Indian Society for Medical Statistics

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Revised Recommendations of the High Power Committee on Biostatistics Speciality for Enhancing Health Research Output and its Quality in AIIMS like Institutes{ie, New AIIMS} in the Country

1. Preamble

Medical education and training in India, for the past several years, has been under intense debate – mostly for quality of training and paucity of medical manpower. In past decades, efforts of erstwhile Medical Council of India (MCI) could not make much perceptible difference. The present National Medical Commission (NMC) is now trying to introduce reforms to streamline the medical education, patients care and research in the country. These measures of NMC have generated a great hope and expectations amongst the people.

It is generally believed that knowledge of Biostatistics improves medical research; research improves medical teaching and teaching improves our ultimate goal of patient care. Generally, resource inputs are prioritised for patient care and teaching but, infrastructure for research - particularly for Biostatistics, is neglected and often runs on extramural resources. In fact, most of medical schools in our country – both in public and private sector, have no research environment. The globally known medical journal – the Lancet[1] and the Supreme Court of India[1], during May 2016, have commented on poor research output from Indian Medical Schools. Also in 2016, Ray et al[2], based on 10 years analysis of publications from the country, have brought-forth alarming results. They[2] have illustrated that the research output of Indian Medical Institutes was quite poor during the 10 years period (2005 - 2014). Around 57% of the institutions, not having even a single publication included in the Scopus database between 2005 and 2014, and only 25 (4.3%) Institutes (out of 579, which were affiliated to the MCI and NBE) produced only 100 papers a year.

There is a great deficit of medical and paramedical manpower in the country. To overcome this deficit, AIIMS like Institutes (also called, new AIIMSs) and other medical schools are being created by the Government of India & State Government and so also, by the private sector.

The annual intake of undergraduate medical students has now gone up over 35,000. This has generated more demand for PG and super-speciality seats in the country. Availability of trained faculty to cater such a large number of students and to impart a quality education seem to be a big challenge to the NMC as well as medical academia.

2. Teaching and Training Needs of Medical Students in Biostatistics

2.1 At the Undergraduate Level :

The Undergraduate Medical Education - leading to MBBS degree broadly requires training in *twenty subjects,* spread over nine semesters, which are further divided into 3 categories: pre-clinical (1-2 semesters), para-clinical (3-5 semesters) and clinical (6-9 semesters). *Biostatistics Speciality (including Research Methodology)* is introduced under the discipline of Community & Family Medicine, to a very limited extent. There is no need-based teaching of the subject and also, there is hardly any University level examination of the students in the subject. Not only this, the Biostatistics Speciality does not get proper attention of students during these semesters due to their focus mainly being on clinical training. Also, there is no pressure of passing any University examination in the subject. Most importantly, there is poor infrastructure of Biostatistics in medical schools of the country (in terms of qualified faculty, good computer laboratory, adequate data analysis tools and good books & journals etc).

2.2 At the Postgraduate & Super Speciality Levels:

The Postgraduate Medical Education is mostly imparted as per the erstwhile MCI (Now, NMC) regulations (amended / updated in May 2018). Accordingly, the postgraduate teaching & training, with regard to the speciality of Biostatistics & Research Methodology, requires that a medical student should be able to:

a) demonstrate competence in basic concepts of Research Methodology and Epidemiology, and be able to critically analyse relevant published research literature;
b) function as an effective leader of a health team, engaged in health care, research or training; and

c) acquires thesis skills as well as

d) training in Research Methodology.

All these expectations from a PG medical student can't be really achieved without the guidance of the qualified & trained Biostatistics faculty. For example, the critical appraisal of published research can't be completed without the consideration of different biostatistical aspects like - the sample size adequacy, application of appropriate analytical techniques, adjustments for any confounding effects etc. Only a qualified Biostatistics faculty can address to these needs. Sadly, the situation of Biostatistics resources in the PG Medical Institutes is also almost the same as that in PG Medical Schools of the country - with often no qualified Biostatistics faculty, poor computer & internet facilities and with no appropriate statistical software at all or have outdated pirated software, used by non-Biostatistical faculty / staff with limited understanding of the techniques and of the statistical software being used, etc

3. Institutions Offering PhD, M Sc & Other Courses in Biostatistics in the Country and Those Having a Separate Department of Biostatistics.

