

Bridging the gap between alternative medicine and evidence-based medicine

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Complementary Alternative Medicine (CAM) was defined as “those treatments and health care practices that are not an integral part of conventional western medicine, not taught in medical schools, and not generally used in hospitals”.^[1] The gap between the traditional complementary alternative medicine and the conventional main stream western medicine has been widening ever since the adoption of the principles of evidence-based medicine, as well as the guidelines of good practices by major competent health authorities and health policy makers in this new era of globalization and international harmonization.

Evidence Based Medicine (EBM) was defined as “the integration of current best research evidence with clinical expertise and patient values/circumstances”.^[2] Research evidence was further defined and hierarchically arranged in what is called the evidence pyramid [Figure 1]. The highly costly multiple large sized randomized controlled double blind clinical trials (RCTs) and their systematic reviews and meta-analyses are the only justification for the highest level (level A) evidence for efficacy and safety of a treatment at the summit of the pyramid, whereas smaller sized or few RCTs qualify for level B. The safe and effective use of a treatment, which has historical evidence or any other unpublished real-life experience of treatment, cannot provide the needed research evidence to qualify as an accepted line of therapy.

Though evidence-based medicine rests on a rigorous scientific rationale, its blind adoption without considering the differential

geographical, historical, cultural, and economic issues could create a bias on its own. Giant multinational corporate companies compete for creating the highest level of evidence to support their brands to clear the challenging registration process and to seek a higher rank in the frequently updated practice guidelines.

Further to this, the new globalized International Conference on Harmonization (ICH) - guided harmonized regulations though seemingly constructive, mandates increasingly sophisticated and expensive requirements, and obligations for new drug development. This has created challenges for small and medium-sized drug enterprises and research centers, which are not able to comply with the requirements due to cost considerations.

The early phases of development of a drug chemistry, formulation, manufacturing, and quality processes is guided by many complicated regulations such as compliance to the guidelines of good laboratory practices, good manufacturing practices, the ICH guidelines for conducting and reporting clinical trials, and good pharmacovigilance practices. In spite

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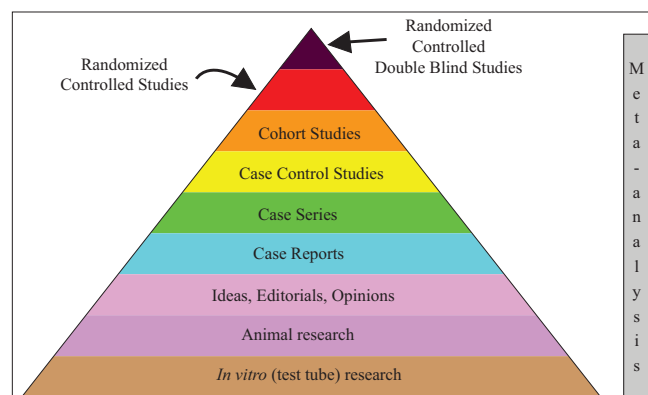


Figure 1: The evidence pyramid

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of all these protections to ensure safety, many of the newly released drugs are being actively banned shortly after being registered due to safety reasons (Rofecoxib and Rosiglitazone are two famous examples).

CAM therapies have been classified by the United States (US) National Centre for CAM into five domains:^[1]

- Alternative Medical Systems, which are built upon complete systems of theory and practice, and include as examples: The traditional Indian Ayurveda, traditional Chinese medicine, and Homeopathy
- Mind-Body Interventions, which include for example: Meditation, hypnotherapy, biofeedback, yoga, and cognitive behavioral therapy
- Manipulative and Body-Based Methods, which include the chiropractic, massage therapy, reflexology, and osteopathy
- Energy Therapies, which include two categories: (a) Biofield therapies like the qi gong, reiki, and therapeutic touch. (b) Bioelectromagnetic-based therapies like the magnetic field therapy, pulsed fields as well as the direct and alternative current field therapy
- Biologically-Based Therapies, which includes herbal medicine and dietary supplements.^[1]

Lack of evidence of efficacy is not an evidence for lack of efficacy:

Alternative medicine practices are facing a unique and difficult situation where there is no sponsor who can afford to pay large sums of money to create the research evidence to register a product or a technique that he or she can never claim an ownership or property rights. Even though some patent rights are being issued for a few therapeutic uses of some herbal products, such a product cannot be actually protected because it is in the public domain through its traditional use and can be simply used under any other claim or even the same claim with minor modification.

