Proposals from *Indian Society for Medical Statistics* for

Pharmacy Council of India on

Biostatistics Teaching (Curriculum as well as Infrastructure) in Different Pharmacy Courses

Postgraduate (Pharm. D.) Curriculum of Biostatistics including Data-Analysis, Demography, Research Methodology, Remedial Mathematics and Medical Informatics.	
Extracts from the Existing Regulations Pharm. D. Regulations, 2008 (Latest available as of January 2015)	**Proposed by the Indian Society for Medical Statistics NOT SEEKING ANY INCREASE IN TEACHING – ONLY MORE MEDICAL FOCUS**
BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY) Theory: 2 Hrs. / Week 1. Detailed syllabus and lecture wise schedule **1. Research Methodology:** a) Types of clinical study designs: Case studies, observational studies, interventional studies; b) Designing the methodology; c) Sample size determination and power of a study, determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width; d) Report writing and presentation of data. **2. Biostatistics:** **2.1** a) Introduction; b) Types of data distribution; c) Measures describing the central tendency, distributions - average, median, mode; d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean. **2.2 Data graphics:** Construction and labelling of graphs, histogram, pie charts, scatter plots, semilograthimic plots **2.3 Basics of testing hypothesis:** a) Null hypothesis, level of significance, power of test, P-value, statistical estimation of confidence intervals; b) Level of significance (Parametric	**MEDICAL BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY) Theory: 2 Hrs. / Week (Exam – One paper with 100 marks) I. Detailed syllabus and lecture wise schedule** **1. Research Methodology:** i) Review of literature and lacunae, selection of topic (feasibility), framing of objectives and hypotheses; ii) Elements of research designs (observational studies, experiments and clinical trials); randomization, blinding and matching; Statistical requirements of phases of clinical trials; Adaptive trials; iii) Medically important difference and statistical power, sample size for tests of significance and confidence intervals (CIs) – Refer to biostatistics course; iv) Protocol preparation; v) Medical ethics; vi) Designing data collection forms; vii) Importance of truthful data; viii) Elements of an impressive thesis; ix) Communication of findings (publication of papers, and oral and poster presentations) **2. Biostatistics:** No extra teaching, no extra hours – only medical orientation. Details are provided so that the content is clear **2.1 A. Introduction** (Omni-presence of epistemic and aleatory uncertainties and variations in health; Need to depend on probabilities; Simple rules of probability; Role of biostatistics in controlling and

data) - students t-test (paired and unpaired), chi-square test, Analysis of Variance (one-way and two-way); c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann-Whitney U test, Kruskal-Wallis test (one way ANOVA) d) Linear regression and correlation - Introduction, Pearson's and Spearman's correlation and correlation co-efficient; e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology:
Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy:
Computer system in hospital pharmacy: Patterns of computer use in hospital pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.
Computer in community pharmacy: Computerizing the prescription dispensing process, Use of computers for pharmaceutical care in community pharmacy; Accounting and general ledger system; Drug information retrieval & Storage: Introduction – Advantages of computerized literature retrieval.

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY) Theory: 3 Hrs. /Week REMEDIAL MATHEMATICS:
1. Scope and objectives: This is an introductory course in mathematics. This subject deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, Laplace transform.
2. Upon completion of the course the student shall be able to : –
a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
b. solve the problems of different types by applying theory; and
c. appreciate the important applications of mathematics in pharmacy.
 4. Lecture wise programme : Topics

measuring uncertainties). B. Medical measurements (Nominal, ordinal and metric scales, advantages and pitfalls of categorizing medical data; Tabular and graphical presentation – where to use which diagram, including log-scale)

2.2 Clinical assessments – A. Normal range of medical parameters: Measure of central values (mean, median, mode), why and where to use each; need to assess variation (variance, SD and CV); need to explore statistical distribution of values (Gaussian and skewed distributions, binomial distribution for proportions); proper interpretation of mean±2SD range as normal. B. Individual diagnosis, treatment, prognosis assessment in terms of Gaussian, binomial and other probabilities; combining several measurements by scoring systems, use and misuse of individual and hospital records for patient evaluation

2.3 Medical data – A. Incidence, prevalence, duration of disease and outcomes; Relative risk (RR), attributable risk (AR), odds ratio (OR) and number needed to treat (NNT). B. Sensitivity-specificity of medical tests, Bayes rule for predictivity; ROC curves for overall performance and best cut-offs; Bioavailability and bioequivalence – area under the concentration curve; T_{max} and C_{max}

