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Evidence Based Medicine: A Peek in Inevitable Journey for India

Moving from Experiential to Evidence based Medicine



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It gives us immense satisfaction to come up with the FICCI HEAL knowledge Paper, **"Evidence Based Medicine: A peek in inevitable journey for India"** at the fifth edition of FICCI HEAL 2011 on September 8 & 9, 2011 on the theme, **"From Dis-ease to Health-ease"**.

The study encompasses the evolution of evidence based medicine in the country including the principles and rationale of Evidence Based Medicine (EBM), the barriers to practice and a broad based approach for adoption through practice of Standard Treatment Guidelines.

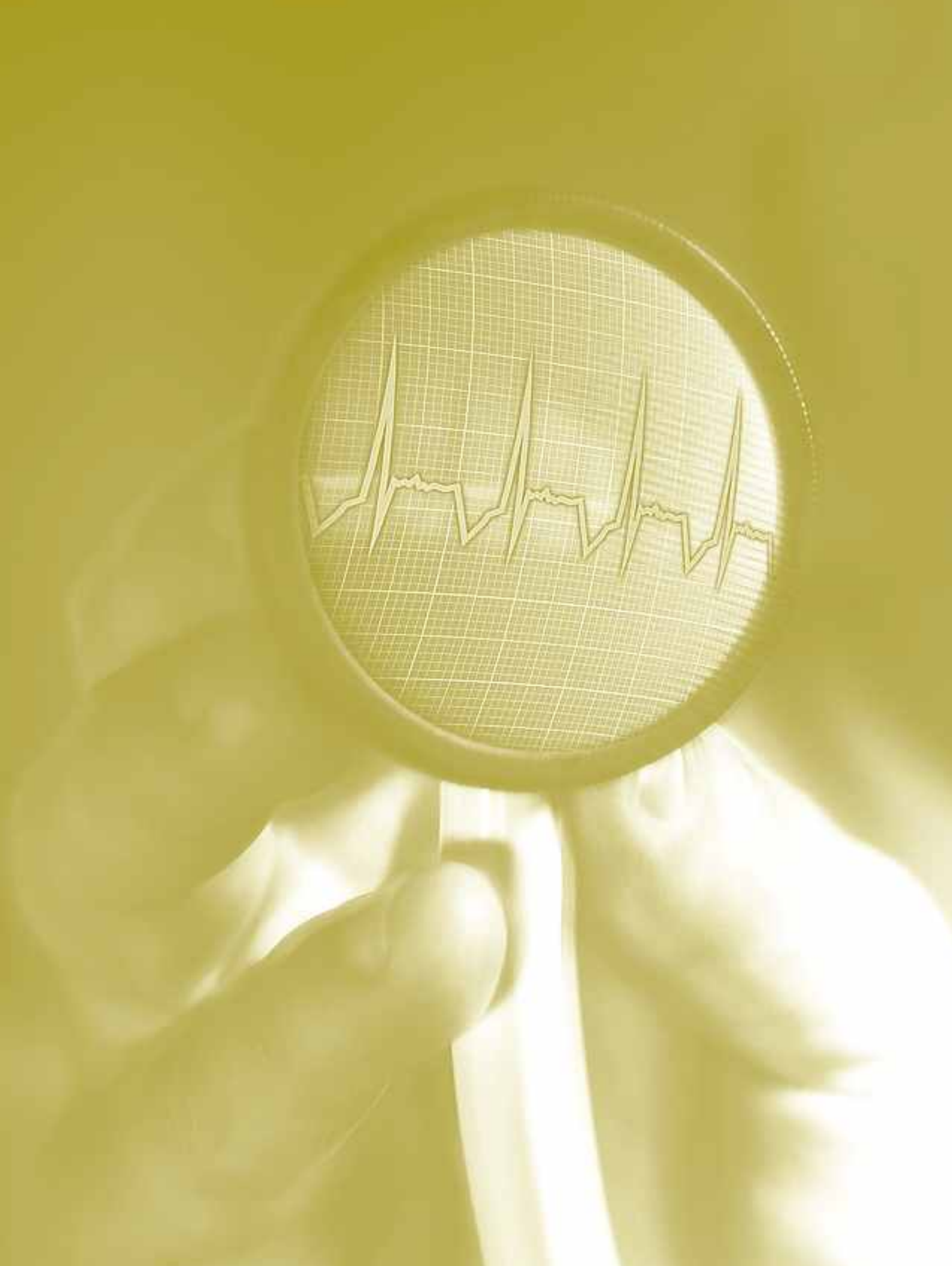
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Moving from Experiential to Evidence based Medicine



Abstract



The subject experience based medicine / experiential medicine (ExBM) and evidence based medicine (EBM) evoke a competing, if not conflicting view point, even today. This is despite the fact that, world over, there has been a shift towards rational and logical evidence based medicine. The argument opposing EBM, especially in developing countries, has been the lack of resources and economic factors. It is not that only the developing countries have been delayed in wider acceptance of practice of evidence based medicine. Even the developed countries with fairly matured health systems have also struggled in succeeding in implementation of practice of EBM.

The current endeavour is focused on formulating a knowledge paper on the subject - Moving from Experiential Medicine to Evidence Based Medicine. The methodology included an extensive meta-analysis of available literature with regard to traditional way of practice of medicine including the aspects related to narrative medicine, clinical judgement and evolution of evidence based medicine encompassing the principles and rationale of EBM. The paper also explores the barriers to practice of evidence based medicine, with focus on South Asia, especially in India, along with the current status and physician's attitude towards EBM and strategies and approaches to overcome these constraints.

Further, the factors influencing practice of EBM in India have been analyzed in the context of healthcare eco-system today. A detailed appraisal has been done for the proposed approach to catalyze a broad based adoption of EBM in India through practice of standard treatment guidelines (STGs). This endeavour has been initiated by Ministry of Health & Family Welfare, Government of India with collaboration with Federation of Indian Chambers of Commerce and Industry (FICCI). The STGs, thus formulated, will be disseminated and implemented across the country in the selected disease entities from twenty clinical specialities to catalyze practice of EBM universally through voluntary adoption by clinicians. These STGs will undergo review periodically to remain in sync with the requirements of the prevailing healthcare delivery eco-system maintaining rationality and cost effectiveness.

Introduction



Through the whole history of medicine, there runs a long struggle between two principal tendencies - empiricism and rationalism. The empirical trend lays its emphasis on "experience" for the cure of the sick. The rationalistic trend lays its main emphasis on "mechanism" for the causes of diseases. Experience Based Medicine (ExBM) versus Evidence Based Medicine (EBM) is a matter of continuous debate since early nineties when Gordon Guyatt proposed the concept of evidence based medicine at McMaster University in Canada in 1992. This was published in Journal of the American Medical Association (JAMA) in 1992. Guyatt defined Evidence based medicine (EBM) - "the process of systematically finding, appraising, and using contemporaneous research findings is the basis for clinical decisions".

Primarily, the trigger for propounding the concept lay in the fact that the healthcare costs have been rising thereby raising a question mark on cost effectiveness of the delivery of care on one end and efficacy of delivery of care on the other end. Another factor that has been instrumental for evolution of the concept of EBM is the consistency of healthcare delivery services for same set of presenting disease symptoms expecting similar outcomes. Thus, the significance of practice of evidence based medicine.

The question, therefore, is - how did evidence based medicine evolve? Needless to mention, experience, i.e. clinical judgement producing same result in repeat transactions (read consistency) forms the very basis of adoption of the hypothesis for future action. Hence, it appears that evidence based medicine and experience based medicine are intertwined. One cannot vouch for one or the other and it is pertinent to mention that the two need to be there to influence and vice versa. The popular perception that experience based medicine (ExBM) or clinical judgement and evidence based medicine (EBM) are at loggerheads is incidentally an imaginary divide.

Moreover, the problems faced with regard to acceptance of EBM rather reflect reluctance on the part of established clinicians to get motivated for adoption as a result of rigidity & unawareness and to some extent misinformation. Misperceptions and absence in medical curriculum coupled with resource constraint are also cited as key factors for adoption of EBM whereas the reality is otherwise. Relevance of EBM, therefore, assumes larger importance for developing economies, especially in Asia, Africa and Latin Americas.

Though the framework of EBM was laid in West, its basic essence seems to have existed in Asia long before its formal inception. South Asian countries and their societies are influenced by several faiths and religions like Hinduism, Islam, Jainism, Buddhism and Sikhism. These religions are variably scientific, logically defined and can be adaptable to change. It is difficult to believe that

countries with such a rich cultural and ethnic heritage have not yet adapted the concept of EBM. Possibly, the problems with acceptance of EBM are not unique to EBM, rather reflect the overall poor socio-economic status of this region which itself is a major hindrance in health delivery.



Philosophically EBM and the traditional medicine (experiential / evidence based medicine) embody different approaches, but this does not mean that they are competitors. In fact, the two approach need each; neither can stand alone for the development of clinical practice. Practice of EBM can rationalize the treatment and simultaneously be cost effective by reducing elements in clinical practice that have no proven benefit. Therefore formulation of locally applicable treatment guidelines assumes a significant importance such that these guidelines can play an important role in adoption of EBM. Actually, these guidelines are formulated by the clinicians themselves and that they, therefore, have to play a very critical and central role in the scheme of practice of EBM. Hence there is a need and time for integrating the knowledge and wisdom gained as a result of experience in to an objective mode for practice of clinical evidence that will lead to standardization of practice of medicine.

Increasing penetration of health insurance in the country after opening up of insurance sector has resulted in not only increasing affordability for the citizens but also increasing challenges for the health insurance companies in servicing their clients. The challenges being - high claim ratio, quality of care delivery and variations in cost of care across different cities and even various hospitals / health facilities in the same city. In order to find solutions to overcome these challenges the health group and health insurance group of Federation of Indian Chambers of Commerce & Industry(FICCI) came together in 2009 to develop Standard Treatment Guidelines (STGs) for about fifty most common ailments which formed the bulk of claims. A process of involving experts who formed core groups for each of these selected ailments to formulate treatment guidelines followed by peer review and review by steering committee formed for the purpose was followed to complete the task. However, STGS could be completed for twenty one disease entities due to paucity of resources. These STGs were then forwarded to Insurance Regulatory and Development Authority (IRDA) in 2010. The Chairman IRDA found these STGs as a prudent approach in meeting the twin challenges from the point of view of beneficiary - the quality of care and affordability thereby supporting the health insurance companies in bringing down the claim ratio and servicing their client. The Chairman recommended the Ministry of Health & Family Welfare, Government of India to consider formulation of STGS as way forward for ensuring quality of delivery of health services across the spectrum of the entire country.

Ministry of Health & Family Welfare, Government of India, recognizing the importance of standardization of treatment such that it supports decision making for the patients and their



families on one end and bring consistency and uniformity in treatment on the other end initiated the task of formulation of Standard Treatment Guidelines (STGs) for most commonly encountered diseases that form the bulk of disease burden in twenty specialities. Experts from across the nation were invited to formulate STGs through a detailed process of consultation, consensus building and peer review including from their individual professional bodies such that these guidelines serve as a template for standardization leading to rational and cost effective treatment for citizens of the country. It is envisaged that this process of formulation of STGs and implementation thereof will catalyze the practice of medicine leading to adoption of the concept of evidence based medicine (EBM). FICCI has collaborated with the Ministry of Health & Family Welfare, Government of India to facilitate, support and co-ordinate completion of the stated task for equipping the healthcare delivery eco-system for rational and cost effective treatment for all concerned.

Experiential / Experience Based Medicine, Narrative Medicine and Clincial Judgement



Experiential / Experience Based Medicine

Experience Based Medicine (ExBM), as the name denotes, is simply understood as practice of medicine based on experience. The term experiential medicine (experiential i.e. derived from, or pertaining to, experience) is used many a times in place of experience based medicine. Thus experience reflects the most important and critical element in the term experiential / experience based medicine.

Experience, as defined in Wikipedia, is

- An act of knowledge, one or more, by which single facts or general truths are ascertained; experimental or inductive knowledge; hence, implying skill, facility, or practical wisdom gained by personal knowledge, feeling or action; as, a king without experience of war.
- The effect upon the judgment or feelings produced by any event, whether witnessed or participated in; personal and direct impressions as contrasted with description or fancies; personal acquaintance; actual enjoyment or suffering.
- Trial, as a test or experiment.

A simple illustration of ExBM is - If I have treated 30 patients a certain way and almost always had a good result, I'm inclined to treat any following patients the same way, until my luck changes. It is in no way based on pure luck, since that wouldn't work. It is based on theoretical knowledge of patho-physiology coupled with real-life experience and it usually works fairly well.

The problem is that you never know exactly why you have good results or if the same treatment would be valid in the hands of other physicians having another group of patients. You don't know if your own person has anything to do with it, or if you happen to live in an area where the patients react a certain way. Or possibly, if your therapy only works, because most of your patients are on another therapy of yours, that is uncommon in other areas. Or maybe your patients are mostly related and have a common gene setup.

In the context of ExBM, physicians discharge their professional duty towards their patients through the repository of knowledge and wisdom built up through experience over a period of time, over and above the theoretical knowledge gained through training. The experience gained could be of



one's own self and / or from the shared experiences of colleagues and peers with whom the individual practitioner feels comfortable and / or shares experiences. Generally it has been seen that the set of actions, starting from hypothesizing for diagnosis to management of treatment process follow a very similar pattern amongst the practitioners. The whole process of delivery of care depends mainly on drawing as much detail as possible from patient and / or their accompanying attendant(s) and family about the symptoms involving and employing a lot of narration which is both ways, i.e. patient and doctor and doctor and patient (patient denoting the patient himself / herself and the family); linking and relating with the knowledge about the possibility of causative disease entities, past experiences in dealing with similar presentations / cases and judgement based on intuitive insights and / or shared experiences of the peer group.

Hence it has been observed that the clinicians prefer to develop formal and / or informal networks of their own wherein they derive comfort in discussing the needs of their patients and / or derive expertise for managing them. In addition, the clinicians feel comfortable and confident in seeking advice for their patients and / or refer or transfer the patient to the care of other clinician in the said network where they need a particular skill and competency to treat the patient. There is mutual respect for each other in such networks and opinion of successful clinicians carries a lot of weight in formulation of so called unsaid guidelines for managing particular types of cases thereby influencing the decision making by the members. The flip side of the formation is the fact there develops a bias for a particular mode and / or modality of treatment without actually evaluating the effectiveness for the particular individual patient. Additionally, it is felt that such networks also lead to or are susceptible to compromise the appropriate line of management with or without consideration of any financial incentives.

The traditional way of practice of medicine, as enunciated above, has largely based itself on narrative expressions and clinical judgement. While the narrative expressions involved the stakeholders including patient, clinician, and society clinical judgment which is derived out of information and knowledge about the disease entity (its symptoms, causative factors, patho-physiology, pathogenesis, differential diagnosis, investigative guide etc.); past experiences of different modes of management - success or otherwise; intuitive judgment about the choice of modality for the particular patient involved only the clinician. Approach towards managing the suffering of the sick in its totality rather than just the disease entity entailed fair bit of narration including for building trust and confidence in the clinician and therefore the term has been coined as 'Narrative Medicine'; and it too requires a degree of competence that contributes to the overall process of care delivery. It is quite evident that narrative medicine and clinical judgement form the two pillars of the clinician's conduct of his professional duties forming the base for practice of ExBM.

