DRAFT REPORT

Proposal from *Indian Society for Medical Statistics* for Medical Council of India for Medical Biostatistics in Undergraduate (MBBS) and Postgraduate (MD/MS) Courses

Undergraduate (MBBS) Curriculum of Biostatistics, Health Statistics, Medical Statistics, Demography, Informatics, etc.	
Existing Regulations Medical Council of India Regulations on Graduate Medical Education, 1997 (Amended upto February, 2012) – Latest available on MCI website	**Proposed by the Indian Society for Medical Statistics for MBBS course**
Chapter 1 – 2. General considerations and teaching approach (9) **… ability to collect and analysis information and to correlate them.** Chapter III – Curriculum (Subject-wise) (2) Human Physiology including Bio-Physics (A) Physiology b) Skills - (2) **Interpret experimental/ investigative data.** (3) **Distinguish between normal and abnormal data derived as a result of tests which he/she has performed and observed in the laboratory.** (3) Biochemistry b. Skills – (2) **Analyze and interpret investigated data.** (4) Introduction to Humanities & Community Medicine Objectives – a) Knowledge 1. **Explain the principles of demographic population dynamics.** Para Clinical subjects of Phase II (5) Community Medicine Objectives – a) Knowledge (4) **Apply biostatistical methods and techniques.** (6) **Describe the health information systems.** b) Skills –	Needs to be reoriented to medical issues. Current teaching is too much mathematical and alien to medical sciences. Although biostatistics is woven into several teaching-learning activities at undergraduate (MBBS) level, there is no recommendation for structured lessons. At undergraduate level, this is taught as part of the Community Medicine and the convention is to allocate 15 didactic lectures (spread across first, second and third professional classes) and 10 practical sessions to this subject. In view of emphasis now on evidence-based medicine and need to interpret large chunks of medical data that are generated due to digitization, there is a need now to formalize this without increasing the burden on the students. The teaching may continue to be 15 hrs of lectures and 10 hrs of practical, but the curriculum be specified as follows so that it gets complete medical orientation: An integrated curriculum that highlights the relevance of Biostatistics to medical sciences be adopted. This is as follows: 1. **Introduction:** What is medical biostatistics, how it can help in medical decision making. 2. **Medical uncertainties:** Omni-presence of aleatory and epistemic uncertainties; sources of medical uncertainties; probabilistic nature of all medical decisions (diagnosis, treatment and prognosis) 3. **Evaluation of probabilities:** Essential empiricism, need for

(2) **Collect, analyse, interpret and present simple community and hospital based data.** Chapter IV - 12. Examination Regulation (3) University Examination (c) Community Medicine including Humanities **Practical/Project evaluation 30 marks** Appendix 'A' Curriculum for family Welfare 4. Community Medicine (6) **Demography and Vital Statistics** Chapter V- Internship (9) Internship- Discipline Related (i) Community Medicine (6) Assessment of Internship: **(2) Develop capacity for analysis of Hospital based morbidity and mortality statistics.**	collection of reliable data, data analytics, medical decisions with the help of simple rules of probability 4. **Qualitative and quantitative measurements:** Nominal, ordinal and metric scales of measurement; advantages and pitfalls of categorizing medical measurements into normal and abnormal, and other categories 5. **Health assessment and demography:** Incidence, prevalence, duration of disease; Fertility and mortality; elements of demography; Sources of medical data; causes of death and International Classification of Disease; indicators of health infrastructure; indicators of mental and social health 6. **Presentation of medical data:** Features of good tables; graphical presentation in terms of bar, histogram, curve, scatter, pie, line, etc. – where to use which diagram 7. **Normal range of medical parameters:** Measure of central values, and why and where we need mean, median and mode; need to assess variation in terms of variance, SD and coefficient of variation; need to explore the statistical distribution of values; elementary kinds of statistical distribution of medical measurements – Gaussian and skewed distributions, and how they affect the mean ± 2SD and other normal ranges; proper interpretation of normal range in the context of patient management. 8. **Hospital statistics:** Quality of care and utilization indicators; Medical record keeping, linkages and concept of electronic medical record (EMR); International Classification of Diseases (ICD-10). Practicals will be on calculation of diagnostic probabilities, identifying scales of measurement in hospital data, calculation of incidence and prevalence rates, calculation of various fertility and mortality indicators based on actual data, choosing and making appropriate diagrams for a set of medical data, identifying Gaussian and other distributions by histogram/polygon, setting up normal range of medical parameters from a set of data on healthy subjects, interpretation of these ranges for a new