2.4 Medical generalizations – A. Sampling fluctuations; standard errors of mean and proportion; types of statistical generalizations (the concept of CI and tests of significance with their medical implications); null and alternative hypotheses; Type I and Type II errors and need to control them; statistical power and sample size. B. Comparison of means (Student t test, one-way ANOVA, Wilcoxon and Kruskal-Wallis test; comparison of efficacies, RR and OR by chi-square test; Comparison of NNT; Equivalence and noninferiority tests

2.5 Medical relationships – Simple linear and nonlinear regression and correlation, their validity in explaining and prediction; Criteria for causal inference

2.6 Introduction to software packages (SPSS, Epi-Info and Stata/SAS)

3. Computer applications in pharmacy: To be renamed as Pharmacy Informatics

1 **Algebra :** Determinants, Matrices 2 **Trigonometry :** Sides and angles of a triangle, solution of triangles 3 **Analytical Geometry :**Points, Straight line, circle, parabola 4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables 5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals. 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order. 7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.	Contents as it is (no change required) **1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)** **May be dropped altogether – hardly ever used in pharmacy** **Also may be too much for pharmacy students**
Staff and Facilities – Pharm. D. Present Regulations 3) **TEACHING STAFF REQUIREMENT** 18.Computer Science or Computer Application in pharmacy MCA 19. Mathematics M.Sc. (Math) **Non-Teaching Staff:** 6. Computer data Operator BCA or Graduate with computer Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required. **8. Computer and other Facilities**	**Staff and Facilities – Pharm. D. Proposed Changes** 3) **STAFF REQUIREMENT** Colleges with Pharm. D. courses will have an independent Department of Biostatistics and Pharmacy Informatics. This Department will take care of all research and data analysis requirements of postgraduates and faculty, and teaching of biostatistics, research methodology and pharmacy informatics, and maintain the institutions computer network and website. The Department will consist of the following: **Teaching Staff:** Associate Professor of Biostatistics – 1 (PhD in Biostatistics/Medical Statistics/Health Statistics with at least 5 years' experience out of which at least 3 years as Assistant Professor in a College of Pharmacy, and training in Informatics Technology) Assistant Professor – 1 (MSc in Statistics/Biostatistics/Medical Statistics/Health Statistics. Desirable: At least 2 years' research experience and training in Informatics Technology) **Non-Teaching Staff:** Programmer-cum-Statistician – 1 (MSc in Statistics/ Biostatistics/ Medical Statistics/ Health Statistics. Desirable: At least one year

	training in computers) Statistical Assistant – 1 (MSc in Statistics/ Biostatistics/ Medical Statistics/ Health Statistics) Technical Assistant – 1 (BCA or Graduate with computer science/applications) Computer Data Operator – 2 (Science graduate with training in computers) Steno and other ancillary staff Computers and Internet connection (Broadband), six computers for students with internet and computers for each of the staff member **Functions of the Department of Biostatistics and Medical Informatics** • Provide data analysis facilities to the postgraduate students and faculty for their research; assist in interpretation of findings • Assist in designing of research and do sample size calculations • Teaching of Biostatistics, Research Methodology and Informatics to PG and UG students • Maintaining computer network of the institution and website **Infrastructure Requirement** i) Space/ rooms for the staff and also for Biostatistics Laboratory. ii) Laptops– 2 (for faculty) and Desktop Computer 1 for every 6 students in the Biostatistics Lab. iii) Statistical Software Packages (SPSS, Epi Info). iv) Printers - 2 and Scanner – 1 v) Internet connection– Broadband with Wifi facility vi) Recent books and Journals (epidemiology/biostat) vii) Necessary furniture (for staff, students & office) viii) Necessary consumables.