Narrative Medicine



Narrative Medicine connotes a medicine practiced with narrative competence and marked with an understanding of the highly complex narrative situations among doctors, patients, colleagues, and the public.

In addition to the experience of the clinicians, the effective practice of medicine requires narrative competence, that is, the ability to acknowledge, absorb, interpret, and act on the stories and plights of others. Medicine practiced with narrative competence, called narrative medicine, is proposed as a model for humane and effective medical practice. Adopting methods such as close reading of literature and reflective writing allows narrative medicine to examine and illuminate four of medicine's central narrative situations: **physician and patient, physician and self, physician and colleagues, and physicians and society**. With narrative competence, physicians can reach and join their patients in illness, recognize their own personal journeys through medicine, acknowledge kinship with and duties toward other health care professionals, and inaugurate consequential discourse with the public about health care. By bridging the divides that separate physicians from patients, themselves, colleagues, and society, narrative medicine offers fresh opportunities for respectful, empathic, and nourishing medical care.

Since the 1970s critics have alleged that Western medicine has fallen victim to the professionalism movement. According to this critique, many medical schools and residency programs train physicians to treat medical problems merely as problems to be solved, without taking into account the specific psychological and personal history of the patient. As of late 1990s physicians like Rachael Niomi Remen and Rita Charon have emphasized that medical practice should be structured around the narrative. As Charon stated: **"The sick need people who can understand their diseases, treat their medical problems, and accompany them through their illnesses"**

The value of Narrative Medicine is summarized as follows in an article in the British Medical Journal:

In the diagnostic encounter, narratives:

- Are the phenomenal form in which patients experience ill health
- Encourage empathy and promote understanding between clinician and patient
- Allow for the construction of meaning
- May supply useful analytical clues and categories

In the therapeutic process, narratives:

- Encourage a holistic approach to management
- Are intrinsically therapeutic or palliative
- May suggest or precipitate additional therapeutic options



In the education of patients and health professionals, narratives:

- Are often memorable
- Are grounded in experience
- Encourage reflection
- In research, narratives:
- Help to set a patient centered agenda
- May challenge received wisdom
- May generate new hypotheses

Narrative Medicine aims not only to validate the experience of the patient, but also to encourage creativity and self-reflection in the physician.

Obstacles

As Remen notes, people who are physicians have been trained to believe, that it is a scientific objectivity that makes them most effective in their efforts to understand and resolve the pain that others bring them, and a mental distance that protects them from becoming wounded from this difficult work

Clinical Judgement

The application of information based on actual observation of a patient combined with subjective and objective data that lead to a conclusion.

...Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.

Clinical judgment is exerted while the patient is still alive; the critical decisions made on the basis of scientific observations but with the added skill provided by long experience of similar cases. To this must be added an innate ability to make balanced judgments based not only on the state of the animal and its predictable future but also on some consideration for the patient's overall well-being and the client's financial status and degree of psychological, or in some cases actual, dependence on the patient.

Clinical judgment, then, can be understood as bringing to bear all relevant kinds of medical knowledge, along with patient goals, values, and preferences, in order to reach the best possible decision for the patient-at-hand. Clinical judgement often involves weighing conflicting warrants for action and negotiating between them. Each of these kinds of medical knowledge has its own strengths and weaknesses. It is here that the experience of clinician(s) over the period of practicising life span plays an important role in decision making for the benefit of the patient. However, it cannot be said that every time the clinician(s) apply the above the outcome is favourable. Therefore the fact that clinical judgement does play a significant role in decision making for the final choice of mode or modality of treatment cannot be overemphasized.

Limitations of Experiential / Experience Based Medicine, Narrative Medicine and Clinical Judgement



Areas of professional practice, such as medicine, psychology, psychiatry, rehabilitation and so forth, have traditionally been domains wherein practice was based on loose bodies of knowledge. Some of the knowledge was lore that drew upon the experiences of generations of practitioners, and much of it may not have adequate or optimum valid scientific evidence on which to justify various practices.

In the past, this has often left the door open to quackery perpetrated by individuals who had no training at all in the domain, but who wished to convey the impression that they did for profit or other motives. As the scientific method became increasingly recognized as the means to provide sound validation for such methods, it became clear that there needed to be a way of excluding quack practitioners not only as a way of preserving the integrity of the field (particularly medicine), but also of protecting the public from the dangers of their "cures." Furthermore, even where overt quackery was not present, it was recognized that there was a value in identifying what actually does work so it could be improved and promoted.

Experiential / experience based medicine (ExBM), Narrative Medicine and Clinical Judgement combined together form the traditional way of practice of medicine. However, individual experiences including of peer group and / or formal & informal network may suffer from the bias or prejudice against or in favour of a particular modality of treatment with or without rational effectiveness or otherwise. Similarly narrative medicine, as the name itself connotes, requires a fair amount of proactive effort to ascertain adequate information and data that contributes to establishment of reasonable diagnosis which leads to analysis of comparative evaluation of choices for treatment. It is here that the clinical judgement plays a very important part in the overall process of decision making for the benefit of patient.

It is evident from all of the above that the three components make the essential triad for decision making. However, the triad of attributes involves fair bit of subjectivity, dependence on memory - for knowledge and experiences, analytical capability and assessment of overall context with relation to the patient and his / her environmental attributes for arriving at perceptibly correct choice. Thus, the final choice may be limited because of inadequacy of any of the above attributes. Moreover, it is a constant endeavour of all clinicians to deliver good clinical outcomes for their patients all the time and patients desire to have them delivered always. Hence the quest for constant improvement in practice of medicine propels further research and exploration to find better solutions.

Evidence Based Medicine



Concept and Meaning

The term "evidence-based medicine" (EBM) has spread through medicine with amazing speed during the last few decades. The pace speaks to the attraction and fundamental soundness of the core idea: that what happens to patients should be based, to the greatest extent possible, on evidence. Gordon Guyatt proposed the concept of evidence based medicine at McMaster University in Canada in 1992. This was published in Journal of the American Medical Association (JAMA) in 1992. Guyatt defined Evidence based medicine (EBM) - "the process of systematically finding, appraising, and using contemporaneous research findings is the basis for clinical decisions". Then in 1996, the term was more formally defined by Sacket et al., who stated that EBM was "the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients."

The proponents have described EBM as a "paradigm shift" that will change medical practice in the years ahead. But there has been considerable debate about the value of EBM. The modern medicine, following philosophy of modern science such as the 'realism controlled by empiricism', has developed biomedical model. But the EBM wrapped with clinical epidemiology and statistics, represents response of empiricism to the rationalism (realism).

Since its introduction in the early 1990s, evidence-based medicine (EBM) has been extremely influential, simultaneously generating considerable controversy. This controversy may be puzzling to some. After all, if medicine is to be based on something, evidence would seem to be a good choice. It is certainly better than "vehemence-based medicine" or "eminence-based medicine", as some of the more sarcastic defenders of EBM point out [Isaacs and Fitzgerald, 1999, p.1618]. In fact, the ubiquitous EBM movement relies heavily on this initial impression. EBM has gained at least some of its popularity from the intuitively obvious nature of its name as well as its apparently innocent and widely accepted goals. A closer look at the details of the movement makes the controversy more understandable.

As the EBM ideology is rapidly and often uncritically adopted in medical settings around the world, as well as integrated into new domains ("evidence-based practice" is now common in nursing, physiotherapy, occupational therapy, dentistry, veterinary science, health management, library science, public policy, social work and economics, just to name a few areas), reasonable concerns about the assumptions, implications and epistemological limitations of such an approach are mounting. Yet behind this wide acceptance is the curious fact that there are several different routes by which the principles of EBM are being introduced into medical practice, and the most commonly cited definition-that EBM is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients"-addresses only one of them.

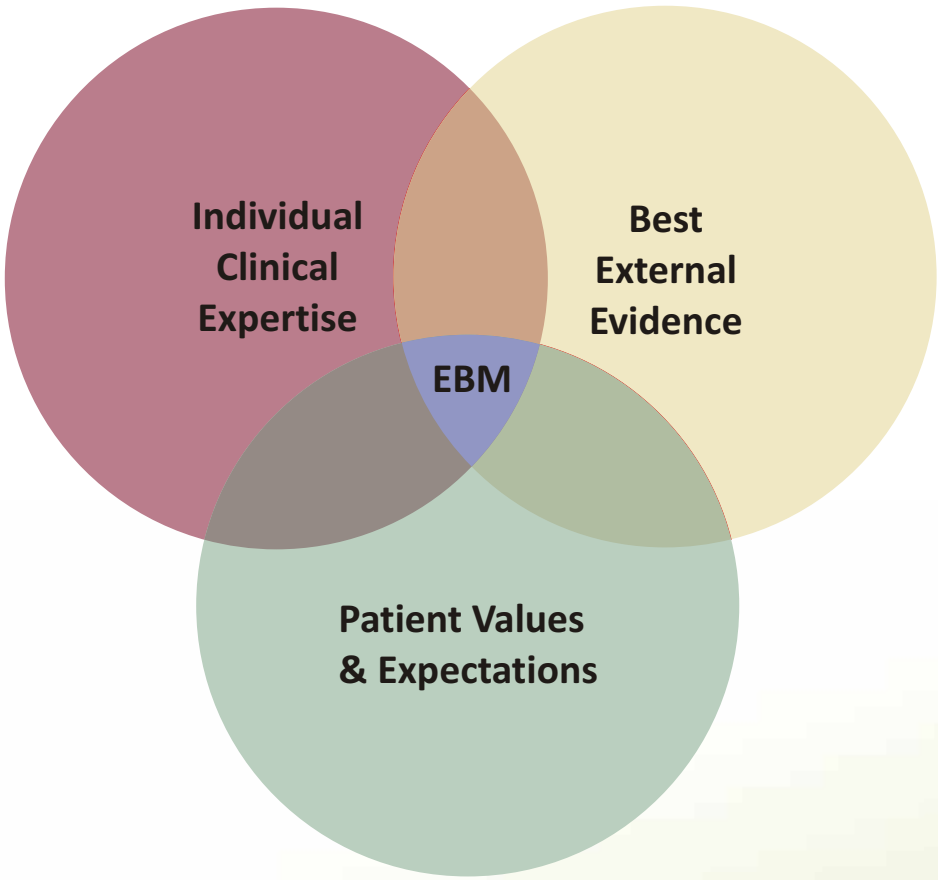
Evidence-based medicine (EBM) has been touted as an effective series of mechanisms not only for improving health care quality, but also for reducing medical errors precipitated in part by clinical practice variation. John Wennberg and colleagues have compiled a body of work documenting the great variability in care that patients receive often by virtue of where they live. The variation inevitably translates into sometimes sizable disparities in the quality and safety of care that patients ultimately receive. Ideally, EBM strikes at the heart of the poor health outcome end of the spectrum by reducing some of this variation.



The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

- Individual clinical expertise means - the proficiency and judgment that the individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care.

The Evidence-based Medicine Triad (Source: Florida State University, College of Medicine)





- The best available external clinical evidence means - clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatment and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer.

Good clinicians, use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannized by external evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best external evidence, practice risks becoming rapidly out of date, to the detriment of patients.

Moreover, the practice of evidence-based medicine is a process of life-long, self-directed learning in which caring for patients creates the need for clinically important information about diagnosis, prognosis, therapy, and other clinical and health care issues as under:

- Conversion of the information needs into answerable questions
- Tracking down, with maximum efficiency, the best evidence with which to answer them (whether from the clinical examination, the diagnostic laboratory from research evidence, or other sources)
- Critically appraise that evidence for its validity (closeness to the truth) and usefulness (clincial applicability)
- Integrate this appraisal with clinical expertise and apply it in practice; and
- Evaluate performance

It is obvious from the above that evidence is the key factor in determination of change of course, wherever required, in the context of patient care.

The power of evidence

Evidence-based medicine is the application of scientific research within a healthcare setting. It improves the quality and consistency of health care, by putting the most current knowledge about the effects of different diagnostic and treatment options into practice, alongside healthcare professionals' experience and expert opinion. This allows clinicians and patients to make informed diagnosis and treatment decisions within a rational and transparent framework.

History and Evolution



The History

Traces of evidence-based medicine's origin can be found in ancient Greece. Although testing medical interventions for efficacy has existed since the time of Avicenna's The Canon of Medicine in the 11th century, it was only in the 20th century that this effort evolved to impact almost all fields of health care and policy. Ancient era EBM consists of ancient historical or anecdotal accounts of what may be loosely termed EBM. This was followed by the development of the renaissance era of EBM, which began roughly during the seventeenth century. During this era personal journals were kept and textbooks began to become more prominent.

This was followed by the 1900s, during an era we term the transitional era of EBM (1900-1970s). Knowledge during this era could be shared more easily in textbooks and eventually peer-reviewed journals. Finally, during the 1970s we enter the modern era of EBM. Evidence-based medicine first became established in the global medical community during the early 1990s. Professor Archie Cochrane, a Scottish epidemiologist, through his book Effectiveness and Efficiency: Random Reflections on Health Services (1972) and subsequent advocacy, caused increasing acceptance of the concepts behind evidence-based practice. Cochrane's work was honoured through the naming of centres of evidence-based medical research -Cochrane Centres - and an international organization, the Cochrane Collaboration.

However, the roots of EBM, as understood and practiced today, extend back at least as far as the Paris clinical school and the work of Pierre Louis in Paris in the early 19th century. During the late 1970s, a group of clinical epidemiologists at McMaster University including Dr. David Sackett prepared a series of articles to assist clinicians interpreting clinical research. These articles, introducing the term "critical appraisal", appeared in the Canadian Medical Association Journal beginning in 1981 and were immensely popular. The explicit methodologies used to determine "best evidence" was largely established by the McMaster University research group led by David Sackett and Gordon Guyatt. Guyatt later coined the term "evidence-based" in 1990. The term "evidence-based medicine" first appeared in the medical literature in 1992 in a paper by Guyatt et al. Relevant journals include the British Medical Journal's Clinical Evidence, the Journal of Evidence-Based Healthcare and Evidence Based Health Policy. All of these were co-founded by Anna Donald, an Australian pioneer in the discipline.

Introduction of this term "Evidence-based medicine" by Dr. Gordon Guyatt catalyzed a paradigm shift in medical practice that stresses the role of rigorous, systematic evidence from clinical research in conjunction with patients' values and preferences in clinical decision-making. A group



of academic physicians subsequently formed the first international Evidence-based Medicine Working Group and published an article expanding on the concept of Evidence-based medicine.

The Evidence-based Medicine Working Group next decided to build on the popular series in the Canadian Medical Association Journal by creating a more practical approach to applying the medical literature to clinical practice. Championed by Dr. Drummond Rennie, an editor of the Journal of the American Medical Association, the result was the Users' Guides. The guides originally consisted of 25 topics, covered in a series of 32 articles, published in JAMA between 1993 and 2000, describing approaches to different types of medical questions and the study designs that may answer them. More recently, Dr. Guyatt and Dr. Rennie have edited the articles and compiled them to form a book, titled "Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice".

