

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 Medical Colleges of the Country

1. Preamble

The training of medical education in our country continues to attract intense debate. It is generally perceived that quality of training in medical education in our country needs considerable improvement. Incidentally, systematic efforts to evaluate institutions' products in terms of clinical competence and teaching are often hard to be seen. Particularly, for teaching & training of biostatistics, it is often pointed out that teaching of the subject in medical colleges at the undergraduate as well as postgraduate levels, is neither need-based nor up to the mark and at some places, it is almost missing.

As research output is easy to measure, some Investigators have made occasional efforts - using available databases, recently^{1,2,3}. The World Report² appeared in the year 2016, has revealed that contribution of Indian medical colleges in health research has been negligible. It has also been found¹ that India has been amongst the major contributors of research articles, published in poor-quality predatory open access journals. It is often thought that poor research skills, especially in Biostatistics, in Indian medical colleges are largely responsible for sub-optimal medical research output and its quality. Some brief highlights in this regard, are given below.

2. Status of the Health Research Output in Country's Medical Colleges:

The Lancet Report² on 'poor research output from Indian medical schools has attracted attention of policy makers of the country and medical professionals alike. This Report also mentioned a disturbing observation by the Hon' ble Supreme Court of India, in a judgement delivered on 6 May 2016 relating to a private medical college, where it described the state of country's medical colleges as "rotten". Citing views from selected eminent medical authorities of the country, this Report has stressed that research funding agencies have neglected country's medical colleges and that, funding support to the medical research in the country in past years, has been terrible. Their assertion is – "unless we invest and strengthen biomedical research capacity now, it is unlikely that we will see the kind of

improvements in health outcomes we would like to see in next 20-30 years”. Similarly, Dr Soumya Swaminathan, the then DG – ICMR (now, Chief Scientist – W H O HQ), in one of her interviews, given to Shreya Shah⁴ of *IndiaSpend* sometime back, had indicated - while emphasizing on unsatisfactory status of medical research in the country, that “there have been only a few medical colleges in our country which have encouraged and promoted the culture of research and we need to ensure that in the coming years, many more medical colleges and their faculty get involved in the research”.

A systematically conducted study - undertaken in India by Ray et al³, on research output from Indian medical institutions, have brought forth alarming results for country’s medical colleges. Using SCOPUS data base, they analysed research outputs of 579 Indian medical institutions and hospitals – Government and of the private sector, 316 under MCI (now, the National Medical Commission) and 263 under NBE, between 2005 and 2014. The total research output during 2005 - 2014 was of 101,034 papers with average number of publications per institution being 14.5 papers only, each year. The above Study revealed that 332 (57.3%) institutions did not publish even a single paper during above 10 years. The Southern States of Kerala, Andhra Pradesh, Maharashtra and Tamil Nadu had 55.6 % of the total number of the MCI/NMC recognized medical colleges of the country but a large percentage of these medical colleges had no publications during the above period. The above findings suggested that the research output of the Indian medical colleges during the past 10 years (2005-2014) has been quite poor.

3. Present Status of Teaching Facilities of medical Biostatistics in the Country : Availability of Ph D, M Sc & Other PG Courses in Biostatistics and Institutions with a Separate Department of Biostatistics:

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

Brief Details on Generation of Biostatistics’ Faculty and Man Power in the Speciality.

1.	Universities & institutions in the country, offering Ph D (Biostatistics) Course:
	<ul style="list-style-type: none"> • Rajendra Institute of Medical Sciences, Ranchi, Jharkhand. • NIMAHNS, Bangalore, Karnataka. • Manipal Academy of Higher Education, Manipal, Karnataka.

	<ul style="list-style-type: none"> • KLE Academy of Higher Education, Belgaum, Karnataka. • IIPS, Mumbai, Maharashtra. • 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
2.	Universities & institutions in the country, offering M Sc (Biostatistics) Course:
	<ul style="list-style-type: none"> • 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, Maharashtra. • 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.
3.	Universities & institutions in the country, offering PG Diploma, Certificate or Fellowship Course (s) in Biostatistics:
	<ul style="list-style-type: none"> • 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.