	patient and for improvement/deterioration in existing patients. In theory examination, there must be at least one full question and one short note on biostatistics topics in Community Medicine. In practical examination, at least one of the exercise should be from biostatistics. **The Society welcomes the decision of the MCI to have a Research Cell in each medical college. MBBS students should be exposed to elementary research methods by conducting small study themselves in groups. Same data could be used for practical sessions.**

Postgraduate (MD/MS) Curriculum of Biostatistics, Health Statistics, Medical Statistics, Demography, Research Methodology, Informatics, etc.	
Existing Regulations Medical Council of India Postgraduate Medical Education Regulations (Amended upto May 2013) – Latest available on MCI website	**Proposed by the Indian Society for Medical Statistics for MD/MS courses**
Page 3: **3.2 General Objectives:** **VII.** Morbidity and Mortality rate **XII.** Competence in basic concepts of research methodology and epidemiology, critically analyse relevant published research literature. **5.Components of the Postgraduate Curriculum:** Writing thesis/ Research articles Training in Research Methodology …. **Page 6:** **(4) a.** Basic of statistics to understand and critically evaluated published research paper. **Page 23:** **(4) a. Thesis:** Techniques of research, critical analysis	All PGs should necessarily undergo a 20-hour foundation course in Biostatistics and Research Methodology, followed by an examination which must be passed by each student with at least 50% marks before s/he submits the PG thesis. This must be the part of the certificate signed by the head of the institution in the front pages of the thesis. This course will be conducted by the Department of Biostatistics and Medical Informatics with the assistance of teachers from other departments who have conducted funded research. The following proposal is completely oriented to medical issues and integrated into medical teaching. 1. **Introduction to biostatistics and research methodology:** A refresh of UG biostatistics; uses and misuses of biostatistics and research methodology in medical research; purpose and importance of theses and research articles; measurement scales; organization and presentation of data with diagrams; simple and composite tables for data and statistical results

	2. **Clinical assessment:** Individual assessment in terms of probability using normal range and statistical distribution of medical measurements; combining several measurements by scoring systems (APACHE and other scorings); use and misuse of individual and hospital records for patient management 3. **Health surveys:** Effect of random and nonrandom selection of the subjects; community assessment in terms of incidence, prevalence, duration of disease and mortality; elements of health surveys – questionnaires, schedules and proforma – proper recording, training and data entries; random and nonrandom sampling methods 4. **Medical studies:** Exploratory and descriptive studies; antecedent–outcome relationship in analytical studies; observational (merits and demerits of prospective, retrospective and cross-sectional) studies; medical experiments on biological specimens and animals; phases of clinical trials; controlled and uncontrolled trials; need for randomization, blinding and matching; equivalence and noninferiority trials; CONSORT requirements 5. **Research protocols:** Contents of protocols (lacunae in knowledge, selection of topic, objectives and hypotheses, methodology, inclusion and exclusion criteria, sample size, statistical analysis, forms of data collection and coding, scoring where needed, Vancouver system of references 6. **Thesis writing and research publications:** IMRAD format with contents of each, role of tables and graphs, system of references; impact factor and other bibliometric indices; need and importance of good publications 7. **Assessment of medical tools:** Sensitivity-specificity and predictivity, Bayes rule and the effect of prevalence; ROC curves for overall performance and for best cut-offs 8. **Medical generalizations:** Need to go from individual measurements to generalized conclusions; sampling error; standard errors of sample summaries; types of statistical generalizations – the concept of

