

Time for evidence-based Ayurveda: A clarion call for action

PRESENT CRISIS

Several thought leaders in Ayurveda and health sciences infer that the sector is in crisis and facing formidable challenges. The inference is based on the unimpressive performance of the sector on all fronts, education, research, clinical practice, industry, and regulation. Reasons for the crisis are complex. Visible, right on the surface reasons, include proximate causes such as the conservative and short sighted attitudes of entrenched administrators, educators, scientists, practitioners, industry, and above all lack of strategic vision and political will at the government level. At a deeper more invisible level is the cultural and epistemological divide between globally dominant western science and still marginalized Indian knowledge systems. The colonial legacy of decrying Indian sciences has yet to be outgrown. More reasons for arrested progress Ayurveda derive from history, especially that of the last millennium when our cultural and intellectual freedom and traditions were trampled and state patronage was ceaselessly denied by foreign rulers. The renaissance, in Europe, and the subsequent developments in science, technology and medicine, almost bypassed the subjugated India.

Even after independence “mainstreaming Ayurveda in national health” has been a loud political slogan and even from the 1st to the most recent 12th 5-Year Plan, it has been bereft of any substantive funding, innovative programs, smart strategy, or a clear roadmap. As a consequence, performance of the independent Department of AYUSH over the last 18 years, since its inception in 1995, has been dismal. While other departments and councils like Council for Scientific and Industrial Research (CSIR), Department of Science and Technology (DST), Department of Biotechnology (DBT), and Indian Council of Medical Research (ICMR), have been governed transparently and professionally by renowned scientists, the Department of AYUSH continues to be at the mercy of bureaucracy. The immense loss of opportunities is not even recognized.

The last three years in particular were unusually damaging, despite a significant global demand and extra-AYUSH efforts for evidence-based Ayurveda.

TIME TO ADD VALUE

Despite these formidable obstacles many significant intellectual efforts have taken place as interpretations, reinterpretations, and critical scholarly commentaries duly recognized by scholars like Meulenbeld. Ayurveda draws its philosophies from *Darshanas*, which teach relentless and objective search for the truth. The *Darshanas* expect reproducible knowledge earned through rigorous *pramana*-based and ethical practices. *Charaka* and *Sushruta* laid foundations for logical analysis, sequential nidana and its experiential reversal methods with an emphasis on practical management of patients. *Vagbhata* reconstructed the texts according to contemporary needs. These Samhitas, in hundreds of verses, explain methods of studying cause-effect relations, evaluation of true associations, and unbiased meticulous observations. But these classics have to be rewritten incorporating the major medical discoveries of the last 2 centuries. The arrested growth of Ayurveda has to be compensated by incorporating the basics of biology, chemistry, and physics. Ayurvedic physicians should not be deprived of major disciplines like microbiology, immunology, biochemistry, genetics, pathology, imaging techniques, endoscopies, and minimal access surgery.

DARE TO EXPERIMENT

Ayurveda in the 21st century needs a fresh wave of new ideas, adventures and liberation, in order to play its required role in the newly emerging era of medical pluralism. We need frank and objective introspection to ask intrepid questions in the same spirit of the *Upanishads*, where students were encouraged to question their mentors. The *Apta* are revered because of their unbiased knowledge and minds open to inquisitive approach. The inquisitive culture in Ayurveda has deteriorated over the centuries. We can no longer live on the glory of the past. The critical outlook of Ayurveda must be regained to build a progressive future. We need to challenge assumptions, try to re-interpret meanings in new contexts and, most importantly, dare to experiment to generate fresh evidence^[1]. Today's Evidence based medicine (EBM) expects exactly the same.

