EDITORIAL

Do We Need to Change the Outlook?

Surekha Kishore

[1]Professor and Head, Department of Community and Family Medicine, All India Institute of Medical Sciences (AIIMS), Rishikesh, Uttarakhand

Corresponding Author

Address for Correspondence: Dr. Surekha Kishore, Professor and Head, Department of Community and Family Medicine, All India Institute of Medical Sciences (AIIMS), Rishikesh, Uttarakhand.
E Mail ID: surekhakishore@rediffmail.com

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Family Medicine is a complex branch by virtue of its nature. Broad in its perspective, it involves high proportion of poorly differentiated problems along with overlapping biological, psychological, and social factors.(1) EBM (Evidence Based Medicine) which originated in second half of 19th century, roused greater interest among health professionals especially during last decade (1). With time as medical knowledge grew, EBM was internationally accepted as gold standard for decision-making and standard for medical practice. It facilitated clinicians in providing up-to-date scientific evidence which in combination with clinical expertise was utilized in medical practice to achieve best possible outcomes (2). Evidence-based practice guidelines and EBM approaches are recognized as the core of today's scientific thinking with randomized controlled trials (RCTs) being regarded as fundamental research response of EBM for healthcare (3). However, the most troubling aspect of EBM is that it provides the restricted view of evidence. As advocated since 1990s, it was based on the notion that medical practice was subjective and evidence should rather be prioritized on hierarchical system. To promote greater reliance on published literature, RCTs were introduced as a powerful tool for measuring effectiveness and safety of treatments. It argued that clinical judgment and mechanistic reasoning are less reliable forms of evidence in medicine (4,5). Despite EBM era, they still continues to exert influence, resulting in confusion and controversy.

A recent example occurred when public health physicians in United Kingdom recommended the prophylactic use of antiviral drug oseltamivir in an effort to mitigate influenza spread (6). Family doctors objected, fearing that it might not be in the best interest of their patients because of uncertainties about the benefits and safety of these drugs, particularly in elderly people with co-morbidities who might not be suffering from influenza (7). A letter from Public Health England to family doctors escalated the issue, arguing that its advice was on the basis of the best available evidence, and hinting that noncompliance might result in legal and regulatory consequences (8). The Medical Defence Union, which offers legal advice and support to doctors, intervened and clarified that, "guidelines inform practice but don't dictate it. They do not replace knowledge and skills of clinicians. Doctors are expected to be familiar with guidelines, but this does not mean they cannot depart from guidance when in the best interest of their patients. They must be prepared to explain and justify their decisions and actions in such cases" (9).

Such conflicts raised a very important issue that EBM should not be recognized as a "cookbook" medicine (1). It is important to understand that no matter how strong the external clinical evidence be, it can never

replace individual clinical expertise (1). It is the latter that decides whether external evidence needs to be extrapolated to an individual patient or not and, if so, how it can be integrated into a clinical decision. (1) Because it requires a bottom up approach that integrates best external evidence with individual clinical expertise, it cannot result in slavish, cookbook approaches to individual patient care (1).

It also a high time to realize that as researchers we are unable to trace the exact natural history of the diseases. Instead, evidence based practice mainly relies on the results of meta-analyses and systematic reviews for their accuracy, as exemplified by Cochrane Reviews. They contribute data from large numbers of patients and may provide legitimate basis for subgroup analysis. However, it is needless to say that there exists major concerns pertaining to their validity for variety of reasons. Bias in reporting of clinical trials is well recognized and can arise for several reasons, such as inappropriate subject selection, poor study performance, or incorrect analysis of data. Despite the evidence that quality of published clinical trials has improved in recent years, the risk of bias still persists to be significant (10). Bias is also known to occur due to journals' reluctance to publish negative results wherein a positive trial of one of the author carried out on 300 patients pertaining to pre-hospital thrombolysis was published in BMJ while, at the same time, a negative study of 5,500 similar patients was rejected by The Lancet (11).

