

A CASE STUDY OF TIBETAN MEDICINE: EXAMINING CHALLENGES OF  
ESTABLISHING THE CREDIBILITY OF TRADITIONAL MEDICAL SYSTEMS

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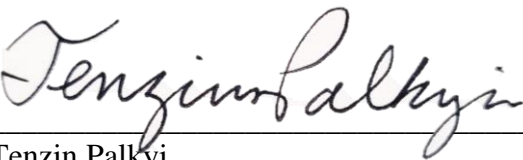
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**A Case Study of Tibetan Medicine: Examining Challenges of Establishing the Credibility of Traditional Medical Systems**

  
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5/14/21  
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## **Abstract**

The medical field is seeing a shift in healthcare delivery from a disease-centered model that focuses on curing acute illnesses to a more holistic approach which prioritizes overall well-being and preventive care. With this transition, there has been an increased interest in complementary and alternative medicine- (CAM) based interventions, leading to the emergence of the Complementary and Integrative Health (CIH) field. As CIH interventions like Tibetan medicine (TM) become more widely used, recent research is being conducted to determine these treatments' potential effectiveness and to address skepticism about their relevance in health care. This thesis intends to explore TM as a case study of traditionally- based systems of care, which consider all aspects of a patient, including mental, physical, and social factors. Furthermore, this thesis will outline the evolution of TM from its inception through recent geo-political changes in addition to the global reach TM has had in Western societies. A non-systematic literature review was conducted to identify current studies available on TM's effectiveness, explore gaps in TM research, and articulate challenges that traditional medical systems must overcome to further develop its evidence base. Some of these challenges include improving research quality, navigating inconsistent regulations of herbal compounds, and balancing the difficulty of conducting scientifically sound medical research without sacrificing the cultural integrity of non-biomedically based systems of care. Based on this analysis of Tibetan medicine, I propose recommendations that may serve to systematically integrate complementary medicine into future Western medical training. By addressing challenges with tangible solutions, traditional medical systems can further develop their evidence base, build credibility in Western societies, and be more accessible by being safely offered independently or together with allopathic medicine.

Key terms: traditional medicine, CAM, Tibet, challenges, integration

## **Introduction**

Currently, in the United States medical field, there is an evident commodification of health care that caters to providing acute, quick fixes to patients' concerns (Rosenthal, 2018). For example, to treat chronic back pain, a physician may prescribe over-the-counter medicine or refer patients to a specialist to complete additional imaging. If a patient chooses to do the imaging but it comes back with no explanation for their pain, how would they feel knowing that their constant discomfort is not validated by modern technology and that their symptoms would most likely be superficially managed with prescription medications?

This belief that health simply encompasses the physical state of not having illness is incomplete. Additionally, according to Manahan (2011), this single cause/single treatment approach presents healthcare professionals as experts that laypeople should unquestioningly listen to and believe. Not only are physical and mental well-being symbiotic, a holistic perspective towards health care which encourages an active dialogue between patient and healthcare professional is vital. Holistic care, also known as patient-centered care, takes a person's entire life into consideration when providing care: physical health dispositions, mental health, demographic factors, spirituality, and socioeconomic circumstances (NCCIH, 2021).

Since the 1990s, complementary and alternative medicine (CAM) forms began to increase in usage in the United States (Eisenberg et al., 1998). According to the 2007 National Health Interview Survey, almost 40% of adults used some form of CAM (Barnes et al., 2007). As these practices grew in their use, the field of Complementary and Integrative Health (CIH) emerged. Complementary medicine is provided when "a non-mainstream practice is used together with conventional medicine", and integrative health "emphasizes a holistic, patient-

focused approach to health care and wellness”, often bringing standard biomedicine and complementary approaches “together in a coordinated way” (NCCIH, 2021). With this growing popularity, the efficacy of CIH practices needs to be investigated so that patients can be more informed as they make decisions about their health. This thesis will take a deeper look at traditional Tibetan medicine (TM), a lesser known but growing CIH system.

As the health care landscape adapts to the growing popularity of patient-centered care and integrative medicine practices, skepticism is warranted. Because traditional medicine has only gained prominence in Western countries in the past few decades, there has not been an ample amount of literature available to fully support these practices. Many critics claim that CAM practices induce a placebo effect, where patients report positive results because they have a preconceived expectation of CAM treatments (Waldram, 2000). However, evidence on CAM is a network of knowledge that is currently being built to address these counterarguments. Finding promising, reliable studies on TM will add to the CAM literature base and can aid in decreasing stereotyped assumptions. By increasing awareness of TM and its effectiveness rooted in evidence-based reports, patients can turn to TM as an additional treatment option.

Research on Tibetan medicine has steadily increased since the 1990s, with several studies focusing on specific herbal compounds and their efficacy or toxicity (Sallon et al., 2006; Zhao et al., 2018). Existing research only scratches the surface in terms of Tibetan medicine’s potential benefits and has not fully determined risks with certain treatments. Once adequate background is provided on the history, foundational principles, and diagnostic processes of Tibetan medicine, this thesis will explore the changes Tibetan medicine has undergone from its inception to present day and compare the current state outside and inside Tibet. An unstructured literature review of 16 published studies will then provide an overview of the TM research that is being done in the

realms of safety, animal and molecular studies, observational studies, randomized controlled trials, and systematic literature reviews.

Using Tibetan medicine as a case study for CAM systems as a whole, challenges that traditional medical systems face in terms of conducting efficacious and productive research are identified. These hurdles include lower amounts of funding allocated towards the CIH field, a heterogenous regulation system for herbal medicinal products, and a loss of cultural richness given standard biomedical research methods (National Institute of Health, 2020; Alostad et al., 2018; Shekelle et al., 2005). To address these challenges, this thesis will recommend several strategies that traditional medicine practitioners and biomedical researchers can work on together. These include adapting translational research strategies, merging national herbal medicinal product classifications into one universal system, and increasing CAM exposure during allopathic medical training.

