

Finding a sustainable prototype for integrative medicine

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ABSTRACT

Mainstreaming traditional systems of medicine and integrating them with the established health delivery mechanisms is an important step in accelerating advancement of health sciences to achieve current global health care goals. This paper proposes the “axial-model” of Integrative Medicine (IM). A replicable model, viable across multiple IM possibilities, which are clinically beneficial, supports evidence-based evolution and is socially acceptable. Axial model may be implemented to integrate two or more systems of medicines, provided they are legally regulated and approved for clinical administration. It proposes three consecutively phased clinical processes, named parallel, complementary and protocol, respectively. The model supports translational medicine by mainstreaming beneficial practices of traditional medicine as a part of its process of execution.

Key words: Integrative medicine, mainstreaming traditional medicine, translational medicine

INTRODUCTION

Mainstreaming traditional systems of medicine and integrating them with the established health delivery mechanisms is an important step in accelerating advancement of health care to achieve current global health care goals. It would offer financially viable, safe, and efficient health care.^[1,2] Economic benefit and affordability of Integrative Medicine (IM) is evidently implied by Herman *et al.* who, analyzing comparative input costs and economic outcomes of complementary therapies concludes that complementary therapies show 29% improvement in cost savings in the 56 of comparisons, which administered higher-quality methodologies from

among 338 publications reviewed.^[2] The widening scope of healthcare delivery, from the current focus on curative care, to include preventive and promotional components, and supporting goal-oriented, patient-centric care, increases the relevance of exploring new models.^[3-5] The new found readiness to accept traditional systems of medicine based on scientific evidence provides an excellent opportunity for such exploratory endeavors.^[6,7] IM is broadly defined as the process of bringing different systems of medicine together to offer best modalities of prevention, cure, care, and management in healthcare.^[8] Many examples of benefits exist to support the cause of IM.^[9-12] These remain exceptions, in silos and not replicated mostly for want of personal interest. Even IM initiated through research programs, do not get translated in day-to-day clinical practice. Those who have such opportunity, shy away owing to lack of information, knowledge, belief on evidence, reliability and safety of such practices.^[13,14] A replicable model supported by scientific evidence, which is socially acceptable and has regulatory viability, is needed for successful establishment of IM. In this context, we propose the “axial model”. Axial model represents a structured approach adoptable by societies where regulatory and sociocultural environment accepts independent coexistence of multiple medical systems.

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FINDING A MODEL FOR INTEGRATIVE MEDICINE

Integrating medical systems is very similar to integrating culturally divergent societies. Their diverse philosophies and

approaches perceive the same reality differently, in terms of science, outcome expectations, patient perceptions, social outlook and even clinical endpoints. However, unlike cultural integration, where multiple choices may be implemented simultaneously, medical pluralism of IM, does not imply that every system practices what they believe to be right on a patient, which would be unethical, impractical and often dangerous to the patient.

Seven different models representing as many stages of integration have been described. These evolve from parallel practice followed by consultative, collaborative, coordinated, multidisciplinary, interdisciplinary and integrative, respectively in the order of least to most integrated.^[15] Current models of IM,^[8,9,16,17] could be appreciated in terms of patient perspective, scope of integration or delivery processes and may be classified as “selective integration” (integrating select modalities in certain clinical areas), “comprehensive integration” (as-many known beneficial modalities added to the treating protocol) and “the whole system integration” (combining two medical systems in all aspects of treating a specific disease). Use of leech therapy by vascular surgeons in microsurgery and in the treatment of patients with postphlebotic syndrome at the Institute of Hematology, Tel-Aviv Sourasky Medical Center and The Sackler Faculty of Medicine, Tel-Aviv University, is an example of selective integration.^[18] Use of Yoga, Music, Massages, Reiki, Acupuncture, *Prakriti* based food and lifestyle modifications, Aroma therapy and counseling offered to the same cancer patient in addition to conventional cancer management, through the IM program run by Osher Center at the University of California, San Francisco, is an example of comprehensive integration.^[8] Approach of Institute of Applied Dermatology, Kasargod, in integrating Ayurveda and Allopathy at a conceptual level to manage lymphedema,^[9] and the NIH supported clinical trial conducted at Arya Vaidyasala, Coimbatore^[19] combining standard methotrexate therapy for Rheumatoid arthritis with classical Ayurvedic management are examples of whole-system integration. Most models use preexisting information (beliefs, perceptions, anecdotal evidence, textual reference, etc.) as the basis for decision of integration. Process of IM delivery varies according to clinical settings and lets the patient decide from a choice of therapies (cafeteria model), or referred to an integrating system expert by the primary physician (referral model), or examined simultaneously by doctors of different medical systems (concurrent consultations).