	<ul style="list-style-type: none"> • Cliniminds Academy for Clinical Research & Training Management, NOIDA, UP. • AIIH & PH, Kolkata, West Bengal. • West Bengal University of Health Sciences, Kolkata, West Bengal. 																								
4.	Universities & institutions in the country having a separate Department / Centre of Biostatistics or Department of Data Science - independently or with Epidemiology or Cancer Registry, etc :																								
	<ul style="list-style-type: none"> • NIMAHNS, Bangalore , Karnataka • 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 																								
5.	States & UTs in India, having no recognized facility of biostatistics' teaching, such as a Course in Biostatistics (viz., Ph D, M Sc or PG Diploma, Certificate or Fellowship in Biostatistics) :																								
	<table> <tr> <td>1. Arunachal</td> <td>9. Meghalaya</td> <td>17. Tripura</td> </tr> <tr> <td>2. Assam</td> <td>10. Mizoram</td> <td>18. Uttarakhand</td> </tr> <tr> <td>3. Bihar</td> <td>11. Nagaland</td> <td>19. Jammu & Kashmir</td> </tr> <tr> <td>4. Chhattisgarh</td> <td>12. Orissa.</td> <td>20. Andaman- Nicobar</td> </tr> <tr> <td>5. Goa</td> <td>13. Punjab</td> <td>. Island</td> </tr> <tr> <td>6. Haryana</td> <td>14. Rajasthan</td> <td>21. Ladakh</td> </tr> <tr> <td>7. Himachal Pradesh</td> <td>15. Sikkim</td> <td>22. Dadra and Nagar Haveli</td> </tr> <tr> <td>8. Manipur</td> <td>16. Telangana</td> <td>23. Lakshadweep</td> </tr> </table>	1. Arunachal	9. Meghalaya	17. Tripura	2. Assam	10. Mizoram	18. Uttarakhand	3. Bihar	11. Nagaland	19. Jammu & Kashmir	4. Chhattisgarh	12. Orissa.	20. Andaman- Nicobar	5. Goa	13. Punjab	. Island	6. Haryana	14. Rajasthan	21. Ladakh	7. Himachal Pradesh	15. Sikkim	22. Dadra and Nagar Haveli	8. Manipur	16. Telangana	23. Lakshadweep
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Note: The information given above is based on our personal communications from selected ISMS members belonging to different States & UTs of the country and also, on an article, appeared in the Indian Journal of Public Health⁵ sometime back.

It is evident from the above information, that each of the Ph D Course and M Sc Course in medical biostatistics are presently available in 13 Institutions / Universities of the country whereas, only 10 such Institutions / Universities offer some other PG level courses in medical biostatistics, like PG Diploma in the Speciality and a Certificate Course or Fellowship in biostatistics. Further, only 13 Institutes / Universities of the country presently have a separate Department of Biostatistics – either independently or with some other medical speciality like Epidemiology & Cancer Registry, etc. The important point from the above analysis is that, there are 23 States in the country which do not have any recognized facility of the teaching / training of medical biostatistics in the country. Thus, in order to generate additional teaching faculty in the speciality on regular basis in the country, we shall have to improve upon its teaching facilities – in terms of M Sc & Ph D Courses in the discipline, in various States and increase number of seats in the institutions which are already offering such courses in the country. Twenty three States, which do not presently have any recognized facility related to the teaching & training of medical biostatistics, require more attention of the NMC and State Government as well as Union Health Ministry, for commencing such courses, at least, at one or two good institutions, in each of these States.

4. Present Status of Biostatistics Speciality in Medical Colleges in terms of Faculty Positions, its Teaching to Medical Students and Biostatistical Consultations with Medical Teachers & Resident Doctors :

It appears, proper attention has not been paid towards Biostatistics Speciality in medical colleges of the country since very beginning. It is often realized that we should not think of imparting good quality training in medical education or undertaking quality medical research, unless there is well trained faculty in biostatistics with us and that, there are adequate data-analysis facilities in the institution. Since very beginning, there has been only one junior level technical / teaching position in biostatistics, namely. *Statistician-cum- Lecturer* (which recently was further downgraded - as per the 2017 MCI Recommendations, to the position of *Statistician – cum – Tutor*), in the Department of Community Medicine of the Medical Colleges.

