

## Preface

Integrative medicine (IM) is developing in India and has been described as frugal innovation<sup>1</sup> contributing to the health design for well being of patients affected by chronic illness<sup>2</sup>. There has been some claim that yoga protocols which are part of IM for lymphoedema are a reverse innovation<sup>3</sup>. The Prince of Wales advocated for integrated health care<sup>4</sup>. IM intensely engaged the most thoughtful of Indian Ayurveda and Yoga leaders<sup>5-7</sup>. Albeit at the bottom of the evidence pyramid, there are a few success stories of Ayurveda treating patients who could not be managed by Allopathy. Such traditional medicine interventions are aimed at improving the quality of life of 'incurable' and 'chronic' patients. Hundreds of ayurveda groups now focus on chronic diseases using Allopathy diagnosis<sup>8</sup>. In 2010 only few papers could be found in PubMed for a search term Ayurveda and over 46 databases had to be searched to locate scientific publications<sup>9</sup>. In 2016, 106 journals are publishing papers on Ayurveda and 11 dedicated Ayurveda journals are indexed in PubMed<sup>10</sup>. The Council for Research in Ayurveda Science started the 'AYUSH portal' to consolidate all related scientific publications. All these received liberal funding and were supported by modern scientific wisdom. The Indian Council for Medical Research and the Department of Science and Technology, Government of India supported these initiatives. The benefits of Complementary and Alternative Medicines are often ignored mainly due to the methodological errors in its publications. Albeit decades of efforts have resulted in better evidence base for Indian studies<sup>11</sup>. This special section on IM summarizes studies integrating Ayurveda treatments with biomedical diagnosis, investigations and or drugs.

Initially the British compartmentalized Biomedical and Ayurveda systems of medicine in India. Genuine efforts were not made to improve interaction between their practitioners which would have contributed to better care of patients. The Government of India is now encouraging an integrated approach to health care and as a policy intends to earmark large funding for such studies. Nandini and Pradeep Dua (page 293) narrate the history of evolution of IM in India. They describe gradual strengthening of 'regulation of traditional medicine formulations and natural products' as classical Ayurveda has expanded incorporating modern technology. They emphasize that for IM studies involving traditional Indian medicines, regulatory control is relaxed and supportive but stronger norms are desirable in future. They conclude that if the existing norms of regulations are implemented in a meaningful way, traditional Indian medicines would contribute to improve public health.

Reluctance among biomedical practitioners to appreciate the contribution of traditional medicines to public health or personalized medicine is due to the lack of evi-

dence. A majority of studies on traditional medicines contain methodological errors or are at the bottom of the evidence pyramid. WHO's expert committee concluded that 'as far as possible it is preferable to conduct the studies using double-blind techniques but it may be difficult [to do this] in procedure-based therapies of traditional medicines'<sup>12</sup>. Although the level of evidence of a well-conducted randomized control trial (RCT) design is desirable for IM studies, a large case series using objective outcome measures could only be possible subject to improved funding opportunities in India. However in silos lead institutions have shown that Ayurvedic medicines passed the litmus test of RCTs. Bindu Kutty and co-workers (page 283) report that '*Manasamitra Vataka* and *Shirodhara* treatment preserved slow wave sleep and promoted sleep continuity in patients with generalized anxiety disorder'. The study had participation of both Ayurveda and Allopathy health care providers. They used proven objective outcome such as whole night polysomnography to assess the sleep architecture.

In the background of successful RCT, studies of IM<sup>13</sup> perfected clinical methods, structured documentation of evidence and attention to every clinical feature and its comparable interpretation in both Ayurveda and Allopathy<sup>14</sup>. During the development of protocols for managing diseases using IM doctors from both Ayurveda and Allopathy should work together when treating patients. 'Descriptive details of ayurvedic patient selection criteria and measures to decide improvement are essential for a biomedical doctor to understand the complete IM processes.' Narahari *et al.* (page 302) explain why such investigators should be 'intense clinicians and intense researchers at the same time'. The protocol is presented using 'SPIRIT' guidelines for enhancing the credibility and reproducibility of IM studies and discuss the 'systems-based' conclusive process referring to the standard guidelines in therapeutics of Ayurveda and Allopathy. The clinical methods of IM described in this special section are supported by 'Integrative Medicine atlas of skin diseases' (page 318). Using clinical photos for *Vatha*, *Pitta* and *Kapha* presentation in five common skin diseases the interpretation of Ayurveda versus allopathy is illustrated.

