Biostatistics and Evidence based medicine: Why we need an attitudinal shift?

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ABSTRACT
Biostatistics is basically a way of thinking about data that are variable and is very much an art as well as science. Biostatistics is well recognized as an essential tool in medical research, clinical decision making, health management and cost effective policy making. Medical education should give greater attention to the fundamental teaching of practical statistics to medical professionals.

Introduction
Biostatistics is well recognized as an essential tool in medical research, clinical decision-making, health management and cost effective policy-making.¹ Recently, accreditation bodies are seeking more stringent confirmation of successful trainee achievement,² calling for medical education to move toward a more evidence-based approach to teaching and curriculum development.³ To meet these challenges, educators must have knowledge and skills in developing, analyzing and disseminating interventions as part of their academic and research work. This includes a fundamental knowledge of study design and statistical methods. Although medical training equips medical educators with a general background in epidemiology and biostatistics, many physicians lack the confidence and full conceptual knowledge to apply these skills on a regular working basis.⁴⁻⁶

Biostatistics: The concept
Statistics is basically a way of thinking about data that are variable and is very much an art as well as science. As such it can neither prove nor disprove anything. But without scientific application, statistics has no roots and is simply a tool.⁹ Thus, statistics may be defined as the discipline concerned with the treatment of numerical data derived from a group of individuals or living organisms. It implies both, data and statistical methods.⁹ Biostatistics on the other hand is a branch of applied statistics focusing on biological or medical sciences. It covers applications and contributions not only from health, medicine and, nutrition but also from fields such as genetics, biology, epidemiology, and many others.¹

History of Biostatistics in India:
India has a long history of applying statistical concepts in terms of data collection and its simple analysis, which got strengthened during the rule of the British East India Company who mainly use it for trade and commerce. The origin of statistics in India dates back to the Mauryan period (321 –296 B.C) in the Arthasastra by Kautilya, which explained the data collection system in agriculture, population, and economic censuses in villages and towns.¹⁰⁻¹¹ The practice of collecting and compiling data continued during 1590 A.D, in the period of Emperor Akbar, and during 1596-1597 A.D in the Ain-i-Akbari written by Abul Fazal.¹¹

Attitudes towards biostatistics among medical professionals:
Given this rich history, biostatistics should have enjoyed a welcoming position amongst academicians in India. It should have represented a critical methodological skill for post-graduate medical trainees and researchers. Take a look at the only Indian study on attitudes towards biostatistics in medical faculty and post-graduate trainees, by Gore et al. The majority of respondents at 55.5% were unaware about different sampling techniques, and those who claimed adequate statistical knowledge, could not mention the various sampling techniques correctly. 65.5% of the respondents admitted

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to preparing dummy tables in their research project.\textsuperscript{12}

85.5\% of the respondents felt that they would need the help of a statistician for proper presentation of data, whereas only 14.5\% respondents considered themselves capable of doing this without help.\textsuperscript{12} These numbers itself prove the need for a consensus on Biostatistics education is urgently required in India.

Statisticians have long expressed concern about the slow uptake of statistical ideas by the medical profession and the frequent misuse of statistics when they are indeed used. On the other hand, published original medical research articles now nearly always include statistics, and the complexity of the statistical methods has increased over time. Doctors have been worried about the increasing pressure to make use of techniques that they do not fully understand.\textsuperscript{12,13} Thus the “biostatistics literacy” of medical students is a problem all over the world.\textsuperscript{14}

**The world of Evidence based Medicine:**

Evidence based medicine (EBM) is receiving considerable attention within the field of human services and within the disciplinary literature of several specialties in Medical education and research. In fact, EBM encompasses a broad range of topics, from clinical epidemiology to biomedical informatics to evidence-based guidelines. The concept and impetus for EBM can be attributed to an increasing awareness of the weaknesses of standard clinical practices and their impact on both the quality and cost of patient care.\textsuperscript{15,17}

Aimed at decreasing subjectivity in clinical judgments, based on previous experiences and traditional protocols, EBM and biostatistics brings objectivity in assessment and treatment choices. To conclude, the effort to bring more certainty to clinical decision-making, spurred this novel approach.

Clinical practice was historically viewed as the “art of medicine.” Expert opinion, experience, and authoritarian judgment were the foundation for clinical decisions. The use of scientific methodology, as in biomedical research, and statistical analysis, as in epidemiology, were rare in the world of medicine. Historical precedence and indoctrinated political mistrust of these other disciplines posed barriers to incorporating these tools into medicine.\textsuperscript{18} However, several events in different parts of the world during the 1960s paved the way for EBM.

**The evolution of Evidence based medicine:**

Sacket et al (2000) simply defined EBM as, “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients, taking into account each individual patient predicaments, rights and preferences [using] best evidence from clinically relevant research. Thus forming a “diagnostic and therapeutic alliance between clinicians and patients which optimizes clinical outcome and quality of life”.\textsuperscript{19} It is indeed the demand for today by health care providers, cost effective policy makers and patients alike.