A person appointed on the above position plays a very limited role in teaching of the subject to the medical students and training to the young teaching & research faculty. His / her role in medical research is also negligible. This junior level faculty in biostatistics takes only 10 - 15 classes of the subject (lectures as well as practicals) to the undergraduate medical

students during their 4 ½ years of stay in the institution. This teacher has no role to play in the University level examinations of MBBS, PG or Super Speciality Courses. Also, this Statistician-cum -Tutor is denied of all promotional avenues and other perks that are given to the faculty of other specialties. In view of all this, competent biostatisticians are not willing to join such inconsequential position with poor remuneration. Several amongst those who decide to join on this junior position; they are always at the look- out of a better position elsewhere. All this is leading to the absence of proper or inadequate teaching of biostatistics in medical colleges, like a Foundation Course or Orientation Course in Biostatistics to PGs, doctoral and post-doctoral medical students; integration of biostatistical rigor into PG & Ph D thesis works and training of young medical faculty in biostatistics & research methods in the institution, from time to time.

In addition, Biostatistics Speciality in medical colleges has no independent status and that, its faculty, support-staff and data – analysis facilities, are poor. Resultantly, quality teaching of the subject to the medical students and application of advanced biostatistical methods in health research are often not possible. Further, bio-statistical consultation or data – analysis help, required by a medical faculty or postgraduate students from time to time, particularly – from the Departments other than their own. is often not available. Also, as research environment in medical colleges is often unsatisfactory and biostatistical facilities in them, are poor, funded research as well as quality publications, particularly those appearing in high impact journals, have become almost negligible.

5. Major Factors Responsible for Poor Health Research Output and Unsatisfactory Quality of Teaching & Training of Biostatistics in Medical Colleges:

There could be many factors responsible for this state of affairs, but in the *Indian Society for Medical Statistics (ISMS)* – based on our own experience and interactions with our fellow medical colleagues working in these institutions, we are of the view that poor faculty positions in biostatistics, almost no support staff, inadequate infrastructural facilities in biostatistics and very limited role of biostatistics in medical education & research, play a major role on the above issue. Resultantly, there is no proper training & teaching of biostatistics and of research methods to the young faculty and students, bio-statistical consultation practices in these institutions are poor, funded research is not encouraged, in-patient as well as out-patient hospital data often remain unutilised for teaching & research purposes and proper technical help on application of biostatistical methods and also in data – analysis, is often not met to the medical faculty and PG students of these institutions, thus

-resulting in poor health research outputs. In addition, quality of medical research is also often adversely affected. A study⁶ on 'quality of reporting statistics in two Indian Pharmacology journals' found that inappropriate descriptive statistics was used in 78.1 % of the articles and that, in 31.7 % of papers, incorrect statistical tests were applied.

What is the Way Forward?

Several steps are needed to strengthen quality teaching of the subject and enhance medical research output in our medical Institutions. We, in ISMS, strongly believe that research output of these institutions can significantly be enhanced by considerably improving present shape of biostatistics speciality by re-organizing it – in terms of teaching faculty, support staff, infrastructure, need-based teaching / training curriculum and data-analysis facilities and thereafter, by increasing role of biostatistics' faculty in teaching & training of PG & super speciality students and young faculty (in bio-statistics & research methods), creating a good research environment in the institutions, encouraging them for their involvement in sponsored / funded research, providing them frequent bio-statistical consultation-opportunities and helping the faculty & PG students in the data – analysis in their research studies. In fact, MCI (now, NMC) in recent past, have redefined role of various basic specialities of medical colleges (like Microbiology and Biochemistry), but it has not revisited the role of Biostatistics in these institutions during past 5 decades.

