Editorial

Need of Strong Biostatistics Component in Medical Colleges in India: Time to Accept the Overdue Reality

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Statistics may be defined as "Methods to plan a study scientifically, collect quality data, analyze appropriately, interpret analytical results correctly and derive implications accurately." To be more specific, all methods of gaining knowledge are essential statistics. Statistics principles remain the same regardless of the area in which it is used. However, it is differentiated by area of its use, like biostatistics, while it is used in medical sciences, business statistics in business research, and agricultural statistics in agricultural sciences. A host of literature is available on various aspects of statistics, including its varying applications, uses and misuses. The present write-up aims to briefly emphasize the need of strong biostatistics components in medical colleges in India.

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Introduction

Before joining the present reputed medical college, the privilege to work at a premier medical institute as a faculty at the Department of Biostatistics, All India Institute of Medical Sciences (AIIMS), New Delhi, for more than three decades, and also as adjunct faculty at its Clinical Epidemiology Unit for more than two decades, has made me fully aware about the pivotal role of strong biostatistics component in medical colleges in strengthening and retaining high standard teaching and research. Further, its role is equally crucial regarding the translational/ transformational research standard. Also, research quality and teaching quality support each other. In one of the addresses to medical fraternity, our Prime-Minister appropriately emphasised the need for quality research in every single medical college of the country. A cutting-edge research invariably demands a strong component of biostatistics. To strengthen it further, a continuing debate is going on for evidence-based biostatistics use.[1,2] As such, in absence of a strong biostatistics component, a medical college may not be able to achieve high standard research and teaching in true sense.

As a matter of fact, a biostatistician may be helpful at each of the various steps of research methodology, beginning from definition of exposure/ outcome, conceptualisation of a research question/ hypothesis of the study, planning of the study, including study design and sample size, execution and management, and analysis & interpretation, to related implications. For optimal contribution by a biostatistician, his one-to-one healthy academic discussion and working with medical researchers is must. Therefore, his involvement as a colleague may serve the purpose in a better way leading to high-standard research. However, a very few in number, only premier/ reputed medical institutions like AIIMS, New Delhi; Post-Graduate Institute of Medical Education and Research, Chandigarh; Jawaharlal Institute of Post-Graduate Education and Research, Pondicherry; National Institute of Mental Health and Neuro-Sciences, Bangalore; Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow; and Christian Medical College, Vellore, have strong biostatistics component as a separate department. Unfortunately, almost all other public/ private medical colleges have hardly a single faculty of biostatistics in the department of community medicine. Further, their services are often underutilized because of obvious known/ unknown reasons. As a

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result, high-quality research from these institutions still remains only a dream, even if they have post-graduate (PG) academic programs. Often, dissertations by PG students are considered mere a formality. As observed being a reviewer for national/international journals, this also gets reflected very well in articles submitted to the reputed journals. It is very well realized now that scientifically valid high-quality research may be possible by a devoted multidisciplinary research team involving potential biostatistician(s) who can go in a long way to ensure evidence-based quality health care.

As a support to above mentioned points, I would like now to quote couple of examples out of my various experiences at AIIMS, New Delhi. First, to treat the differentiated thyroid cancer patients, our clinical colleague used to give them I-131 therapy (i.e., radioiodine active doses ranging from 15 mCi to above 100 mCi) after surgery to achieve ablation of cancer cells. He communicated an article using non-randomized data and came to me with the reviewer's comments to prepare reply. It took time to understand the treatment process and next day I asked him few questions related to deciding on varying doses. To cut the story short, he told me that there is no randomized trial on the optimization of doses locally and globally. They used to decide the dose using their clinical wisdom as per guidelines of the International Committee on Safety of using radioiodine active dose. Often, high doses used to be preferred to achieve better results.

Finally, after a detailed discussion, I could convince him to support a non-inferiority randomized controlled trial to be done by one of our Ph.D. students. The study hypothesized that a small dose might be non-inferior to a higher dose with consideration of the highest non-inferiority margin as absolute 13% ablation rate. Out of weekly available 600mCi of I-131 from Bhabha Atomic Research Centre, Mumbai, to be used in day to day management of thyroid cancer patients, he agreed to spare 300mCi for the study. The patients receiving higher dose also needed admission in isolation rooms to take care of possible side effects. A non-inferiority [3,4] randomized trial involving unequal allocation to three discrete doses (25mCi, 50mCi, 100mCi) could be completed with full devotion by a Ph.D. student in Biostatistics. The smaller dose was observed as non-inferior to higher dose. Further, more than 80% patients treated with smaller dose achieved ablation after six months of first dose, as a defined outcome of the trial. As a result of this trial, out of 100 mCi, now four patients may be treated using 25mCi each. Remaining less than 20% patients may be given additional dose. As a result, not only optimal use of available doses in managing more patients became possible but also involved cost of doses, as well as isolation rooms required for admission, could be minimized. To recognize his full cooperation and scientific support as a Co-Guide to a Ph.D. student in biostatistics, our clinical colleague was requested to remain first author of the research article published in a reputed journal5. It may be worthwhile to mention here that another important component for quality research is an ego free environment among the multidisciplinary research team members including biostatisticians. Otherwise, one has to face difficulties in the completion of study, and/ or compromise with quality of data, its analysis, interpretation and implications.

