

# Traditional medicine for global health

Public health and intellectual property aspects

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**This article focuses on the utilization of traditional medicine as an important catalyst to bridge the equity gap in global health care delivery. The authors touch upon validation of efficacy, regulation of safety, standardization of materials and harmonization of practices. The article draws substantially, though not only, from a study the authors had conducted for CIPIH-WHO in 2005.**

### Introduction

Unprecedented advances in science and technology have created a global village, breaking down geographical barriers and diffusing cultural boundaries. Ironically, as far as health care is concerned, the world population seems to have become more granular and polarized.<sup>1</sup> Though many of the health problems that bother developed countries have become distinct from those that threaten developing ones, in general, inequities in availability, accessibility and affordability of health care have increased, between as well as within populations the world over. While the costs of health care have increased everywhere, the quality of health care seems to be declining in every quadrant; and the percentage of population being denied sufficient quality health care is rising; though the reasons may be different for different groups of populations.<sup>2</sup>

Through the semi-permeable membrane that is globalization, the diffusion, transfer and exchange of benefits across the developed world and developing world and the problems related to health care are neither uniform nor equal. Problems related to health issues appear to enjoy higher permeability than benefits. This seems to indicate non-linear responses to health hazards, which in turn holds the distinct possibility of wiping out many steps of human progress.

In the field of health, developed countries seem to be encountering bottlenecks in drug discovery research and arriving at impasses in genomic and sub-cellular molecular research. These problems could be due to the complexity of the subject matter; or due to barriers of ethical, moral, or political dilemmas.<sup>3</sup> On the other hand, in developing countries, the non-availability of modern medicine, whether due to

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poverty or due to the absence of infrastructure; and the unreliability of alternative models of health care delivery like traditional medicines, whether due to the lack of proper and valid knowledge, or due to the lack of infrastructure to produce or distribute health care, or due to governmental oversight in ensuring the safety of consumers who avail of traditional medicines, seem to epitomize the challenges. While the two sets of challenges are quite distinct, they appear to work hand in hand to create a vicious spiral against human well-being.

But now traditional medicines (TM) are attracting more and more attention in the context of health care provision and health sector reform. Studies show that many patients use TM therapies concurrently with conventional medicine in developed countries,<sup>4</sup> while most people in most developing countries use traditional medicine for routine health needs.<sup>5</sup>

These are more than coincidences. The authors, like many others, contend that the rejuvenation of TM might be a result of adapting to the problems of health care,<sup>6</sup> and that the problems of both the worlds can be symbiotically addressed, and partly conquered, by scientifically developing and utilizing traditional medicines. This article takes a brief overview of some of the issues involved.

### Recognition

For full actualization of their potential, it is necessary that TMs are recognized, respected and endorsed by governments. The World Health Organization has defined three types of health systems to describe the degree to which TM is an officially recognized element of healthcare: the Integrative system (China, the Koreas, Viet Nam); the inclusive system (India, Equatorial Guinea, Nigeria, Mali, Canada and the UK); and the tolerant system (USA).<sup>7</sup>

The African Union has recognized TM. Kenya is seeking to catch up with Uganda and Tanzania.<sup>8</sup> Ghanaian health authorities took a major step in seeking to encourage TM practitioners. Integration is currently being supported in Australia.<sup>9</sup> China and India, among others, provide governmental support to strengthen training, research

and the use of TM in their national healthcare strategies.<sup>10</sup> Similar practices are also observed in other parts of the world, including the EU and the Americas. The recently published WHO Global Atlas of TM/CAM remains an excellent information and reference resource.<sup>11</sup>

Though tentative, these are encouraging signs in the right direction.

### Quality and safety

Safety is another important concern of TM. There are two aspects of safety evaluations: one, to ensure right quality of material and apt processes; and two, to ascertain no contamination, adulteration or spiking. In an analysis of Chinese herbal creams, Keane *et al* found that creams contained steroids.<sup>12</sup> Saper *et al* have reported heavy metal content in Ayurvedic herbal preparations.<sup>13</sup> Such studies are important and needed, but in essence they are more related to quality control (QC) failures of mass manufacturing activities. Often they are wrongly used to limit the use of TM. In fact, such a QC failure should not create a bias against TM.<sup>14</sup> Herb-drug interaction is another dimension of safety around TM. Botanicals are bound to contain several chemical ingredients - some useful and some harmful.

Addressing QC and standardization is vital, but needs broader consideration that gives due importance to traditional practices along with physico-chemical approaches. There are very few studies on the conjunctive use of TM and modern medicine, but they are very poignant.<sup>15</sup> The regulatory and legal situation regarding TM and herbal preparations varies from country to country, and the Traditional Medicine Programme of WHO has taken an excellent worldwide overview.