Technology has had a large role in the advancement of EBM. Computers and database software have allowed compilation of large amounts of data. The Index Medicus has become a medical dinosaur of the past that students of today likely do not recognize. The Internet has also allowed incredible access to masses of data and information. However, we must be careful with an overabundance of "unfiltered" data. As history, has clearly shown us, evidence and data do not immediately translate into evidence based practice.

The Evolution

It is important to begin with a review of the environment from which the phrase "evidence based" arose; the environment created the need, determined the principles, and shaped the evolution of EBM. Till about half a decade back, medical decisions were taken to be doing very well on their own, or so people thought. The complacency was based on a fundamental assumption that through the rigours of medical education, followed by continuing education, journals, individual experiences, and exposure to colleagues, each physician always thought the right thoughts and did the right things. The idea was that when a physician faced a patient, by some fundamentally human process called the "art of medicine" or "clinical judgement," the physician would synthesize all of the important information about the patient, relevant research, and experiences with previous patients to determine the best course of action. "Medical decision making", as a field worthy of study, did not exist. Analytical methods and mathematical models were limited to research projects. Guidelines were merely a way for experts to pass occasional pieces of advice to non-experts. Coverage and medical necessity were defined tautologically; if the majority of physicians were doing it, it was medically necessary and should be covered. Diseases did not require any management beyond what physicians were already providing, and performance was taken for granted.

Beginning in the early 1970s, however, following major flaws began to appear in this fundamental assumption.



- One was a growing body of research showing that key aspects of the assumption were simply wrong. In 1973 John Wennberg and his colleagues began to document wide variations in practice patterns. The implications for the fundamental assumption were undeniable. When different physicians are recommending different things for essentially the same patients, it is impossible to claim that they are all doing the right thing. In the 1980s a group at RAND began publishing studies showing that large proportions of procedures being performed by physicians were considered inappropriate even by the standards of their own experts. These empirical observations were given a disconcerting explanation in a third set of papers that described the complexity of medical decisions, errors in medical reasoning, and wide ranges of uncertainty. It is not possible for anyone, even physicians, to accurately process in their heads all of the information needed for a complex medical decision. Decisions could not be based solely on the art of medicine or clinical judgement; some other anchor had to be found.
- A second flaw in the fundamental assumption was the gap between clinical research and what was actually happening in clinical practice. One problem was the lack of good evidence for many important practices. An estimate that only 15 percent of medical practices were based on solid clinical trials became famous. Another problem was that many practices taken for granted by physicians were actually found to be ineffective when subjected to clinical trials. Archie Cochrane, among others, argued persuasively for much more attention to Randomized Controlled Trials (RCTs).
- A third problem was that even when RCTs were done, it could take years for physicians to actually change their practices to incorporate the new information. The effect of all of this was to identify research evidence as the obvious new anchor for medical decisions.
- An additional factor was a deeper appreciation of the role played by guidelines and other types of clinical policies in influencing individual physician-patient decisions. This line of reasoning began with the fact that most medical decisions are far too complicated for the human mind, and then observed that textbooks and articles were filled with thousands of statements saying, essentially, "If you see this, then do that." It became clear that in fact the great majority of medical decisions were not reasoned from scratch every time a physician faced a patient, but rather were based on relatively simple "if...then" statements. At the very least, these statements served as the initial reference points for decisions, with the physician's task being simplified to tailoring an "if...then" statement up or down to fit an atypical patient. These informal guidelines were playing an essential role in medicine by simplifying decisions to a



point manageable by busy physicians. However, when they were tracked back to their origins, it became clear that they were simply the beliefs of the authors, or at best a consensus of experts. In none of the cases was there an explicit rationale tied to evidence. Taken together, these findings highlighted the importance of changing the methods by which the "if...then" statements were created, and they identified a natural and powerful mechanism by which evidence could be transmitted to physicians and incorporated in their decisions. If the "if...then" statements could be based on evidence, then any decisions based on those statements would be based on evidence.

During the same period as this work, a large number of new methods for improving medical decisions and policies were being developed. They included decision trees, utility theory, Bayes theorem for analyzing diagnostic tests, mathematical models, cost-effectiveness analysis, technology assessment, clinical epidemiology, outcomes management, and meta-analysis. These and other tools had two effects. The most obvious is that they began to provide the means by which evidence and related factors could be brought to bear on medical decisions. A more subtle but still powerful effect is that they highlighted the gaps between traditional decision making and more formal methods, and they strengthened the argument for bringing more evidence into decisions.

A final factor looming over everything was the cost of health care, which was increasing at a rate at least twice the general rate of inflation. When this was coupled with the growing awareness of the questionable quality of traditional decision making, the need for corrective action became acute.

Current Status

Is EBM a paradigm shift? To answer this question, it is required to specify the alternative with which EBM is being compared. The alternative to EBM is the basic science approach: studying the patho-physiological mechanism of the body. But EBM is so clearly intertwined with and complementary to the basic science that it would make little sense to see EBM as a paradigm shift away from basic science. In a sense, evidence-based medicine shows only methodological contribution aimed at improving the gathering and sorting of the best information published by biomedical scientists and clinical epidemiologists for use in clinical practice. Although EBM and the traditional medicine embody different approaches, this does not mean that they are competitors. In fact, the two approach need each; neither can stand alone for the development of clinical practice. This has been brought out in a very interesting manner in one of the early papers – ***"Evidence based medicine: Socratic dissent"*** by Professor David Grahme-Smith, Professor of Clinical Pharmacology, Department of Clinical Pathology, Radcliffe Infirmary, Oxford, published in British Medical Journal (BMJ 1995;310;1126-7) below:

"Evidence based medicine: Socratic dissent" by Professor David Grahme-Smith

SOCRATES: Tell me, Enthusiasticus (Meta-analyticus), they say you are espousing a new form of medical practice. Is that so?

ENTHUSIASTICUS: Indeed Socrates, and very effective it is.

SOCRATES: Does it have a name or description?

ENTHUSIASTICUS: Yes, we have called it evidence based medicine.

SOCRATES: How very interesting, albeit unaesthetic. But I do find the title that you have given this new form of medical practice rather alarming. I thought that all doctors were trained in the scientific tradition, one tenet of which is to examine the evidence on which their practice is based. How then does this new evidence based medicine differ from traditional medicine?

ENTHUSIASTICUS: Well, Socrates, one problem is that most doctors have a very narrow perspective, limiting themselves to their own experience and that of a relatively few colleagues with whom they exchange views. This sometimes leads them to make erroneous conclusions.

SOCRATES: Do you imply that in their narrowness they fail to search for evidence which might cause them to reach a different conclusion or allow them to come to a more balanced decision?

ENTHUSIASTICUS: Precisely, Socrates, you have hit it in one.

SOCRATES: How do you, Enthusiasticus, manage to gain access to this evidence which more ordinary doctors find inaccessible? Is it hidden away?

ENTHUSIASTICUS: Sometimes it is. We have sophisticated methods, using information technology, for searching out and recording information about the efficacy of treatments and case management from all over the world. Also scientists and doctors do not always publish the results of their studies, particularly if they have been negative. I and my colleagues have ways of unearthing such results, which can on occasion change views about the efficacy of a treatment.

SOCRATES: What is the cause of this reluctance to publish negative results? Is it because the science is poor?

ENTHUSIASTICUS: No, the science is often quite good, but journals and authors are not so interested in negative conclusions; things are much more interesting if they turn out positive.

SOCRATES: So, Enthusiasticus, sentiment still holds sway in medicine.

ENTHUSIASTICUS: What do you mean?

SOCRATES: I have often wondered about the application of the null hypothesis to studies planned to find out if a new treatment works.





ENTHUSIASTICUS: How so?

SOCRATES: Is it not the purpose of the null hypothesis to assume that the new treatment is no better than the old treatment or even no treatment at all? This is then the beginning of the application of statistical theory to the practical problem.

ENTHUSIASTICUS: I had no idea you were so well versed in statistical theory.

SOCRATES: I am not. The null hypothesis is commonsense, albeit a bit topsy turvy. Statistical theory is something else. My point is that I have never met a doctor who practises medicine in full accordance with the null hypothesis, nor, and this is more pertinent, one who applies it completely dispassionately to the investigation of the efficacy of treatments. All the doctors I know hope very much that their new treatments will work, whether it be in individual patients or in groups of patients in a clinical trial. Is it really possible to theorise on the question of proof of efficacy by one set of rules but approach the practical aspects of clinical testing of treatments by another?

ENTHUSIASTICUS: Well, that is the exact purpose of the double blind, randomised clinical trial: to remove from clinical studies the bias produced by just these motives you describe.

SOCRATES: So is this evidence based medicine going to fundamentally change the way doctors test their treatments?

ENTHUSIASTICUS: Not essentially, but it will help doctors take a wider view of the results of clinical trials and practice and avoid the tendency of doctors to rely too much on their own limited experience, which may be flawed because of its numerical inadequacy and biased recollections. We have developed statistical methods and reasoning to enable us to take a dispassionate overview of the results of given medical practice.

SOCRATES: This seems admirable to me. I cannot understand why doctors might choose to practise by a method based on inadequate personal impressions rather than the more objective and comprehensive method you describe.

ENTHUSIASTICUS: Perhaps it is because personal experience in medical practice has such a strong influence on a doctor's future actions.

SOCRATES: Is this an expression of the conflict between the science and the art of medicine?

ENTHUSIASTICUS: Perhaps.

SOCRATES: Does it apply equally to the matter of diagnosis as much as treatment?

ENTHUSIASTICUS: Why do you ask?

SOCRATES: Because my physician friends are always emphasising to me how important experience and pattern recognition are in the making of a good diagnostician. Do you agree with that?

ENTHUSIASTICUS: To a great extent I do, though there are areas of diagnosis which can be improved by the application of the methodology I have described in respect of treatment assessment.

SOCRATES: Is this difference between the impact of personal experience on the diagnostic art, but its misleading influence in the appraisal of practice outcome, emphasised during the education of young doctors?

ENTHUSIASTICUS: I think not.

SOCRATES: What do doctors learn first and what aspects of medicine are most emphasised during medical education?

ENTHUSIASTICUS: Undoubtedly all those matters which aid the accurate diagnosis of disease.

SOCRATES: A strong part of which is this experiential aspect?

ENTHUSIASTICUS: Indeed.

SOCRATES: Perhaps then, the young pick up the experiential art of diagnosis from their teachers and mistakenly hope to apply the same approach to treatment, which as you have explained would lead to bad habits.

ENTHUSIASTICUS: I shall have to think about that.

SOCRATES: Tell me, do you yourself apply the fruits of your labours?

ENTHUSIASTICUS: Unfortunately not. I am so busy applying this new methodology to the appraisal of medical practice that I no longer have time to see patients myself.

SOCRATES: I sympathise. I spend so much time in critical philosophy of an abstract nature that practical application of it has become impossible. I must warn you though that your colleagues, like mine, might not always appreciate your good intentions.

Even now my detractors are planning to put me on trial for subversive thought. You must see that if you yourself are not constantly versed in the infinite variables of patient presentation and response to treatment, and dealing with them every day, you will be prey to criticism from those who do.

ENTHUSIASTICUS: I have recently become aware of that and I am unsure how to deal with it. The matter is particularly acute because the cause of evidence based medicine has been taken up by those who now manage our medical practice.





SOCRATES: What is their interest?

ENTHUSIASTICUS: They are particularly anxious to get value for money and wish to be sure that doctors' actions are effective and worth paying for.

SOCRATES: So there must be a large number of doctors practising cost ineffective medicine for such a grand scheme to be enacted.

ENTHUSIASTICUS: I guess so.

SOCRATES: Those are words I would never have expected to hear pass your lips. That aside, however, are you sure that the motives of the managers are as pure and intellectual as you imagine?

ENTHUSIASTICUS: How could it be otherwise?

SOCRATES: Is it not a manager's job to ensure that health care is delivered in the most cost effective way possible? And do not all politicians exhort purchasers to get the best bargain?

ENTHUSIASTICUS: Indeed.

SOCRATES: Then what do they perceive as the main barrier to their purpose?

ENTHUSIASTICUS: Lack of evidence as to what is really effective.

SOCRATES: It would be nice, Enthusiasticus my gullible friend, if it were really so, but I doubt it. The main barrier they perceive is an anarchic medical profession spending their money in a profligate and unnecessary manner. They see your beloved evidence based medicine as a means to shackle the doctors and bend them to their will. That, I am certain, is why they are so enthusiastic about it. Beware, Enthusiasticus, that you are not used as a dupe in a political game of health economics. Remember, hemlock may be down the line.

"Are scientific methods used to determine which drugs and procedures are best for treating diseases? The answers may surprise one and all. Modern healthcare is undergoing a long-overdue and dramatic evolution."

Evidence-based medicine, an attempt to use standards from scientifically-collected evidence to improve medical practices by assessing risks and benefits of treatments and / or the lack of treatments, therefore becomes basis for activities that guide various facets of healthcare delivery. The term can be taken to cover a wide variety of recommendations and guidelines, as well as the basis for decisions regarding pharmaceutical reimbursement. Evidence-based medicine influences in a variety of its guises, illustrating the pervasive nature of evidence-based decisions in healthcare and pharmaceutical environments.



In recent years, evidence-based medicine has emerged as one of the most pertinent topics of discussion within the field of medicine, involving - on the one hand - patients and - on the other - a variety of healthcare policy-makers, practitioners and regulators. In the United Kingdom, evidence-based practice has been implemented in a variety of fields, including adult medicine, child health, surgery, pathology, pharmacotherapy, nursing, general practice, and dentistry, as well as in the field of pharmaceutical reimbursement. Evidence-based medicine has also been practiced by the governments of Canada and Australia for some time, while Germany, Japan and the United States have lately begun to utilize evidence-based medicine for both private and public reimbursement.

The use and applicability of evidence-based medicine in various therapeutic areas in six major global medical and pharmaceutical markets is an explicit evidence of acceptance and popularity of EBM. First three of these (namely Australia, Canada and the United Kingdom) are seen as pioneers in the utilization of evidence-based medicine, while the other three (namely Germany, Japan and the United States) have more recently become interested in wider applicability of such practices. The future prospects for evidence-based medicine are dependent upon the list of factors driving wider application of such practices. A number of constraints come in to the way of practice of use of evidence-based medicine, which includes a range of practical considerations, such as a lack of time and information overload, as well as more culture-specific resistance to compliance with imposed guidelines.