6. Recommendations for Reshaping the Bio-statistics Speciality in Medical Colleges of the Country:

6.1 General Recommendations:

- i) The Biostatistics Speciality in medical colleges should be re-organized as an independent discipline. Thus, there should be a separate independent Department of Biostatistics in all PG medical colleges of the country with some senior faculty positions. In Colleges with PG and super speciality courses, this Department should be headed by at least Associate Professor (Biostatistics).
- ii) This Department should be equipped with data-analysis facilities, like internet, computers & printers, statistical software, electronic projectors and technical manpower (support staff), etc.
- iii) Gradually, the *e-health record system* of the associated hospital should function under the control of this Department, so that generation of hospital data should properly be monitored and utilized for teaching, training, research policy formation and effective management health care system.

- iv) For teaching of Biostatistics to medical undergraduate, post graduate & super speciality students and training to the young faculty of medical colleges, a need-based course curriculum in biostatistics & research methods, should be re-designed.
- v) Role of biostatistics faculty in biostatistical consultations with PGs, Ph D & Super-speciality theses and their involvement in research projects should be considerably increased.
- vi) The Department of Biostatistics should also create and train biostatistics' manpower for future needs of the nation's health and medical education system. More specifically, this Department should be encouraged to start M Sc (Biostatistics) and Ph D (Biostatistics) Courses, with adequate seats, to generate technical & teaching manpower in the speciality.
- vii) The Institutional Ethics Committee should work more effectively in these institutions, with essentially a senior faculty of biostatistics, being one of its members. This Department should take major responsibility of the institutional research output and its quality. It should encourage and extend all possible technical support to the different Departments of the medical college for preparation, submission of research proposals for funded research and collaborate with them in running such projects in institutions.

6.2 Recommendations for Faculty Positions in Biostatistics : for Medical Colleges without Post Graduate Course and Medical Colleges with Post Graduate Courses:

There are two categories of Medical Colleges in the country – i) without PG Courses and ii) with PG & Super Speciality Courses. The reshaping of the Biostatistics Speciality in them should be done, as given below:

6.2.1 For Medical Colleges without PG Courses:

An independent **Biostatistics Unit** should be created in these Medical Colleges and following staff should be provided in this Unit for teaching and research activities. This Unit should also control College computer network and e-health system of the associated hospital. For administrative purposes, this Unit should work directly under the control of the Principal of the Medical College.

Recommendations for the Minimum Faculty Positions:

The staffing position of the Unit should include:

- a) Assistant Professor of Biostatistics – 1 (Qualification: Ph D in Biostatistics / Health Statistics / Medical Statistics or equivalent).
- b) Biostatistician - 1 (M.Sc. Biostatistics / Health Statistics / Medical Statistics or equivalent)

6.2.2 For Medical Colleges with PG & Super Speciality Courses:

There should be a separate independent Department of Biostatistics (with minimum faculty positions, data-analysis facilities, support staff & the other necessary resources) in each PG Medical College of the country. In view of scarcity of trained / qualified teachers (with Ph D in biostatistics) in the country, this could be done in stages, following two models, given below:

- a) **For new PG Medical Colleges**, this Department of Biostatistics should be started from very beginning. The College Computer Network and e- health staff of the associated Hospital should be under the control of this Department (as suggested for the Biostatistics Unit above).
- b) **For the Existing Medical Colleges**, however, this Department of Biostatistics can be established gradually in the phased manner (say, it may be established in coming 5 years from now). Till the establishment of the Department, the arrangement of the **Biostatistics Unit** (as suggested above) with some improvement in the facilities may continue in these PG Medical Colleges.

Further, the Biostatistics Department in PG Medical Colleges should be headed, at least, by the *Associate Professor of Biostatistics*, supported by one *Assistant Professor of Biostatistics* and one Biostatistician, along with other facilities.

The Department should have a computer laboratory for training of students and for carrying out advanced statistical analysis of research data of the faculty as well as outdoor & indoor hospital data. The Department should provide biostatistical and research methodology consultation to all the PGs and ensure that all research (including PG theses) have used proper & adequate statistical methods

Recommendations for the Minimum Faculty Positions:

The following staff should be provided for teaching and research activities of the PG Medical College. They will also manage College's computer network and its website.

