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Title Globalisation of Ayurveda: importance of scientific evidence base

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Abstract

Ayurveda, one of the world's oldest medical systems, is popular or is gaining popularity not only in South Asia but globally, especially for preventing and managing chronic diseases. However, strong concerns remain about the sub-optimal management and care of many people, arising from the unacceptable usage of non-evidence based Ayurvedic interventions. One of the major hurdles in the globalisation of Ayurveda is its poor scientific evidence base and there is a strong need for robustly designed pragmatic studies. Research studies on Ayurvedic interventions should include a range of pathways to impact (such as user involvement and the involvement of key stakeholders) and communication plans (for academic and non-academic audiences). These studies have the potential to directly benefit people (patients and the public), health policymakers and managers (of public and private healthcare providers), Ayurveda practitioners and academics. Thus, research studies on Ayurvedic interventions have the potential to impact around the world.

Keywords Ayurveda, Evidence base, Globalisation

1. Introduction

This chapter is written from an evidence-based perspective, which is needed for the globalisation of Ayurveda. The author is a qualified Ayurveda practitioner and an evidence-based healthcare academic in a world-class university. This chapter is divided into sections like Ayurveda and its popularity, problems associated with Ayurveda, scientific evidence base of Ayurveda – the way forward, pathways to impact and communication plans, and beneficiaries and impacts.

2. Ayurveda and its popularity

Ayurveda is one of the world's oldest medical systems, which originated in the Indian subcontinent more than 5,000 years ago. Ayurveda can be considered as a complex intervention, which includes maintaining a healthy lifestyle and using Ayurvedic therapies and medicines (such as herbal and herbo-mineral formulations). Ayurvedic interventions are written in Sanskrit, in the form of classical texts, such as Charaka Samhita (400-200 BC), Sushruta Samhita (400-200 BC) and Astanga Hridaya (600-500 BC) (Sharma, 1981; Bhishagratna, 1991; Murthy, 1991). Ayurvedic interventions are particularly used for the prevention and management of chronic diseases (Sharma et al, 2007a, 2007b; Rudra et al, 2017). In India, the Ministry of AYUSH is dedicated exclusively towards traditional therapies, including Ayurveda (Katoch et al 2017). Globally, different rules and regulations are in place, which may change over time. Many countries had less stringent laws but have now implemented well-defined and well-enforced laws. Some countries consider Ayurvedic medicines as conventional pharmaceuticals and some as dietary supplements (Barnes et al, 2016; Job et al, 2016; Sammons et al, 2016; Teng et al, 2016).

In general, the acceptability of and faith in Ayurveda are high among South Asians, especially among older, women, rural, poor and tribal populations. Ayurveda fits their health beliefs and is compatible with their social and cultural expectations. Many of them do not prefer western medicines – to avoid the associated side-effects and costs (Roy et al, 2015; Rudra et al, 2017; Srinivasan et al, 2017). In fact, western medicine is facing new challenges arising from its limitations when applied to chronic diseases and ageing (Warrell et al, 2010). Globally, Ayurveda is gaining popularity due to its

holistic approach (Patwardhan, 2014). Ayurvedic therapies like Panchakarma (i.e., detoxification of the body) are popular among people, especially among foreign tourists who travel to Indian states like Kerala (Ramesh et al, 2010).

3. Problems associated with Ayurveda

Many times, Ayurvedic medicines are either prescribed by an unqualified practitioner or used as self-medication. One of the major reasons behind self-medication is the easy availability of these medicines over-the-counter (which includes online shopping). Many people blindly follow the claims made by others or use a 'trial and error' approach in deciding the medication (Bhamra et al, 2017; Rao et al, 2016; Rudra et al, 2017; Srinivasan et al, 2017). A wide range of non-evidence based Ayurvedic medicines are used by people, which can have serious negative health and socio-economic consequences. Globally, many cases of heavy metal poisoning (such as lead and mercury) have been reported among people using Ayurvedic medicines (Ernst, 2002; Lynch et al, 2005; Karri et al, 2008; Kales et al 2009). Although many Ayurveda practitioners claim that heavy metal poisoning occurs due to the inadequate processing of heavy metals before they are used in Ayurvedic medicines (i.e., if the exact processing methods, as mentioned in Ayurvedic classical texts, are not followed), but robustly designed scientific studies are still lacking on this issue. In addition, many people simultaneously use multiple western and/or traditional medicines (i.e., polypharmacy) - many times without any evidence of effectiveness and safety and can lead to harmful drug-drug interactions (Aslam et al, 1995; Bhamra et al, 2017; Bush et al, 2007; Sarkar et al, 2013). Thus, strong concerns remain about the sub-optimal management and care of many people, arising from the unacceptable usage of non-evidence based Ayurvedic interventions. It is important to use only effective and safe Ayurvedic interventions and minimise the use of interventions that are of no, minimal or questionable value.

One of the major hurdles in the globalisation of Ayurveda is its poor scientific evidence base. Unfortunately, the interest of commercial pharmaceutical companies in conducting research studies is not always strong, as it is not possible to patent prior published knowledge (Chaudhary et al, 2012). In most cases, the scientific evidence base does not exist. Even if it does, it is of poor quality. Most of them are short-term

studies and are often associated with considerable methodological limitations, such as small sample sizes in treatment groups, resulting in lack of statistical power for outcome assessment, and poor concealment of treatment allocation, leading to potential analysis bias. In addition, most of them have evaluated Ayurvedic medicines but not Ayurveda as a system of care or complex intervention (Patwardhan, 2014).