In April 2008, Bryan R. Luce, Rebecca Singer Cohen, Craig Hunter, Lael Cragin, and Jeanene Johnson prepared a report for National Pharmaceutical Council - The Current Evidence-Based Medicine Landscape. This reference guide was developed to identify and document all relevant organizations, activities, proposals and key individuals associated with the evidence movement in the U.S. This includes anything of note under the rubric of evidence-based medicine (EBM), comparative effectiveness, health (or medical) technology assessment (HTA), outcomes research, effectiveness research, etc. This identification process was accomplished via literature review, Web exploration, word of mouth and, generally, via existing professional contacts. The report also lists and outlines the efforts made in USA and globally for promoting evidence based medicine, as under:

- Independent Evidence-Based Medicine Initiatives
  - Institute of Medicine (IOM) Roundtable on Evidence-Based Medicine
  - The James Lind Alliance
  - The Cochrane Collaboration
  - ECRI Institute
  - Hayes, Inc. - The Health Technology Assessment Company



- Academy Health Support of Comparative Effectiveness Research
- Academy of Managed Care Pharmacy's Format for Formulary Submissions

❖ Consumer-focussed Initiatives

- Consumer Reports Best Buy Drugs
- American Association of Retired Persons (AARP) ResearchRx
- Alliance for Better Medicine
- National Working Group on Evidence-Based Healthcare
- US Cochrane Collaboration's Consumers United for Evidence-based Healthcare (CUE)

❖ Measuring Value in Health Care: Standardizing Metrics

- National Committee for Quality Assurance (NCQA)
- The Health Plan Employer Data and Information Set (HEDIS)
- Pharmacy Quality Alliance

❖ International

- U.K.'s National Institute for Health and Clinical Excellence (NICE)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Australia's Pharmaceutical Benefits Advisory Committee (PBAC)
- Germany's Institute for Quality and Efficiency in Health Care (IQWiG)
- The International Network of Agencies for Health Technology Assessment (INAHTA)
- Health Technology Assessment International (HTAi)
- The OECD Health Care Quality Indicators Project

Martin J. Tobin, Professor of Medicine and Director, Division of Pulmonary and Critical Care Medicine, Loyola University of Chicago Stritch College of Medicine in his paper **"Counterpoint: Evidence-Based Medicine Lacks a Sound Scientific Base"** in Chest, questions the scientific basis of practice of EBM citing five reasons.

These reasons and along with the supporting arguments are:

❖ Grading - A fundamental premise on which EBM is founded is the ability to grade the quality of research studies. EBM grading is based on neither empirical investigation nor rationalist theory. Therefore, EBM grading is flawed.

❖ Requirements for Reliable Research - Out of the eight examples of requirements for reliable

research, if one is absent, the research are no longer reliable. A grading system premised on the belief that randomization can cancel every other methodological error is contrary to the most elementary understanding of science.



- Guidelines - Clinicians have been lured into accepting EBM-based, clinical-practice guidelines in the belief they place medicine on a more scientific basis. A recommendation based on "precision of the estimated intervention effects … the narrower the confidence interval … the greater the ability to make strong recommendations." Confidence interval is largely determined by sample size. This type of "precision" has nothing to do with "scientific precision," such as ensuring internal validity. The graders' emphasis on confidence interval confuses statistics with science. The small confidence interval is a trap for the non-thinker: statistical precision is misinterpreted as "scientific exactness."
- Harm - It is thought that EBM does no harm. Not so. Clinical medicine requires thoughtful reflection about each individual patient, whereas graded guidelines encourage reflexive action. Reflex response to level 1 evidence without reflection about underlying patho-physiology and individual context, can kill.
- EBM Proves That EBM Is Unsound - The fundamental assumption of EBM is that physicians who practice EBM provide superior care. But EBM founders have never undertaken an RCT of the effect of EBM on patient outcome. So EBM does not satisfy its own basic requirements, which it demands of everyone else.
  - RCT of EBM is unnecessary because "outcomes researchers consistently document that patients who receive proven efficacious therapies have better outcomes than those who do not." With this non sequitur, EBM advocates claim credit for all research done under the heading of clinical research.
  - But EBM is not a product of research. It is an activity for ranking the products of research. EBM advocates conflate the two. They need to disentangle them.
  - EBM founders say an RCT of EBM would be "impossible to do," another non sequitur. Not true. All that is needed is to undertake a matched comparison of institutions where physicians practice EBM versus institutions where physicians do not believe in the tenets of EBM.
  - EBM founders say clinical decisions should be based on empirical evidence, and that expert opinion is untrustworthy. But EBM founders have never subjected EBM to empirical testing. Instead, EBM (and grading) is solely based on expert opinion. Thus, if EBMs tenets are true, then EBM should not be trusted, quod erat demonstrandum.



What Is the Alternative?

A major attraction of EBM is that it offers a means of coping with uncertainty. Given a physician's responsibility-to make life-and-death decisions about another human-the wish for certainty is understandable, as is the wish of wanting to act like the wisest physician when faced with a problematic patient. But these wishes are contrary to the reality of medicine.

A wise physician makes decisions on a background of scientific theory (universal principles). Clinical practice, however, involves primarily phronesis (practical wisdom): a customized decision for one particular patient. A wise clinician bases each customized decision on a sound knowledge of science. Many physicians have been seduced by marketing of the "EBM-grading construct," believing it makes clinical practice more scientific. These physicians, however, seem unaware that the EBM-grading construct is detached from science and poses a serious risk to patient safety.

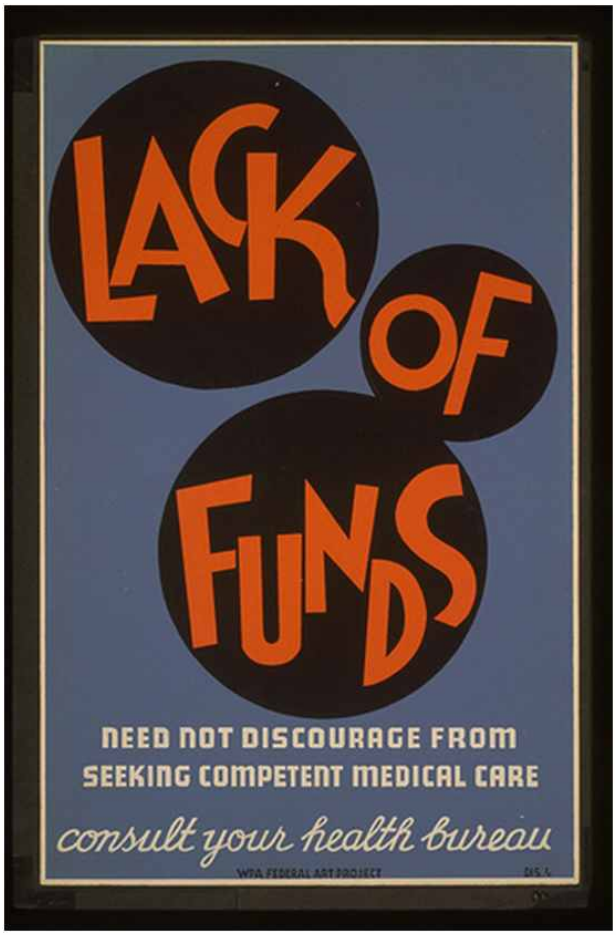
Despite the dichotomous commentaries, view points, counterpoints and dogma of the medical profession to resist the change, evidence based medicine has influenced and is used as a synonym with evidence based practice (EBP) and evidence based healthcare (EBHC). The rationale and basis of explanation of concept of EBM has been applied in practice in various clinical specialities - medicine, respiratory medicine, critical care, dermatology, psychiatry, surgery etc; nursing; physiotherapy; medical ethics; medical education; management and policy formulation. Actually, the wider acceptance of EBM has shifted the focus more and more on the power of evidence and systematic research to continue enhancing the value of practice of EBM. The advent of information technology, communication and convergence tools have made it possible to be able to download the latest best evidence at the point of care along with tools for comparative analysis of various diagnostic, therapeutic and prognostic measures to choose from.

Relevance and Current Status of Evidence Based Medicine in Developing Countries



The Official Weblog of 'The Basilic Insula' in My Dominant Hemisphere describes the scenario for the developing countries as "Evidence Based Medicine in Developing Countries" wherein the large caption given below captures the predicament and suggested way forward for such countries.

Have developing countries actually been active in EBM (Evidence Based Medicine)? Enquiring from



any medic in any of the medical establishments in a country like India, it clearly evident that developing countries for the most part have become consumers of research that cannot be applied to them. These medics are not only being taught but are also being tested on guidelines developed by a plethora of alien organizations such as NICE (National Institute of Clinical Excellence-UK), SIGNS (Scottish Intercollegiate Guidelines Network-UK), Cochrane (UK), ACP (American College of Physicians-US), CDC (Centers for Disease Control-US), NIH (National Institutes of Health-US) and many others in their curricula. Most of these guidelines have been produced for patient populations that are entirely foreign to them.



The only international body with a modicum of relevance to their lives and that of their patients and one which cuts across all geographical and cultural lines is the WHO (World Health Organization). Some might argue that such an enormous and overarching agency as the WHO is intrinsically incapable of producing practice guidelines that might be sufficiently context-centric to be of any use. The WHO sure has a lot of responsibility on its hands and it really is difficult to produce guidelines that apply to all geo-cultural contexts. Indeed, the WHO has produced only a handful of guidelines to date.

Needless to mention, there is definitely a need to promote, practice and evaluate the practice of evidence based medicine in the developing countries. The same is re-enforced by various studies and research papers that have been published in recent times as cited in

- Value Health, 2009, Nov-Dec; 12 Suppl 3:S 18-25 - Evidence-based decision on medical technologies in Asia Pacific: experiences from India, Malaysia, Philippines and Pakistan by Thatte U, Hussain S, de Rosas-Valera M, Malik MA from Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai, India - the paper discusses the national programmes implemented in India, Pakistan, Malaysia, and Philippines to generate and apply evidence in making informed policy decisions on the approval, pricing, reimbursement and financing of medicines, diagnostics and medical devices. It concludes, saying that one of the priority areas that the different regulatory agencies would benfit from is human resource development ot facilitate the process of evidence based assessment of health technologies.
- Knowledge-based changes to health systems: the Thai experience in policy development in the Bulletin World Health Organization 2004 Oct;82(10): 750-6 by Tangcharoensathien V, Wibulpholprasert S, Nityaramphong S from International Health Policy Program Thailand - the paper describes how research in to health systems and health policy contributed to the move towards universal coverage through an evidence-based political decision making; and
- A review article in Biology and Medicine, Vol 2 (1): 1-5, 2010 titled - Evidence-based medicine - a new approach to teach medicine: a basic review for beginners by Sanchaya Selvaraj, Yeshwant Kumar NNT, Elakiya M, Prarthana Saraswathi C, Balaji D, Nagamani P, Surapaneni Krishna Mohan from Saveetha Medica College & Hospital, Saveetha University, Chennai, India - the paper focused on introduction of EBM to beginners.

The concept of EBM, as has been spreading far and wide, as a result of experiences in developed nations, has definitely percolated in the developing nations. The above cited papers re-enforce the said thoughts. St. John's Medical College Bangalore, India conducted a course "How to Practise Evidence-Based Medicine", Introductory Course from 23 - 25 November 2009. The course was organized jointly by The Centre for Evidence-based Child Health in London, UK and PGIMER,

Chandigarh, India. This was a joint initiative between the Indian Academy of Paediatrics and The Royal College of Paediatricians and Child Health UK, funded by the David Baum International Fund. Thus, what emerges from the foregone is the fact that it is required to answer - **"Why EBM in developing countries is necessary and possible?"** The following reasons and their impact on overall healthcare delivery - quantum and quality are found to be important:



- Financial resources being limited, the provision of effective health care is even more vital as in most of the developing countries people pay out of pocket for healthcare services. Provision of ineffective care leads to patients' deprivation and poverty. As a corollary, increasing evidence based clinical care in middle and low income countries can have substantive health gains.
- Expert opinion and personal experience are not sufficient to produce high-quality care for people in the less-developed world. There is a dire need to address the existing barriers rather than to advocate second-best options. Clinicians such countries have learnt to tolerate a great deal of uncertainty in their daily practice. They prefer to rely on poorly generalizable evidence. This needs to change!
- The Cochrane Collaboration is actively encouraging participation of reviewers from poorer countries. There are Cochrane Centres in Brazil, China and South Africa. The number of systematic reviews relevant to developing countries is increasing. The WHO and World Bank are making investments in EBM and evidence-based policy.

All of the above point towards the fact that the practice of EBM has got significant relevance to not only the developed countries wherein questions on effectiveness and efficacy of health services have been raised but also the developing countries where affordability and expenditure on health is woefully inadequate. The initiatives started by world bodies and institutions of excellence in developing nations are just a drop in ocean. Actually, it is required to facilitate and support more such initiatives such that locally relevant best evidences are documented and made available at the point of care.

Special Relevance of EBM to Asian Countries

The southern region of Asia has one of the poorest health indicators in the world. It houses the largest number of people with micronutrient deficiencies and diabetes; carries 40% of the world's tuberculosis burden, has high burden of cardiovascular diseases and one of the worst indicators for reproductive health in the world. Health systems across the region are characterized by limited resources, poor infrastructure, no national health insurance schemes and large burden of diseases. Despite these sobering issues that affect over 1.5 billion people, South Asia spends far more in arms and weapons than on health and education. In most parts of SAARC countries there is continuous conflict and upheaval. The long standing feuds between India and Pakistan, war in Afghanistan,



Maoist uprising in Nepal and smoldering civil war in Sri Lanka have had huge impacts on the lives of people in the region.

In general, the financial commitment to health care in South Asia is low compared to other parts of the world, Maldives and Sri Lanka being exceptions. The people of South Asia have more similarities than differences and people in this region need to work together towards maintaining peace and channelizing the resources to improve the health of the region. Per capita health care access in almost all of South Asia is less than half to what a citizen of China has access. Health spending as a share of GDP in South Asia is 4.4% as compared to developed countries where it ranges from 7.9%-9%. Unfortunately, in South Asia large number of people lives in poverty. According to World Bank, poverty is defined as living on less than $1.25 per day (at 2005 prices, adjusted to account for the most recent differences in purchasing power across countries) as minimum expenditure to meet the basic living needs. The percentage of poor in Bangladesh is 50.1%, Nepal 35.0%, India is 34.2%, Pakistan 31%, and Sri Lanka 22.7%. Because of financial constraints people are forced to choose cheap medicine and often no treatment at all.

In South Asia, there is no centralized system for health care. Many qualified doctors work in private institutions or clinics where care is close to western standards but majority of population has to depend on sub optimal primitive or even no medical care. In many rural areas, there is no specialist treatment, except for service from occasional medical officer. People have to travel long distances by cattle drawn cart or public transport, so that even the sub optimal treatment is also delayed. In the present scenario, practicing rational medicine based on sound scientific evidence is of utmost importance especially in the developing countries where resources are scarce and pubic healthcare coverage is inadequate or nonexistent. In many developing countries physicians struggle to provide care on less than £7 per person each year. These countries cannot waste resources on a single treatment that is not effective. Equally important is the time and money that patients spend on their health care. EBM can be a solution for providing optimal health care with limited resources.

