

## CONFERENCE PROCEEDINGS

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# Integrating evidence-based traditional Asian medicine and Western medicine: Highlights from the Evidence-Based Traditional Asian Medicine Conference at the Stanford Center for Asian Health Research and Education

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Traditional Asian Medicine (TAM) encompasses a variety of modalities that are utilized by large segments of the world populations. This conference was convened to discuss the interface of TAM with Western medicine, highlighting issues of quality, safety and trust as well as future areas of development and research.

**Key Words:** Traditional Asian Medicine ■ Evidence-Based Traditional Asian Medicine ■ Traditional Chinese Medicine ■ Ayurveda ■ translational research ■ clinical practice ■ policy implications

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### KEY POINTS

- Traditional Asian Medicine (TAM) encompasses a variety of practices and is commonly used by a significant proportion of the world's population.
- As awareness of these practices increases in the West, the need for parameters to research interventions and establish the quality and safety of as well as trust in TAM practices is essential for more widespread adaption.
- The Stanford Center for Asian Health Research and Education (CARE) convened an international conference to share evidence for TAM practices in the areas of nutrition, mental health and pain as well as highlight areas of further research.
- Collaboration with partners to develop common research methods, increasing educational opportunities and creating clinical practices incorporating both 'Western' and TAM are opportunities for future advancement.

**T**raditional Asian Medicine (TAM) encompasses various interventions that are used by large segments of the global population, both in the countries of origin and beyond.<sup>1</sup> Based on population surveys, TAM comprises about 40% of all health care delivered in China, 69% in Korea, 70% in Japan,<sup>2</sup> 66% in India,<sup>3</sup> and 30% in Bangladesh.<sup>4</sup> In the United States, about 33% of adults report using herbal treatments, 14% yoga, and 14% meditation. As these ancient practice-derived healing modalities interface with 'Western' medicine, the interplay brings about three key issues in its use and evolution: evidence, quality, and trust. Examining TAM through this framework of evidence, quality and trust is important in advancing the conversation on optimal use of TAM.

Therefore, to study health conditions of interest to many populations and to explore which conditions are equally or better treated by TAM or by a combination of Western and Asian medicine, the Stanford Center for Asian Health Research and Education (CARE) held a virtual conference on Evidence-Based Traditional Asian Medicine from March 4th to March 6th, 2021.

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## POPULAR SCIENTIFIC SUMMARY

- Traditional Asian Medicine (TAM) is utilized in large parts of the world. This conference was convened to discuss the promise and challenges in utilizing evidence based TAM in treatment of common health conditions.

The event sought to answer three key questions regarding the evidence, quality, and trust surrounding Evidence-Based Traditional Asian Medicine (ETAM) practices:

- Evidence:** Are TAM practices effective in promoting health, addressing disease, or improving quality of life?
- Quality:** Is there sufficient commitment and consensus on the study components required for high-quality clinical research studies in TAM?
- Trust:** How can TAM make use of modern research to build public and clinician trust in its practices?

The conference first introduced the evidence-based applications of traditional Chinese medicine (TCM) and traditional Indian medicine (Ayurveda) in the realms of diet and nutrition, pain management, and mental health. It then highlighted the crucial need for common and rigorous guidelines by which to evaluate and compare ETAM practices from around the world. Finally, the conference called for building upon Western precision medicine through ETAM methods and integrating practices from each to build a more robust, global, and individually tailored approach to health and health care.

## BACKGROUND

Modern-day Western medicine values theory-driven empiricism, with the goals of prevention of illness as well as the identification and treatment of illnesses. TAM focuses on maintaining balance for the prevention of illness and restoring balance for treatment of illnesses.

Traditional Chinese medicine envisions health as a balance among five elements – wood, fire, earth, metal, and water – each of which corresponds to different parts of the mind and body. Balance through *yin* and *yang* (complementary forces of dark and light that make up all of life) is also key. An imbalance among *yin* and *yang* and the five elements can lead to various ailments. For example, if a patient were to lack *yin*, then the cooling aspects of the body would be low compared with the warming aspects, manifesting in a fast pulse, excess sweating, or dry mouth and skin.<sup>5</sup>

Similarly in Ayurveda, mind–body balance depends on the unobstructed movement of three energy principles (*doshas*) through the body. The combinations of these

three principles are known as *pakriti* (constitution), and the proportions of each vary and are unique to the individual. An imbalance of *doshas* can affect health in multiple ways. For example, if a patient's *pitta dosha* is out of balance, the increase in the 'fire element' may lead to heartburn, rashes, irritability, or inflammation.<sup>6</sup>