## **The Evolution of TM: History and Fundamental Principles**

### **Historical Background**

The roots of Tibetan medicine extend far back into history, to over two thousand years ago when pre-Buddhist, Bon religious practitioners kept text records of their healing practices, “medical divination,” and astrology (Sarsina et al., 2011). This divination component consisted of identifying an imbalance in a person’s natural composition of the five elements (Earth, water, fire, air, and space) and using this personalized information to recommend specific treatments. Herbal remedies were added to the repertoire of early Bon medicine practices, and these practices would soon be intertwined with Buddhism in Tibet during the rule of King Songtsen Gampo in the 7<sup>th</sup> century. Buddhist scholars from India and China would often interact with the



Tibetan king, and as collaboration between these scholars increased, their conversations branched out from Buddhism into medicine, leading to conversations with prominent Bon, Ayurvedic, and Chinese practitioners (Sarsina et al., 2011).

Using momentum that was established in King Songtsen Gampo's reign, his successor, King Trisong Deutsen organized a medical conference in the mid-8<sup>th</sup> century. This first-ever international conference was not only attended by practitioners and scholars from neighboring countries like India, China, and Nepal, but also from farther countries such as Persia and Greece (Sarsina et al., 2011). An international exchange of medical information took place, and after this event ended, a prominent Tibetan doctor, Yutok Yonten Gonpo, synthesized information from the conference into The Four Tantras (*rGyud bzhi*, pronounced *Gyueshi*). The Four Tantras is an amalgamation of the best recognized practices from each of the countries invited to the conference with aspects of the indigenous Bon medicine. From its establishment, The Four Tantras served as the foundational text for Tibetan medicine, and schools for Tibetan medicine were soon founded in the years afterwards (Arya, 2009).

## **Tibetan Medicine Philosophy**

### *Fundamental Principles*

In Tibetan medicine (TM), the body, illness, and therapies are all seen to comprise the five elements: earth, water, fire, air, and space. Earth is tied to stability and development of body structures like flesh and bone. Water provides moisture and lubricates tissues. Fire correlates with temperature regulation, growth, and development. Air is connected to breathing and movement. Finally, Space consists of the empty space that allows maturation and plays a role in movement and sound (Cameron & Namdul, 2020).

Optimal health is achieved when an individual's elemental composition is in balance, and disease is associated with an imbalance in these elements. Often, this imbalance is present even before noticeable physical symptoms are apparent. In contrast to conventional Western medicine which may prioritize treating symptoms, TM aims to find and correct the root of the imbalance in addition to providing recommendations for living a healthy lifestyle which can have long-lasting effects in maintaining internal balance (Loizzo et al., 2009).

Although internal balance is the goal in TM, the approach to achieve this in each individual patient can vary due to different constitutions of energy that each person carries within themselves. There are three *nyepas*, or primary energies in our bodies: *loong*, *tripa*, and *baekan*, and every individual is born with a certain innate constitution of these energies (Sarsina et al., 2011). Loong, which translates to wind in Tibetan, is the energy of movement and is related to the Air and Space elements. Tripa is considered the "hot energy", correlating to the element of Fire. Finally, baekan is known as the "cold energy" and comprises of the Earth and Water elements (Cameron & Namdul, 2020).

Cameron and Namdul (2020) describe that from the three primary nyepas, there are seven combinations of constitutions that individuals can have. The first three types of general constitutions are: Loong, Tripa, and Baekan, which is when a single nyepa dominates in proportion over the other two. The next three constitutions are Loong/tripa, Loong/baekan, and Tripa/baekan, and these consist of two nyepas having similar proportions which dominate over the remaining nyepa. Lastly, there is one constitution type that consists of all three nyepas being present in equal amounts; however, this constitution is extremely rare. Based on diagnostic processes (detailed further in the "Diagnostic Processes" section), TM practitioners can discern

the constitution that best fits their patient and move forward with a treatment plan that corresponds well with that constitution.

### *Buddhism and Tibetan Medicine*

The foundational text of Tibetan medicine, the *Gyueshi* (The Four Tantras), is interlaced with Buddhism. Buddhism not only guides TM practitioners in how they treat patients, but its principles can also be applied by patients to their daily lives (Tibetan Medicine Education Center, 2020a). Though Buddhism is considered a religion, its basic tenets can be practiced secularly as a form of philosophy or psychology. The central idea in Buddhism is that all living beings experience suffering and seek a way to avoid suffering, which is caused by ignorance and mental afflictions such as anger, greed, and closed-mindedness (De Silva & De Silva, 2011). To alleviate suffering and liberate the mind, one can develop mindfulness and understand that all living things are interconnected and impermanent. By incorporating practices like mindfulness, self-compassion, and universal compassion, a person's perspective on life can change from narrow to more accepting (Shapiro et al., 2005).

Connecting Buddhism with TM, mental afflictions that lead to suffering also impact the body's elements and can create imbalances in an individual's constitution. With TM, both the body and the mind are taken into consideration and appropriately managed (Cameron & Namdul, 2020). Only addressing a patient's physical symptoms neglects the mind-body relationship. The effects that an underlying negative mentality can have on physical health can also be uncovered. Therefore, lifestyle, meditation, and mindfulness exercises can be recommended to patients to encourage positive mental states that work to pacify ignorance and negative emotions (De Silva & De Silva, 2011).

## **Diagnostic Processes**

Visual observation, touch, and inquiry are the three overarching categories of methods that TM practitioners use to examine patients to gain greater insight into their health issues and nyepa constitution. Furthermore, TM practitioners often use more than one method to gain a more holistic view of their patient.

As detailed by the Tibetan Medicine Education Center (2020), visual observation involves the TM practitioner using their five senses to notice physical details about their patient that may indicate any imbalances in constitution. Skin complexion, body language, and eyesight/hearing problems are possible factors that TM practitioners consider from a patient encounter. A subtype of visual observation is tongue analysis, and the color, texture, and presence of coating can be attributed to a certain nyepa that may be out of balance. Similarly, urine analysis reflects the patient's internal bodily state and possible imbalances. Characteristics that TM practitioners focus on while analyzing urine are presence/characteristics of bubbles, color, consistency, smell, and presence of sediment (Cameron & Namdul, 2020).