Current Status of EBM in South Asia

South Asian countries are characterized by diversity not only in their culture but also in medical practice, ranging from large super speciality hospitals with doctors trained in latest interventions to quacks who treat patient merely on experience or tradition. Unfortunately, these large and well equipped hospitals are able to cater to only small privileged fraction of the population and majority of patients are being treated by insufficiently trained or untrained practitioners. Using a Pubmed search for term "Evidence based medicine", a total of 29,650 articles were found but only 102 articles were from South Asian countries. They were from India (75), Pakistan (16), Bangladesh (7),

Nepal (4). None were from Sri Lanka, Afghanistan, Bhutan, or Maldives. This reflects scarcity of awareness about EBM in this region.



A survey was conducted in India on the use of computer based electronic literature search as a surrogate marker for EBM. Out of 194 respondents, 103 were from Post Graduate Institute with better infrastructure and training and 91 from Medical College. Computer based literature search was done at least once a month by 89%, motivation being presentation in a lecture or seminar (90%), research (65%) and patient management (60.3%). The benefit of search was acknowledged in learning and teaching (80%), research (65%) and patient care (64.4%). Formal training in computer based literature search was received by 41% responders. Another survey was conducted among medical practitioners in Dhaka, Bangladesh to investigate the views, attitudes, and practice concerning EBM. Out of 300 approached, 226 (75%) responded. Of the respondents, 118 (52%) owned a computer, 95 (42%) had never used email communication, and 111 (49%) had never accessed the internet. The most popular source of information about clinical evidence was textbooks (152; 73%) and review articles (134; 64%). Electronic resources, such as professional guidelines (24; 11%), the Cochrane Library (14; 6.8%), and hospital intranet protocols (11; 5.3%) were less popular sources of information. These data suggest that EBM has already been introduced in some regions of South Asia whereas at other places it is uncommonly practiced.



Barriers to Evidence Based Medicine in South Asia and Potential Solutions to Overcome Barriers

The South Asian countries share common health challenges with very poor health indicators in the world. This is primarily because of political apathy, poverty and staggering health infrastructure. In resource-limited countries, an evidence-based approach can rationalize the treatment and be cost effective by reducing clinical practices that have no proven benefit. However, at present, evidence based medicine is virtually non-existent because of its inherent complexity, misperceptions, absence in medical curriculum, rigidity and unawareness of practicing clinicians and misinformation.

What are the barriers to practice of evidence-based medicine in developing countries, especially Asian Countries?

The key factors that form the core of resistance and / or failure to promote practice of EBM include:

- Resource limitation - unreliable drug supply, inadequate staffing, poor laboratory support, high patient volume.
- Lack of pharmaceutical regulation and economic incentives - the influence of pharmaceutical companies in developing countries is even more profound. There may be overuse of diagnostic tests and ineffective or harmful treatments. Dispensing doctors and ownership of equipment or hospital facilities are commonly coupled with influence by drug companies and foreign "experts." Medical questions are commonly so complex as to make the application of best practice obtained from clinical trials a rarity rather than the norm
- Information available to health professionals in less-developed countries is outdated and incomplete - there is insufficient evidence-based content that is cost-comparative and directly applicable to resource-poor settings
- Lack of investment in biomedical research in less-developed countries, in the dissemination and organization of research findings, and in adapting source information into end-user products that are easily accessible, readable, reliable, and relevant - research done in less-developed countries is under-represented in the major databases (MEDLINE and EMBASE) poor access to computers and electronic searches; capacity for individual practitioners to undertake systematic reviews is greatly reduced costs and benefits of introducing EBM into health-care systems of such countries application of available evidence to the population at hand may be difficult. Patients from less-developed countries may be different from those included in published studies and so results may not be generalizable a particular patient population.

The practice of EBM comprises 5 steps (Table 1), each being a complex and multi-step process which are difficult to resolve even by the most vehement protagonists of this "new paradigm".



Table 1: Steps involved in the practice of EBM and problems encountered at each step

Step	Steps	Problems
Step 1	Converting the need for information into an answerable questions	• Do not know where to start • Trouble in articulating a question • More questions than time
Step 2	Tracking down the best evidence with which to answer the question	• Where to find the best evidence? • Accessibility not only to computer but also database and computer knowledge • No relevant evidence available to every clinical situation encountered
Step 3	Critically appraising the evidence for its validity (closeness to truth), impact (size of effect), and applicability (usefulness in the clinical practice)	• Avalanche of published articles • Articles are inconsistent, inconclusive
Step 4	Integrating the critical appraisal with the clinical expertise and with the patient's unique biology, values and circumstances	• Universal occurrence of biological variation hampers attempts to extrapolate evidence, to individual patients
Step 5	Evaluating the effectiveness and efficiency in executing steps 1-4 and seeking ways to improve the next time	• No regular feed back or data collection system at most of the health centers

Constraints of most health care settings in South Asia allow the full cycle of this approach to a limited number of problems only. Most problems have to be solved at the intuitive end of the cognitive spectrum. Unquestionably EBM requires the acquisition and development of new skills (literature searching and critical appraisal) which are considered formidable by most practitioners. Since the introduction of EBM, it has evoked both positive and negative reactions from academicians and clinicians. Like any other science, EBM has its own limitations. Commonly cited limitations and misperceptions of evidence-based medicine are:



Limitations

- Universal to the practice of medicine
  - Shortage of coherent, consistent scientific evidence -Difficulties in applying evidence to the individual patients
  - Barriers to the practice of high quality medicine
- Unique to the practice of EBM
  - The need to develop new skills
  - Limited time and resources
  - Paucity of evidence that EBM "works"
- Misperceptions
  - Denigrates clinical expertise
  - Ignores patients values and preferences
  - Promotes a cookbook approach to medicine
  - Cost cutting tool or an ivory tower concept
  - Limited to clinical research
  - Leads to therapeutic nihilism in the absence of evidence from randomized trials

Although in recent years, there has been wide-spread inclusion of EBM into medicine training programs, it is still poorly integrated into the clinical teaching of trainees. In medical schools, the venues for teaching are journal club, ward rounds, grand round, out-patient department, lectures and seminars. Journal club is an established means of medical education which increases familiarity with the latest medical literature, improves reading habits, promotes critical review of author's conclusions and promotes skill in clinical epidemiology. A study evaluating the pattern, motivation and facilities for choosing journal club topics by residents in two medical institutions (Post Graduate Institute and Medical College) in India revealed that topics were selected when considered good by residents or faculty rather than being case driven. Despite better infrastructure and training, quality of journal club did not improve at the Post Graduate Institute. Patient's problems were not addressed through the journal club discussion.

Other difficulties encountered in teaching EBM include the following

- EBM requires skills that are not traditionally part of medical training
- Cookbook medicine provides quick and easy answers, whereas critical appraisal involves additional time and effort

- Lack of high quality evidence for many clinical situations encountered
- Faculty members are skeptic about concepts of EBM, hence unenthusiastic about modifying their teaching and practice in accordance with its suggestions
- Limited resources including poor infra-structure, insufficient computer terminals, restricted budget of most of the medical libraries so that access to authentic journals is often not possible



Muir Gray captured the second essence of EBM when he proposed that it is about doing the right things right for the right people at the right time. Each country differs in patient empowerment, information system, socio-economic status and individual disease prevalence. In a very real sense, all health care is local, including evidence-based health care. However; most of the evidence based guidelines are based on data from Western countries which might not be applicable in our setting. This is primarily because of paucity of good quality research in this region. Despite an enormous disease burden in South Asia, research is often viewed as expenditure rather than an investment. It should be emphasized that solutions to challenges faced by South Asia's health system need to be refined and tested within the region. For example, standard guidelines for antenatal care in many countries recommend up to 14 visits per pregnancy, although a trial in developing countries revealed that fewer visits had no adverse effects on pregnancy outcome. Physicians who have been in practice for a long period may become rigid and not up-to-date with current approaches to patient care. Even disseminating reviews and recommendations may fail to motivate such clinicians to abandon ineffective practices.

While India does have bodies like the ICMR (Indian Council of Medical Research) making some bit of progress, but honestly that is not enough. The arguments linking this appalling void to decreased government funding are no doubt valid. Budgets allocated to healthcare are grossly below the minimum '5% of Gross Domestic Product' standard set by the WHO and quite surprisingly have kept declining. Amidst this budget-strapping, public healthcare establishments are overwhelmed by the demand for clinicians whose focus is on the manual delivery of healthcare services rather than research. In the 'medical automobile', these clinicians are just too busy being passengers in their back seats to care about driving. This unbalanced emphasis has had a profound impact on the very nature of our medical society. Its effects are visible right from the very beginning, as medical students enroll into institutes. Students are not even remotely exposed to the tenets underlying academic medicine and there is absolutely no mentorship mechanism in place at any level, all the way up to post-graduation and beyond. Departmental research is obscenely underfunded and students lack motivation to get involved in the absence of a nurturing environment. To make matters worse, owing to the abject lack of any academic medical component whatsoever in their curricula, students find it near impossible to take time out to engage in any form of academic



activity at all. Even if they do manage it, their efforts often receive no curricular credit. Post-graduate students take the thesis requirement casually and often resort to a trial-and-error hodgepodge approach in the absence of necessary guidance. The situation finally spirals down to a vicious cycle where the blind lead the blind. End result: Institutes in chaos whose sole purpose is to produce en masse, semi-literate manual clinicians of low-innovative-potential who can't even search or appraise medical literature, let alone use it properly.

In South Asia, many other traditional forms of medicine like "Ayurveda", "Unani", "Homeopathic", "Siddha" are being practiced, particularly in rural India, where 70% of the Indian population lives. Many of these systems are based on experience, observations, empiricism, and intuition; and have been passed down generations both through word of mouth and treatises. The risk benefit profiles of such alternative treatment have rarely been subjected to randomized controlled trials. It is a paradox that despite not being adequately studied, 80% of the Indian population depends on these therapies which are often not evidence-based.

Why this is the need of the hour. It not only paralyzes the current education system but also the fragile economy. How does it degrade the economy? Well, without national guidelines there can't be a just audit system in healthcare establishments. Without audits, resources are squandered and quality of care declines. When quality declines, the disease burden in a population rises and that in turn leads to an economic vicious cycle as national productivity declines.

What are the potential solutions to overcome these barriers?

Although the current picture is gloomy, the resilience of the South Asian people and their ability to find solutions to difficult problems raises some hope. The fundamental obstacle remains the willingness of governments and policy makers to give due importance to implementation and education of EBM. Effective education is the most powerful tool for overcoming barriers to EBM. Early introduction of EBM principles as a short course even to pre-clinical medical students is feasible and practical. Introducing a short course on literature search and critical appraisal at the beginning of residency can provide the basic skills in EBM. Even a two weeks EBM rotation in residency program reported change in patient care among the residents as well as the faculty. Attending physicians must be enthusiastic, effective role models for the practice of EBM, even in high pressure clinical settings such as ICUs. Literature search and critical appraisal skills should be integrated into clinical training. Conventional teaching and presentations should be replaced by case based journal clubs and seminars. Students can be provided incentives for learning EBM via scholarships or EBM based questions in the final assessment. Fellowships or diploma courses in EBM can be initiated at selected centers to increase awareness and application.

In India though some institutes are using computers for storing patient information, patient care and hospital management, actual computerization of health care is still in its infancy. The following are the recommendations regarding resources to provide an environment encouraging the use of EBM in the delivery of quality and cost-efficient patient care



- The system must be accessible round the clock whenever a clinical question is formulated
- The system must have many user stations available at strategic points within the hospital, if possible in the wards themselves
- The required reference must be available immediately if dealing with a question on patient care, and within forty-eight hours in all other circumstances
- Journal selection must be maximized and additional hospital funding should be provided to expand library resources
- If increasing the number of available journals is not feasible, then an effort must be made to ensure that interlibrary loans are very efficient
- The role of librarian as a team member in the EBM training process should be enhanced.

The computer should become as indispensable as the stethoscope and prescription pad for practicing clinicians. Even established and senior clinicians should be taught the basic skills of EBM via educational seminars. It should be emphasized that this is not to curtail their freedom but to add justification to their decisions. Educational seminars and conferences should be conducted and updated information should be conveyed in these meetings. To overcome the barrier of limited time among clinicians, systematic reviews (as by Cochrane collaboration) and critically appraised topics should be made available in "ready to use format". Finally, several questions can be generated for each patient and can slow clinicians by trying to address all of them. The question most important to the patient's well being should be given priority.

Legislation should be modified to constrain malpractice in the form of unnecessary prescriptions and investigations. In India, the inclusion of medical services under the Consumer Protection Act has increased the accountability of doctors and made patients more aware of their rights as consumers. Local health guidelines should be formulated by authorities in respective fields which are feasible and applicable to people in their countries. High quality research should be conducted which can provide databases for these guidelines. Various other measures like telemedicine facility should be made available at peripheral centers. This is an effective though under utilized mode of scientific communication. Practitioners at the peripheral centers where facility for literature search is not available can communicate with faculty in higher institutes who are well informed and can help provide solutions to their clinical problems. A website can be launched which can answer



clinical queries of practitioners in consultation with various experts who are well aware with the methodology of EBM and guide the clinicians naïve to EBM in making quick decisions and delivering optimal health care. Journals publishing relevant reviews, updated guidelines and meta-analysis should be made free so that their accessibility is enhanced. If possible, latest guidelines can be disseminated via local scientific journals.

Government funding on healthcare ought to increase. Clearly, providing concessions and subsidies to private establishments hasn't and most definitely isn't going to produce results. Private establishments only care about making money - from the public or the government, and that's all. Unless incentives are provided to them to engage in academic medicine or research, they aren't going to bear the torch. In a developing country like India, the sheer demand for manual services forms a competing interest for these entities. Even if public funding is lacking, it might be possible to develop meaningful research. Some of the most groundbreaking research comes out of very small undertakings. It didn't take a million dollars to realize the benefits of surgical asepsis.

Hierarchical translational research bodies ought to be created - private or public or a possible mix of the two. Guidelines need to be produced and taught at medical schools. Students should no longer need to put up with the arbitrary whims of their superiors in the face of inapplicable guidelines in their textbooks.

Audit systems should be enforced at all healthcare establishments. Students and practitioners should be taught how to audit their departments or practices.

An academic component should be incorporated into the medical curriculum at all career grades - whether optional or otherwise. Mentorship mechanisms should be brought into place and could be incentive driven. Sources of funding and grants should be made more accessible and greater in number.

To sum up the fundamental steps to bridge these barriers, as outlined above, include effective teaching of skills of evidence-based medicine during residency, motivating the established clinicians, constraining malpractice, formulating locally applicable guidelines, increasing the accessibility to internet, availing telemedicine facility at peripheral centers and disseminating appropriate information via free journals or even newspapers. In association with strong political commitment, these steps can lay the foundation stone of evidence based practice in SAARC region. Despite this gloomy picture, the overall economic growth of South Asian countries in the past decade and practice of evidence-based medicine in some tertiary care centers are a ray of hope.

