experiments and Clinical Trials</td>
<td>100</td>
<td>50</td>
<td>150</td>
</tr>
<tr>
<td>Paper-10</td>
<td>Multivariate Analysis Methods</td>
<td>100</td>
<td>50</td>
<td>150</td>
</tr>
<tr>
<td>Paper-11</td>
<td>Optional Subject</td>
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<tr>
<td>Total</td>
<td></td>
<td>500</td>
<td>250</td>
<td>750</td>
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<tr>
<td>Max/Min</td>
<td>500/250</td>
<td>250/125</td>
<td>750/375</td>
<td>100/50</td>
</tr>
</tbody>
</table>

The duration of both theory and practical examinations will be three hours for each paper.

## Total Marks

- First year : 1150
- Second year : 1200
- Grand Total : 2350
TYPICAL QUESTION PAPER PATTERN (THEORY) FOR THE UNIVERSITY EXAMINATION

Time: 3 Hrs.

Essay 2 x 10 marks = 20 marks
Short essay 4 x 10 marks = 40 marks
Short notes 2 x 5 marks = 10 marks
Problems 3 x 10 marks = 30 marks

Total 100 marks

TYPICAL QUESTION PAPER PATTERN (PRACTICALS) FOR THE UNIVERSITY EXAMINATION

Time: 3 Hrs.

Small Problems 4 x 10 marks = 40 marks
Large problems 4 x 15 marks = 60 marks

Total 100 marks

NOTE-1

Variations may be made in the above indicated pattern and in the marking system for the different types of questions depending upon the requirement.

NOTE-2

Lectures on Allied Health Sciences (Physiology, Biochemistry, Anatomy, Microbiology, Pathology, Pharmacology and Medical Subjects) have been included in the Syllabus only for helping the students to get themselves familiar with the important terms and terminologies of these topics so as to enable them to understand the medical and health problems for which project planning and data analysis have to be done by them. There will not be any examination for the students in these subjects.
<table>
<thead>
<tr>
<th>IMPORTANT TELEPHONE NUMBERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amrita Institute of Medical Sciences : 0484-2801234/2851234</td>
</tr>
<tr>
<td>Principal's Office : 0484-2858132/2858331</td>
</tr>
<tr>
<td>Chief Programme Administrator : +91 7034028019, oncall: 1919</td>
</tr>
<tr>
<td>Programme Co-ordinator : +91 7034028118, oncall: 6976</td>
</tr>
</tbody>
</table>