Touch is also a crucial component in diagnostic processes, and pulse analysis is the primary avenue for this (Cameron & Namdul, 2020). In Tibetan medicine, the pulse analysis is most often done on the first crease of the wrist on the radial artery. The TM practitioner uses their index, middle, and ring finger to analyze the pulse with three types of pressure (Pupysheva & Boronoev, 2020). Differentiating between the intensity, the speed, and other qualities of the pulse requires meticulous focus and is a complex skill that requires years of schooling to master.

The last category of diagnostic method is inquiry in which the TM practitioner will take ample time to listen to the patient's concerns, ask questions about their lifestyle and mental health, and provide a safe environment for the patient so they are comfortable. Taking a detailed

history and establishing a trusting relationship with patients are the most important components of inquiry (Cameron & Namdul, 2020). Questions a TM practitioner may ask overlap with those that a conventional Western medicine doctor would ask, such as the location of discomfort, how long symptoms have persisted, and health history of the patient. Additional details that TM practitioners could be interested in that are not inquired about as often in conventional medical practices are the specific foods that a patient's diet consists of. Consuming fresh, nutritious food may be an acceptable answer in a Western medicine practice, but TM practitioners also want to know about the meat (if any) a patient consumes, the spices commonly used to season food, types of cooked vegetables and fruits, and even the quantity of dairy products consumed (Tibetan Medicine Education Center, 2020b). Because each constitution type has their own natural preferences for certain foods, imbalances could be attributed to a patient's diet. Using information from inquiry, visual observation, and touch, TM practitioners can move forward with finding treatment options and/or lifestyle changes that would best suit the patient's constitution and the imbalances they are currently facing.

## **Treatment Options**

Tibetan medicine, traditional Chinese medicine, Homeopathy, and Ayurvedic medicine are traditional healing systems, which are considered whole systems of care. As a complete medical system, Tibetan medicine includes treatment domains from several different categories, which may include biologically based-practices, manipulative and body-based practices, mind-body medicine, and energy medicine (Koithan, 2009). Biologically- based practices (BBP) comprise anything edible that is used to promote health, such as herbal compounds or pills that a TM practitioner may prescribe a patient and recommended nutritional changes (Koithan, 2009).

Manipulative and body-based practices (MBBP) are therapies that require the body to be manipulated in a certain manner (Koithan, 2009). Heated oil massage is a common method of MBBP in TM where herbal infused oils are rubbed on the body to relieve nerve pain or stiffness. Another example of MBBP is cupping, which involves heated glass or copper cups being applied to the body and moved around the area of interest to improve circulation and alleviate tension. Furthermore, medicinal baths infused with herbs can be used for chronic pain and can ameliorate some skin conditions (Committee on the Use of Complementary & Alternative Medicine, 2005). Because musculoskeletal concerns such as back and neck pain are medical conditions seen often by CAM practitioners, it is vital to expand the literature base on these practices to ensure safety and the best outcomes for patients (Barnes et al., 2007).

Energy medicine involves the movement of energy in the body. In biomedicine, energy is understood through physics, with electromagnetic or acoustic energy being the most relevant (Srinivasan, 2010). In TM, energy is a vital life force that can promote healing when in balance with the body's natural constitution. Other common examples of energy medicine in CAM are the Chinese medicine concept of chi and the Ayurvedic concept of prana (Committee on the Use of Complementary & Alternative Medicine, 2005). In TM, moxibustion is common in energy healing, and the main premise of this treatment is to stimulate the body's natural flow of energy and optimize nyepa constitution for the patient. The moxibustion treatment uses dried herbal materials to form small moxa sticks; then, the moxa is burned like an incense stick, and this is slowly held and moved around the acupressure points of interest on the patient's body (Cameron & Namdul, 2020).

Mind-body medicine is an increasingly popular category of TM and other traditional medical systems, and it includes practices that use the mind, attention, and emotion to affect

physiology. Common mind-body medicine therapies are mindfulness exercises, meditation, and prayer (Committee on the Use of Complementary & Alternative Medicine 2005). Even though Tibetan medicine is rooted in Buddhist philosophy, it generally advocates for sentient beings to minimize the suffering that is experienced by living a compassionate life. Mindfulness encompasses self-regulation of attention focused on the present moment. It requires an open, curious, and non-judgmental perspective on one's life experience, and practicing mindfulness has improved people's ability to cope with stressful events in their lives (Shapiro et al., 2005). Research on established types of mindfulness-based practices has shown ample evidence that these exercises have positive health outcomes such as reducing chronic pain, boosting the immune system, and improving sleep (Grossman et al., 2004). Apart from physical health, mindfulness practices also can improve attention, reduce stress, and increase productivity (Keng et al., 2011).

Practitioners can decide which treatment recommendations would best suit the patient based on the comprehensive diagnostic process, and they can include treatments from multiple categories to achieve optimal results in the long term. The key takeaway from whole systems of care is that it is prioritizing the patient as a whole person and not just focusing on a particular disease or isolated organ to treat (Committee on the Use of Complementary & Alternative Medicine, 2005).

Ever since the origins of TM sprouted out of Bon shamanistic healing, there have been continuities as well as changes over time in the practice of Tibetan medicine. Many aspects of diagnostic and fundamental principles remain constant and true to original practices. However, as globalization increases, certain components of complementary and integrative health have

been modified to fit an expanding patient population and modern society's shifting perspective on CIH altogether.

## **The Current State of Tibetan Medicine**

### *In Tibet*

Since Tibet was annexed by China and became the Tibet Autonomous Region (TAR) in the 1950s, there have been changes to how Tibetan medicine is practiced. Many communist government officials in the first decade of controlling Tibet were in favor of either completely eradicating TM or drastically decreasing its practice. TM training, education, and private practice were stopped due to social reforms from this new government, and local TM traditions began dying out (Janes, 1999). Currently in the TAR, larger cities have an increased presence of pluralism where state-run, biomedical hospitals are often surrounded by traditional medicine clinics of various cultures - Tibetan, Chinese, and even Ayurvedic medicine. On the other hand, rural areas suffer from access to care. Tibetan medicine in the TAR has become more limited in its practices because of religious restrictions in the country. For example, many spiritual aspects of TM like Buddhist principles have been condensed or eliminated in favor of more standardized treatments like westernized laboratory workups (Janes, 2002).