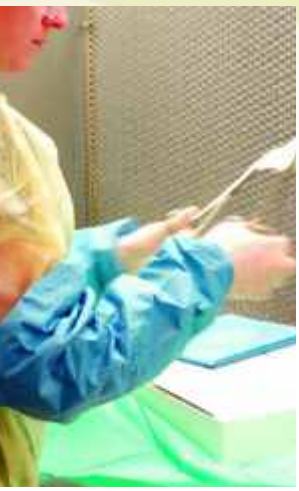
India and similar developing countries desperately need indigenous agencies to construct and regulate guidelines that are appropriate to their peoples' resources and needs. It is extremely

common, for example, to see how guidelines by some agency are taken lightly solely because of resource constraints (transportation problems, lack of appropriate instruments, etc.). Actions that a clinician needs to make, given these constraints, need to be backed by evidence. The whole idea of EBM is that actions need to be based on the 'best available' collective body of scientific evidence pertaining to a problem - pathological, economic, whatever. Doesn't it make sense then, to look for 'evidence' backing a given course of action to our problems? Therefore evidence based practice (EBP) is like "data-driven decision making".



Future of EBM in South Asia

At present it is difficult to guess about the future of EBM in South Asia. The hope lies in the fact that steps are already being taken to encourage evidence informed practices and these need to be augmented. In a study on computer based literature search in 2 medical institutes in India (Post Graduate Institute and Medical College), 20% of Post Graduate Institute and 66% of Medical College respondents made their literature search at their residence. The inadequacy of infrastructure in Medical College did not seriously jeopardize literature search where 66% respondents did their search in cyber cafés (which need payment) and 65% at their residence. That the students are ready to spend time and money for literature search gives hope for better prospects of EBM in the country. We can try to draw lessons from models of evidence-based health care delivery provided by the institutes like Sanjay Gandhi Post Graduate Institute of Medical Sciences, a tertiary care center in Lucknow, India. In the Institute, there are free internet facilities in wards, out patient departments, laboratory, library and the resident's room. Websites such as MD consult, Science Direct, Proquest are subscribed in addition to large number of medical journals. Twenty-four hour's library service, brief curriculum of introduction to EBM at the beginning of every session and motivated teachers further assist in incorporating the basic skills of EBM among residents. With increasing emphasis in EBM and recent socioeconomic growth of South Asian countries, there is hope of better medical care practice in the future.



Physician's Attitude towards Evidence Based Medicine Practice (EBMP)

The critical importance of physicians' proactive participation and commitment to practice EBM need not be over emphasized. It is essential for effective and appropriate care delivery. Therefore, without the involvement of the physicians the practice of EBM and therefore the impact thereof cannot be passed on to the community. The dilemma - whether practice of medicine is science or art will continue to question the best of minds. However, one can ill afford to ignore the fact that decision making requires data and information, evidence about success and / or failure of similar decision in comparable settings, possibility of applicability of the experience to the present context, analytical ability and ultimately the conviction to make clinical decision that is in the interest of the patient. If one constructs the overall process flow for the clinical decision making it is imperative that uniformity and consistency becomes the core values for effective and efficacious decisions. Therefore, a matrix defining the logical steps - encompassing to include or exclude becomes the basis of key step for decision making, thereby laying the foundation for evidence-based practice. Irrespective of the dilemma of physicians to adopt or disagree with the practice of EBM, both the groups have acknowledged that clinical decision making has definitely been improved when reference to available evidences is made.

The extracts from various studies across the globe in the box refer to the varying responses of the physician community towards practice of EBM. These responses have varied from non-acceptance to middle path wherein it has been accepted even by those who oppose EBM that reference to accurate information at the point of care has definitely improved the clinical decision making and the impact of

Evidence Based-Medicine (EBM), Evidence Based Medical Practice (EBMP), Evidence Based Teaching, Evidence Based Management….

Extracts from Various Studies across the World

The healthcare management literature states that physicians often coordinate their activities within and between organizations through social networks. Previous studies have also documented the relationship between professional networks and physicians' attitudes toward evidence-based medicine (EBM). The present study sought associations between physicians' self-reported attitudes toward EBM and the formation of inter-physician collaborative network ties.

Communities of practice within healthcare organizations are likely to contain separate clusters of

physicians whose members are highly similar. Organizational interventions are needed to foster heterophily whenever multidisciplinary cooperation is required to provide effective health care.

…Physicians' propensity to collaborate and their attitude towards EBM: A cross-sectional study, Daniele Mascia, Americo Cicchetti, Maria Pia Fantini, Gianfranco Damiani and Walter Ricciardi

The likelihood that physicians will incorporate EBM into their practice cannot be predicted by any demographic or practice-related factors. Even those physicians who are most enthusiastic about EBM rely more on traditional information sources than EBM-related sources. The most important barriers to increased use of EBM by practicing clinicians appear to be lack of knowledge and familiarity with the basic skills, rather than skepticism about the concept.

…Evidence-Based Medicine and the Practicing Clinician, Finlay A McAlister, Ian Graham, Gerald W Karr, and Andreas Laupacis

The present study demonstrates that the majority of trainee physicians at a Tehran University hospital lack adequate knowledge about basic concepts of EBM. Furthermore, most of them continue to use traditional sources of knowledge rather than evidence-based sources. On the positive side, there was an overall positive attitude towards EBM and the majority had a positive tendency to take part in EBM training courses.

…Knowledge and attitudes of trainee physicians regarding evidence-based medicine: a questionnaire survey in Tehran, Iran, Ahmadi-Abhari S, Soltani A, Hosseinpanah F

Jordanian family physicians showed eagerness to learn and implement EBM in their daily practices. Nevertheless, they need more guidance and training to ensure the correct application of EBM ideals.

…Evidence-based medicine among Jordanian family physicians: Awareness, attitude, and knowledge, Farihan Barghouti, Lana Halaseh, Tania Said, Abdel Halim Mousa, and Adel Dabdoub

EBM has become feasible for practicing clinicians due to: new strategies for appraising studies; availability of systematic reviews (summaries) of current best evidence; and information technology (computers with Internet access). In a resource-limited country such as Pakistan, an evidence-based approach can be cost-effective by reducing clinical practices that have no proven benefit. Commonly perceived obstacles to EBM include limited access to computers, the Internet and online resources. Reliable resources of EBM are available (such as The Cochrane Database of Systematic Reviews http://www.cochrane.org) although many of these require paid subscriptions. Another difficulty is the issue of applicability of data from other countries to patients in our setting with different socio-economic factors. Other barriers to EBM in developing countries include: inexperience in small-group learning, limited time to attend workshops, and the lack of role models for practicing EBM. We have also tried to address the common fallacies related to EBM in the hope of greater use of these skills by busy clinicians as well as academic researchers.

… Paving the way for evidence-based medicine in Pakistan, Zaidi Z, Hashim J, Iqbal M, Quadri KM





…the systematic acquisition of unbiased evidence is essential to support daily surgical practice, hence the need for EBS is not a passing creed - it is a lasting need.

…Evidence-based surgery, D. T. Ubbink and D. A. Legemate

EBM is a growing worldwide movement in health care that aims to bring the best evidence from medical research to the bedside, clinic and community. EBM appeared early in 1990 and since then it has developed and expanded worldwide. It has met a considerable success over the past three decades in promoting critical scientific and practical awareness of the status of different after research claims to therapeutic knowledge. This subject of EBM is only theoretically known to only some of our physicians. We assessed physician's attitude towards EBM in a cross-sectional study conducted in the district of Lahore, Pakistan; from March 2005 to August 2006, by a self-administered questionnaire (proforma), which included questions on whether the physicians were in favour of EBM, and at what level EBM should be taught. A fairly reasonable response (63.6%) was received from the physicians and among these, most had a fair idea about EBM. They believed that EBM, if practiced, will improve patient care (68.8%), can reduce health care cost (59.1%) and will update the knowledge of the physicians (92.7%). A large majority (91%) believed that EBM and its usefulness should be taught only at postgraduate level.

…Physicians' Perception of Evidence Based Medicine: A Survey In Lahore, Pakistan -S. N Ibne Rasa, M. S Bhatti, A. H Nagi And I. A Naveed

It has been more than a decade since evidence-based medical practice (EBMP) became a top cuirriculum in medicine. Developing countries, however, have problems practicing EBM since it needs skills, time, and resources. Libraries and librarians can play a vital role in providing physicians with evidence-based information. This user study was directed at exploring physician's attitude towards EBMP, their awareness and pratical knowledge in finding and evaluating evidence / information, and the implication of these findings for health science library services.

The study revealed that physicians have positive attitudes towards EBMP. They also agree that EBMP is obligatory on the part of physicians - professionally, ethically, and legally. They indicated a high usage rate of print and electronic resources, which suggests that health science libraries should be equipped to support physicians in EBMP.

This study concludes that efficient librarian information support services should be provided to physician in order to practice evidence-based medicine.

…Physicians' Attitude Toewards Evidence-Based Medical Practice and Health =Sciences Library Services, Vahideh Zarea Gavgani and Vangari Vishwa Mohan, Osmania University, Hyderabad, India

the decision in favouring the outcome for the patient. Needless to mention, universal and ubiquitous adoption of evidence-based practice requires a mindset change not only for the physicians but also for all the stakeholders - patients & community, associated health services

professionals, health managers, and policy makers. The drivers for such change, besides good clinical outcomes are economic benefits and therefore newer studies and research need to focus on highlighting cost effectiveness, cost efficiencies and overall reduction of cost of delivery of services keeping the quality of health services at acceptable standards.



The above challenges are difficult to overcome but definitely not insurmountable. And above all, it would have to be physicians, who have taken the lead, but will have to step up the tempo to pass on the benefit to all. The biggest challenge as well as opportunity lies in teaching the future generations of medical and healthcare professionals along with other associated professionals the advantages of evidence-based medicine. The journey in this regard has already commenced and the information technology coupled with the communication technology has facilitated and supported one of the key requirements - availability of best external evidence at the point of care. While the debate and differing viewpoints amongst the proponents of practice of EBM and those who oppose it are not going to end soon yet it is evident that it is time that physicians from both groups agree to reconcile their views for the benefit of the most important and key stakeholder - the patient.

Need & Time for Reconciliation of Clinical Judgement and Evidence Based Medicine

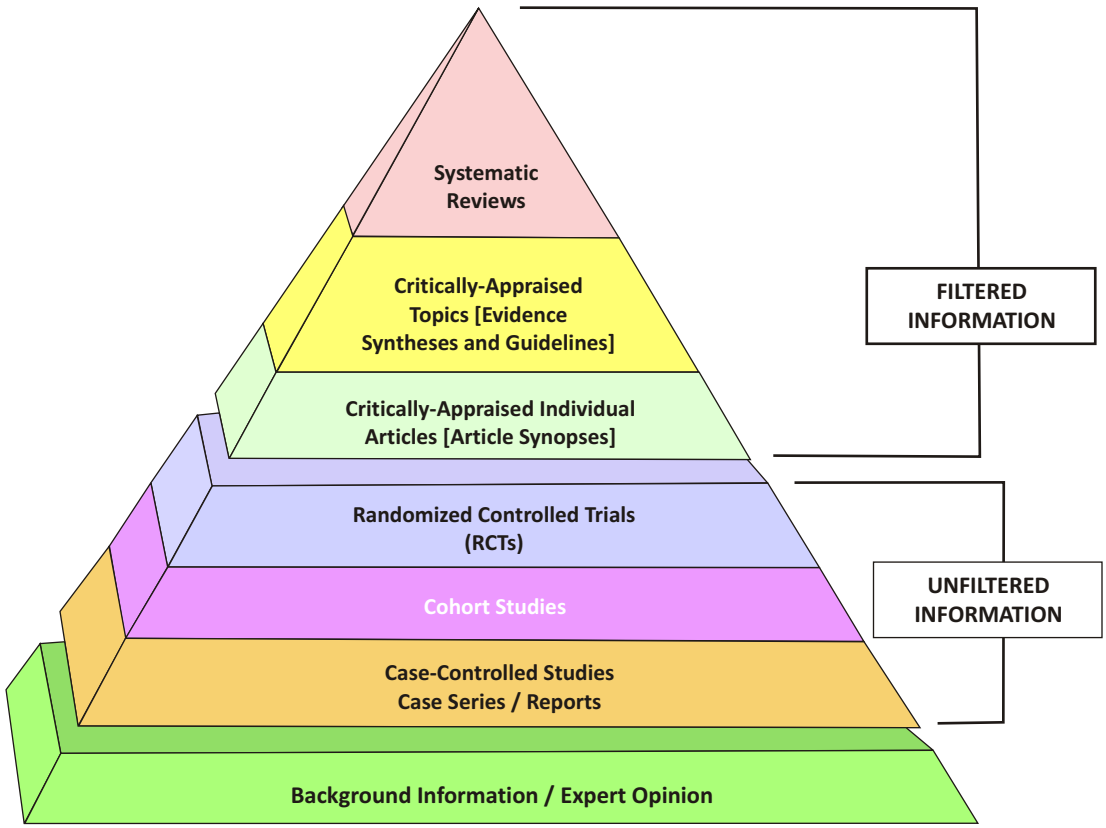
The need and time for reconciliation of clinical judgement (including for and encompassing - experience-based medicine or experiential medicine, narrative medicine, clinical decision making and art of medicine etc….) is probably most opportune moment at this point in time. With information and data available at a click of button; access to network or connect with peers and / or expert possible as a result of breaking of barriers of geography, professional arrogance and socio-cultural practices; and changing consumer behavior it is inevitable that two groups need to reconcile and bridge this imaginary divide.

Studies, surveys and researches carried out to validate the hypotheses and recommendations of working groups created from time to time in various specialities and / or studies carried out by different disciplines as randomized controlled trials, critical appraisals of topics and individual articles, systematic reviews including grading of quality of evidence and strength of recommendations, as depicted in figure below, have all pointed towards a growing acceptance of proposed principles of practice of evidence-based medicine. The initiatives of individual specialities - surgery, dermatology, psychiatry, cardiology, respiratory medicine, critical care, nursing, physiotherapy, medical education - both at under graduate and post graduate level, management teaching, and residency trainings etc. have all contributed towards adding to the



repertoire of evidence in favor of practice of EBM. The key elements that are essential towards practice of EBM are:

- Information and Data: The pyramid below divides the information and pool in to two distinct sub-groups - Filtered and Unfiltered Information on the established base of background information and / or expert opinion. On the top of the pyramid lies the systematic reviews which forms the basis for formulating the evidence.



- Evidence:
  - US Preventive Services Task Force - Systems to stratify evidence by quality have been developed, such as this one by the U.S. Preventive Services Task Force for ranking evidence about the effectiveness of treatments or screening:
    - Level I: Evidence obtained from at least one properly designed randomized controlled trial.
    - Level II-1: Evidence obtained from well-designed controlled trials without randomization.

- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.



- National Health Service - The UK National Health Service uses a similar system with categories labeled A, B, C, and D. The above Levels are only appropriate for treatment or interventions; different types of research are required for assessing diagnostic accuracy or natural history and prognosis, and hence different "levels" are required. For example, the Oxford Centre for Evidence-based Medicine suggests levels of evidence (LOE) according to the study designs and critical appraisal of prevention, diagnosis, prognosis, therapy, and harm studies:
  - Level A: Consistent Randomised Controlled Clinical Trial, cohort study, all or none (see note below), clinical decision rule validated in different populations.
  - Level B: Consistent Retrospective Cohort, Exploratory Cohort, Ecological Study, Outcomes Research, case-control study; or extrapolations from level A studies.
  - Level C: Case-series study or extrapolations from level B studies.
  - Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles.