The experience of Ayurvedic clinicians is fundamental to treatment success in IM. They have to collaborate with experienced Allopathy clinicians. Nobel Laureate Joseph Goldstein described such studies as 'patient-oriented research' (POR)<sup>15</sup> and such a physician 'PORer'. POR requires a complete knowledge of pathophysiology of disease and the ability to recognize similar patterns across multiple patients. 'POR is performed by physicians who observe, analyse and manage individual patients.' Developing IM protocols and clinical methods occurs through POR. Ryan, a PORer in Oxford's Medical School, discussed a low-cost integrative treatment

paradigm for lymphoedema, using traditional Indian medicines and yoga, suitable for administration in rural communities<sup>16</sup>. Our IM protocol for *Lymphatic filariasis* was developed based on this publication. It adhered to the regulations and adopted the clinical methods described in this special section. English translations of Ayurvedic texts written in Sanskrit were used extensively for Filariasis protocol design before clinical trial. Kalsi and Ryan (page 343) describe how English translations of Ayurveda terminologies and accounts of its practices could be used to build a theoretical base for developing a patient care protocol. Narrative reviews of Ayurveda treatments for intestinal disorders were used to suggest ways for integration of its treatments based on physiology of digestion. The authors discuss that language and presentation style in Ayurveda are major barriers to understand its therapeutics for irritable bowel syndrome.

Arianayagam and Ryan (page 325) present a different view of Melanocyte biology and explain the role of IM in Vitiligo. As the pathogenesis of Vitiligo is not understood clearly holistic management including herbals and yoga could be justified. The authors argue to investigate richer descriptions available in Ayurveda and as many as 120 drugs listed for its treatment. This paper attempts to integrate systems of medicine at pathophysiological level, a hotly debated subject, which especially core Ayurvedists believe should be the fundamental investigation before embarking on therapeutic integration.

Future direction IM research should take all these developments on the same platform. 'Garrod inspired intense clinical work' is required for 'expanding the scientific horizon of Integrative Medicine' (page 280). Conducting clinical studies directly using Ayurveda drugs in routine use is a unique opportunity provided by the Indian Government. Such studies should be based on international consensus on clinical evidence. Candidate herbal medicines emerging out of the several processes discussed in this special section should be subjected to 'reverse pharmacology' experiments as described by Ruat *et al.* (page 337). The authors narrate their experience of using 'evidence by reverse pharmacology' to 'rationally understand Ayurveda'. This is the essential concluding step before developed countries are invited to adopt Ayurvedic drugs as reverse innovation<sup>1</sup> alongside biomedical treatments to manage chronic hitherto difficult to treat diseases.

Indian public health programmes would be the major beneficiary if it uses the health care workforce of Ayurveda. David Chandler (page 351) suggests integration of their services especially in remote rural and tribal areas. He argues for giving orientation training to Ayurveda practitioners on easily detectable and often missed common communicable diseases like leprosy. He cites studies that demonstrated an improved knowledge of leprosy among traditional health practitioners empowering them to identify early signs of disease. During 1950s the

Indian Government offered biomedical degrees (MBBS) to Ayurveda doctors (GCIM [Graduate of College of Indigenous Medicine] degree holders) by giving short courses in biomedical hospitals<sup>14</sup>. Subsequently this system met resistance from the biomedical sector who now dominate Indian health care. Coordination between the Ministry of AYUSH and professional bodies would break the barrier.

The hard work and dedication have gone to develop IM protocols discussed in this special section. Proactive support by agencies is crucial especially because IM studies in India are frugal research developed by voluntary involvement of investigators in India and their collaborators from abroad. Often investigators and their collaborators worked without remuneration and funded their own travel. Government should ensure intersectoral funding to bring all related expertise of IM on a single platform. Such funding would accelerate IM treatment delivery to the poor especially in rural and tribal areas, to incorporate protocols to the syllabus in medical universities and expand research to new horizon. Successful IM protocols could be scaled up for pan India programmes for morbidity reduction of diseases such as Lymphatic Filariasis where no specific treatments are available in Allopathy. This is the one plausible strategy to attract young and talented to the field of IM and to slow the rapidly declining acceptability of Ayurveda among patients<sup>17</sup>.

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