Postgraduate (M. Pharm.) Curriculum of Biostatistics including Data Analysis, Demography, Research Methodology and Medical Informatics, etc.	
Extracts from the Master of Pharmacy (M. Pharm.) Course Regulations, 2014	**Proposed by the Indian Society for Medical Statistics** **NOT SEEKING ANY INCREASE IN TEACHING** **– ONLY MORE MEDICAL FOCUS**
6. GOALS AND GENERAL OBJECTIVES OF POSTGRADUATE PHARMACY EDUCATION **6.1 Goal –** iv. Have acquired a spirit of scientific inquiry and is oriented to the principles of research methodology. **6.2 General objectives of post-graduate training expected from students at the end of post-graduate training** vii. Demonstrate competence in basic concepts of research methodology and be able to critically analyze relevant published research literature. Theory papers 4 **8. Components of the Postgraduate curriculum –** • Thesis skill. • Training in research methodology. • Basics of statistics to understand and critically evaluate published research paper. • Introduction to the non-linear mathematics. **14. Thesis –** 1. Every candidate shall carry out work on an assigned research project under the guidance of a recognized postgraduate teacher, the result of which shall be written up submitted in the form of thesis. 2. Work for writing the Thesis is aimed at contributing to the development of a spirit of enquiry, besides exposing the candidate to the techniques of research, critical analysis, acquaintance with the latest advances in medical science and the manner of identifying and consulting available literature.	**6.GOALS AND GENERAL OBJECTIVES OF POST GRADUATE PHARMACY EDUCATION** **6.1 Goal**: No change required **6.2 General Objectives of the Post Graduate Training in Pharmacy**: vii. Demonstrate competence in basic concepts of research methodology and be able to critically analyze research data and relevant published research literature. 8. **Components of the Postgraduate curriculum – No change required. Everything is clearly mentioned. We could not locate detailed curriculum in the course regulations. The following may be incorporated so that everyone knows what exactly should be taught.** i) **Thesis skill**: Concept of scientific research, steps, writing skills, format / structure of Thesis – introduction, objectives, material & methods, results, discussions, key messages, limitations & references. ii) **Training in research methodology**: Steps in medical research, principles of medical ethics, formulating objectives and hypotheses, searching medical literature, research designs, sampling methods, sample size, data management, scoring, reporting results and limitations of scientific research. **iii) Medical Biostatistics to do elementary research and to understand and critically evaluate published research paper**s **Introduction** (Medical uncertainties; Need to depend on probabilities; Simple rules of probability; Role of biostatistics in controlling and measuring uncertainties); Tabular and graphical presentation – where to use which diagram, including log-scale) **Clinical assessments –** A. Normal range of medical parameters: Measure of central values (mean, median, mode), why and where to use each; need to assess variation (variance, SD and CV); need to explore statistical

	distribution of values (Gaussian and skewed distributions, binomial distribution for proportions); proper interpretation of mean±2SD range as normal **Medical data –** A. Incidence, prevalence, duration of disease and outcomes; Relative risk (RR), attributable risk (AR), odds ratio (OR) and number needed to treat (NNT). B. Sensitivity-specificity of medical tests, Bayes rule for predictivity **Medical generalizations –** A. Sampling fluctuations; standard errors of mean and proportion; types of statistical generalizations (the concept of CI and tests of significance with their medical implications); null and alternative hypotheses; Type I and Type II errors and need to control them; statistical power and sample size. B. Comparison of means (Student t test, one-way ANOVA, Wilcoxon and Kruskal-Wallis test; comparison of efficacies, RR and OR by chi-square test **Medical relationships –** Simple linear and nonlinear regression and correlation, their validity in explaining and prediction; Criteria for causal inference **Introduction to software packages** (SPSS, Epi-Info and Stata/SAS) **Out of 4 theory papers, half of one of the papers will be devoted to research methodology and biostatistics** 14. **Thesis: No change required**
Staff Requirement – M. Pharm. Nothing stated in the current regulations (we could not locate)	**Staff and Facilities – M. Pharm. Proposed Changes** 3) **STAFF REQUIREMENT** Colleges with M. Pharm. courses will have an independent Biostatistics and Pharmacy Informatics Unit. This Unit can be under any interested department. This Unit will take care of all research and data analysis requirements of postgraduates and faculty, and teaching of biostatistics, research methodology and pharmacy informatics, and maintain the institutions computer network and website. The Unit will consist of the following: **Teaching Staff:** Assistant Professor – 1 (MSc in Statistics/Biostatistics/Medical

	Statistics/Health Statistics. Desirable: At least 2 years' research experience and training in Computers)
	Non-Teaching Staff:
	Statistical Assistant – 1 (MSc in Statistics/ Biostatistics/ Medical Statistics/ Health Statistics)
	Technical Assistant – 1 (BCA or Graduate with computer science/applications)
	Computer Data Operator – 1 (Science graduate)
	Office Assistant – 1
	Computers and Internet connection (Broadband), four computers for students with internet and computers for each of the staff member
	Functions of the Biostatistics and Medical Informatics Unit
	• Provide data analysis facilities to the postgraduate students and faculty for their research; assist in interpretation of findings
	• Assist in designing of research and do sample size calculations
	• Teaching of Biostatistics, Research Methodology and Informatics to PG and UG students
	• Maintaining computer network of the institution and website
	• Maintaining student database
	Infrastructure Requirement
	i) Space/ rooms for the staff and also for Biostatistics Laboratory.
	ii) Laptops– 1 (for faculty) and Desktop Computer 1 for every 6 students in the Biostatistics Lab.
	iii) Statistical Software Packages (SPSS, Epi Info).
	iv) Printers - 2 and Scanner – 1
	v) Internet connection– Broadband with Wifi facility
	vi) Recent books and Journals (epidemiology/biostat)
	vii) Necessary furniture (for staff, students & office)
	viii) Necessary consumables.