	confidence intervals and tests of significance; philosophical basis of statistical inference – null and alternative hypotheses, Type I and Type II errors and need to control them; where to use parametric and where nonparametric tests; statistical power and sample size; confidence intervals for means, proportions and differences 9. **Assessment of risk factors for medical outcomes:** Relative (RR) and attributable risks (AR); odds ratio (OR); differences and similarities between the two; where to use which 10. **Comparison of two treatment modalities:** Comparison of means of quantitative measurements (Student t-test, Gaussian conditions, and reference to nonparametric tests); comparison of efficacies (proportions) by chi-square test; comparison with RR, AR and OR; comparison with number needed to treat; bioequivalence and area under the concentration curve 11. **Relationship between two medical measurements:** Simple linear regression and correlation for quantitative measurements; use in explaining and prediction; criteria for causal inference 12. **Further topics:** Mention (no details) of – ANOVA for comparison of means in three or more groups, chi-square test for bigger tables, difference-in-differences approach, logistic regression, multiple regression, multivariate methods, survival analysis, etc. 13. **Computers:** Hands-on training on literature databases and search; Internet resources; Excel worksheet and elementary graphics; Introduction to statistical software such as Epi-Info.

Teaching Staff for Health Statistics, Medical Statistics, Demography, Research Methodology, etc. and Ancillary Staff for Data Entry, Data Analysis and Informatics Activities.	
Existing Regulations	**Proposed**
Page 29: **B. Staff Requirements:** **(b)** Statistician-cum-Lecturer: One in the Department of Community	**For colleges with only MBBS courses (no PG Course):** The following staff should be provided for teaching and research activities

Medicine	of the college as well as to look after the medical record section of the hospital. They will also manage college's computer network and website. For administrative purposes, they can be placed under the Department of Community Medicine as done now. **Assistant Professor** –One (Qualification : MSc Biostatistics/ Biometry/ Health Statistics/ Medical Statistics/ Statistics with at least three years' experience in a medical or health institution or organization out of which one year is training or experience in computers; Desirable: PhD) **Statistician** - One (M.Sc. Biostatistics/ Biometry/ Health Statistics/ Medical Statistics/Statistics) **Data entry operator/ Computer operator** - One (BCA/ O-level Diploma in Computer Applications) **For colleges with PG courses:** **A full Department of Biostatistics and Medical Informatics** The following staff should be provided for teaching and research activities of the college as well as look after the medical record section of the hospital. They will also manage college's computer network and website. The Department will also provide statistical support to all the PGs, faculty and also super-speciality courses if present as well also to the PhD students including for their Research methodology course as now prescribed by the UGC. **Professor** – One (Qualification: PhD in Biostatistics/ Biometry/ Health Statistics/ Medical Statistics/ Statistics, with at least 5 years; teaching experience as Associate Professor in a medical college) **Assistant Professor** – One (Qualification: Masters degree in Biostatistics/ Biometry/ Health Statistics/ Medical Statistics/ Statistics, with at least 3 years' experience in a medical/health institution/organization; Desirable: PhD) **Statistician** – One (M.Sc. Biostatistics/ Biometry/ Health Statistics/ Medical Statistics/Statistics with at least one year experience) **Statistical Assistant** – Two (Qualification: M.Sc. Biostatistics/ Biometry/ Health Statistics/ Medical Statistics/Statistics) **Data entry operator/ Computer operator** - One (BCA/ O-level Diploma in Computer Applications) The Department will have a computer laboratory for training of students

	and for carrying out advanced statistical analysis of research data of the faculty and hospital data. The Department will provide statistical and research methodology consultation to all the PGs and the faculty, and ensure that all research (including PG theses) have used adequate statistical methods. All research must meet international statistical standards.