### Efficacy and evidence

There are philosophical and methodological aspects involved in evaluating the efficacy of TM. Reports of efficacy or otherwise have been published in prestigious international scientific journals. However, very few randomized-controlled trials (RCTs) have been carried out. A comparison of *Ginkgo biloba* with acetazolamide could not establish its efficacy as being significant-

ly different from that of a placebo; while another study reported side effects of its chronic treatment following rhytidoplasty and blepharoplasty.<sup>16</sup> *In vitro*, *in vivo* and gene expression studies on *Uncaria tomentos* extracts indicated anti-inflammatory activity mediated through negation of NF-kappa activation and TNF alpha synthesis suppression,<sup>17</sup> while randomized clinical studies on its purified extract demonstrated safer and moderate benefits in patients with active RA.<sup>18</sup> Several randomized trials on *Echinacea purpurea* extracts have reported health benefits in upper respiratory tract infections.<sup>19</sup> The Ayurvedic medicine *Withania somnifera* has shown cytoprotective, immunomodulatory and immunoadjuvant potential.<sup>20</sup> There is evidence that turmeric may slow down Alzheimer's and multiple sclerosis.<sup>21</sup> The Research Initiative on Traditional Anti-malarial Methods has attempted to standardize the quality of clinical studies on herbal antimalarials.<sup>22</sup>

Such mixed responses to efficacy and safety make a case for TM more difficult to sustain on evidence-based approaches. However, there are divided opinions on usefulness of RCTs in evaluating the efficacy of TM. A better understanding of the placebo effect is also vital in such evaluations.<sup>23</sup> It is argued that TM needs an entirely different methodology. For example, how does one measure changes in *qi* - a concept in traditional Chinese medicine - or the concept of *Prakriti* - a way to determine individual constitution in the Ayurvedic system?

An interesting study reporting genetic correlations between the various classifications of human beings based on an Ayurvedic concept underlines the importance of scientific research in these areas.<sup>24</sup> Evaluation of experiences and bringing consistency and objectivity to clinical studies on TM still remains to be attended satisfactorily.

### Education

It is becoming important to educate medical students and registered practitioners about TM therapies.<sup>25</sup> Scholars stipulate that formal collaborations between modern and traditional medical sectors needs to be encouraged and promoted.<sup>26</sup> Sri Lanka has a Min-

istry of Ayurveda. In India there are over 200 degree-granting colleges of Ayurvedic and TM-related education. In China and Korea, the teaching of TM has been institutionalized for many decades.<sup>27</sup> There has been a continuous debate in the Medical Council of India about adopting some essential components of TM in training modern medicine practitioners, but so far without much success. There have been legal cases related to cross-clinical practice, but in such process, the way is not only to prevent frauds, but also to facilitate dialogue between various healthcare providers and their patients.<sup>28</sup> Among countries, integration is currently being supported in Australia through government and organizations such as the Australian Medical Association, the Royal Australian College of General Practitioners and the Australasian Integrative Medicine Association. Similar practices for economic and social reasons are also observed in other parts including the EU and the Americas.<sup>29</sup> The National Center for Complementary and Alternative Medicine, established under the National Institutes of Health in the USA, remains exemplary and an inspiration to many. There is an urgent need to create world-class institutions of TM that are based on science and evidence-based research, where the state-of-the-art technology goes hand in hand with traditional wisdom and human resource development in this area is a priority.

### Availability, accessibility and affordability

Recent years have seen a range of initiatives targeted at improving the prevention and treatment of major diseases, especially tuberculosis, HIV/AIDS, and malaria. The growth of such campaigns, coupled with promises of new funding and high awareness of the health-dominated Millennium Development Goals (MDG), suggests that health in less developed countries can improve.<sup>30</sup> The Mexico Ministerial Summit was expected to assert that the traditional biomedical model of health research is wholly inadequate to tackle disease alleviation in the less-developed world.<sup>31</sup> The absence of health care is a driving force for the genera-

tion and maintenance of poverty and the issue is less science than it is of public policy but of the will of the rich world to generate the infrastructural environments to enable rewards of science shared equitably.<sup>32</sup> More studies on inequalities in health care use and expenditure are needed to inform policymaking.<sup>33</sup>

Although, there are very limited systematic studies to compare affordability and cost effectiveness of TM, some recent reports have substantiated the general belief that TM is affordable as compared to Modern Medicine.<sup>34</sup> In a recent RCT on 401 patients with chronic headache, the use of Acupuncture significantly improved health related quality of life at a small additional cost, compared with a number of other available interventions in the modern medicine.<sup>35</sup> Similarly, interventions through yoga and meditation especially in cardiovascular, psychosomatic, musculoskeletal and mental disorders have been beneficial at a considerably low cost and risks.<sup>36</sup> Saper et. al. reported that an estimated 15 million American adults had used yoga at least once in their lifetime and 7.4 million during the previous year. Yoga was used for both wellness and specific health conditions, often with perceived helpfulness and without expenditure.<sup>37</sup> Although, some of TM therapies offer a safer, better and cost effective alternative, more systematic research is needed to multiply these effects.