Although there have been cultural restrictions on TM, it was still rated better in terms of quality when compared to Western medicine care in a pilot study done by Wang and colleagues in 2015 (Wang et al., 2015). The study aimed to examine differences and similarities between patient experiences at traditional Tibetan medicine (TM) facilities or western medicine (WM) hospitals in two Tibetan regions. Additional information on the methods and implications of this study are discussed further in the "Observational Research" section. Ultimately, the authors found that, out of a total quality of care score of 100, TM patients gave an average score of 80.0



while the WM patients gave an average score of 74.6, a significant difference. If more observational studies are done and consistently have promising results, this trend can be used as evidence to support culturally relevant patient-centered care models.

### *In Exile*

Globalization in the past several decades has allowed aspects of various cultures to be disseminated internationally, and in the case of Tibetan medicine, this has had the greatest effect in India, the United States and in European countries. Following the annexation of Tibet in the 1950s, the Dalai Lama (Tibet's spiritual leader) sought refuge in India, and once a Tibetan government in exile was established, the first small Tibetan medical center was founded in 1961. After decades of gathering financial resources, support from the Indian government, and interest from the general Tibetan refugee population, the Tibetan Medical and Astro-science Institute (*Men-Tsee-Khang* in Tibetan) was created in the early 1980s and became well-established in the mid-1990s (Kloos, 2013). As the Men-Tsee-Khang garnered an increasing patient population, individual TM practitioners created private practices to meet the needs of patients as well. With hundreds of branch clinics and patients of all backgrounds (Tibetan, Indian, tourist, refugee), TM in India was officially recognized as a medical system in 2004. Although there is discourse around TM being recognized as an "Indian system of medicine" and occasional conflict between Men-Tsee-Khang and the Tibetan government in exile, the Dalai Lama supports TM in India and it is practiced as closely to original TM as possible (Kloos, 2013).

In the United States, Tibetan medicine is seen most prominently in regions that have a sizeable Tibetan population such as New York City, Boston, San Francisco, and Minneapolis (MacPhearson et al., 2008). This is valid because TM practitioners have a built-in patient population by catering services to individuals already familiar with TM. Of course, this does not

restrict non-Tibetan populations from exploring the practice. It simply provides TM practitioners an easily accessible group of patients while they try and increase awareness of TM in surrounding non-Tibetan communities.

Vargas (2008) describes a case study done by Harvard University which collected ethnographic data on how Tibetan medicine (TM) has impacted fields such as religion and Asian medicine in the state of Massachusetts. With respect to religion, TM's root in Buddhism has been a strong pulling factor for non-Tibetans. The Shang Shung Institute, an organization founded in Massachusetts, has offered several different courses on massage therapy, Buddhist meditation techniques, yoga, and Tibetan medical training. This wide variety of spiritual practices has attracted more of the general public's interest since the Institute's establishment in 1994 (Shang Shung Institute, 2021a). TM has also expanded the horizons of Asian medicine offerings in the West, with many Tibetan medicine practitioners acting as advocates and increasing awareness of the practice in their respective communities by branching outside of traditional courses. For example, Dr. Yangdron Kalzang, a TM practitioner in California, collaborated with Stanford University to host integrative medicine symposiums and created online TM webinars for the public (Kunde Tibetan Wellness & Healing Center, 2020).

Additionally, some Tibetan medicine practitioners have begun to modernize their practices to adapt to changing views of health care by connecting TM principles to Western medicine concepts to make it easier for patients to understand. With the increased reach of TM today, there is still considerable skepticism towards complementary medicine practices due to the low supply of high-quality research studies in addition to mistrust of CAM practitioner credentials. To address credentials of CAM practitioners, TM practitioners undergo a rigorous training process akin to conventional Western medical education. This path consists of five years

of coursework and one to two years of post-graduate internship at TM clinics before completion at the Tibetan Medical & Astro-science Institute (Men-Tsee-Khang), in India. To make this profession more accessible in the west, there are accelerated three- and four-year training programs at institutes like Shang Shung. Shang Shung Institute still emphasizes the key foundational principles of TM but does not require excessive amounts of rote memorization of Tibetan medical text for non-native speakers (Tibetan Medical & Astro-science Institute, 2017; Shang Shung Institute, 2021b).

With the gradual spread of TM practice into other countries comes the need to ensure that these traditional medical systems are safe for people to use. Research on TM has slowly increased since the late 20<sup>th</sup> century and is gaining attention as an increasing number of studies are producing promising results.

## **Empirical Research on Tibetan Medicine**

Because of the nascent but growing literature base for TM empirical studies, an unstructured literature review was done to gather evidence which can provide an overarching view of the kind of research that is currently available on Tibetan medicine. There are a wide variety of research topics as well as study methodologies given the extensive applications of TM, so a non-exhaustive list of studies was included in this thesis.

## **Safety of TM Herbal Compounds**

A component of Tibetan medicine, and other traditional medical systems, that is often used is herbal medicine (Rabten, 2018). However, herbal compounds are not well-regulated in many countries. Especially with Tibetan medicine compounds, there is concern about compounds that contain tsothel, a detoxified form of mercury. Ensuring the safety of herbal

compound ingredients is crucial to assuring safety when accessing TM because mercury has well documented detrimental health effects.

Even though there has not been any evidence citing mercury poisoning from tsothel, high levels of detoxified mercury have been detected in TM compounds. Sallon et al. (2006) conducted a study to see if tsothel had any side effects on three groups of patients- Group 1 was given the tsothel-containing compounds on a regular basis, Group 2 took TM compounds without tsothel, and Group 3 did not take any medicine. The study took place over the course of 51 months, and after all patients were done with their assigned treatments, various laboratory tests were run for blood pressure, blood mercury levels, kidney and liver function, and urine mercury levels. The primary takeaway from this study was that the tsothel medicine group (Group 1) had an increased mercury content in the urine, but not in the blood, compared to the other two experimental groups. The authors suggest that this outcome occurred because the detoxified mercury from the tsothel compound would have been absorbed by the blood when initially ingested, but it would be filtered out by the kidney and excreted from the body, resulting in the high mercury levels in the urine and no other adverse side effects. As a result, these researchers found this form of detoxified mercury to be safe for oral ingestion. However, the study needs to be replicated first.