The situation of CAM in Egypt is an example of a developing country characterized by a wealth of ancient traditional medical heritage, and inadequate resources allocated to conduct modern medical research. Most physicians in Egypt now adhere to the practice of evidence-based medicine and guidelines for diagnosis and therapy coming from the American and European medical societies. The great advances in communications, information technology, and the internet have introduced new and effective marketing channels for CAM directly to consumers. This has helped to markedly increase the use of CAM practices and products in the United States of America and Europe over the past 20 years.^[3] This has been reflected in countries like Egypt as public demands for traditional healing practices like herbal medicine, cupping, needling, etc., are getting higher. This has created a kind of unresolved debate between advocates and opponents of CAM that is confusing the public as the mass media has stepped in to fuel the controversy.

These debates are usually dominated by opponents of CAM who are mostly represented by physicians from governmental health authority and universities as all medical schools in Egypt are purely western with no studied curricula for alternative or herbal medicine practices.

The question is that although the public access to crude herbal medicines is very widely opened through thousands of shops of herbalists who used primitive methods in milling and processing their herbal products without standardized quality control procedures; the access to the use of these herbs under optimal hazards-free manufacturing, quality control and on evidence-based medicine basis is very narrow.

This is due to the interplay of many factors including the high cost of creating research evidence for unpatented product as mentioned above. Besides, there are no clear, practical, and understandable codes or regulations for herbal medicine. The governmental committees that preview the files submitted for new herbal drug registration and the research ethics committees usually find it difficult to give an approval for any investigator to start a human clinical trial on whole herbal extract. They normally demand very sophisticated preclinical and pharmacokinetic studies on each active component of an herb as a prerequisite for approval, even for those edible plants with a long history of traditional use.

To solve this problem, the following recommendations may be considered:

- To consider the fact that lack of a research evidence of efficacy is not evidence for lack of efficacy.
- Officials of the Ministry of Health should embrace, supervise, and authorize alternative medicine practitioners with a licensing system and help them to upgrade their procedures, research, and quality control
- The government should encourage medical investigators and pharmaceutical companies to extend scientific bridges with old herbalists from the lands of Sinai and Upper Egypt, who had inherited their knowledge through generations dating back to great ancient civilizations and direct contact with ancient scientists as well as prophets, whose science has withstood the repeated testing of time for thousands of years
- Establishment of a higher multidisciplinary committee, with members from all scientific disciplines related to herbs like botanists, pharmacognosists, chemists, physicians together with herbalists to study and classify herbs that are still used while remaining unclassified. This will help the new generations of scientists and herbalists who have begun to neglect this science so that they may not make mistakes in identifying and prescribing herbs
- Also, to fund and sponsor some clinical research in accordance with the new protocols of evidence-based medicine and share

in preparing the legal codes and guidelines for registration authorities and research ethical committees

- Assigned members of registration authorities and Research Ethics Committees should receive scientific guidelines and training to ensure the ultimate safety of volunteers but without hindering the advance of this science or regarding herbal drugs as being inferior.
- Adoption of the World Health Organization (WHO) and European regulations^[4] by considering the whole herb as one active ingredient, without the need to perform sophisticated impractical pharmacokinetics and bioavailability studies as a prerequisite before approving clinical trials
- Encouraging drug companies to increase research on fractionated mono-component herbal preparations, but not to neglect research on whole herbal extracts with long history of use by herbalists. These may have added holistic and synergistic benefits.

Unless we make a start in the right direction this situation will continue to remain for years to come and the scientific

basis of CAM may never be investigated and evidence accrued.

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