Undergraduate (B. Pharm.) Curriculum of Biostatistics, Data Analysis, Demography, Informatics, etc.	
Extract from existing Regulations **Bachelor of Pharmacy (Practice) Regulations, 2014**	**Proposed by the Indian Society for Medical statistics** **NOT SEEKING ANY INCREASE IN TEACHING – ONLY MORE MEDICAL FOCUS**

CHAPTER-III
17. Assignment work –
1. To allow the student to understand and develop data collection and reporting skills in the area of community, hospital and clinical pharmacy in particular and principles of pharmacy practice in general, the assignment work shall be carried out under the supervision of a teacher of the Academic Institution on the topic approved by the Head of the Academic Institution.
18. Objectives of Assignment work-
(ii) Develop the students skills in data collection, analysis and reporting and interpretation skills.
 	
APPENDIX-III
 Detailed Syllabus and Lecture Schedules-
3. b) **Patient Data analysis** - 02 hours
Patient case history, drug therapy evaluation, identification and resolving of drug related problems.
 	
1.5 Applied pharmaceutics: Lecture wise program and detailed syllabus
11. (a) Bioavailability and equivalence
    (b) Factor affecting bioavailability.
 	
2.4. Pharmacy Practice IV
Detailed syllabus and lecture wise program
5. Clinical Research -
Introduction to Clinical trials
Various phases of clinical trial.
 	
6. Introduction to Biostatistics - 3hrs
	CHAPTER-III
	17. **Assignment Work:**
	No change required
	18. **Objectives of Assignment work:**
	No change required
	
	APPENDIX-III
	 Detailed Syllabus and Lecture Schedule:
	3. b) **Patients' Record Analysis** -02 hours
	Patient's case history, drug therapy evaluation, identification and resolving drug related problems.
	
	1.5 Applied Pharmaceutics:
	Lecture wise Program and Detailed Syllabus
	1.1 (a) Bioavailability and equivalence
	    (b) Factor affecting bioavailability.
	
	2.4 Pharmacy Practice IV- Detailed Syllabus and Lecture-wise Program:
	5. Clinical Research: Teaching hours - 5 Lectures (1 hour each)
	Basics of medical research, uncertainties in clinical practice, biases in clinical research, medical experiment designs, laboratory experiments, concept of clinical trials and their various phases
	6. Introduction to Biostatistics: **Teaching hours - 7 Lectures (1 hour each)**
	Medical uncertainties and probabilities; control and measurement of uncertainties by biostatistics; data collection and presentation methods, summarization of data in terms of mean, median and mode (where to use which), variation (SD, CV) and distributions
	7. Research in Pharmacy Practice Areas :

7. Research in pharmacy practice areas. **12. Applications of IT and computers in pharmacy practice - 2 hrs.**	**Teaching hours – 5 Practical / Demonstrations (for 2 hours each)** These classes should be based on theoretical teaching on clinical research methods and biostatistics. **12. Applications of IT and Computers in Pharmacy Practice** **Teaching hours : 3 Practicals / Demonstrations (for 2 hours each)** These classes should be based on IT / Computer teaching in Pharmacy.
Staff and Infrastructure for Biostatistics, Research Methods, Computers - B. Pharm.: **Computer Room for B. Pharm Course :** 01 system for every 2 students (with internet and Printer facilities) **Computer For Model Pharmacy:** As required for teaching and practice purposes and for drug information services **Computer (Latest configuration):**1 system for every 10 students (UG & PG) **5. Number of non-teaching staff available for D. Pharm and B. Pharm Course for intake of 60 students-** 6. Computer Data Operator BCA or Graduate with computer No teacher provided for biostatistics and research methodology.	**Staff and Infrastructure for Biostatistics, Research Methods, Computers - B. Pharm.:** **Computer Room for B. Pharm. Course :** 01 system for every 2 students (with internet and Printer facilities) **Computer For Model Pharmacy:** As required for teaching and practice purposes and for drug information services **Computer (Latest configuration):**1 system for every 10 students (UG & PG) **5. Number of non-teaching staff available for D. Pharm and B. Pharm Course for intake of 60 students-** 1.**Teaching Staff :** **Assistant Professor of Biostatistics – 1** (MSc in Biostatistics / Medical Statistics/ Health Statistics. Desirable: Some training in computers and at least one year work experience in medical or health area). **2. Nonteaching Staff:** Programmer-cum-Statistician – 1 ((MSc in Statistics with at least one year work experience in medical or health area). Computer Data Operator – 1 (Graduate with computer training) Beside teaching, this staff will maintain institutional computers and college website