Another study that discusses possible toxicity with regards to tsothel in TM compounds is an animal study conducted by Xiang et al. (2018) that was interested in tsothel's potential effects on the kidney. Three groups of rats received a fixed amount of tsothel every day for six months, and after that, there was a withdrawal period to allow any lingering tsothel to be cleansed from their systems. After the withdrawal period, the researchers found mercury buildup in the kidneys for all experimental dosages; however, the dosages used were 25, 50, and 100 times the clinical

dosages, so the effects could be more magnified than normal. The blood levels of mercury were also dose-dependent, but they returned to normal after withdrawal. In terms of the internal mechanisms of the kidneys, there were normal creatine (CREA) and blood urea nitrogen (BUN) levels, two important signals for kidney damage. Overall, the authors suggest that patients limit long-term medications involving tsothel to minimize any potential kidney injury.

### **Animal and Molecular Research**

Closely associated with toxicity research, which examines effects of TM mercury-containing compounds, is the branch of study that tests effectiveness of TM treatments on varying medical conditions. Interestingly, all TM research studies described in this thesis that included animal or molecular models focus on variations of cancer.

A study done by Choedon et al. (2011) examined the anticancer properties of Thapring, a complex TM herbal compound used since the early 20th century as a treatment for various cancers. To quantify the effects that Thapring had on both cellular and animal models, the investigators looked at hepatocellular carcinoma, a common type of liver cancer. In the cellular model, the Thapring-treated cells were able to selectively induce apoptosis (cell death) in the hepatoma cells and leave the healthy cells undisturbed. After succeeding in establishing a cellular model, the researchers created an animal model of mice with the same liver cancer. The mice were divided into three groups (n=5 per group): mice receiving Thapring, mice with no treatment, and mice that received Silibilin (a conventional chemotherapy drug) as a positive control. After 10 months of treatment, Thapring significantly decreased Alanine Aminotransferase (ALT), one of the main indicators of liver damage, similar to Silibilin, which further indicated that Thapring may have anticancer properties. From this study, Thapring shows

promising evidence in both animal and cellular models to be potentially effective in inducing cell death in liver cancer, paving a path for future study.

To further research of leukemia, Fan et al. (2015) conducted a cellular study on K562 leukemia tumor cells using the TM herb *Meconopsis integrifolia* (*M. integrifolia*) to determine its apoptotic and toxicity effects. When testing cytotoxicity, different dosages were given to the K562 cells, and researchers found that the herb had a negative relationship with the proliferation of the tumor cells. As the *M. integrifolia* dosage increased, the tumor cell survival rate decreased significantly. Also, when the herb was given in the same dosages to non-tumor cells, there was significantly less damage, indicating that there is a preferential mechanism of the herb to target abnormal cells. The apoptotic effects of *M. integrifolia* are also dose-dependent, signifying that as the dose increases, the apoptosis ratio, or proportion of total cells which have undergone cell death, increases accordingly. From this study, there is evidence that *M. integrifolia* can have effective anti-tumor properties while leaving normal cells relatively unharmed, warranting additional investigation into this mechanism and other herbs that could have similar effects.

Finally, Zhao et al. (2018) studied Triphala, another TM herbal remedy, to determine if it has antitumor effects on gynecological cancers. In TM, Triphala is known to re-establish homeostasis of the body's three energies (mkhris pa, rlung, and bae kan), and this is useful because cancer is viewed as certain imbalances in these nyepas. This study design consisted of three types of cancer cell lines that were treated with varying dosages of Triphala: human ovarian carcinoma, cervical carcinoma, and endometrial carcinoma. Compared to the control group, Triphala clearly showed a capacity to inhibit cell growth and induce apoptosis in tumor cells, and there was a positive relationship between tumor inhibition and Triphala dosage. The results from this study align with earlier research done on Triphala and it adds to the field

because it focused on gynecological tumor cell lines, a field that had not been deeply studied for TM. An area of improvement for the future would be to include a positive control group that receives a typical chemotherapy drug to see how the Triphala effects on growth inhibition and apoptosis induction compare to the standard treatment that is already widely used.

## **Observational Research**

Even though observational research is typically not regarded as highly as RCTs, observational studies have several applications such as providing insight to create new research questions and assessing the validity of previous RCTs. The Bauer-Wu et al. (2014) study will be highlighted, with the Wang et al. (2015) study mentioned in the “Current State of Tibetan Medicine in Tibet” subsection briefly revisited as well.

Bauer-Wu et. al (2014) used a retrospective case review method to study three cases of either cancer or blood disorders and the impact that Tibetan medicine (TM) had on the health outcomes of the patients. The selection criteria included patients who had a confirmed diagnosis of cancer or blood disorder by Western medicine standards in addition to only being treated by Tibetan medicine or previously unsuccessful Western medicine treatment. TM practitioners advised the patients to maintain a healthy diet such as “green leafy vegetables, fresh seasonal local fruits”, and green tea daily (p. 506); in terms of lifestyle, TM practitioners recommended daily meditation exercises, deep breathing, and physical activity. For herbal compounds, each patient was prescribed different Tibetan medicines because of their differing conditions. From the data, each patient had various promising outcomes from the TM treatment, such as healthy levels of white blood cells, improvement in quality of life, and medical scans (like computer tomography- CT scans) which “showed no evidence of cancer” (p. 506), even years later. A small sample size limits the generalizability of this study’s results, especially since the three

cases focused on different diseases. However, this dive into TM medical records done by Bauer-Wu et al. (2014) can serve as inspiration for TM practitioners around the world to find ways to collaborate on retrospective studies like this one and have a greater pool of cases to study.

As a patient-centered modality for care, Tibetan medicine establishes long-lasting relationships with patients to discuss their overall health and wellbeing. An observational study done by Wang et al. (2015) used a modified version of the Primary Care Assessment Tool (PCAT-T) and 692 patients above 18 years old completed this survey (332 patients from Western medicine hospitals and 360 patients from Tibetan medicine hospitals). Socioeconomic and demographic factors were also gathered in the assessment tool. Interestingly, the study reported differences in the patient populations who use Tibetan medicine (TM) hospitals compared to the patients who use Western medicine (WM) hospitals, namely the age of patients, education levels, and income levels. Patients at the TM hospitals tended to be older, have lower education levels, and lower income levels as well. This result could indicate that in areas where healthcare is not as abundant, such as lower income and rural areas, traditional systems of care play a vital role in the wellbeing of the people.