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DOI:

10.4103/0975-9476.113860

EVIDENCE-BASED AYURVEDA

J-AIM wish to reiterate commitment for evidencebased Ayurveda and endorse need to evolve epistemologically appropriate models to achieve this goal.^[2] A recently published special research monograph vividly discusses evidence-base issues in the context of AYUSH.^[3,2] Evidence-based practice comprises best research evidence, clinical experience, and patients' preferences. Every healthcare system needs to be evidence based and Ayurveda should be no exception. However, when pleading for evidence, the concept of evidence also needs to be defined appropriately for the in right context. Issues related to the nature of evidence, whether primary or secondary, and whether applicable to the science of Ayurveda, or limited only to Ayurvedic drugs should be thoroughly debated. New scientific evidence is genuinely important though often about evidence for safety and efficacy of AYUSH drugs. As rightly stated by senior thought leader R.H. Singh, we need more research on development of appropriate research methods than aimlessly borrowing outdated, beaten off or conventional biomedical methods which may lead to distortion of Ayurveda with no benefit to either side. We do not mean to abandon biomedical or therapeutic research, but we must invent methods appropriate to generating scientific evidence for Ayurveda. Sadly, little has happened in this direction. Now is the time for action. An innovative R & D path based on reverse pharmacology as proposed by another thought leader Ashok Vaidya is receiving greater acceptances especially when now that the pharmaceutical industry is also facing innovation deficit crises^[4].

NEW MODELS FOR EVIDENCE

We seem to have better consensus on the urgent need for newer models and methods for evidence-based Ayurveda.^[5] Arguably, evidence need not always be restricted to randomized clinical trials (RCTs). Simple and clearly defined research questions are better answered with hierarchical evidence models, in contrast to assessment of complex interventions which needs corroboration of observational research and RCT methods.^[6] The rigid hierarchy of evidence where meta-analysis is considered topmost, may not be relevant to, simply because of absence of sufficient clinical data. While the hierarchical evidence model can be challenged, the resolve to do so may not succeed unless we suggest other options for systematic studies. We need to take the onus to develop and adopt appropriate models in practice. The objective of any research design should be to assess causality and minimize bias, chance effects and confounders. Evidence-based Ayurveda may need appropriate blends of modern rigorous trial methods and strengths of observational studies. The

Ayurveda research can also benefit from the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) initiative, which involves methodologists, epidemiologists, statisticians, researchers, and journal editors for strengthening the planning and reporting of observational studies.^[7] Ayurveda sector has to take cognizance of important initiatives in the methodological domain and develop appropriate methods.

Instead, today's Ayurveda sector seems to be trapped in copying modern medicine protocols, many times without understanding the contrasting epistemologies and principles of the respective systems. Scientometrics of published scientific papers reveals that many researchers have applied existing models without confirming relevance to Ayurveda. Obviously, results of such ill-designed studies are unlikely to add any value either to science or to Ayurveda. Over more than 3500 papers on Ayurveda in PubMed include only 15 case series and observational studies. Among case reports published in reputed journals, 79 concern toxicity of Ayurvedic drugs with practically none on safety and efficacy. Five lakh practitioners, 200 colleges, national institutes and a legacy of hundreds of years, has not resulted in any note worthy paper discussing systematic clinical practice data in reputed peer-reviewed journals. Gurudev Tagore once remarked, "What is huge is not necessarily great and pride is not everlasting," efforts to make Ayurveda more open, visible, and respectable in the scientific literature should not be further delayed.

We must either create our own open access scientific repositories or publish our data in scientific databases like Cochrane where currently Ayurveda is almost nonexistent. The efforts to compile Ayurveda research at postgraduate and doctorate levels by M.S. Baghel of Gujarat Ayurved University, and A. K. Sharma of NIA Jaipur, Digital Helpline for Ayurveda Research Articles (DHARA) and RUDRA by Arya Vaidya Pharmacy (AVP) Coimbatore have made some beginning. However, quality and impact of such postgraduate dissertations remains to be evaluated. While Traditional Knowledge Digital Library (TKDL) was a timely effort to protect intellectual property rights, we need to develop its knowledgebase and developing comprehensive libraries integrating other efforts like AyuSoft.

Ayurveda scholars and practitioners must be given credit for protecting its knowledge during the dark periods; however, it is high time now to face realities of today. Ayurveda practice needs to be dynamic, scientific, ethical, and integrative. It must be liberated from emotional, pride-based, blind-following practices, and refrain from spurious advertisements, mysticism, and self-propagation. *Charaka* also condemns quackery among practitioners as "*Rogabbisar Vaidya*," which literally means "a doctor who spreads

diseases rather than providing health.” The expectations from EBM are no way different than the qualities of a good doctor detailed in the Samhitas. The ability to evaluate the strengths and limitations of existing knowledge is necessary for rational decisions.