We gathered information from different sources on Universities & medical Institutions in the country, offering Ph D, M Sc and Diploma or Certificate Courses in medical Biostatistics and also those, which have a separate Department of Biostatistics, in the country. Such information is given below.

Brief details on generation of Biostatistics faculty / manpower in the country.

a)	**Universities & institutions in the country, offering Ph D (Biostatistics) Course:**
	• Rajendra Institute of Medical Sciences, Ranchi, Jharkhand. • NIMAHNS, Bangalore, Karnataka. • Manipal Academy of Higher Education, Manipal, Karnataka. • KLE Academy of Higher Education, Belgaum, Karnataka. • IIPS, Mumbai, Maharastra. • CMC, Vellore, Tamil Nadu

	• SGPGI, Lucknow, Uttar Pradesh • IMS, BHU, Varanasi, Uttar Pradesh • Rama University, Kanpur, Uttar Pradesh • AIIMS, New Delhi. • PHFI, New Delhi. • JIPMER, Puducherry • St. Thomas College, Pala (Mahatma Gandhi University),Kerala
b)	**Universities & institutions in the country, offering M Sc (Biostatistics) Course:**
	• National Institute of Epidemiology, ICMR, Chennai • NIMAHNS, Bangalore, Karnataka. • Manipal Academy of Higher Education, Manipal, Karnataka. • KLE Academy of Higher Education, Belgaum, Karnataka. • St. Thomas College, Pala (Mahatma Gandhi University), Kerala. • Amrita School of Medicine, Kochi, Kerala. • IIPS, Mumbai, Maharastra. • Berhampur University, Berhampur, Orissa. • CMC, Vellore, Tamil Nadu. • Smt. Devkunwar Nanalal Bhatt Vaishnav College for Women, Chennai (TN). • SRM University, Chennai, Tamil Nadu. • Lucknow University, Lucknow, Uttar Pradesh • IMS, BHU, Varanasi, Uttar Pradesh.
c)	**Universities & institutions in the country, offering PG Diploma, Certificate or Fellowship Course(s) in Biostatistics:**
	• IIPH, Hyderabad, Andhra Pradesh. • Global Institute of Medical Sciences, Baroda, Gujarat. • Sardar Patel University, Vidyanagar, Gujarat. • Manipal Academy of Higher Education, Manipal, Karnataka. • KLE Academy of Higher Education, Belgaum, Karnataka • Madurai Kamraj University, Madurai, Tamil Nadu. • SGPGI, Lucknow, Uttar Pradesh. • Cliniminds Academy for Clinical Research & Training Management, NOIDA, UP. • AIIH & PH, Kolkata, West Bengal. • West Bengal University of Health Sciences, Kolkata, West Bengal.
d)	**Universities & institutions in the country having a separate Department / Centre of Biostatistics or Department of Data Science, independently or with Epidemiology & Cancer Registry, etc :**

	• NIMAHNS, Bangalore , Karanataka • Manipal Academy of Higher Education, Manipal, Karnataka • KLE Academy of Higher Education, Belgaum, Karnataka • Kidwai Memorial Institute of Oncology, Bengaluru, Karnataka • Amrita School of Medicine, Kochi, Kerala • St. Thomas College, Pala, Kerala. • CMC, Vellore, Tamil Nadu • Cancer Institute (WIA), Chennai, Tamil Nadu • SGPGI, Lucknow, Uttar Pradesh • IMS, BHU, Varanasi, Uttar Pradesh • PGIME & R, Chandigarh. • AIIMS, New Delhi. • JIPMER, Puducherry

Note: The information given above is based on our personal communications with ISMS Members from different States & UTs of the country and also, on an article[3] appeared in the Indian Journal of Public Health (2012).

It is evident from the information shown above, that each of the Ph D & M. Sc Courses in Biostatistics are being offered by 13 different Institutions / Universities of the country where as 10 such Institutions / Universities are offering some other courses, like PG Diploma in the Speciality and Certificate or Fellowship Courses in Biostatistics. Only 13 Institutes / Universities of the country presently have a separate Department of Biostatistics – either independently or with some other medical speciality, like Epidemiology or Cancer Registry, etc.