Thus, the public health agenda to health delivery in general, and then for using TM, has already taken roots. Yet, as the data show, it is sub-optimal to say the least, as of date, and a lot can be and needs to be done in order to utilize TM, a hitherto under-used resource, to serve the needs of population and diseases of developing countries.

### Innovation deficit

One of the most unsettling facts that the modern pharmaceutical industry has recently been facing is that its pipeline of new drug discovery seems to have almost dried up. The age of the blockbuster drug seems over, or at least in its last days and the usual distinctions drawn between breakthrough and me-

too drugs may not be very meaningful.<sup>38</sup> The pharmaceutical industry has not been as innovative as it claims to be, and regulatory processes are adding more risk and years for the pharmaceutical companies and it is predicted that the worst is yet to come.<sup>39</sup> To make matters worse, within developed countries themselves, the segments of price-controlling countries as in Canada, are growing larger by the day and making the bottleneck still tighter. Thus modern drug discovery processes, especially for developing countries like India, have started revisiting TM.<sup>40</sup>

### Reverse pharmacology

The TM knowledge database allows drug researchers to start from a well-tested and safe botanical material. For instance, with knowledge of Ayurveda, the normal drug discovery course of laboratory to clinic actually becomes from clinic to laboratory - a true Reverse Pharmacology Approach.<sup>41</sup>

A brief description of the reverse pharmacology approach and how it could save time, cost and toxicity - the three main bottlenecks in drug discovery - are given in the CIPHI report as a case study. In this process, safety remains the most important starting point and efficacy becomes a matter of validation. Globally, there is a positive trend towards holistic health, integrative sciences, systems biology approaches in drug discovery and therapeutics that has remained one of the unique features of Ayurveda.<sup>42</sup>

The concept of Rasayana has an important role in regeneration technologies research and immunodrugs discovery.<sup>43</sup> A golden triangle, consisting of traditional medicine, modern medicine and modern science will converge to form a real discovery engine that can result in newer, safer, cheaper and effective therapies.<sup>44</sup> It will be in the interest of pharmaceutical companies, researchers and ultimately the global community to respect these traditions and build on their knowledge and experiential wisdom.<sup>45</sup>

### Intellectual property

In a utopia, intellectual property rights (IPR) would belong to the entire humanity. But we are far from being there.

Until globalization, which began in a real sense only after World War II, and gathered unprecedented tempo in the last three decades or so, the IPR landscape was fairly stable, if not utterly calm. Like any other industry, the pharmaceutical industry goes by the rule that industry must make profit and expand, or, at worst, maintain it in a status quo. Market and regulatory incentives are two slopes towards which production and its precursors gravitate. Demand backed by affordability (at least true until recently) in the western world drove the pharmaceutical industry to be highly innovative, and the IPR protection of market economy in the form of patent monopolies fuelled its progress. The importance of TM in developing countries cannot be over-emphasized, as indigenous people cannot survive or exercise their fundamental human rights as distinct nations, societies and people without the ability to conserve, revive, develop and teach the wisdom they have inherited from their ancestors. Principle 22 of the Rio Declaration states that 'indigenous people and their communities have a vital role in environmental management and development because of their knowledge and traditional practices'.

### Ecological obligation

The significance of this concern becomes evident in connection with the discussion of article 8(j) of the Convention on Biological Diversity 1992, where it is implied that medicinal plants, blood samples from indigenous people and research conducted by foreigners into indigenous ways of life, supported by indigenous possessors of traditional knowledge, have led to patentable discoveries of benefit solely to those foreign researchers, with no economic return to indigenous people themselves.<sup>46</sup> The traditional medical knowledge of indigenous peoples throughout the world played an important role in identifying biological resources worthy of commercial exploitation.<sup>47</sup> Knowledge about the way in which local people have used plants has always been important to collectors. Unfortunately, no international system has yet successfully designed and implemented a mechanism that provides for an ef-

fective legal protection to traditional knowledge holders' rights at the international level.