Whereas this paper will primarily discuss TCM and Ayurveda, many more systems of TAM exist. For example, Siddha is used in South India, Kampo in Japan, Jamu in Indonesia, and Unani in the Middle East.<sup>7</sup> Each of these TAM systems—TCM and Ayurveda included—is centuries or thousands of years old and uses multiple modalities, including external treatments (acupuncture, moxibustion, heated herbs) and internal treatments with herbal, mineral, and/or dietary interventions paired with spiritual and cultural practices.<sup>8,9,10,11</sup>

Nearly 40% of adults in the US report using approaches that complement or substitute for methods recommended by conventional Western medicine.<sup>12</sup> These complementary or alternative medicines include TCM, Ayurveda, mind–body interventions, dietary supplements, chiropractic care and other body-based methods, and energy therapies such as *qui gong* or *reiki*.<sup>12</sup> The increasing popularity of such treatments has raised concerns about gaps in knowledge and communication between patients and providers, who are often unable to provide counsel about the risks and benefits of these treatments.<sup>12</sup>

Despite efforts at the government, academic and private levels to support research and education in this field, more evidence, quality and trust are required to integrate complementary and alternative approaches into conventional medicine.<sup>12</sup> Therefore, to increase evidence for, quality of, and trust in these practices, systematically collected practice data and more well-controlled clinical trials focusing on measurable and reproducible outcomes need to be published. Given the high level of use of TAM in the general population, it is crucial to integrate Western and Asian medical practices by sparking a dialogue that investigates the advantages and merits of both. Western medicine, for instance, is strengthened through scientific rigor, documentation of efficacy and safety and regulation. Incorporating both Western and Asian models can strengthen current research, clinical practice, and delivery of alternative and complementary treatments.

## ISSUE 1: EVIDENCE

Historically, challenges in developing consistent research methodologies have hindered the development and implementation of traditional practices into modern medicine. Although research in ETAM is conducted in both countries of origin and in the West, variability exists in the production and administration of ETAM treatments. For example, the distillation of herbal products to their active ingredient can vary between countries, as can standards for tailoring treatments to individual patients.<sup>13</sup>

Identifying placebos for multi-herb herbal products is also challenging. Differences in these protocols impede the comparison and meta-analysis of a single ETAM treatment across different countries. Comparing multiple practices is even more difficult. Therefore, a rigorous, mutually agreed-upon methodology to establish and evaluate evidence is fundamental to developing patient-centered care and integrating Western and Asian Medicine.

One possible methodology is the comparative effectiveness study: determining the effectiveness of different medical strategies by testing them in a real-world setting. Under the US Food and Drug Administration (FDA) mandate, American clinical trials emphasize testing new therapeutic drugs against a placebo control arm in a population of patients with a given condition.<sup>14</sup> In contrast, the Patient-Centered Outcomes Research Institute has shifted research toward comparative effectiveness and patient-centered outcomes in a real-world setting, without the limitations of patient selection and study procedures.<sup>15</sup> Under the '21st Century Cure Act', real-world health care data and real-world clinical evidence are allowed to support regulatory decision making by the US FDA.<sup>16</sup>

Some TAM practices have been shown to be effective. Acupuncture, for example, has been shown to improve patient outcomes in chronic pain, back and shoulder pain, headaches, rheumatoid arthritis, and other afflictions.<sup>5</sup> In one study, 40–60% of patients with chronic low back pain respond well to treatment.<sup>5</sup> Furthermore, similarities in the effects of real and sham acupuncture needling have raised uncertainty about acupuncture's mechanism of action and posed a challenge to find an appropriate control intervention for acupuncture trials.<sup>17</sup>

How, then, can comparable research methodologies be created in TAM?

In TAM, evidence takes on a different meaning. It incorporates direct observation, inference, knowledge passed down through a lineage of healers, and knowledge derived from reasoning. Moreover, recommended treatments are tailored based on the overall constitution of the patient.