4. Establishment of AIIMS like Institutes (new AIIMSs) in the Country

The Government of India, after establishment of the All India Institute of Medical Sciences (AIIMS), New Delhi in 1956, has, till now, established 16 AIIMS like Institutes in the country and that, 13 of these Institutes, have already granted admission to the MBBS Course through the NEE- UG 2021. Further, to the best of our knowledge, 9 more such Institutes have been approved by the Government of India and are in various phases of their establishments. Each of these Institutes is expected to serve as nucleus for

nurturing excellence in all aspects of the health care. These new AIIMSs are often seen as the *Institutes of National Importance.*

The mandate of these new AIIMSs is that of the main AIIMS in New Delhi and include establishing standards for patient-care, teaching and research. These Institutes are also expected to bring together, at one place, educational facilities of the highest order for the training of personnel in all branches of medicine, public health, clinical and epidemiological research, to address the myriad health problems that differ from place to place in a vast country like ours.

With regard to the above, it will not be the out of place to reiterate that a medical specialists' training would be considered incomplete without reasonable acquaintance with the potentialities of applications of bio-statistical techniques to enable them to plan research studies with scientifically valid designs and apply appropriate biostatistical methods to arrive at valid and meaningful conclusions. However, unfortunately, this important aspect of biostatistics' teaching & training did not get its due place in the medical training of the country.

5. Present Status of Biostatistics Faculty, Resources & Facilities in AIIMS like Institutes (new AIIMSs) in the Country

It appears to us, like medical colleges of the country, proper attention has not been paid to *Biostatistics Speciality* in the AIIMS like Institutes also. This can be realized by the fact that other than the main AIIMS at New Delhi, none of the AIIMS like Institutes in the country - some of them even years after their establishment and also with PG, doctoral and post–doctoral courses, have competent biostatistics faculty to teach research methods properly and collaborate and assist the clinical faculty in their research projects and guide post graduate, doctoral & post doctoral students in their theses work.

Since very beginning, there has been only one junior level faculty position in the speciality in these Institutes, viz. *Assistant Professor of Biostatistics*, that too, in the Department of Community & Family Medicine (even this post is not yet filled in most of the new AIIMSs). The person appointed (or to be appointed) on this position, plays only a limited role in teaching of the subject to medical students, training to the young faculty

of the Institute and in collaborative medical research (as this faculty is posted under the Department of Community & Family Medicine). He / she takes only limited number of classes of the subject (lectures as well as practicals) to the undergraduate batches during their stay in the Institutes, as directed by the Dept. of Community & Family Medicine, under whom the appointed Biostatistical faculty is supposed to work through-out). This teacher has no much role to play in the Institutes' examinations of MBBS, PG or Super Speciality Courses. There is almost no formal need-based teaching of Biostatistics to PG and super speciality Courses' students. Also, there is hardly proper involvement of Biostatistics faculty in PG, Ph D & post doctoral theses work. In the present set-up, an appropriate research environment with facilities for free & independent academic discussions with clinical faculty and doctoral & post-doctoral students in collaborative research work is not possible in absence of an independent Department of Biostatistics in these Institutes.

Further, neither the young medical faculty of these Institutes is properly trained in Biostatistics nor the continuing medical faculty is re-oriented in research methods and advanced data–analysis techniques, from time to time. Also, PG Courses, like MSc (Biostatistics) and Doctoral Courses, like PhD (Biostatistics) in the speciality are lacking in these Institutes. To generate regular faculty in the specialty of Biostatistics, commencement of such PG as well as Doctoral Courses in Biostatistics in these Institutes is must for which an independent Department of Biostatistics with necessary facilities is a pre-requisite.

Thus, *Biostatistics Speciality* has no independent status in these Institutes. Its teaching faculty, staffing position including support personnel as well as other infrastructure facilities are poor. So, any professional bio-statistical consultation or data analysis help, if required by a medical faculty of the Institute or any PG, Ph D or Super-Speciality Course student, is often not available. This situation is, in spite of the fact that all over the world, major scientific medical and research journals have made it mandatory for statistical peer reviewing of the papers, to be published.