4. Scientific evidence base of Ayurveda – the way forward

In the case of Ayurveda, there is a strong need for robustly designed pragmatic studies. One of the major research areas should be the evaluation of effectiveness and safety of Ayurvedic interventions through randomised controlled trials. The World Health Organization says that a traditional therapy (including Ayurveda) with an established history of use can proceed directly from basic animal toxicity studies to a phase III clinical trial (Chaudhury, 1992). The UK Medical Research Council's guideline for developing and evaluating complex interventions can be used for designing such studies (MRC, 2006). Many internationally recognised checklists for reporting research studies are available, which should be used to design such studies, such as the Consolidated Standards of Reporting Trials (CONSORT) 2010 (includes a specific checklist for herbal medicines) (Gagnier et al, 2006a, 2006b, 2006c; Moher et al, 2010; Schulz et al, 2010). However, research studies on Ayurvedic interventions should not be restricted to randomised controlled trials and should also include basic pharmacological studies, observational (epidemiological) studies, qualitative studies, economic evaluations, and systematic reviews (and meta-analysis). Some other important research topics are Ayurveda related education, health services and systems, and diagnosis methodologies. These studies will provide a complete picture of the situation and have the potential to make the scientific evidence base of Ayurveda strong.

5. Pathways to impact and communication plans

User involvement (patient and public involvement) in research studies is a major pathway to impact (Staley, 2009; Bagley et al, 2016). It should also be the backbone of research studies on Ayurvedic interventions. Such studies need to be carried out with patients and the public, to meet their needs and preferences. Research topics

should be identified and discussed with users and user groups. They should agree and acknowledge the importance of the research topic. The issues identified during these discussions should be taken into consideration while designing and developing such studies. These users and user groups should regularly take part in discussions and give feedback on different aspects of the project, including research tools, data analyses and interpretation, research updates and reports, and different mediums for communicating results. These collaborations should build relationships within the research community and should extend beyond the life of such projects. It is highly recommended to produce reports on user involvement and disseminate such reports.

In order to ensure the translation of research outputs into actions, key stakeholders should be continuously engaged from the beginning of any study. A range of key stakeholders, representing health policymakers and managers (of public and private healthcare providers), healthcare professionals including Ayurveda practitioners, patient and public groups, non-profit organisations, non-governmental organisations and international organisations, should be involved. Public-friendly research updates and brief final reports should be produced and disseminated through various avenues, including meetings, study and institutional websites, and online forums (e.g., Facebook, Twitter). The press offices of host institutions should also advise on how best to present and disseminate the findings. They usually have good contacts with the media. Press releases should be sent to the media in advance of newsworthy publications. The host institutions can release MP3 podcasts of topical research, an additional medium for dissemination.

The findings of research studies should be widely disseminated in the scientific community through publications in high-impact peer-reviewed open-access journals and presentations at national and international conferences. Both general and specialist conferences should be targeted for a wider coverage. The data (anonymised) on which a journal paper is based should be made available to the readers as an additional supporting file. Publications and additional supporting files should also be made available on the study and institutional websites. These dissemination strategies also have the potential to attract researchers for further collaborative research studies.

6. Beneficiaries and impacts

Research studies on Ayurvedic interventions have the potential to directly benefit people (patients and the public), health policymakers and managers (of public and private healthcare providers), Ayurveda practitioners and academics.

If Ayurvedic interventions are found to be clinically and cost effective, the clinical, personal and economic burden of diseases on people and their families/carers will be prevented or reduced. They will be provided with more evidence-based choices to prevent and manage diseases. These interventions may simultaneously empower people to manage their health. These interventions may reduce health inequalities and be beneficial to all of the society.

Health policy makers and managers will benefit from the availability of low-cost and acceptable evidence-based solutions to prevent and manage diseases since more expensive disease prevention and management models are in use. The economic burden of diseases on the health systems and the economies will be prevented or reduced.

Ayurveda practitioners will have access to evidence-based Ayurvedic interventions. They may potentially get a boost due to greater interest in their services, which may also enhance their job opportunities. These interventions may close the gap between what they do for preventing and managing diseases and what scientific evidence supports. These interventions may reinforce their position in prevention and management of diseases and offer them medico-legal protection.

The scientific research on Ayurvedic interventions has the potential to directly benefit academics working in at least two research disciplines - specific diseases and traditional therapies including Ayurveda. Such projects can bring together western medicine and Ayurveda experts. There will be mutual academic benefit and capacity building by cross-sharing of expertise and experience within the groups. A good quality cross-country project should be a collaboration between academics with complementary strengths, such as the UK's methodological expertise and India's large clinical networks. Such projects have the potential to improve scientific links between

countries and more broadly through wider collaborative links and networking. Greater use of these interventions has the potential to highlight the gaps in evidence, which may stimulate further research activities. Funding opportunities for research on Ayurvedic interventions are growing but are still limited. Conclusive evidence of the beneficial effects and safety of some of these interventions may lead to greater funding opportunities and conduct of robust studies. All these may greatly enhance the acceptance of Ayurveda by the scientific and wider communities.

Given that chronic diseases and ageing are global concerns and the cost is a concern everywhere, low-cost Ayurvedic interventions will be of interest to many countries, particularly South Asian countries and in countries with South Asian ethnic minorities. Such projects will involve collaborative research work to evaluate and implement these interventions in a range of settings and populations. Thus, research studies on Ayurvedic interventions have the potential to impact around the world.

7. Conclusion

Globally, the scope of Ayurveda is huge and has the potential to benefit a range of beneficiaries. In order to achieve this, the scientific evidence base of Ayurveda must be made strong.

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