- a) Associate Professor of Biostatistics –1 (Qualification: PhD in Biostatistics / Health Statistics / Medical Statistics or equivalent, with at least 4 years teaching &

- research experience as Assistant Professor or Lecturer or Tutor etc in the speciality from any medical or health organization or population studies)
- b) Assistant Professor of Biostatistics –1 (Qualification: Ph D Degree in Biostatistics/ Health Statistics / Medical Statistics or equivalent)..
 - c) Biostatistician – 1 (M.Sc. Degree in Biostatistics / Health Statistics / Medical Statistics or equivalent).

6.3 Some Relaxation in the Eligibility of Biostatistics' Teachers in their

Appointments May be Considered: If required number of trained biostatistics faculty (with Ph D Degree) are not adequately available initially, some relaxation in their eligibility in initial appointment, may be considered, as proposed below:

- a) If Ph D (Biostatistics) qualified candidates are not adequately available in the beginning, those with PG qualification in the speciality (M Sc in Biostatistics / Health Statistics / Medical Statistics or equivalent, with 3 years teaching or research experience from medical, health & population studies) may be appointed as Lecturer in Biostatistics (against the position of Assistant Professor) but purely on contract basis till a candidate with Ph D Degree, becomes available for regular appointment.
- b) Candidates' Ph D completion - tenure should be considered as their 3 years teaching experience (in the light of the provision made by UGC⁷) for appointing them as faculty.

6.4 Efforts should be Made for Generating Qualified Faculty in Biostatistics on Regular Basis in the Country: For this purpose,

- a) This Department of Biostatistics, subject to availability of qualified faculty, should run M Sc (Biostatistics) & Ph D (Biostatistics) Courses on regular basis to generate technical manpower in the speciality.
- b) The number of seats of M Sc (Biostatistics) and Ph D (Biostatistics) Courses at the existing centres of the country should be considerably increased (in the light of availability of qualified teachers and other facilities in the Department).

7. Teaching of Biostatistics to the Medical Students:

7.1 For Undergraduates / MBBS Students

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 and 10 practical sessions to this subject (spread over 4 & ½ years of their MBBS). 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 to formalize this, without increasing the burden on the students. The teaching of the subject, for the time being, may continue to be 15 hours of lectures and 10 hrs of practical, till the designing of its need-based syllabus (by the NMC) so that it gets a complete medical orientation:

7.2 For Post Graduate (MD & MS) and Super Speciality Students:

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 he or she submits the PG thesis. This must be the part of the certificate, signed by the Head of the institution in the front page of the thesis. This offline Course should be conducted by the Department of Biostatistics with assistance of teachers from other Departments.

Perhaps due to lack of infrastructure to impart on-site (offline) training of biostatistics, a distance learning approach has now been recommended by the NMC. This is, for the time being, a welcome step taken by NMC and may improve the learning of research methodology. but on-site support to research and collaboration is still lacking. Our view is – such a Course & Training in Biostatistics and Research Methodology to the PG students and young faculty in the institution, should be given on-site by the Department of Biostatistics.

At present, except the above online Course to the medical PG students, there is hardly any formal teaching of Biostatistics & Research Methods. The NMC should look into the need-based syllabus of their teaching in the speciality and formalize the topics and nature of learning for this purpose.

8. University Examination in Biostatistics

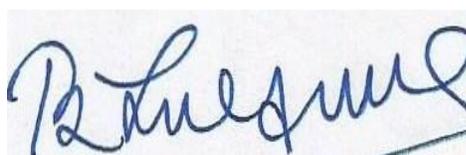
Medical Students at the Undergraduate as well as PG & Super Speciality levels should be assessed in biostatistics & research methodology through a University level examination. To conduct this examination should be the responsibility of the Biostatistics Unit / Department of Biostatistics. In ISMS, we feel, unless it is done, students will not take interest in the teaching of the subject at both the levels of their medical education.

9. Technical Assistance By the ISMS, if Asked by the NMC

The NMC should decide about different aspects of the need – based syllabus of Biostatistics & Research Methodology and also, for students' University examination in the subject (at both, Graduate & PG levels). The ISMS – particularly this High Power Committee of the Society, if invited by NMC, will be pleased to join hands in providing technical assistance for the purpose.

10. References

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