

Scientific Validation Review
Indigenous Knowledge Distance Learning Course
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National Centre for Complementary and Alternative Medicine, National Institute of Health, USA

The National Centre for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science, educating and training CAM researchers, and disseminating authoritative information to the public and professionals.

NCCAM's vision is to advance research to yield insights and tools derived from complementary and alternative medicine to benefit the health and well-being of the public, while enabling an informed public to reject ineffective or unsafe practices.

NCCAM currently supports a broad portfolio of research. The Center conducts outreach activities, including the dissemination of information through the NCCAM Clearinghouse and the NCCAM website. Programs to expand basic and clinical research, train investigators to conduct CAM research, disseminate information, and facilitate integration of CAM and conventional healthcare delivery are essential in moving the CAM field forward. The Center has four priorities: Research, Research Training, Information Dissemination, and Integration.

In Research, NCCAM promotes the use of clinical trials of CAM substances and modalities that appear from evidence-based reviews to be the most promising and important. NCCAM also aims to study entire systems of traditional and indigenous medicine that have been practiced over the centuries. Such studies may identify additional health tools of potential use to the American public and may present opportunities to address health disparities and the needs of special populations.

NCCAM also conducts basic science research to understand how mechanisms of action with mixtures of herbs and not as single agents. The research center also contributes to other NIH projects such as the biology of brain disorders; new preventive strategies against disease; and new avenues for the development of therapeutics.

In Training, NCCAM encourages skilled researchers to investigate CAM approaches and train CAM and conventional practitioners to conduct or participate in rigorous studies.

Finally, in Integration, NCCAM must work to overcome the reluctance of conventional healthcare providers to consider CAM therapies. NCCAM plans to increase these opportunities for training medical and post-graduate professional students to become educated about CAM. With this information, they may knowledgeably guide and refer patients toward safe and effective CAM applications and practitioners experienced in delivering them.

NCCAM has identified four strategic areas to achieve its mission: Investing in Research, Training CAM Researchers, Expanding Outreach, and Facilitating Integration.

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In Investing in Research, NCCAM will advance research by encouraging and supporting CAM research projects. The Center's highest priority is clinical research, both with respect to individual therapies and entire systems of medicine. The largest investment will be in clinical trials. The center is also committed to building research capacity and infrastructure, both intramurally and extramurally (US and abroad).

Goal 1: Stimulate submission of high-quality applications in CAM priority areas by both CAM and conventional investigations. The objectives in this goal are to exhibit NCCAM information at professional meetings and conduct grant-writing workshops; sponsor interdisciplinary conferences to stimulate broad-based research; and assist in extramural CAM researchers and practitioners to develop and participate in high quality research applications.

NCCAM will develop a cadre of investigators in CAM research by providing appropriate career development opportunities; by increasing the knowledge, experience, and capacity of CAM practitioners to conduct rigorous research; and by enhancing conventional practitioners' and researchers' knowledge and experience in specific CAM areas.

Goal 2: Increase the number, quality, and diversity of CAM investigators. The objectives for this goal include: stimulate collaborations between CAM practitioners and investigators in the conventional academic medical community; Develop programs to train individuals in CAM-related laboratory and epidemiological research; train doctors of medicine, osteopathy, chiropractic, and naturopathy, and others with advanced degrees in relevant clinical disciplines, to conduct CAM-related clinical research; initiate quality research training programs; increase the number of trainees from under-represented populations; establish an interdisciplinary, intramural NIH research training program.

In facilitating integration, NCCAM will work to facilitate a more integrated practice of medicine. CAM and conventional healthcare professionals would function as interdisciplinary teams to deliver an expanded repertoire of safe and effective treatments that include a focus on the whole person.

Goal 1: Facilitate the development of health education curricula that respect and incorporate insights and opportunities afforded by safe and effective CAM and conventional practices. The objectives include: fund educational grants to develop model curricula regarding CAM practices for schools of medicine and allied disciplines; and fund educational grants to develop model curricula regarding conventional medical practices and research methods of schools of complimentary and alternative medicine disciplines.

Goal 2: Facilitate coupling of effective CAM and conventional practices within a coordinated, interdisciplinary delivery system. The objectives in this goal include: sponsor national meetings, conferences, and workshops on validating CAM therapies to enable practitioners and all other concerned parties to identify effective interventions for use in treating patients; disseminate CAM research findings to healthcare providers; identify and develop methods to overcome barriers to the investigation of safe and effective CAM practices; support the demonstration projects focusing on how most effectively to translate CAM research findings into

practice; facilitate integration of effective CAM practices into routine healthcare delivery for NIH clinical center patients; support enhanced communication and partnership-building between conventional and CAM healthcare institutions.