### Sue Generis system

While the international focus is on issues surrounding the patenting of TK, it can be argued that a potent threat to the IPR of TK holders comes from the herbal sector. For instance, an appetite-suppressant of the San people of the Kalahari; a tradition-based AIDS medicine in South Africa; the Andean Maca and *Jeevani* plant of the Kani tribes of Kerala, South India, remain good examples of benefit-sharing between the communities and the herbal industry. The international view on this issue is best reflected in NIH-funded research in Australia, which led to the discovery of two cytokines that are now marketed by companies such as Amgen and Schering-Plough and have generated revenues of more than \$ 1.5 billion a year, raising questions about the substance of the benefit-sharing arrangements in the many inter-country agreements of NIH's National Cancer Institute.<sup>48</sup> The complexity of the situation outlined above brings us inevitably to consider some *sue generis* options to protect TK and its legitimate owners from exploitation. By their very definition, such laws do not fit within the existing frame of law and such a class does not belong to any taxonomic class. However, *sue generis* evolved exactly to accommodate such an impasse. This would require WIPO, the CBD and the WTO to coordinate their policies and legal instruments in partnership with TK holders as well as with conventional stakeholders, such as governments and industry. If this can be achieved, the health benefits offered to the world through the globalization of traditional medical knowledge will benefit communities and countries in terms of economic development and the growth of national pride in the preservation of culture and its harnessing for human well-being within the context of fair trade.<sup>49</sup>

### Conclusion

The health care system the world over, and more so in developing countries, seems to have become more complex

in the last half century, quite contrary to the astonishing advances in medical sciences and technologies. Riding the mammoth of progress, we humans unknowingly seem to have migrated to a new planet on the same old earth. The new ecosystem we have become a part of, is not quite the same as existed just five decades ago. The situation is precarious - though not yet calamitous. It may well become so, however, if we fail to address it in a rational and practical way.

Holism and integration-inclusion were once fashionable ideas of an isolated elite. Today, they are compelling necessities.

Modern medicine has reached an impasse. Its dilemma is not just technical or technological, even though superficially at places it may appear to be so. Deep within, however, it is connected to our very identity, values and aspirations. The questions that confront it are, in fact, echoes of the questions we ask of our destiny. Can a social system long endure, where a selected few humans get the best of the medical advances, while the bulk of humanity perishes for want of the basic needs of food, hygiene and elementary health care? Innovation in medical science needs and must be rewarded but the question is to what extent? Can innovations come out from within boxed laboratories alone? If not, then do innovators have an obligation to share their profits with the sources - even if indirect and remote - that contributed to novelty? Knowledge and research are means to an end - of serving humanity. We must not forget what Einstein said half a century ago, "Confusion of goals and perfection of means seems, in my opinion, to characterize our age."

Against modern medicine, TMs may not appear much but they are like catalysts and enzymes in biological processes - small in size and amount but beacons and guides to macro-processes. While the powerhorse of modern medicine mightily gallops, TM might keep it from falling into a sociopolitical trap that might throw the entire health care system quickly and decisively into irreparable jeopardy. TM seems a good buffer to level off extreme disparities in global health. It is hoped that research-

ers, policy makers and practitioners will see the pivotal place of TM in the global health-care system and use them wisely to navigate through the choppy waters of global unity.

### Acknowledgements

Thanks to WHO CIPIH Geneva for allowing use for some material from our report on TM; and to Dr R.A. Mashelkar for encouragement and guidance.

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Note: This article is based on a study report titled 'Traditional Medicine: Modern Approach for Affordable Global Health' created for the Commission on Intellectual Property Innovation and Public Health (CIPIH), World Health Organization, Geneva, in March 2005, and is available at the website: [http://www.who.int/intellectualproperty/studies/traditional\\_medicine/en/index.html](http://www.who.int/intellectualproperty/studies/traditional_medicine/en/index.html)

### International programmes on Chinese traditional medicine

China, the world's main producer of traditional and herbal medicines, has launched two international programmes for the modernization and safety research of Chinese traditional medicines.

#### International project on herbal medicines

It is the first time that China has initiated a multinational research project of this kind, which it hopes will provide an opportunity to boost health research in developing nations. The scheme has already attracted countries, including the United States, Japan and Singapore. The first 50 programmes, which will be selected by the ministry and matched with international partners, are due to start by the end of the year. Chinese drug companies will gain extra funding and access to advanced facilities in developed nations to help them develop their traditional medicines.

#### Traditional medicine safety research

The Chinese government has launched a new programme to fund research into the safety of traditional Chinese medicines. The programme aims to address 8-10 urgent technical problems that relate to seven areas of safety control in medicine. These include upgrading drug safety standards, improving pre-clinical safety assessments, improving safe drug production, and strengthening the supervision and alarm systems for traditional Chinese medicine (TCM). A key focus is the toxicity of TCM injections, because they are complicated - composed of dozens of or even hundreds of different herbs - making it difficult to identify the source of any adverse reaction. The new research programme aims to discover which substances cause negative responses - such as redness of the skin and shortness of breath - as a result of TCM injections. One potential research topic will be to find an efficient methodology to help identify which substances cause the reactions. In addition, the programme will help establish general drug quality control standards for laboratories for pre-clinical tests. Foreign researchers or institutes can participate as joint partners in the research, which is expected to begin by the end of the year.

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