Furthermore, TAM offers a myriad of treatments to address a single or multiple illnesses. Chronic lower back pain, for instance, can be treated by traditional Chinese acupuncture, Ayurvedic herbal therapies, oil treatments, cleanses, and massages, or any number of traditional practices. To assess these practices, clinical trials may need to include multiple 'arms', each testing a different practice and approaches within the practice. For example, when studying various treatments for insomnia, different study groups could undergo acupuncture, herbal treatment, Ayurvedic treatment, a Western drug, or a placebo. The best therapies are personalized and designed to alleviate symptoms (which may manifest differently in different patients) and improve patients' quality of life.

The patient-centered, individualized ETAM approach also complements Western medicine's growing emphasis

on 'precision health'. Precision health considers a patient's unique genes, behaviors, and environment to craft treatments and health interventions tailored to the patient's individual needs.<sup>18</sup> Precision health moves beyond the realm of the clinical setting, emphasizing disease prevention and health promotion in the community and home.<sup>18</sup>

Modern medicine has begun to move toward this model, recognizing that there is no 'one-size-fits-all' treatment for illness. Indeed, illness and disease risk may present in a myriad of ways across a non-homogenous population. For example, individuals of Asian descent are at increased risk of type 2 diabetes mellitus at a body mass index (BMI) of 23, compared with a BMI of 25 in non-Asian individuals.<sup>19</sup>

Precision health has long been the standard in TCM, which emphasizes pattern differentiation in the treatment of illness: the analysis and summarization of clinical symptoms obtained through regular inspection, auscultation, inquiry, and other methods. At every stage of illness, the 'pattern' – the patient's unique pathological signs and symptoms – is obtained and analyzed to understand the 'disease' and guide individualized treatment.<sup>20</sup> Similarly in Ayurveda, two patients displaying the same symptoms may receive different treatments based on their individual *doshas* or constitutions. Each person's unique ratio of the three *doshas*—*vata*, *kapha*, and *pitta*—is believed to influence their physiological, mental, and emotional health, as well as provide Ayurvedic practitioners with a roadmap to restoring that person's health.

TCM and Ayurveda also fundamentally embody a holistic approach to medicine, which aims to not only treat illness or injury but also address its symptoms and underlying causes in the context of the whole person.<sup>21,22</sup> A holistic Western or TAM physician analyzes the patient's overall mental, physical, and emotional well-being to craft a treatment plan tailored to the individual, in what is known as a 'mind, body, and spirit' approach to medicine.

Bringing these traditional practices to Western medicine may require the establishment of integrative clinics that address specific clinical illnesses and facilitate the execution of clinical effectiveness and cost-effectiveness trials. It will also require advanced information systems to capture the diagnosis, treatment, and patient outcomes in a real healthcare environment. These separate specialty clinics will incorporate ETAM practices and enable large, collaborative studies across countries and institutions to generate real-world evidence. Experts in China and India have successfully created such clinics, each offering diverse modalities of treatments directly to patients.<sup>23</sup> A study in India, for instance, is investigating the effects of various Ayurvedic treatments on autism. These treatments include Ayurveda herbal medications, herbal massages, and music therapy. By looking at the examples of international experts, these

systems can be replicated in the West to provide more culturally tailored treatment for an increasingly global patient population.

A subset of patients across these international integrative clinics would also help address the challenges of clinical effectiveness studies, namely the large study population required to perform them. The many 'arms' of various ETAM practices can be tested among these patients by assessing the efficacy and effectiveness of each among a non-homogenous population. Pattern differentiation can be leveraged to tailor individual treatment at every stage of disease and promote holistic and precision health to consider the mental, emotional, genetic, and social factors contributing to illness. Partnering with centers who have expertise in this type of research, such as the Stanford Center of Innovative Study Design, can advance this type of research.

In addition to integrative clinics, another approach to gathering ETAM evidence could be to randomize health conditions to Western or ETAM practices and analyze patient-centered outcomes such as safety, effectiveness, equity, or quality of life measures.<sup>24</sup> Given the unique strengths and limitations of these practices, their incorporation into a unified system can increase the options available to patients and providers, expanding the global medical 'toolbox' to improve overall outcomes.

By bringing integrative ETAM to the people, modern medicine can evolve to offer precision health and individually tailored treatment plans directly to patients. Academic institutions may be uniquely positioned to integrate ETAM, leveraging diverse patient populations and clinical expertise to bring East and West together.

## ISSUE 2: QUALITY

Studies of TAM abound in the literature and a few ETAM practices are incorporated into Western clinical practice. The challenge is not a lack of studies, but rather a lack of adequate quality studies for many modalities, a lack of exposure to these studies among Western practitioners, and a lack of familiarity among the public.