By surveying patients' experiences at TM and WM facilities, preliminary evidence was gathered in areas where TM was rated higher than WM, such as "Comprehensiveness (social care), Comprehensiveness (medical care), and Family Centeredness" (p. 49). Although it was a pilot study, researchers used a reliable assessment tool, the PCAT-T, which has been cross-culturally validated, increasing the experimental design credibility. A potential limitation for this study is that it only looked at two regions in Tibet. Nevertheless, results from this pilot study support foundational principles of TM and demonstrate the importance of culturally relevant systems of care (Loizzo et al., 2009; Sarsina et al., 2011).



## **Randomized Controlled Trials**

As the gold-standard for clinical research, randomized controlled trials (RCTs) in Tibetan medicine research encompass several types of medical conditions, ranging from diabetes to postpartum hemorrhage. While all TM research efforts are greatly appreciated, not all the results gathered from these RCTs are definitively beneficial. It is important to emphasize that just because Tibetan medicine is effective for one condition, it does not signify that it has the same benefits on other medical diagnoses. This section will highlight various RCTs studying different pathologies and what the experiments' results entail for TM research going forward.

Mind-body treatments have not been heavily studied in TM, so Cohen et al. (2004) were interested in the effects that a Tibetan yoga (TY) regimen would have on lymphoma patients in terms of their sleep quality and psychological state of mind compared to a control lymphoma group who did not participate in the yoga. After the 7-week study period, both the TY and the control groups completed a sleep disturbance questionnaire in addition to questionnaires on several psychological domains like anxiety levels, depressive symptoms, and distress. Comparing the scores between the TY and control groups for the follow-up assessment, the TY group reported significantly less sleep disturbances, higher subjective sleep quality, and longer sleep duration than the control group. On the other hand, Cohen et al. (2004) found that there was not a significant difference in the psychological factors between the two groups. This study provides mixed findings regarding the possible effects that Tibetan yoga can have on cancer patients. Ultimately, the authors' hypothesis that the yoga routine would significantly improve sleep quality was confirmed whereas their hypothesis that the yoga routine would significantly improve psychological domains was denied.

Pagliari and Bernardini (2019) were interested in the effects that a TM meditation had on breast cancer patients' psychological mood states such as anxiety, depression, anger, and fatigue. The specific meditation is part of a method called "Harmoniously", and its aim is to facilitate balance within the patient's body. Participants completed rating scales on their mood states once before the meditation sessions and once after the five weekly sessions were complete. The results from the study show that there were significant decreases in the participants scores on "anxiety-tension", "depression-dejection", "anger-hostility", and "fatigue" (p.121). These findings suggest that this TM meditation can improve breast cancer patients' psychological states; further research with larger scale studies should be done to replicate these results. The reliability cannot be determined with certainty because, like Cohen et al. (2004), they are the first studies of TM mind-body treatments in the context of their respective diseases.

Another subfield of health conditions that is studied in TM is chronic, pre-existing conditions. For example, Namdul et al. (2001) aimed to study the impact that TM could have on Type 2 Diabetes. The researchers accomplished this by comparing a TM treatment combined with a diet and exercise routine to a diet and exercise routine alone (control) and studying each treatment regimen's ability to control blood glucose in untreated or newly diagnosed type 2 diabetics. For the experimental group, four different TM formulas were used along with lifestyle (diet and exercise) guidelines. The results show that after 6 months, there was a significant difference between the experimental and control group, with the treatment group having a lower level of fasting plasma glucose (blood sugar level before eating) and glycated hemoglobin (a form of hemoglobin that links to sugar). This study is a starting point for research on long-lasting conditions and whether TM can produce beneficial outcomes for these individuals.

Ryan (1997) explored the effect of TM on arthritis, studying 14 matched pairs of patients with either rheumatoid arthritis or osteoarthritis. One person in the pair was randomly assigned to receive standard Western medical (WM) treatment for arthritis- ibuprofen and indomethacin- while the other person was assigned to receive traditional Tibetan medical (TM) treatment which consisted of “herbal pills, dietary restrictions, and behavioral advice” (p. 535). All patients’ routines were followed for three-months, and to measure the efficacy of the treatments, limb mobility based on a 0 to 5 scale was evaluated, with 0 signifying no limitation in movement and 5 signifying no mobility. The results show that out of the 14 pairs, 12 of them had significantly greater improvement in limb mobility from Tibetan medicine treatment compared to Western medicine treatment. The remaining two pairs had no difference in the improvement between Western and Tibetan medicine treatments, overall demonstrating that TM can be promising in alleviating symptoms tied to arthritis.

Coronary artery disease (CAD) was investigated by Von Haeling et al. (2013). A TM-recommended diet was compared to a conventional, evidence-based Western diet in CAD patients over a twelve-month period. There were approximately 250 individuals in each group, and researchers focused on studying patients’ body mass index (BMI), weight, and cholesterol levels. Both groups lost significant amounts of weight, decreased BMI, and decreased their cholesterol significantly after completing the year of lifestyle changes. Comparing the Western diet to the Tibetan diet, the Tibetan diet group had more pronounced differences from baseline than the Western diet in weight loss and cholesterol level. The results from this study provide preliminary evidence that aspects of a TM- based diet can positively benefit patients with CAD who want to make sustainable lifestyle changes.