As a second example, one of our Ph.D. students (Neuro-Surgery), could complete and publish a preliminary Phase II randomized trial in the highest impact journal, New England Journal of Medicine (NEJM)6. It was a superiority trial on surgery for drug-resistant epilepsy in children. In other terms, high standard research requires good practices and reporting the way it was done, not otherwise. The long term prevailing problem is that a researcher often devotes his complete energy in claiming what he could not do (e.g., randomization in a trial). Under this process, he forgets to describe other relevant details which he did while conducting the study. That is why, as often emphasized during talks by me, morality comes before research methodology. One needs to honestly follow the written protocol. If deviated at any step(s) for unavoidable reasons, one needs to document it without failing. A trained biostatistician must be well acquainted with basic issues and maintain friendly relationships with colleagues to take care of every step of research methodology. A regular dialogue among the researchers including biostatisticians must maintain the accuracy of collected data leading to accurate results and related appropriate implications. A biostatistician is supposed to be friendly with each and every medical colleague. This may help sometime in resolving even personal problems of the students. For example, if students are facing problems with preceptors/ guides due to mainly lack of communication, a biostatistician in the team may take the initiative and get resolve the issues.

As followed at AIIMS, New Delhi, in addition to being chief guide/principal-investigator of his own students/ studies, as a biostatistician he needs to be involved in almost every participating study being done by medical researchers (students and faculty) as co-guide, or co-investigator, or doctoral committee member. To further strengthen the quality research standard, a biostatistician

is involved in all major decision making committees like ethics committee, research committee, deans committee, and staff council. Sometimes special committees also involve a biostatistician like a committee for intramural research funding and a committee to assess the need to establish school of public health. For every research paper of numerous national/international reputed journals, there has to be a statistical reviewer regardless of being reviewer, editorial member and editor. To be more specific, I was chief guide/ principal investigator for my own students/ studies, and collaborated as co-guide/ doctoral committee member with medical colleagues regarding MD/MS/DM/MCh and Ph.D. students, and as co-investigator regarding research projects, with utmost mutual respects to each other. Also, I got involvement in all the above-mentioned committees while working at AIIMS, New Delhi. Thanks to the current employer, I am continuing there virtually in ethics committee as well as with research studies of students/ faculty where I am involved as co-guide, co-investigator or doctoral committee member. Further, contributions in translational/ transformational research[5,6] provided me utmost professional satisfaction, and added feeling of being part of related esteemed research teams and true alumni of AIIMS, New Delhi. In addition, I cannot avoid being reviewer, editorial committee member, editor for various national/ international reputed journals. Hence, I had ample opportunity to experience the potential role of a biostatistician in medical institutions of repute.

In addition to biostatistics teaching at MBBS/ undergraduate level, to keep alive the temperament of research among PG students, faculty and other researchers of AIIMS, New Delhi, there used to be training programs on biostatistics/research methodology in every session (January & July), preferably beyond office hours to make their participation more feasible. Later, it was made mandatory for PG students to pass research methodology courses as eligibility criteria for their entry in final examinations. Along with this practice, there is routine annual teaching in biostatistics to PG students of the Centre for Community Medicine; combined routine annual classes in biostatistics for various academic programs like Masters in Nursing, Masters in Biotechnology and Masters in Reproductive Biology. Also, as another academic program, Fellowship in Clinical Research Methodology and Evidence-Based Medicine got initiated exclusively for faculty. But, for optimal use, classes were also open for non-registered faculty/ PG students. Being adjunct faculty, along with sharing biostatistics classes, I used to take almost all lectures related to randomized controlled trials under this fellowship program. Thorough advertisement through pamphlets in every corner of the campus used to make these popular classes very useful, keeping everyone engaged in research thought processes in campus.

Keeping in view of the above points, to ensure high standard of teaching and research, every medical college of the country needs a strong biostatistics component. To ensure this, they need to develop a separate biostatistics department having potential biostatistics faculty at par with those in clinical/ non-clinical medical disciplines. As a founder, vice-president of the society for evidence-based health care, India, president-elect (until 2022) and president (2023-2024) of the Indian Society for Medical Statistics, my humble request to every competent authority is to join hands and make it happen in every single medical college. This overdue step of developing a separate biostatistics department in every medical college might emerge as a boon towards further strengthening a high standard of research and teaching.

Let me end with a very relevant quote: The safety of science depends on the existence of people who care more for the justice of their methods than for the value of any results obtained by using them.[7]

References:

1. Dwivedi AK, Shukla R. Evidence-based statistical analysis and methods in biomedical research. Cancer Rep. Aug 2020, 3(4):e1176.
2. Dwivedi AK. How to write statistical analysis section in medical research? Journal of Investigative medicine. Jun 2022, jim-2022-002479.
3. Pocock SJ. Clinical Trials: A Practical Approach. Great Britain: John Wiley & Sons Ltd. 1986.
4. Armitage P, Berry G, Mathews JNS. Statistical Methods in Medical Research. 2002 (4th Edition), Blackwell Science Ltd., Oxford, UK.
5. Bal C, Chandra P, Kumar A, Dwivedi SN. A randomized equivalence trial to determine the optimum dose of iodine-131for remnant ablation in differentiated thyroid cancer. Nuclear Medicine Communications. 33(10): 1039-1047.
6. Dwivedi R, Ramanujam B, Chandra PS, Sapra S, Gulati S, Kalaivani M, Garg A, Bal CS, Tripathi M, Dwivedi SN, Sagar R, Sarkar C, Tripathi M. Surgery for Drug-Resistant Epilepsy in Children.New Engl J Med. 2017, 377(17):1639-1647.
7. Cohen Morris R. "Scientific Method", in The Encyclopaedia of the Social Sciences. 1930-1935, Edited by Edwin RA Seligman, and Alvin Johnson. New York: Macmillan