It is a common practice to consider $p<0.05$ as "significant". There seems something magical about it; if p falls higher than this, is considered as nonsignificant. But clinical significance cannot be really dichotomized in this way. Furthermore, a skilled statistician can, by introducing "corrections," move a p value from 0.051 to 0.049. What a statistician or epidemiologist sees as "significant" may not seem so to the clinician (10). This is well illustrated by low-dose aspirin trial carried out among subjects at high risk for cardiovascular diseases. Results showed treatment significantly reduced relative risk of cardiovascular deaths by 44% (12). This might suggest that this result should be able to convince practitioners for recommending low doses of aspirin for primary prevention among individuals who have ≥1 risk factors. However, clinicians were aware that this represents a very low reduction in absolute risk (number needed to treat=6 of 1,000). In addition, the treatment was also associated with increased risk of severe bleeding, thus might be reluctant to prescribe.

In research, "evidence" is usually referred to a statistically valid conclusion that pertains for a specific and rigorously defined cohort. (13) An important issue that needs to be highlighted is that conclusions which is labelled as "evidence" is basically evidence considered for a particular cohort, that too under particular circumstances. This may not be extrapolated to other groups. (12) For example, an evidence that is identified for a cohort of an adult male population does not mean it can be applicable for an individual 66-year-old female. (13) Results referred as "evidence" for 24 year-old white males may not be applicable for 24-year-old black females. Despite the fact, EBM is often used inappropriately (13).

Concerns have been raised by many health professionals who were of opinion that pharmaceutical companies are trying to infiltrate medical research institutions. They are able to influence peer-review process to promote drug marketing. A handful of influential medical critics believe that the validity and veracity of peer-reviewed research is being undermined, subverting the essence of EBM (14,15).

Researchers believe that negative or unfavorable results are been eliminated or camouflaged or even remolded in ways that present positive or even favorable results when a more transparent analysis might reveal substantial risk for patients taking 'hyped'' medications (16). Despite the idealized claim that EBM would be the product of objective research conducted by disinterested medical researchers, pharmaceutical industry-sponsored clinical trials, such malpractice can have a corrosive impact on both physicians and the final evidence (17).

EBM is inevitably based on averages which may not always fall into normal distribution curve. It is equally important to accept that this EBM approach is not suitable in current epidemiological context which is characterized by chronicity and multi-morbidity in complex health systems. Patients often differ in age, resilience, concurrent disease, and a host of other genetic, environmental, and other pathophysiologic dynamics. They may also differ in cultural, social, and economic parameters. Such that when a well-acknowledged family physician is confronted with an individual patient, it is often hard to determine where to fit him/her in his/her paradigm of treatment care. Definitely a 25 year old well-fed non-alcoholic south Asian college-going male student

who develops pneumonia is not legitimately placed in the same group of other 20 year old white unemployed male who drinks heavily with inadequate nutritional intake (18). EBM based on RCT is useful mainly for acute (mostly single disease) conditions treated with simple interventions. In particular, EBM has largely ignored the importance of social determinants of health and local context that pose its real impact on the 'effectiveness' and 'efficiency' of healthcare on the 'equality' of needed healthcare services (19,20).

It has been commonly observed that results of trials becomes controversial with due course of time. As and when new drug or vaccine etc. has been discovered, tested, and found satisfactorily efficacious does not necessarily mean it too be correct always. For example – in earlier days, when an antimicrobial called "oleandomycin" was discovered, it was glowingly reviewed in literature at the first place. Few years later, it was found worthless in infection control to an extent that it was taken over by erythromycin, and is now rarely advised for gastric motility disorders in the present day. Imagine if EBM would have included it in their recommendations at the time when enthusiasm for oleandomycin ran high. (18)

It is important to understand that constructing an EBM protocol can be an excellent learning experience, but evidence alone is never sufficient to make a clinical decision. To make valid conclusions, we should rather focus more on tracing accurate natural history of the diseases so as to avoid conflicting results in future trials.

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