In terms of acute conditions, Miller et al. (2009) looked at the effect that the Tibetan medicine (TM) compound Zhi Byed 11 (ZB11) had on preventing postpartum hemorrhage (PPH) and compared this to a standard prescription of oral misoprostol which has the same purpose. This double-blinded study, including 967 participants, found that the rate of PPH was significantly lower in the misoprostol group (16.1%) than the ZB11 group (21.8%), but there was no difference in average blood loss during labor. Additionally, there were no significant differences in side effects from the misoprostol versus the ZB11 treatment groups except that in the misoprostol group, compared to the ZB11 group, a significantly greater number of patients reported experiencing fevers. The results from this study indicate that Western medicine is more efficacious in lowering PPH compared to TM; however, the ZB11 compound did not show any adverse side effects. Consequently, limitations of TM treatments are addressed, and this can serve as a branching point for potential future studies that can help identify the clinical relevance of TM in other medical conditions.

### **Systematic Literature Reviews**

There are currently three literature reviews that are available on Tibetan medicine: one focused on studies conducted in China (Luo et al., 2015), another looked at TM research available in Western countries (Reuter et al., 2013), and the last reviewed the literature on one specific herbal compound, Padma 28 (Vennos et al., 2013).

Luo et al. (2015) reviewed all randomized clinical trials (RCTs) of Tibetan medicine (TM) done in China and ultimately included 227 RCTs which were heterogenous in many aspects like study size, treated condition, and treatments; 103 total diseases or symptoms were recorded. The main categories for TM treatments were either drug treatments like herbal compounds or non-drug treatments. Of the 227 studies, 213 reported positive effectiveness

results, 13 studies had neutral results where the TM intervention was similar to the control, and 1 study resulted in the TM intervention being less effective than the Western medicine treatment. Positive effectiveness was explained by improvements in clinical examinations or scans, symptom severity, and quality of life. This systematic review included many studies that, for the most part, support the assertion that Tibetan medicine can be beneficial. A potential drawback of this review, though, was that the authors stated that only three of the included studies were “low of bias” (p. 456) and that many of the studies had “high or unclear risk of bias” (p. 456) because of insufficient methodological reporting.

Reuter et al. (2013) included 40 studies which encompassed clinical research results from several countries. Studies varied in methodology, from randomized clinical trials (RCTs), observational studies, non-randomized clinical trials, and case studies. Of the 40 studies, 34 provided positive conclusions on the tested Tibetan medicine (TM) practices, 2 out of the 40 studies found that TM treatment was inferior to Western treatment, and the remaining 4 studies had mixed results. Because of the heterogeneity of the research methods and conditions studied, the researchers were unable to glean in-depth conclusions into TM as a whole medical system. This systematic literature review mirrored the Luo et al. (2015) review in terms of their findings since most of the studies had positive results. The Reuter et al. (2013) systematic review improved the external validity of the findings by incorporating studies done outside of China whereas Luo et al. (2015) only looked at Chinese studies. This source is also helpful because it included the studies’ scores for two methodological quality rating scales, and like Luo et al. (2015), acknowledged there is room for improvement in study design for future research.

The overall positive results from the Vennos et al. (2013) literature review is similar to the two literature reviews above. This publication looks at a specific compound, Padma 28,

which is a Tibetan medicine (TM) herbal formulation that includes over 20 ingredients. This TM preparation has been studied in many different contexts, so the authors aimed to conduct a systematic review of Padma 28 studies and see which conditions this compound can treat most effectively. After looking at 30 publications, the authors found the most frequent conditions that have been studied using Padma 28 are: intermittent claudication (muscle pain during mild exertion), certain vascular (blood vessel) diseases, and inflammatory/immunological diseases. Intermittent claudication had the most studies, with 11, and it also exhibited “the highest methodological quality” (p. 26); there were significant increases in patients’ maximum walking distance when taking Padma 28 compared to control groups. In general, this literature review characterized Padma 28 as having a “multi-target mode of action” (p. 28), which can be a factor in its efficacy for multiple conditions. Using rating scales, the authors concluded that the quality of the studies was highly variable, with some achieving the highest rating and others achieving the lowest. This variation in quality can impact the reliability of these studies, indicating areas where future research can work to replicate previous results and verify their consistency.

## **Research Gaps**

A consistent trend in the research is that there are fewer studies on Tibetan medicine’s yoga, meditation and lifestyle changes compared to herbal compound efficacy and toxicity. Even though pilot studies exist on yoga (Cohen et al., 2004; Pagliaro et al., 2019) and diet (Von Haeling et al., 2013), this is a definite gap that needs to be further investigated. With overall wellbeing and lifestyle factors playing an ever-increasing role in health today, more studies dedicated to these research areas can further develop the TM literature base (Koithan, 2009).

Additionally, increased emphasis should be placed on designing more high-quality RCTs. As indicated by the analysis in the systematic literature reviews, many studies, especially the

ones conducted in China, have a high chance of bias (Luo et al., 2015; Reuter et al., 2013). By ensuring that principal researchers are properly educated in research methodology, increasing the sample size of participants, and utilizing a double-blind approach when working with human participants, studies can increase credibility. Also, conducting more research in Western countries can be helpful so that experts are not solely relying on Chinese research for the majority of their literature. Only with new studies can we fully realize the potential of Tibetan medicine and provide the most accurate information about its effectiveness. Certainly, this call to action is common in many papers' discussion sections; however, the reality of accomplishing these goals in traditional medicine is another obstacle that needs to be addressed.

## **Challenges of Studying Traditional Medical Systems**

### **The Hierarchy of Research Quality**

Physicians strive to use the most robust literature to provide care for their patients, and this evidence-based medical practice results in a hierarchy of research quality (Burns et al., 2011). Though there are several different versions of this hierarchy, a general ranking places systematic literature reviews as the highest quality of research that minimizes bias. Systematic literature reviews use a methodological process to provide a comprehensive summary of literature that addresses a specific research question. Randomized clinical trials (RCTs) generally follow systematic literature review in ranking, and RCTs include participants that are assigned to treatments to test whether the experimental condition is significantly different from the control condition. Within RCTs, the quality of the study can further stratify more robustly designed studies from less robust studies on aspects like randomization, blinding, sample population and size, and follow-up results. Observational studies like cohort studies, case-control studies, and

case studies are often ranked below RCTs, in the listed order (Guyatt et al., 1995). Because most observational data is retrospective and only looks at a sub-group of a population, results may not be widely applicable. Finally, animal studies and molecular research are placed at the bottom of the hierarchy because in a clinical research perspective, initial laboratory tests using small-scale models is necessary to ensure safety for scaling to human participants.