- Grading of Quality of Evidence -
  - Classes of Recommendations - In guidelines and other publications, recommendation for a clinical service is classified by the balance of risk versus benefit of the service and the level of evidence on which this information is based. The U.S. Preventive Services Task Force uses:
    - Level A: Good scientific evidence suggests that the benefits of the clinical service substantially outweigh the potential risks. Clinicians should discuss the service with eligible patients.
    - Level B: At least fair scientific evidence suggests that the benefits of the clinical service outweigh the potential risks. Clinicians should discuss the service with eligible patients.
    - Level C: At least fair scientific evidence suggests that there are benefits provided by the clinical service, but the balance between benefits and risks are too close for making general recommendations. Clinicians need not offer it unless there are individual considerations.



- Level D: At least fair scientific evidence suggests that the risks of the clinical service outweigh potential benefits. Clinicians should not routinely offer the service to asymptomatic patients.
- Level I: Scientific evidence is lacking, of poor quality, or conflicting, such that the risk versus benefit balance cannot be assessed. Clinicians should help patients understand the uncertainty surrounding the clinical service.

- GRADE Working Group - A newer system is by the GRADE Working Group and takes in account more dimensions than just the quality of medical evidence."Extrapolations" are where data is used in a situation which has potentially clinically important differences than the original study situation. Thus, the quality of evidence to support a clinical decision is a combination of the quality of research data and the clinical 'directness' of the data. Despite the differences between systems, the purposes are the same: to guide users of clinical research information about which studies are likely to be most valid. However, the individual studies still require careful critical appraisal.

❖ Clinical Judgement - The term **"clinical judgement"** creates an impression of an erstwhile unquestioned infinite wisdom with apparently no room for chance of a failure. Flamboyance bordering towards even professional arrogance comes to the mind. Perceptibly, traditionally clinical judgement seems to be more about the clinician (person) than about judgement (outcome following the process). However, for patients as well as clinicians, clinical judgement can be summarized as the sum total of the cognitive processes involved in clinical decision making. The key pre-requisites for arriving at clinical decision making are - appropriate application of knowledge and individual expertise to the problem at hand. Apparently, there is no conflict between the clinical judgement through the process of clinical decision making and basic tenets of EBM. The difference of opinion about the weightage allotted to different components of the cognitive processes of clinical decision making is probably the reason for an impression that clinical judgment and EBM are two different entities.

Evidence Based Medicine (EBM) - Sackett and colleagues describe EBM as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients,.....integrating individual clinical expertise with the best available external clinical evidence from systematic research". Contrary to popular belief, it is not about slavish adherence to external evidence or mindless extrapolation of trial results to the clinical setting. An essential component of the evidence-based decision making process is the ability of the clinician to comprehend the nature and strength of evidence and appropriately apply it to individual patients in his or her care. This ability to objectively appraise the available external evidence in the context

of individual patients is in fact what clinical judgment is all about. **Clinical judgment, is therefore, a key component of EBM.**



As some critics have pointed out, EBM is indeed "old hat" and has been around since the medical practice started. These clinicians applied the best evidence available to them, in the treatment of their patients. What has changed is the nature of "evidence" itself. Clinicians drew upon their personal experiences, which in some cases were extensive, for evidence to support their practice. In those times, individual physician experience was often the largest and by far the easiest source of the available evidence and therefore the approach. However, with the exponential growth in medical knowledge and technology, there is a large body of easily accessible, good quality evidence, which is incomparably larger than any individual clinician's experience. More importantly, the quality of evidence from these two sources is fundamentally different.

An individual's experience is inevitably influenced by his or her biases, perceptions and preconceptions. More specifically, behavioural psychologists have shown that as a general tendency, people rely on a limited set of heuristics to reduce the complex task of assessing probabilities and predicting values, to simpler judgemental operations. These heuristics, by nature, are unreliable and result in systematic, and sometimes, severe biases. For instance, when a clinician sets out to prescribe a treatment to a patient, based on his experience with the particular treatment, he is likely to be influenced by the results in a similar patient he had previously treated (the representativeness heuristic), and any (easily recalled) dramatic results with the treatment (the availability heuristic). To complicate matters further, because of increasingly effective therapies, the magnitude of benefit (or harm) with any newer treatment is likely to be moderate at best. It is impossible for any individual, however astute, to be able to discern a difference of this magnitude from random, temporally scattered experience. High quality external evidence is, therefore, required so that one does not miss the key factor for decision making. As a process, the five steps for practice of EBM are as under:

- Formulate a sensible, focused clinical question.
- Search the medical literature for evidence related to the focused, clinical question.
- Rate the quality of the available studies.
- Apply the evidence to a particular patient or clinical situation.
- Assess outcomes of decisions.

Numerous "limitations" of EBM have been cited in the literature. As discussed by Strauss & McAlister, much of this criticism arises out of misperceptions or misrepresentations of the basic principles of EBM. The most important issues which are at the heart of the conflict between EBM and its detractors are:



- Denigrates clinical judgment (and the clinician) - This is one of the biggest stumbling blocks in the widespread acceptance of EBM in countries like India, where the practice of medicine is still paternalistic and physician-centered. Unfortunately, some (not all) clinicians differ from EBM adherents in their understanding of what "clinical expertise" entails. While EBM requires that the clinician objectively appraise the strength of evidence and make a decision about its applicability in a given context, some clinicians continue to persist with subjective, "black-box" methods for decision-making ("I feel this patient will do better with treatment A than treatment B"). Such methods have contributed to and propagated the mystique and allure of the erstwhile notion of "clinical judgment". Such decisions are invariably biased and can affect the quality of care. All clinicians have a responsibility to make decision-making process explicit and open to critical appraisal. Viewing this as a curtailment of clinical freedom does justice neither to patient care nor to medical education.

- Does not apply to care of individual patients - This is the most pervasive misconception in the way of widespread acceptance of EBM. As argued by Strauss & McAlister, the universality of biologic variation makes the application of findings to individual patients problematic, whether these findings are from basic or applied research. Therefore this problem is not unique to EBM. Moreover, this issue cannot be resolved by clinical judgment either: short of performing an "n of 1" trial on all patients for all potential treatments (which is impractical), there is no way of definitely knowing the response of an individual patient. Till such time that personalized medicine, based on genomic and other biologic characteristics, becomes practical, EBM provides with the best tools to individualized patient care.

- Advocates a slavish, "cook-book" approach to treatment - EBM advocates the integration of the best external evidence, appraised by the discerning clinician, with patient values and preferences. But unfortunately, even practitioners of EBM have possibly valued the strength of evidence ahead of patient preferences. In an attempt to address this issue, the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group has developed a system, which separates the grading of the strength of recommendations from grading the quality of evidence. In this scheme, the strengths of recommendations are decided based on the balance between benefits and downsides, explicitly taking into account patient values. Ordinarily the quality of evidence would have to be high or moderate for a strong recommendation to be made, and low or very low quality of evidence would result in a weak recommendation. But the recommendation can be modulated to accommodate patient values, preferences and perhaps even social and economic considerations.

- Ignores patient's values and preferences - EBM does not, in any way, come in to the way of clinicians' prerogative, obviously on the basis of sound clinical judgement with regard to

applicability of the recommendation, in not tailoring the decision in light of the patient's values and preferences. It is here that the intuitive analysis and individual experience of the clinician helps in bringing in the evidence to modification to favour the patient.



It is, therefore, apparent that these are misconceptions rather than true limitations. The issue of blind adherence to algorithms is one false notion. It cannot be overemphasized that EBM does not advocate the indiscriminate application of evidence driven by blind adherence to guidelines and algorithms. The issue is highlighted aptly in the section Letters to the Editor in the Journal of American College of Cardiology (Volume No. 49, No. 9, 2007) - Evidence-Based Medicine and Clinical Judgment: An Imaginary Divide by Ganesan Karthikeyan from New Delhi, India (in the box) below:

Evidence-Based Medicine and Clinical Judgment: An Imaginary Divide

...Ganesan Karthikeyan

The study by Pereira et al. and the accompanying commentary by Ben-Yehuda once again bring to the fore some often-raised arguments against evidence-based medicine. Detractors of evidence-based medicine tend to imbue "clinical judgment" with an aura, which barely falls short of the divine, by attributing intangible powers to clinicians. This view of clinical judgment is more about the clinician than about judgment. In reality, individuals, clinicians, or otherwise, are swayed more by anecdotal experience; as a result, they are more prone to systematic errors while making judgments under situations of uncertainty. Evidence from clinical trials, if any, adds objectivity, reduces bias, and refines a clinician's ability to make decisions. In the study by Pereira et al., the participating clinicians were not in agreement with the random allocation in more than half the patients. As pointed out by the investigators, the different prevalence of 3-vessel disease and the complexity of lesions were primarily responsible for this situation. Stated simply, the clinicians were (justifiably) reluctant to send patients with complex lesions and 3-vessel disease for angioplasty, because they were aware of the data that these patients would not have the best results with angioplasty. Numbers permitting, subgroup analysis of the trial would probably bear out these clinicians' concerns. Therefore, what has been somewhat mystically termed "clinical judgment" is nothing but the correct interpretation of available data by discerning cardiologists. It is important for the scientific community to recognize that there is in fact no real disconnect between evidence-based medicine and an individual clinician's judgment. Gone are the days when a few towering experts drew on personal experience to make clinical decisions. Good clinical judgment in the present day has evolved into the clinician's ability to appropriately interpret and incorporate available evidence in the day-to-day management of patients. Of course, some clinicians will be better at this than others!



It is evident from the above discussion that the clinician has the central role to play in the practice of EBM. What the practice of EBM requires is - that the clinician is adequately equipped with the best available evidence in the field of his / her practice and remains objective in appraising the available evidence such that the same could be applied appropriately in clinical decision making. Clinicians need to and have started taking responsibility to stand scrutiny to their acts with regard to efficacy of treatment advised / procedure carried out on a patient relying more and more on the principles of practice of EBM. In the changing context, it is their utmost duty to ensure that uniformity and consistency of treatment modalities empowers the patients to participate suitably and proactively in their treatment. Therefore, as the principal agents of delivery of care, clinicians not only need to equip and educate themselves but also the beneficiaries of their services.

Way Forward



The critical importance of physicians' proactive participation and commitment to practice EBM need not be over emphasized. Without the involvement of the physicians the practice of EBM and therefore the impact thereof cannot be passed on to the most important stakeholder - the patient. Moreover, the key attributes for implementation of practice of EBM will form standardization of practice of medicine to bring in uniformity and consistency not only in the way the patients with similar presenting symptoms are treated and localization of the standard treatment guidelines besides creating the framework for dissemination and implementation of EBM.

Therefore, in order to catalyze and promote the practice of EBM a concerted effort is required to be sustained with the involvement of all the stakeholders as under:

- Framework for dissemination and implementation of evidence based medicine
- Standardization of Practice of Medicine
- Formulation of Standard Treatment Guidelines - A National Initiative

Framework for dissemination and implementation of evidence based medicine

Level 1: Awareness Raising

- Purpose - Increase awareness about effective interventions and the potential gains from using research based knowledge in policy and practice
- Activities - Produce and publish relevant systematic reviews in a variety of professional and consumer publications.
- Communicate potential relevance of systematic reviews to current practice, with examples through commentaries

Level 2: Targeting groups and individuals responsible for implementation

- Purpose - Identify target groups and individuals with specific roles in implementing research based knowledge in practice
- Activities - Identify target groups, such as health ministry policy makers, donor aid advisers, professional groups, managers with responsibility for clinical and public health policy
- Communicate results from systematic reviews and their implications for practice face to face and with short summaries
- Give examples of how others have used systematic reviews combined with audit to change practice for the better in their own hospital or practice.
- Make people aware of the evidence base for effective practice change



Level 3: Pilot and innovation projects

- Purpose - Support individuals in specific pilot projects to evaluate potential ways to implement change in practices that seem to run contrary to current available evidence.
- Activities - Identify collaborators engaged in or interested in developing pilot projects to implement research findings and where they perceive there is an opportunity to make care more evidence based
- Help them in to stimulate change (such as by audit and feedback or by means of opinion leaders) to practices for which there is reliable evidence from systematic reviews of effectiveness
- Ensure collaborators monitor change in policy and practice

Level 4: National or institutional policies for evidence based decisions

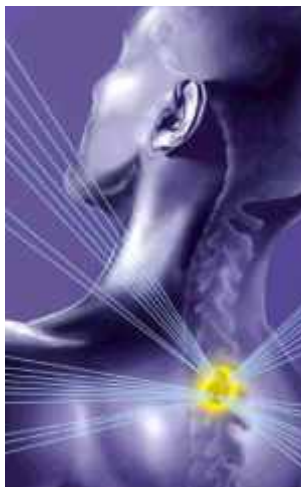
- Purpose - Encourage national governments, institutions, or donors to commit to evidence based approaches, with effective implementation and monitoring systems
- Activities - Work with government and donors in establishing or strengthening health technology assessment offices or similar bodies at national level
- Encourage national policies for evidence based guidelines, with management systems to ensure that guidelines are implemented and monitored
- Help institutions to train doctors, nurses, and other health staff to deliver training in evidence based approaches

Implementation of EBM requires the following steps:

- Formulate a sensible, focused clinical question - In the first step, clinicians decide explicitly what patient population they are studying, what tests, treatments, and alternatives are under consideration, and what outcomes are to be measured. The acronym PICO - Patient, Intervention, Comparison and Outcome is often used to remember these steps, and questions.

  The PICO acronym (patient/population; intervention; comparison; outcome) is used by health professionals and librarians in providing direction for step one of EBM. The PICO framework - diagram guides EBM as it combines elements of the clinical scenario in an orderly fashion. The goal, of course, is to build a focused, answerable clinical question:

  - P - patient, population of patients, problem
  - I - intervention (a therapy or test)
  - C - comparison (another therapy or placebo)
  - O - outcome



- Search the medical literature for evidence related to the focused, clinical question - The second step of EBM is searching the medical literature. Health librarians must therefore have an understanding of the methods, strengths, and weaknesses of search strategies/ tools as they strive to find the highest levels of evidence. In general, systematic reviews (not to be confused with general reviews) are considered the highest level of evidence, followed by randomized controlled trials (RCTs), then case-control studies, followed by expert opinions, and anecdotal evidence.
- Rate the quality of the available studies - The third step - rating the quality of the available studies - involves knowledge of research methodologies in order to make valid conclusions. For example (with RCTs): was a control group used? Was assignment to an experimental vs. control group truly random? Were patients, treatment providers, and outcome assessors blinded to assignments? What is the risk of a Type I or Type II error? What is the effect size? In systematic reviews (involving health librarians), was the literature review truly comprehensive? Was the assessment of study quality done with rigour, and was it subjectively graded? Can numerical assessments be statistically combined (a "meta-analysis") to increase statistical power? Answers to these questions often depends on the particular parameters decided in step one.
- Apply the evidence to a particular patient or clinical situation - The fourth step involves translating findings of controlled studies to the less-ideal and less-controlled situation of particular patients. What are the risks and benefits for this patient? What are his or her preferences? What are the costs, alternatives and availability of treatments? Even for a statistically significant finding is the effect size practically significant? Do practitioners have the skills or resources to deliver treatments or to monitor outcomes?
- Assess outcomes of decisions - The final step involves reassessment of the clinical question and outcomes where the whole process may begin again by returning to the patient.