EVIDENCE FROM AYURVEDA PRACTICE

Discordance between teaching, training, research, and clinical practice of Ayurveda may have led to its present stagnancy and complacency. Diversity in styles of practice, schools of thoughts, and Gurukul training, are strengths of Ayurveda; however, they also pose challenges for research. The role of Vaidyas in knowledge generation is crucial as they carry principles and practice of Ayurveda and gain first-hand experience of clinical outcomes and patients’ perceptions. J-AIM initiated an interesting discussion on observational therapeutics as suitable evidence model for Ayurveda research^[8] as also its advocacy for Vaidya-Scientists.^[9]

Research on clinical practice is a challenge and we may face initial hurdles in documentation, data retrieval, and standardization and analysis. However, it is important to initiate the process and start moving in the right direction. The few exemplary efforts in this direction must be recognized. The science initiatives in Ayurveda and Ayurvedic biology led by M.S. Valiathan, efforts of Saravu Narahari of Institute of Applied Dermatology and Terence Ryan of Oxford in the field of integrative dermatology, whole system trials done by Ram Manohar of AVP in collaboration with Daniel Furst of UCLA, and another systematic drug development effort through robust RCTs in rheumatology by Arvind Chopra and colleagues from Centre for Rheumatic Diseases, Pune. Recent efforts to develop CONSORT like reporting standards for Ayurveda are also important. J-AIM wishes to recognize significant work undertaken by renowned biostatistician Ashwini Mathur with help of Prathap Tharyan, Director of the South Asian Cochrane Network. We commend the efforts of former AYUSH secretary Shailaja Chandra for publishing the status of Indian Medicine and Folk Healing in two volumes and efforts of Pratik Debnath to establish Gananath Sen Institute of Ayurveda and Research in Kolkata, as well as Darshan Shankar and his colleagues at FRLHT in gaining its University status recently conferred by the Government of Karnataka. The new University will be known as “Institute for Transdisciplinary Research in Health Science and Technology.”

J-AIM INITIATIVE

We propose active contributions from the practitioner - Vaidya community in this process of evidence building.

J-AIM invites perspective papers, thought leadership articles, case series, case reports, and data driven debates based on Ayurveda practice. We plan to appoint a team of independent experts to study such data and recognize original contributions publically by establishing national awards. J-AIM will also facilitate and prioritize publication of such selected data. Our reviewers and editorial team will provide methodological and data analysis support for such practice based evidence research.

For this purpose, we suggest three phases and categories in the following order priority: first classical Ayurveda interventions for public health, primary care and difficult to treat diseases where modern medicine has limitations; second, Ayurvedic interventions in chronic, psychosomatic, degenerative conditions to be included as complementary and adjuvant therapies; third, studies on integrative approaches where Ayurveda and modern medicine can add value by offering maximum benefit to patients and the community. J-AIM will form a group of transdisciplinary experts to make indicative list for inclusion and exclusion of diseases, disorders, syndromes, or symptoms in each of these phases. We will also facilitate development of suitable formats for case reports, case series, cohort, case controlled, observational, or controlled clinical studies.

TIME FOR ACTION

We trust that all these encouraging and timely developments will move evidence-based Ayurveda towards being the future medicine for the world. For the present, we need strategy, efficiency, and real action. J-AIM will be happy to facilitate collaborations with existing efforts to systematically document clinical practice, experimental, and clinical data as required for an evidence base. We realize the intensity and magnitude of efforts required for such ambitious initiatives. We sincerely hope that with the help of associated experts, mentors and well-wishers this will be possible. We also hope that such a national level, voluntary, self-motivated effort will finally help ailing patients who have the right to receive effective, safe, accessible, and affordable healthcare. J-AIM welcomes views, critiques and comments on this call for action.

To mark the 150th birth anniversary of Swami Vivekananda and remembering his clarion call, I wish to end the editorial with words of wisdom from Katha Upanishad “*Uttishbhata, Jaagrata, Prapya Varan Nibodbata*”

ACKNOWLEDGMENTS

I thank senior editorial colleagues R.H. Singh, Darshan

Shankar, Ashok Vaidya and Alex Hankey for valuable inputs to this editorial.

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How to cite this article: Patwardhan B. Time for evidence-based Ayurveda: A clarion call for action. *J Ayurveda Integr Med* 2013;4:63-6.

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