Presently, out of all old & new AIIMSs in the country, only the AIIMS, New Delhi, has a full-fledged Department of Biostatistics. For example, AIIMS Jodhpur has only one Assistant Professor of Biostatistics, placed in the Community & Family Medicine Department . As shown in Section 3, none of the AIIMS like Institutes in the country has a separate Department of Biostatistics. Further, Department of Biostatistics at the AIIMS, New Delhi, presently coordinates one-week full time compulsory program on Research Methodology & Biostatistics to all the PG and Post-Doctoral medical students. In addition, it collaborates with several Clinical & Para-Clinical Departments in their research projects and thesis-guidance work, etc. In AIIMS New Delhi, at any given time, there are around 500 funded research projects, apart from nearly 2,000 PG, PhD and Post-Doctoral medical students in the Institute. Thus, the Biostatistics faculty of the Institute is an integral part of the research, teaching and thesis-related activities of almost all the Departments of the Institute.

6. Some Existing Super-Speciality Institutes in the Country Have Better Biostatistics Manpower & Facilities

There are a few super-speciality Institutes in the country where a separate independent Department of Biostatistics exists. These Departments are imparting professional training to medical students and participating in collaborative research. Some of these Departments are offering higher Courses of Biostatistics also. For example, SGPGI, Lucknow (UP) has a separate Department of Biostatistics & Health Informatics since beginning. It has adequate Biostatistics faculty, necessary support staff and other biostatistical facilities. The Institute has a compulsory paper of Biostatistics for MD, DM and M.Ch Courses (running since1990).They have Fellowship & Ph D Courses in Biostatistics also. Similarly, Christian Medical College, Vellore, has a full-fledged Biostatistics Department, catering to the needs of its PG, Doctoral & Post-doctoral students. PGIME&R, Chandigarh, has an independent Department of Biostatistics. The JIPMER, Pondicherry and the NIMHANS, Bangalore, also have separate Biostatistics Departments with adequate faculties. They also have PhD (Biostatistics) Course etc. As a result of this, the research output of these selected Institutes and of AIIMS, New Delhi

– all having a separate full-fledged Biostatistics Department, is often quite high and distinctly different (both, in terms of quantity as well as quality) from many other medical Institutes / schools of the country without having such a Department separately.

Very recently, an Online Course on Research Methodology has been made compulsory by the NMC to all medical PG students of the country. Perhaps, due to lack of infrastructure to impart on-site training course of Biostatistics, a distance learning approach has been considered for the PG students by the NMC[4]. This, for the time being, is a welcome step of the NMC and may improve the learning of research methodology by the PGs, but on-site support to the health research and collaboration is still lacking. An article, entitled *Landscaping Biostatistics Education in India*[3] also had described the status of training and education of biostatistics in the country nearly a decade back. Further, it has also been realized from the analysis, shown in Section 3 above, that country's medical institutions mostly depend for their biostatistical help on Statisticians, trained outside the medical environment (universities) who lack medical exposure and understanding of their requirements.

Further, there is great deficit of trained Biostatisticians in the country which is now being gradually improved with the offering of M Sc (Biostatistics) and PhD (Biostatistics) Courses by some Institutes / Universities, as shown in Section3 above. In addition, some ICMR Institutes like the National Institute of Medical Statistics (NIMS), New Delhi; and National Institute of Epidemiology (NIE), Chennai, are also conducting Biostatistics & Research Methodology Programs.

To summarize, for enhancing training-quality of medical scientists and increase research output and its quality, it is mandatory that all the newly established AIIMS like Institutes (including those which are in pipeline of their establishment), should have well trained personnel in research methods, Biostatistics as well as in Epidemiology. Establishment of a separate Biostatistics Department will be extremely useful towards these aims, as is evident from the quality of health research and health research-outputs from Institutes where such Departments are in existent. The pattern, for establishing the Biostatistics

Department at the AIIMS, New Delhi could be the model for other Institutes. This will enable the young medical trainees to get a firm grounding and use appropriate tools and techniques in their research and publish their work in reputed scientific journals.