Case study: International Center for Indigenous Phytotherapy Studies Project

The NIH has provided the University of Missouri (MU) at Columbia, USA with a research grant to form the International Center for Indigenous Phytotherapy Studies (TICIPS) in collaboration with the University of Western Cape, South Africa (UWC) and the Missouri Botanical Garden, St. Louis (MOBOT). MU has outstanding research and educational programs in health care quality improvement and biomedical sciences, including the MU Center for Phytonutrient and Phytochemical Studies. UWC has outstanding CAM research and educational programs, especially in medicinal plants, and extensive ties with South Africans that use traditional healers, and with the South African government. MOBOT is the North American center for research of African flora.

This grant will build upon a 17-year relationship between MU and UWC, to define the mission, vision and strategic plan for TICIPS. It will develop the administrative infrastructure to support collaborative research studies and joint educational activities and will assess resources and needs required for the establishment of a comprehensive international center for research on complementary and alternative medicine. During Phase I, sound administrative structures and policies will be established to ensure compliance with both countries' regulations on the conduct of research with human subjects and animal subjects, financial disclosure, conflict of interest and intellectual property rights. Several pilot projects will be initiated to demonstrate the capabilities of the partners and to initiate research and training efforts that fulfill the goals of NCCAM.

The first pilot will open a Phase I clinical trial on *Sutherlandia frutescens*, an herbal used to deter wasting in AIDS patients. The second pilot will study *Tulbaghia violacea* as an indigenous phytotherapy for candidiasis. The third pilot will evaluate *Hypoxis hemerocallidea* phytotherapies for prostate hyperplasia and cancer. Planning and execution of these projects and the development of an administrative core will lay the foundation for a desired subsequent ICRC research grant.

National Reference Centre for African Traditional Medicines: A South African Model

“This report reviews the work done to date in African Traditional Medicines and further proposes a framework for African Traditional Medicines of plant origin in the form of the National Reference Centre for African Traditional Medicines.”

Currently in South Africa, at least 70% of the citizens consult one of the 200,000 Traditional Healers in the country. While there is difficulty in the regulation of traditional medicines, the National Department of Health, in South Africa, provided a regulatory framework to register, regulate and control African Health Practitioners.

In addition, there are numerous institutions in South Africa that are conducting research on traditional medicines to preserve its use and promote for the safe, effective, and good quality of the medicines. Efforts are being made to document these medicines and credit them with scientific validation. Some of the institutions involved in this work include, University departments, Government departments (Science and Technology, Agriculture and Land Affairs, and Trade and Industry), and research institutions (Council for Scientific and Industrial Research, Medical Research Council, Agricultural Research Council). The research institutions are discussed in detail below.

The Council for Scientific and Industrial Research (CSIR) is an institution that supports sustainable development and economic growth. Their program focuses on numerous activities including scientifically validating herbal medicines, discovering new pharmaceutical active ingredients from herbal medicines, and creating community-based opportunities to produce medicinal and aromatic crops. The Medical Research Council (MRC) addresses health research priorities that were neglected in the past. The Medicines Control Council (MCC) focuses on safety, quality and efficacy of medicines.

Special committees have also been created to deal with the specific objectives of the National Reference Centre for African Traditional Medicines. Five areas were developed, some examples include: (1) Claims for cure: to consider the propagation of and protection of medicinal plants; (2) database: to organize scientific information on medicinal plants and make it accessible to the public; and (3) Education: provide educational needs to traditional practitioners so they have an opportunity to create a health care system for their patients.

Enlarging the Paradigm – Understanding traditional medicine in modern terms

In *Enlarging the Paradigm – Understanding traditional medicine in modern terms*, D. Balasubramanian, argues for a synergistic approach to modern-day patient treatment. He showcases the traditional medicines in India as a case study.

He discusses popular and effective ancient systems of medicine, such as Ayurveda and Unani that existed in India before the British rule. After the British colonized India, however, these ancient systems of medicine were not valued and validated to the standards and quality of Western medicine. Practitioners of Western medicine were skeptical of these Indian Traditional medicines. They commented that the approaches to treatment and paradigms of thought between the two systems were extremely different, therefore, no connection could be drawn between them. Gradually these medicinal systems were lost to Western medicine and it resulted in a knowledge gap between Western scientific thought and Traditional scientific thought.

Over the past decade, Balasubramanian notes that much research has been conducted to validate these Indian traditional systems of medicine and include this knowledge in the on-going modern scientific dialogues. For example, about 15 years ago, pharmacologists determined that acupuncture treatment increased endorphin and opioid-peptide levels in limbic systems. This explains why acupuncture eases pain from headaches, body aches, and migraines. In addition, Balasubramanian presents studies showing how combining traditional and modern medicines can facilitate and increase the effectiveness of modern medical drugs. For example, he describes a

study in which pepper, a herb traditionally used to repel flies and kill insects in foods, also enhances the transport of modern drugs across the cell membrane.