Currently, there is great variation in the quality of ETAM research, with issues ranging from lack of training of practitioners, infrastructure, and standardization to inadequate numbers of trials and low rates of trial participation. In the West, the quality of a study's design rests upon a rigorous delineation of the study design, study population, comparison groups, interventions, measurability, and outcomes. Many studies of TAM fail to meet adequate standards for these study components. This was also true of Western medicine studies until 1996, with the International Conference on Harmonization Good Clinical Practice (GCP).<sup>25</sup> Studies on acupuncture in the West for pain relief, for instance, suffer from small sample sizes and significant variations in treatment protocols and duration.<sup>5</sup> As a result, comparison of

these protocols to similar studies conducted in Asia is challenging, where acupuncture is the norm and where frequency and duration of treatment differ.<sup>5</sup> Furthermore, studies of acupuncture in Asia utilize greater sample sizes and are randomized, blinded, and placebo-controlled, wherein sham treatments involve non-penetrating needles or needling at non-acupuncture points.<sup>5,17</sup>

Therefore, a consideration is to develop a consistent methodology for study design, conduct, and reporting to guide future ETAM research, incorporating both Asian and Western perspectives to build robust, high-quality studies. There must be a collaboration between Western institutions and ETAM institutions – which primarily focus on the practice of traditional healing systems – to collectively create evidence supporting ETAM approaches. Modern Western medical research guidance, for instance, has already been adopted by TCM.<sup>20</sup> Fostering this collaboration will increase the validity of the data, lead to publications in well-regarded peer-reviewed journals, and increase awareness.

Critical to this effort is the support and approval of the American FDA and global regulatory agencies, which focus on real-world evidence and data. Therefore, in designing well-controlled, prospective ETAM studies, the examples of global experts can be built upon to establish a database of reliable, real-world, unbiased data. Establishing electronic health records (EHR) that can capture and document ETAM interventions in a consistent and accurate manner to allow analysis across centers/platforms (such as the OMOP Common Data Model) would help in establishing a database of knowledge. As in China, ICD-11's new code must be used for studies in TCM, rather than ICD-10, which is used in the United States and contains no such code. ICD-11 is projected to be used in the United States in the next few years.<sup>26</sup>

Interpretation of study findings should also consider scientific integrity in study design and conduct, data sources and quality, clinical validity of the research hypotheses, instead of relying only on the 'P-value < 0.05' for determining clinical effectiveness. There is a need to review current statistical tools and investigative methods to eliminate bias and ensure the validity of clinical research findings.

In addition to validity, the execution of clinical trials in ETAM must follow universal and mutually agreed-upon standards such as GCP.<sup>27</sup> The GCP set an international standard for the design, performance, supervision, reporting, and ethical principles of clinical trials.<sup>27</sup> These standards ensure the credibility and accuracy of a trial's data, as well as the rights, safety, welfare, and confidentiality of its subjects.<sup>27</sup> Although countries in the Asia Pacific region—Singapore, China, Malaysia, Thailand, and Indonesia, among others—have increasingly adapted GCP to formulate their own guidelines, it remains imperative to harmonize these guidelines into a single set

of criteria for ETAM studies and practice<sup>27</sup> and identify areas in which modifications are needed for ETAM-based studies.

Finally, it is vital to ensure the quality of not only ETAM research but also ETAM practices. Western medications are distilled down to their active ingredients, dispensed to patients with an understanding of certain medical risks. In contrast, ETAM studies do not systematically assess the risks associated with certain practices, leading to issues of safety and trust among patients, providers, and skeptics. Certain ETAM products are susceptible to manufacturing errors and lack of quality standards and are not regulated by the US FDA. When manufacturing herbal products, for instance, one herb might be mistaken for another, products might be contaminated, ingredients may be mislabeled, and large variations can be observed in herbs from different regions. It is essential to implement strict safety and quality control measures to eliminate these risks and provide the best care to patients.

In this discussion of the quality of ETAM and Western medicine, the goal is to understand what ‘works’ and what does not in order to integrate complementary practices into modern global medicine. In ensuring the quality and safety of these practices, this goal can be achieved.

### ISSUE 3: TRUST

Bad studies are worse for credibility than no studies. In other words, skeptics will remain suspicious of ETAM in the absence of rigorous research protocols, clinical and practitioner expertise, and governmental support. Trustworthy studies should also consider generalizability: the ability to apply the results of a study to broader patient populations, a marker of high-quality evidence. Therefore, creating uniform standards for research, clinical practice, and policy implementation is critical to gaining public trust in ETAM. Transparent reporting of study findings that follow these established standards is also a critical step in establishing trust and is an opportunity to refine ETAM practices based on research outcomes.