Learning from these diverse approaches and appreciating the unparalleled opportunity presented for medical pluralism by favorable regulations,^[1,16,18,20,21] we propose the “axial model,” which shall support the sustainable evolution of Integrative Medicine. The name “axial model”

implies that it is built around an axis; in this case any “one” established medical system, aiming to improve its clinical outcomes. It has seven critical components.

The axial model - The components of the model are:

- Axis medical system (AMS)
- Integrating medical systems (IMs)/practices (IMPs)
- Competitive intelligence (CI)
- Data management
- Research and analysis
- Communication
- Funding.

Axis medical system

An established system of medicine with well-known predictable outcomes covering a large context of clinical conditions, will serve as the axis/reference point in the model. Allopathic medicine can serve as the axis system in most countries. Though in countries with different regulatory and sociocultural environments, other medical systems, such as Ayurveda (in India), Traditional Chinese Medicine (TCM; in China), and Kampo medicine (in Japan) -could also serve as the axis.^[1] It is important to note that the axis system has to be a whole system of medicine, rather than instances of excellent outcomes in medical practice. For example physiotherapy cannot be an axis system, whereas Ayurveda can be.

Integrating medical system/practices

These are medical systems or select modules of therapies, which are not part of the axis system. If Allopathy is the axis system, the IMS could be Ayurveda, TCM, Kampo and Integrating Medical Practices (IMP) could be practices within these broader systems such as Yoga, Acupuncture, Physical therapies, or Cupping.

Competitive intelligence

Competitive intelligence is a mechanism to identify the “unmet need” of the “AMS” and explore beneficial outcomes from the IMS’ to support that specific “unmet need.” All clinical interventions have expected outcomes, which may be classified into (1) excellent, (2) satisfactory, (3) requires improvement/necessitates support and (4) no benefit (based on perspectives of the patient and caregiver, social acceptability, or economic benefits). Each response (other than excellent) offers chances for improvement and is viewed as an “unmet need” of the system playing “axis” in the model. A team of people or mechanism to identify the “unmet need” of the AMS serves as “CI.”

Data management

It is critical for CI to maintain the model’s fluid nature through continuous analysis of clinical outcomes. This

necessitates collecting quality outcomes data in real-time and creating a database of interventions and outcomes.

Research and analysis

Researched outcomes data provides CI with information on comparative benefits of IM interventions over current standards of care.

Communication

At every phase of integration it is important to engage the clinicians of the integrating systems through regular communication.^[22] We propose a three step communication process in the axial model:

- Personal interactions between the individual practitioners of the axial and integrating systems (to develop the algorithm)
- Small group discussions including all medical personnel directly involved in implementing the proposed IM process (to analyze and fine tune the algorithm)
- Larger group discussions also including nonclinical members from administration (for translational implementation of beneficial IM practices).

Funding

Axial model needs minimal funding as it uses existing resources (the axial and integrative medical teams, also contributing as the CI, and the existing hospital information systems used for data management). Statistical analysis of outcomes may require separate funding.

METHODOLOGY OF INTEGRATION

Axial model proposes three consecutive phases: Parallel, complementary and protocol, respectively [Figure 1].

Parallel phase (Phase I) represents closely observed clinical practice of the axis and IMS, by authorized clinical practitioners. It is essential that parallel practice of Integrating and AMSs are located within same clinical setting as it helps identify societal preferences based on experiences. Parallel phase represents closely observed clinical practices, with all their diversity and limitations. The data from parallel phase of integration when analyzed will look for (1) safety and compliance of drugs and other therapeutic components, (2) number of patients and referral in a clinical area, (3) prescription patterns, and (4) clinical outcomes.