All the above steps will lead to the need of standardization of practice of medicine such that the expected outcomes are efficacious, cost effective and meet the criteria of practice of EBM.

Standardization of Practice of Medicine

Standardization is a framework of agreements to which all relevant parties in an industry or organization must adhere to ensure that all processes associated with the creation of a good or performance of a service are performed within set guidelines. Standardization is also defined as best technical application consensual wisdom inclusive of processes for selection in making appropriate choices for ratification coupled with consistent decisions for maintaining obtained standards. This view includes the case of "spontaneous standardization processes", to produce de



facto standards. This is done to ensure the end product has consistent quality, and that any conclusions made are comparable with all other equivalent items in the same class. The goals of standardization can be to help with independence of single suppliers (commoditization), compatibility, interoperability, safety, repeatability, or quality. In **health services the term quality will automatically include safety.**

In social sciences, including economics, the idea of standardization is close to the solution for a coordination problem, a situation in which all parties can realize mutual gains, but only by making mutually consistent decisions. The existence of a published standard does not necessarily imply that it is useful or correct. Just because an item is stamped with a standard number does not, by itself, indicate that the item is fit for any particular use. The people who use the item or service or specify it have the responsibility to consider the available standards, specify the correct one, enforce compliance, and use the item correctly. Validation of suitability is necessary. By using standardization, groups can easily communicate through the set guidelines, in order to maintain focus.

In the context of social criticism and social sciences, standardization often means the process of establishing standards of various kinds and improving efficiency to handle people, their interactions, cases, and so forth. Examples include formalization of judicial procedure in court, and establishing uniform criteria for diagnosing mental disease. Standardization in this sense is often discussed along with (or synonymously to) such large-scale social changes as modernization, bureaucratization, homogenization, and centralization of society. In the context of business information exchanges, standardization refers to the process of developing data exchange standards for specific business processes using specific syntaxes. These standards are usually developed in voluntary consensus standards bodies.

Similarly, in the overall context of healthcare services standardization has two main components - uniformity and consistency in clinical decision making on one end and compliance or adherence to service delivery standards. Whereas the former is formulated, co-ordinated, and influenced by the respective professional bodies of various clinical disciplines the latter is the responsibility of accreditation bodies. The purpose of both the aspects is to ensure consistency and uniformity of delivery of healthcare services to ensure quality & safety and good clinical outcomes within the ambit of cost effectiveness keeping in mind the overall perspective of individual patients. Adoption and adaptation to the guidelines formulated by the respective professional body for clinical decision making and the accreditation body for quality of delivery of services leads to standardized practices that allows for an evaluation amongst the peer group as well as the beneficiaries.

In order to ensure uniformity and consistency in delivery of healthcare services, evidence-based medical practice entails following a standardized algorithm in the framework of - if not, then. This

leads to elimination of personal bias & prejudices, analysis of best available relevant evidence and accommodation of patient preferences, wherever inevitable coupled with analytical appraisal of probable outcomes in similar situations. Thus, standardization of medical practice is the key for practice of EBM. While standardization of care delivery parameters is far easier than standardization of guidelines for clinical practice in individual specialities yet it may be appreciated that the challenges are not insurmountable. The challenges faced in formulation of standard practices in clinical settings are as a result of varying experiences of clinicians in similar set of symptoms with the same intervention and / or treatment to the preferences & perspectives of the patients along with the issue related to resources (read affordability). However, these challenges have been overcome to a large extent by evaluation, documentation and sharing of results of various research conducted across the wide spectrum of specialities (also read disease entities), sub-group analysis in cases of ambiguity and / or difference in opinion about a particular intervention / treatment modality wherein risk-reward ratio of the same was debatable and willingness to adopt the principles and rationale of evidence-based medical practice including modifications to the existing guidelines.



Formulation of Standard Treatment Guidelines (STGSs) - A National Initiative

The last decade has witnessed the firming up of principles of evidence based medicine (EBM). When faced with its application in clinical practice, the clinicians in India and much of the developing world often face a dilemma - Is EBM feasible / applicable to our settings? Are the developed world standards of medicine applicable to our patients in our conditions? If not, then from where to have high-grade evidence for the practice of EBM?

- In India, the government currently spends less than 1% of GDP on health care. Consequently the state owned health resources are extremely scarce and well equipped tertiary health centers are too few, distant and overwhelmed by patient numbers. In the absence of wide based health insurance network more than 80% of the people (often with very limited and fixed budgets) pay for their own medical expenses. A similar scenario prevails across much of the developing world in Asia, Africa and Latin America.
- In order to appreciate the limitations of 'best external evidence' in such regions, there is a need to discern the specific clinical situations in the context of the backdrop of the dynamics of the healthcare eco-system.
- The most important aspect of EBM that is often ignored but is most applicable for patients in developing world therefore is that the available 'best external evidence' may not necessarily be the most relevant. To elucidate the argument further, the reservations regarding the applicability for Western patients, of an Indian randomized trial and due to differences in patient population, disease spectrum, co- morbidity and setting.



- While on the one hand much of the best external evidence generated in the developed countries is of limited utility, research into indigenous surgical problems in developing countries themselves is virtually non - existent. One of the reasons is that in a majority of these countries the resources or infrastructure to generate high - level evidence is not available. It is often difficult to get the research from developing countries published in high impact factor journals because of its 'relevance' (or the lack of it) to an average Western reader or it not being up to the current Western practices or standards. These result into publication of only a few papers every year in indexed journals (publication bias).
- There are other problems too that limit the utility of EBM in day to day clinical practice. Even as India emerges as an information technology superpower, paradoxically the availability and familiarity with the basic tools of EBM - computers and Internet amongst the medical fraternity remains woefully inadequate.
- The fact that standards of best medical practice in the Western clinical settings are for most of the part not applicable to the developing world is a key barrier for the clinicians in the developing world. This has been very eloquently summarized by none other than David Sackett himself as 'External clinical evidence can inform, but can never replace, individual clinical expertise, and it is this expertise that determines whether the external evidence applies to the individual patient at all'.
- While in the short term it is imperative that to practice EBM one will have to take recourse to the available evidences yet the importance of generating high-grade evidence based management algorithms that address the vital issues like local patient population, disease spectrum, clinical setting and resources cannot be overemphasized. Actually this is the only long-term solution.
- A multi-pronged strategy needs to be adopted to counter the general lack of evidence from the developing world. First is the collection of reliable data the models for which may be developed locally. Second and more importantly the clinicians particularly those at tertiary care centers need to be innovative and find indigenous and appropriate solutions to local problems.
- In conclusion, clinicians in the developing countries should modify the practice of EBM from 'best available evidence' to 'relevant available evidence' tailored to their patients and settings. It is incumbent upon the clinicians in the tertiary care centers in the developing countries to take a lead role and provide appropriate local solutions for local problems.
- While the context defined in the foregone paragraphs outlines the importance of development of locally relevant practice standards and guidelines yet it needs to be

appreciated that there are other additional factors that make it imperative to consider the same as an urgent inevitable consequence:



- Promulgation of Consumer Protection Act (CPA) to health services - In late eighties health services were brought under the ambit of CPA, thereby forcing the medical professionals and health services providers more accountable and become transparent in their conduct.
- Increasing awareness and demand among users about quality of health services - With increasing awareness, changing demographics - increasing disease burden of chronic non-communicable & life style diseases, shifting focus towards health & wellness and above all cost- effectiveness of the treatment.
- Increasing penetration of health insurance in the country - After opening up of insurance sector it has resulted in not only increasing affordability for the citizens but also increasing challenges for the health insurance companies in servicing their clients. The challenges being - high claim ratio, quality of care delivery and variations in cost of care across different cities and even various hospitals / health facilities in the same city.

In order to find solutions to overcome these challenges the health group and health insurance group of Federation of Indian Chambers of Commerce & Industry (FICCI) came together in 2009 to develop standard treatment guidelines (STGs) for about fifty most common ailments which formed the bulk of claims. A process of involving experts who formed core groups for each of these selected ailments to formulate treatment guidelines followed by peer review and review by steering committee formed for the purpose was followed to complete the task. However, STGS could be completed for twenty one disease entities due to paucity of resources. These STGs were then forwarded to Insurance Regulatory and Development Authority (IRDA) in 2010. The Chairman IRDA found these STGs as a prudent approach in meeting the twin challenges from the point of view of beneficiary - the quality of care and affordability thereby supporting the health insurance companies in bringing down the claim ratio and servicing their client. The Chairman, IRDA recommended the Ministry of Health & Family Welfare, Government of India to consider formulation of STGS as way forward, for ensuring quality of delivery of health services across the spectrum of the entire country.

Ministry of Health & Family Welfare, Government of India, recognizing the importance of standardization of treatment such that it supports decision making for the patients and their families on one end and bring consistency and uniformity in treatment on the other end initiated the task of formulation of Standard Treatment Guidelines (STGs) for most commonly encountered diseases that form the bulk of disease burden in twenty specialities. Experts from across the nation were invited to formulate these standard treatment guidelines (STGs) through a detailed process of



consultation, consensus building and peer review including from their individual professional bodies such that these guidelines serve as a template for standardization leading to rational and cost effective treatment for citizens of the country.

The exercise was initiated in 2010 at the behest of Ministry of Health & Family Welfare, Government of India for the following twenty specialities with an intent that the guidelines thus formulated will serve as the first step in this direction:

- Cardiac Sciences
  - Cardiology
  - Cardio-Thoracic & Vascular Surgery (CTVS)
- Neurology
- GI Diseases
  - Gastroenterology
  - Surgical Gastroenterology
- Renal Sciences
  - Nephrology
  - Urology
- Oncology
- Organ Transplant
- Endocrinology
- Interventional Radiology
- Medicine - Non-Respiratory Infectious Diseases
- Medicine - Non-Respiratory Infectious Diseases
- General Surgery & Day Care Surgeries
- Orthopaedics
- Obstetrics & Gynaecology
- Paediatrics
- Opthalmology
- ENT
- Critical Care
- Laboratory Medicine

It has been proposed to focus initially on ten to twenty disease entities in each of the chosen disciplines. The choice of these disease entities has been based on the fact that they form the bulk of clinical volume (80 to 90 %) in the respective speciality. This mandate will be later extended to other specialities which have not been covered at this stage. The guidelines, thus formulated, will undergo a periodic review from time to time, as suggested by the experts to keep them in sync with the requirements of the changing times.



It is envisaged that this process of formulation of STGs and implementation thereof will catalyze the practice of medicine leading to adoption of the concept of evidence based medicine (EBM). FICCI has collaborated with the Ministry of Health & Family Welfare, Government of India to facilitate, support and co-ordinate completion of the stated task for equipping the healthcare delivery eco-system for rational and cost effective treatment for all concerned. One of the key ingredients of the whole process has been inclusion of a wide representation of experts from across the entire country and from different categories of healthcare facilities - teaching hospitals and medical colleges / institutes, non-teaching hospitals, non-government hospitals representing private sector, district level hospitals, and centres of excellence.

The methodology adopted for formulation of these standard treatment guidelines (STGs) encompassed:

- Nomination of Expert from the respective clinical specialities as the Team Leader for each individual speciality
- Nominated expert was invited by Ministry to form the core group for the speciality on the basis of guidelines provided for formation of the core group, as above
- Finalization of selection of disease entities representing the bul volume of clinical load in the respective specialities
- Formulation of draft guidelines for the chosen diseases
- Peer - review by additional experts from the speciality concerned and / or by the professional society

These standard treatment guidelines (STGs) have been submitted to the Ministry of Health & Family Welfare, Government of India for further action for adoption and roll out for implementation such that the clinical practice in these specialities is guided for paving way for universal practice of evidence-based medicine. Simultaneously, the Ministry will put up these STGs on website for dissemination amongst all the stakeholders, and conduct workshops and training programnme for implementation by clinicians in their day-to-day practice. It is contemplated that in order to catalyze broad based success of these STGs, it would be an endeavour to promote voluntary adoption.

Conclusion



Practice of medicine has traditionally been very paternalistic and dependent on the proficiency and competence of clinicians who have based their clinical judgement on the body of knowledge acquired during their training and thereafter their individual practice and at the most, gaining from experiences of peer group members especially the informal peer networks. While this practice continued for time immemorial the quest for improving the effectiveness of interventions and enhancing the range of treatment modalities for newer disease entities as a result of technological advancements resulted in need for scientific evaluation vis-à-vis actual benefit to the end user.

As it happens, a scientific and logical questioning led to breaking of general myths about the infallibility of all pervasive clinicians on one end and benefits to the end user on the other end. This examination also emphasized the need for standardization of practices such that personal prejudices and bias in choice of treatment could be eliminated. The need therefore culminated in to initially hypothesizing principles and rationale of evidence based medicine followed by studies to strengthen the concepts of the same. Once the concept was established in late twentieth century, especially by Gordon Guyatt et al, the working groups for evidence based medicine led by Sacket et al carried forward the modalities for adoption in practice and teaching of young doctors. Simultaneously, work of Scottish epidemiologist Chochrane contributed to dissemination and support practice of evidence based medicine.

While the developed countries with fairly matured health systems initially struggled with universal adoption of EBM the developing countries largely in Asia, Africa and Latin America took refuge under the lack of resources as the reason for delaying the adoption. However, further research, surveys, and studies emphasized that practice of evidence based medicine actually optimizes the resources and eliminates or at least reduces the un-necessary interventions and / or reduces the overall cost of delivery of health services. The evidence, therefore, overwhelmingly supported evidence based medicine. Potential strategies for larger dissemination and implementation adopted by developed countries prompted developing countries including in South Asia and especially India to explore possibilities of adoption of EBM in a rational manner suited to the local context. One of the critical element for success of practice of EBM in such countries emerged as 'relevant best evidence' instead of 'best external evidence'. Accordingly, it is summarized that prudence will require tailoring the standards for delivery of clinical care to the local context.

Following up the initial exercise started by the health insurance and health care group of Federation of Indian Chambers of Commerce and Industry (FICCI) in 2008 for formulating the standard treatment guidelines (STGs) for commonly occurring diseases for which bulk of insurance claims were being made, Ministry of Health & Family Welfare, Government of India in collaboration with

FICCI, kick started a similar exercise in 2010 for twenty specialities. It is envisaged that these STGs are going to be the harbinger of adoption of evidence based medicine in the country through voluntary adoption by clinicians. These STGs will be periodically reviewed to ensure that they meet the overall requirements of the healthcare delivery eco-system of the relevant times. It is expected that the biggest contribution of the overall endeavour for standardization through practice of these STGS will result in quality assurance and cost effectiveness of treatment modalities making it possible for the nation to optimize the resources expended on health services.



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