Although this term was introduced in 1991, many others accomplished the foundation for this new strategy, through years of work. Their arguments were not welcomed at first. Today they are heroes, honored in the history of clinical research, but Archie Cochrane,\textsuperscript{20} Alvin Feinstein,\textsuperscript{21} Frederick Mosteller,\textsuperscript{22} Tom Chalmers,\textsuperscript{23} David Sackett,\textsuperscript{24} and others had first to play the role of outsiders, systematically building evidence for their assertions.

Today thanks to the work of these pioneers, EBM encompasses various terms. Randomized control trials, meta-analysis, Cochrane review, Systematic reviews are just a few of these, with numerous other specialties now part of evidence based medicine research, committed to its 10 principles: collaboration, building on enthusiasm of individuals, avoiding duplication, minimizing bias, keeping up-to-date, striving for relevance, promoting access, ensuring quality, continuity, and worldwide participation.\textsuperscript{15}

**The final word in EBM:**

Critics claim EBM lacks utility, claiming that it transforms the complex process of clinical decision making—which includes data gathering, years of medical knowledge, experience, and astute intuition—into an algorithmic exercise that is not individualized for specific clinical scenarios and therefore subject to error in patient care.\textsuperscript{15} However the argument that EBM incorporates the “the best available external clinical evidence from, systematic research” requires an understanding of what constitutes “best…evidence” cannot be ignored.\textsuperscript{24,15} Radical decision making ultimately needs, EBM guidelines with medical intuition and wisdom.

Hence the need of the day is medical educators having basic knowledge and confidence with interpretation of both epidemiological data and significance of statistical methods used. Notwithstanding these potential deficiencies, EBM has made a clear and permanent mark on the face of medicine and is here to stay.

**So what can be done now?**

Clearly the advent of Evidence Based Medicine (EBM), supported by easier Internet access to research literature for both doctors and patients, has brought an increased
need for critical appraisal of the available literature in itself. EBM has added momentum to the changing aims of statistics teaching, with an increased emphasis on concepts and a move away from techniques. In turn it has raised the question of whether teaching should be directed towards “consumers of research” or “producers of research”.

The goal that medical educators now need to focus on is, understanding the statistical analytical concepts that need to be used, during the design process of research itself. An early involvement of statisticians during planning stage of study designs and “facilitating optimal communication” with them about their specific statistical analytic requirements would go a long way in improving research outcomes. Basic data analysis using software like the SPSS, STATA could be done by researchers themselves, if they know which statistical tests would be appropriate.

Clinicians on the other hand also could benefit for example if they learned how to read a meta-analyses, knowing what a Randomized controlled trial is and how clinically relevant is the statistical significance established. Thus being skilled at critically appraising medical literature to benefit their patients and practice EBM.

Wide ranges of options for biostatistics training for faculty, specialists and post-graduate trainees are available. These include formal academic courses for credit, one-on-one education offered under the guise of consultation, self-paced textbook or computer learning, intensive short courses, portions of extended courses spanning an assortment of other subjects, and a continuing series of seminars or lectures covering selected topics in statistics. Short period intensive workshops accredited by governing boards for ensuring quality biostatistics training of medical educators are the need of the day.

The major goal of these courses is to improve the overall research atmosphere at each university. This is accomplished in two ways. First, we expect that many of those taking the courses will be able to perform simple comparisons without the help of a statistician. Second, we hope that participants will gain a better appreciation for what they do not know. With this knowledge, we hope that physicians will recognize when they need to include a statistician on their research team.

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Cliniminds, Bengaluru a clinical research-training institute runs various post-graduate and advanced postgraduate diploma programs in biostatistics and related fields. These programs are mainly run either as regular weekend courses or in a distance learning mode, considering the target audience is working individuals.

Institutes like the Christian Medical College, Vellore, offers regular training programs of short duration (from three days to one week) in various topics in biostatistics. Short-term training workshops are also organized for building capacity in analysis skills by using statistical software like STATA, SAS or SPSS.

Another method to brush up on statistical skills for medical educators is online credit courses. The Harvard Clinical and translational science center (The Harvard Catalyst) provides opportunity for a 35-week online
certificate course giving a comprehensive overview of the principles of study design in research and methods of biostatistics. It calls for a time commitment of 4 hours per week and eligibility criteria of being an M.D, PhD or equivalent. For cost and details visit http://catalyst.harvard.edu/services/biostatscertificate/.

Long term goals for medical educators in India should now include a greater attention to the fundamental teaching of 'practical statistics' during undergraduate medical training course itself. More stringent confirmation of the “biostatics literacy” of the undergraduate medical student would put India on the map for 'Evidence based medicine' medical education curriculum development.

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