Complementary phase (Phase II) seeks to validate effectiveness and benefits of the integrative processes. Therapies selected as beneficial through the mechanism of CI, get combined with appropriate clinical areas of the axis system in this phase. It is important to concentrate on one clinical area, and to have a leading physician for this experimental phase. During this phase, IM is offered as a choice to the patient. From a patients' point of view, involving in this process presents questions such as the extent of benefit, safety, interaction with current therapies, social acceptance, cost, and insurance. From the physicians' perspective, such complementary approaches raises questions on comparative clinical

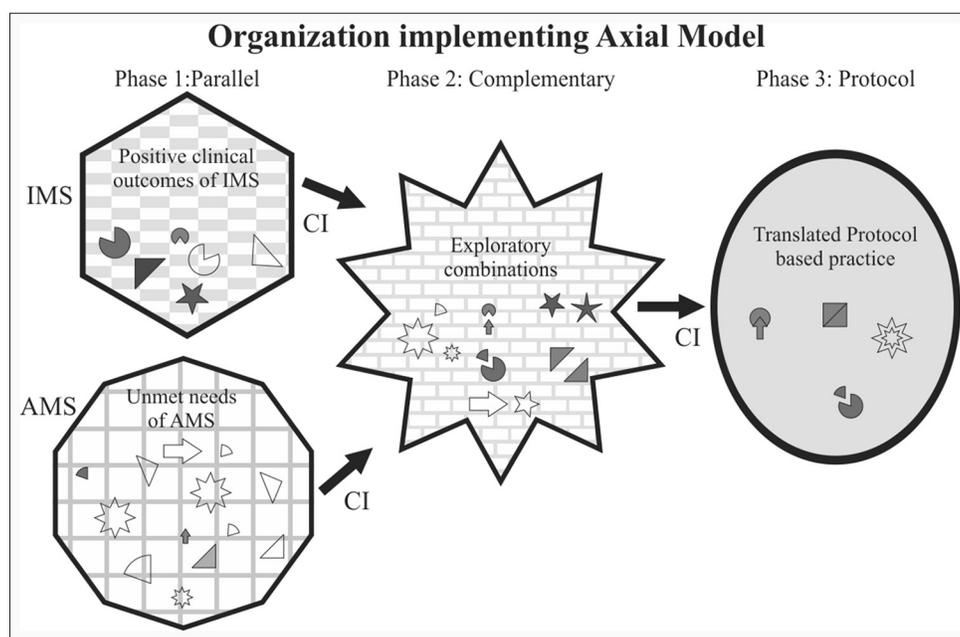


Figure 1: Axial model of integrative medicine - Process of integration. Parallel phase represents closely observed clinical practice of integrating medical system (IMS) along with axis medical system (AMS). It generates competitive intelligence. Complementary phase, combines beneficial practices of IMS, observed in parallel phase, with AMS. Protocol phase represents new standards of care

benefits, cost effectiveness, drug interactions, compatibility, peer-acceptance, and regulations. From the perspective of the integrating organization, questions on regulatory authorization, availability of expertise, social acceptance, logistics of implementation, management of clinical records, and multiple pharmacies are relevant.

The axial model offers a clinical platform to assess the benefits of this experimental integration, represented by complementary phase, as outcomes assessment over several hundreds of patients. Collaboration by multiple centers engaged in such clinical experimentation that allow for research and analysis of the outcomes data, will accelerate the process of evidence-based integration.

Protocol phase (Phase III), the third and final phase of the axial model, represents beneficial outcomes of the complementary phase in translated clinical practice. In this phase, integrated protocols replace current standards of care.

The three phases are distinct by way of patients' right to choose. In parallel phase the patient chooses the medical system on his own, in complementary phase the patient is given the choice by the medical practitioner to "opt into the IM therapy" and in protocol phase the patient has the choice to "opt out of the IM therapy" and continue with the preexisting standard of care.

Owing to its unique social, cultural, economic, regulatory and research capabilities India offers itself as an excellent social laboratory for the evolution of IM.^[17] Other than its nearly 1 billion citizens who will directly benefit a pluralistic medical system, which is more effective, less invasive, economic, and personalized there exists another 4 billion people in this world across Asia, Africa, and South America who cannot afford the present model of health care practiced by the economically stable societies. The axial model would require active support of policy makers, governments and large institutions for its successful implementation to generate credibility, accountability and acceptability for itself, in the society.

CONCLUSION

Integrative Medicine is one of the ways to provide safe, efficient, cost effective and patient centric health care. The proposed axial model offers a sustainable and structured way towards integration, which can be implemented by hospitals and health care centers in conducive regulatory environments. The axial model would require active support of policy makers, governments and large institutions for its success. When implemented it would support patient choice and satisfaction, evidence based selection for

integrative endeavor, and protocol based IM translated in clinical practice.

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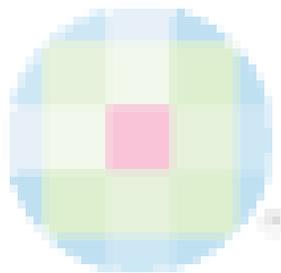
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