What is the Way Forward? :

The *Indian Society for Medical Statistics (ISMS)* strongly believes that quality of medical education and research output can be significantly enhanced by improving the present shape of Biostatistics Speciality in the AIIMS like Institutes. We are also of the view that it is necessary to have a separate independent *Department of Biostatistics* in each of these Institutes - almost on the lines of parent AIIMS in New Delhi, to create necessary research environment that makes intensive periodic academic discussions on already initiated research projects, along with periodic analyses. – thus, paving the way to make close collaborative groups within the Institutes. This is extremely important as funding agencies often require periodic reports with interim results; DM / M Ch Residents stay in the Institutes for 3 years and a PhD student for nearly 5 years, requiring continued association of the same Biostatistical as well as Clinical faculty with them.

7. Recommendations for Reshaping the Biostatistics Speciality in AIIMS like Institutes in the Country

i) In all new AIIMSs, where MD / DM / M Ch & Ph D Programs are going-on, a separate independent *Department of Biostatistics* should be created on the lines of AIIMS, New Delhi , NIMHANS, Bangalore or SGPGI, Lucknow.

To begin with, it may be started with minimum faculty positions (say, with Associate Professor of Biostatistics -1 and Assistant Professor of Biostatistics - 2) and by providing it some other necessary facilities (like data analysis tools, books & journals and small secretarial staff, etc). It should then slowly be upgraded to a full-fledged Department by creating additional faculty positions (like Professor of Biostatistics -1 and Scientist – 1), with additional facilities, during a fixed period of, say 5 years. This Department may be given clear mandate and responsibility, mentioned in the subsequent sections below.

ii) Establish a network of AIIMSs in the country where a separate Department of Biostatistics exists. These Departments should be given mandate to impart teaching of Biostatistics in their own institution, produce Biostatistics manpower and conduct research in their own as well as other collaborative areas of medical and health Sciences.

This Department of Biostatistics should help researchers in designing and execution of research projects, provide data analysis-support to the faculty and PG & super speciality courses students and take lead to manage patient care data, using their electronic medical records (EMR/HIS). This network should be used for teaching & training of biostatistics / research methodology to the medical faculty of AIIMSs.

This network should also teach & train biostatistics faculty of medical colleges of their own States who, in turn, should teach & train medical faculty of their own medical colleges, on regular basis.

iii) The full-fledged Departments of Biostatistics of country's AIIMSs should offer, on regular basis, MSc & PhD programs in Biostatistics to generate trained teachers of Biostatistics from time to time.

Network of AIIMSs offering M Sc (Biostatistics) and PhD (Biostatistics) courses should first be established in the country. If such programs are already being conducted by the established Departments, Health Ministry / NMC should review these programs, bring uniformity in the nomenclature of degree, course contents, duration, admission process, exit examination, number of seats and infrastructure required, etc and ensure that all such Departments, on regular basis, work in tandem, to produce quality manpower in biostatistics.

iv) To generate manpower in Biostatistics Speciality in bulk, at a faster rate, efforts should be made to considerably increase the number of seats of M Sc & Ph D Courses in biostatistics in the existing Departments. Thus, number of seats of M.Sc (Biostatistics) and Ph D (Biostatistics) Courses, if already existent, in the

on-going super-speciality Institutes of the country, like AIIMS New Delhi, PGIME&R, Chandigarh, NIMHANS, Bangalore, CMC Vellore, JIPMER Pondicherry and SGPGI, Lucknow, etc should be considerably increased (in light of availability of qualified teachers).

v) Some relaxation in the eligibility of faculty (in teaching experience only) in their appointments may be considered*:* as required number of trained Biostatistics faculty (teachers with PhD Degree and having required years of post Ph D teaching experience) may not be presently available in adequate number.

Thus, for the time being, candidates' Ph D completion – tenure, should be considered as their 3 years teaching experience (in view of the UGC ruling[5]) while appointing them as faculty.

Further, if the ***Indian Society for Medical Statistics (ISMS)*** is asked by the Health Ministry or by any Government Department to extend some technical assistance, in any form, in implementing the above recommendations for promoting Biostatistics Speciality in new AIIMSs of the country, the Members of the High Power Committee of ISMS (see, the List appended in the end of this Document), will be happy to join hands with the Government. Departments.

8. References

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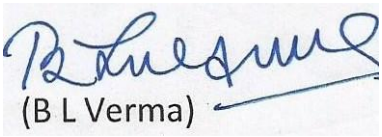

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