Evidence made medicine

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Physicians, whether serving individual patients or populations, have always sought the best possible evidence to base their decisions and actions on. Previously, it was considered sufficient to understand the pathophysiological process of a disorder to prescribe a therapy that interrupted or modified the process. However, there is increasing awareness that such approaches are insufficient and must be complemented by demonstration of clinical benefit in humans before new therapies are accepted. Significant advances in healthcare have been made in the past few decades through extraordinary expansion of academic-industrial ties and by conducting large population-based, industry-sponsored, mega trials evaluating newer therapies. Various old principles and methods of healthcare have been challenged. Treatments that seem promising in observational studies are often refuted in randomised controlled trials. Randomised trials have strengths over observational studies, but they hardly are the last word.

The new information is coming so fast that staying updated with this information requires significant effort on the part of the busy clinician who not only has limited time but has little knowledge of research methods. By the time the physician tries to grasp the information obtained through one trial, its findings are challenged by those emanating from another trial. To circumvent this problem, a group led by Gordon Guyatt at McMaster University in 1992 consolidated the concepts and re-claimed the term Evidence-Based Medicine (EBM), the origin of which dates back to ancient times (Buddha – 6th century BC). The idea has been mentioned in the ancient Chinese medicine too. It is currently defined as “the explicit, judicious, and conscientious use of current best evidence from healthcare research in decisions about the care of individuals and populations.” The concept when developed perfectly sense that therapies based on randomised double-blind controlled trials would provide better care and combined findings of several researchers would have advantages over the experience and memory of a senior physician. The industry enthusiastically promoted this concept and in recent years has started designing trials in a manner that would help prove what they want to prove. In that sense, the industry has misused this concept for perpetuating its own benefit. This raises a question that, in current times with the intrusion of industry, what actually is the “Evidence” in Evidence-based medicine? Is evidence true or created?

Evidence is simply “a ground for belief” — any grounds, not merely scientific. Evidence, as used in law, is a presentation of facts before a judge for a decision to be made. It could be derived on several planes. Evidence could be based on inductive or deductive logic or merely on experience. Inductive logic is the basis of the scientific method that involves making observations to make conclusions. Deductive logic allows conclusions to be made without observations. Deductive evidence is deduced from our knowledge and understanding of the pathophysiology of the disease process. There is a third level of evidence based on experience or anecdote — not highly valid but in many instances better than inaction. The evidence is not eternal and can be annulled or thrown out, and is inherently provisional so it could be altered with new findings. It is clear that evidence, no matter how it is collected, is not without bias and there are many constraints to gathering evidence.

In the past few decades most research has been conducted using pharmaceutical support. In most circumstances, the evidence is generated from trials performed only on select populations and in the true sense is not generalisable to all or individual patients. Many of us have participated as investigators in trials and know that often it is very difficult to enrol patients because of the strict selection criteria. However, if the results are positive, they are widely publicised in the media and are construed to be applicable to the general population, even though most of the patients might not have fulfilled the selection criteria described in the clinical trial. The question one is tempted to ask is: Is this true Evidence-based medicine?

The recent extraordinary expansion of academic-industrial ties has decreased the public’s confidence in the objectivity of clinical trials. Industry funding, although important to conduct expensive large trials, does influence the conclusions of published literature and guidelines. Several university and medical-school departments now seem to operate as subsidiaries of pharmaceutical companies. Nowadays, corporate affiliations are more common than academic titles. Academic physicians may not be willing to criticise the sponsors of their study, whose final responsibility is to their shareholders, not to the patients or physicians.
There is no doubt that without industry support major advances that have occurred in the past few decades would not have occurred. Industry plays a significant role in the design, conduct and publication of trials. As industries are amalgamating to become Mega-industries, this influence is likely to increase in future. Government regulations should be designed to prohibit this kind of influence worldwide. It is, however, doubtful if such controls can be exercised in reality. It is time to reconsider very seriously the kind and extent of support that one should avail of from the industry for conducting research. There are no strong reasons for continuing to pursue a policy that could bring medicine into disrepute and would hinder rather than favour real scientific progress in the long run.

Researchers should try not to exaggerate results (that is mostly done, whether to gain fame or due to the influence of the industry) and should remain truthful not just to the public but more importantly to themselves, so that their credibility is sustained. If the current trend continues it would become difficult for a busy clinician to differentiate a “true” researcher from others. Authors of various guidelines, in addition to ranking the level of evidence should also review the conduct (for bias in the design of trials) and first decide if the evidence produced by that trial is admissible or not, as done in the court of law. They should then decide if the trial results need be taken into account while developing the guidelines. If not, one should discard such studies. Such actions would serve as a deterrent for undertaking biased trials in future. Clinicians, no matter how little time they have, should review the results of important studies to make their own decision(s) rather than depending on the conclusions of the researchers who might be “under the influence” of the industry and might present a jaundiced view of their study.

In the end, we should follow the same principle in accepting the results of trials, as Buddha (6th Century BC) in Anguttara Nikaya III – 65, explained to a group of sceptics: Do not believe in anything simply because you’ve heard it. Do not believe in traditions because they have been handed down for many generations. Do not believe in anything because it is spoken and rumoured by many. Do not believe in anything simply because it is found in your religious books. Do not believe in anything merely on the authority of your teachers and elders. But after observation and analysis, if you find anything agrees with reason and is conducive to the good and benefit of one and all then accept it and live up to it.

References