First, trust in ETAM must be increased among patients and providers alike, namely by translating research into common clinical practice. In the world of Western medicine, the dissemination of scientific information takes on average 17 years for research findings to be incorporated into the clinic and mastered by providers.<sup>28</sup> Starting with the available resources, studies and known outcomes can be the foundation of further investigation. It is important, for instance, to learn from experts in China about the clinical side effects associated with acupuncture treatment or from experts in India about a prospective observational study, utilizing subjective and objective assessments, biochemical markers, and brain imaging indicating that treatment of the digestive system reverses

memory loss, a condition for which there are few treatment options.<sup>29</sup> Creating a database of clinical knowledge based on studies like these will help build upon pre-established foundations of trust, experience, and practice.

Second, common ETAM clinical practices must be broadly disseminated through medical education and increased awareness. Whether in medical school curricula, residency, fellowship, or continuing medical education (CME), evidence of effective TAM practices must be taught and shared throughout medical learning. Another key step in advancing ETAM education is to increase the publication of ETAM studies in reputable medical journals, which can spark international dialogues on the integration of ETAM into medical education.

Third, the role of the government in certifying and licensing ETAM practitioners must be addressed. Currently, practitioners of TCM in the United States must complete various requirements set by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). These requirements include attending an NCCAOM-certified school, completing relevant courses, and passing an NCCAOM-administered exam.<sup>30</sup> Requirements for certification and licensure vary based on the TCM practice.<sup>31</sup> Acupuncture, for instance, is strictly licensed, but exact requirements vary between states.<sup>31</sup> In contrast, *gua sha*—a facial massage technique aimed at relieving muscle pain—is not considered for certification or licensing at all.<sup>31</sup>

Currently, few TCM practitioners in the United States are certified or licensed, leading to skepticism among patients and providers alike.<sup>31</sup> For example, in places like Hong Kong, licensing and registration requirements are difficult to enforce.<sup>32</sup> It is therefore critical to build upon the licensing and clinical management practices of international experts to combat this skepticism. Besides schooling, written and practical exams, and legal registration with supervisory departments,<sup>33</sup> modern methods must be implemented into traditional clinics. Many TCM clinics—and rural and remote Western clinics—lack the basic infrastructure for electronic medical records, which would help with issues involving management, communication, legibility, and coordination of care.<sup>34</sup>

Finally, to complete the translation of ETAM from bench to bedside, insurance coverage for ETAM practices must be secured and their accessibility to the general public facilitated. Except for acupuncture for chronic lower back pain, most practices from TCM and Ayurveda are not covered by Medicare.<sup>35</sup> (And acupuncture coverage arrived only in January 2020, in response to the increasing abuse of opioids across the country.<sup>35</sup>) It is vital to secure similar coverage for other proven TAM treatments in order to integrate ETAM into everyday Western medical practice.

## A CALL TO ACTION

Currently, there are challenges in the areas of evidence, quality, and trust surrounding the practices of TAM. It is essential to reach across international borders to develop research, clinical, and policy guidelines that determine, for instance, the efficacy and quality of practices as well as the licensing of ETAM practitioners.

Therefore, major ETAM interventions must be strategically targeted that address major public health issues afflicting both Western and Asian populations. Specifically, these targeted health conditions might be those (1) inadequately treated by Western medicine strategies, (2) equally or better treated by ETAM alternatives, or (3) improved by a combination of complementary Western and ETAM strategies. Based on these criteria, these conditions might include cardiometabolic diseases, neurodegenerative diseases, mental health disorders, and autoimmune diseases.

Through these areas of strategic focuses and validated outcome measures, Western precision medicine can be improved through the framework of TAM: tailoring health recommendations and treatments based on the needs, symptoms, and conditions of the individual patient.

In sum, it is not the 'superiority' of one system or another that dominates this discussion of Asian and Western medicine. Rather, it is the recognition of the strengths and limitations of each, and the assessment of how each can complement the other, that will move the field of medicine forward. Daring to innovate, sparking dialogues about medical integration, and ensuring the evidence, quality, and trust of ETAM practices will foster collaboration across international borders and build a truly global approach to modern medicine.

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