<http://www.jadecampus.com/news/ap19mar00.htm>

Traditional Chinese Medicine

In *Traditional Chinese Medicine*, Robert Yuan and Yuan Lin discuss how ancient Chinese practices of medicine can complement modern Western medicine. They write that Traditional Chinese Medicine (TCM) is an important part of the Chinese cultural heritage and dates back to thousands of years. They reference Nei Jing's *the Yellow Emperor's Classic of Internal Medicine* as the world's "first known medical document." This document is from 3rd century BC. In addition, to Nei Jing, they write that a century later Shen Nong in the Han Dynasty wrote "the first known guide to herbal medicine" documenting over 365 substances and their pharmacological effects.

In the modern era, however, they note that TCM lacks scientific basis and is seen as mythical. Mainstream America, therefore, fails to understand the beneficial uses of TCM and remains skeptical. Western scientists also fail to understand TCM because of the philosophical differences that exist in TCMs approaches to treatment. In addition, the mechanisms of action seen in TCM drugs do not align with Western Standards such as those written out by the FDA. For instance, results with TCM are not seen immediately because the focus is more on improving one's health for the long term instead of immediate. Patent protection is also of issue. The authors write that since TCM preparations are in the public domain, patent protection on them is difficult to establish.

The authors note that in order for TCM to be considered scientifically valid, FDA protocols cannot be used to validate the use of them. The authors present seven research steps to thoroughly understand TCM and scientifically validate them to Western science.

The authors conclude by noting the importance of integrating Western medicine and TCM. They write that such efforts are already taking place in North Korea and parts of China, partially due to economic necessity, however, more due to improving the quality of life. As an example, they present that cancer patients in these countries receive chemotherapy, radiation, and surgery to fight the cancer cells. In addition these treatments, however, they also receive Chinese herbs (TCM) to fight the side effects of nausea, pain, and weight loss that accompany such Western treatments. They believe that this type of integrated approach will help maximize treatment for patients.

<http://www.cosmos-club.org/journals/2002/yuan-lin.html>

Clinical trial platform for Traditional Medicine

The Medical Research Council of South Africa writes that it is necessary to conduct clinical trials on traditional medicines. This is in order for the products of traditional medicines to be marketed to the public nationally, regionally and internationally. They provide guidelines for testing the safety, effectiveness, and quality of the traditional medicines in preparation for clinical trials. In addition, they provide the duration of the clinical trials in order to meet

acceptable Western scientific standards. Funding is provided by the Medical Research Council of South Africa. In addition, research projects, such as creating databases to document traditional medicine use, are also occurring. Most of the databases are open for public use.

<http://www.mrc.ac.za/innovation/iksclinical.html>

Complementary and Alternative Medicine: a Japanese Perspective

In *Complementary and Alternative Medicine: A Japanese Perspective*, Nobutaka Suzuki writes that the use of complementary and alternative medicine (CAM) is increasing rapidly. Suzuki writes that the World Health Organization classifies 65-80% of the world's health care to be traditional; hence, more people are using CAM than the conventional medicines available to them. Suzuki presented a case of study of the use of CAM in Japan.

Though limited scientific evidence has been researched on CAMs, they are popular among Japanese consumers for several reasons. These reasons include including, CAM is non-invasive, has few side-effects, improves the quality of life and daily life, and it is a holistic medical approach.

He writes that unlike Western countries, Japan's public health insurance covers CAM treatment. In fact, Japanese doctors have positive attitudes towards CAM. In a questionnaire, 267 out of 300 doctors in Japan (73%) reported that they use CAM in their practice.

In addition, Suzuki presents studies of CAM and patient use. For example, he goes into detail on the use of CAM dietary supplements among the Japanese population. He writes that in a telephone survey most people in Japan prefer using CAM for minor illnesses than seeing a doctor or using conventional medicine. He writes that the high use of CAM in Japan may be due to the cultural connection Japanese have to CAMs, however, integration between Western and CAM systems should also occur in other countries, especially in America.

<http://ecam.oupjournals.org/cgi/content/full/1/2/113>

Regional Medical Research Centre, Belgaum, India

The Regional Medical Research Centre in Belgaum is an institute dedicated to proving "the scientific validation of traditional medicine, improving the infra-structural facilities and strengthen human resources in the area of traditional medicine. The centre is also creating general awareness and promoting scientific temperament in traditional medicine and to disseminate information." The major areas of research at this centre are cardiovascular diseases, diabetes, hepatoprotectants, tuberculosis, malaria/filariasis, STD/RTI, wound healing, geriatric medicine, topical microbicides, and immunomodulators and adaptogens. Some of their current research projects include, studies on prevalence of diseases in Belgaum division, survey on traditional formulations/products practiced for treatment of various diseases especially in the area of maternal health and childcare in Belgaum division, and medicinal plants of Western Ghat region.

http://icmr.nic.in/000522/ins_profile.htm