Level of Research Quality	Type of evidence
I	Systematic literature reviews
II	RCTs, internally ranked from higher to lower quality
III	Cohort studies
IV	Case-control studies or case series
V	Animal or molecular studies

**Table 1:** A visual representation of the general hierarchy used to classify clinical research.

Though there have been advances in the scientific literature regarding traditional medical systems, many of these papers are classified lower in the hierarchy, with very few publications in the highest tier of evidence: systematic literature reviews. Regarding Tibetan medicine, a vast majority of studies, especially from China, focus on animal and pharmacological studies (Luo et al., 2015). There is also an increasing number of observational studies and a small but growing literature base of RCTs. Although animal and molecular research is essential to determining the safety of herbal compounds and setting a foundation for RCTs in the future, a higher level of research quality is crucial to increasing reliability of TM practices.

Shekelle et al. (2005) explain that with regards to the available research on traditional medicine, there may be publication bias. Some journals may not elect to publish traditional medical studies over conventional medicine studies, and reputable journals may tend to publish



more traditional medicine studies that resulted in negative results in comparison to CAM-specific or non-English journals. By filtering the research that is available to the scientific community, mainstream journals that have greater readership can impact more people's views on traditional medicine. Additionally, some traditional medicine research requires extensive search terms for discovery, which can further limit the number of individuals who could easily access these studies. Because skepticism of traditional medical systems primarily revolves around the unfamiliarity of other cultures' therapies and the safety of treatments, an extensive body of evidence can address these concerns and be used to inform integrative medical practices (Joyce et al., 2016; Maha & Shaw, 2007). However, with various publication biases, traditional medical systems face additional hurdles that conventional science fields do not have. This scenario inhibits the potential growth of research studies and findings of traditional medical systems that could increase their visibility to the general public and scientific community.

Other underlying reasons that may contribute to the lower quality studies of traditional medical systems include possible limitations in funding and small sample sizes. Wardle & Adams (2013) found that, in Australia, CAM practitioners are not involved with a majority of nationally funded research; over half of all chief investigators on CAM research studies were conventional medicine physicians. High-level research engagement is essential for more CAM research to be initiated, and if CAM practitioners can more actively advocate and design high-quality studies that gain funding, the field can gain more visibility. Additionally, CAM practitioners interested in research can obtain research method training so they can design studies with as robust a methodology as their resources allow them to (Lewith et al., 2006).

Looking at the United States National Institutes of Health (NIH) budget of \$41.7 billion, over \$6.5 billion was invested in cancer research, \$7.2 billion was invested in biotechnology

research, and \$6.9 billion was invested in brain disorders in 2019. In contrast, the whole Complementary and Integrative Health research area received \$517 million in 2019, which was less than research specifically on kidney disease (\$649 million) and pneumonia & influenza (\$521 million) in the same year (NIH, 2020; NCCIH, 2020). From research done by Wang and Shapira (2015), it was found that studies that were sponsored by grants had a positive relationship with research impact, citation counts, and prestige of the journal where the research was published. Similarly, chemistry research also had a positive correlation between the amount of Research & Development (R&D) funding and knowledge production (Rosenbloom et al., 2015), providing evidence that investing in complementary and integrative health with targeted funding can result in greater understanding of the field.

Connecting U.S. funding to CAM research engagement found in Australia, having CAM practitioners invested in research and collaborating with researchers to secure more funding can improve study quality (Wardle & Adams, 2013). As referenced earlier in this section, many TM studies are classified lower in the general research hierarchy. Consequently, with increased financial support from the NIH, this can subsequently lead to the ability to gather larger and more representative samples which can increase study reliability (Rosenbloom et al., 2015).

### **Herbal Compound Complexities and Regulation**

Though herbal formulas are a prominent feature of traditional medical systems, the use of botanical compounds presents two key intersecting challenges that need to be overcome: (1) conducting more research on the safety of herbal compounds before public consumption and (2) establishing regulations on herbal compounds that are internationally uniform.

Safety is a major factor in the herbal medicine space and having robust studies on herbal compound elements is essential to minimize negative side effects. However, many herbal

compounds consist of several different pharmaceutical ingredients, so it is difficult to isolate each component and conduct experiments on their safety (Ekor, 2014). Additionally, the regulation of herbal compounds varies in different countries, and as a result, there are nuances in quality control and consumer accessibility (Alostad et al., 2018). For example, in the United States, herbal compounds are primarily classified as dietary supplements which makes them more accessible to consumers; however, they are not subject to tight quality control (Ekor, 2014). Dietary supplements do not require an extensive review process by the Food and Drug Administration's (FDA), so there is no standardized oversight on items ranging from energy bars to traditional herbs (FDA, 2015). Manufacturers have responsibilities to maintain product safety and ensure that product claims are not misleading through Current Good Manufacturing Practices; however, the FDA itself is not directly involved in regulation of dietary supplements unless there is an adverse event after a product has reached the market (FDA, 2019).

Perceived validity of herbal medicines is reduced because all dietary supplement products must state that they have not been reviewed by the FDA. Even if further research were to be done on herbal compounds' effectiveness for certain conditions, an IND (Investigational New Drug) application must be sent to the FDA and IRB (Institutional Review Board) to be approved before clinical trials could proceed (FDA, 2013). This IND must include ample empirical evidence that the product is safe for clinical testing in humans. This poses a challenge for traditional herbal products since many of them are a complex mix of more than one herb, making it difficult for toxicity studies to effectively parse out each component's safety, creating another barrier to further study traditional medicines.

A lesser-known registration system for herbal compounds in the U.S. is the botanical drug pathway, where the products are "intended for use in the diagnosis, cure, mitigation,

treatment or prevention of disease in humans” (FDA, 2017). The main issue with this regulation pathway is that its requirements are unattainable for most traditional herbal medicinal products. This is because it requires the same strict empirical guidelines that conventional drugs must satisfy, and only two products have ever met these guidelines (FDA, 2017). Consequently, with standards of classification either too high (botanical drug pathway) or too lax (dietary supplement pathway), herbal medicinal products in the United States remain in an ambiguous limbo between the two disparate ends of the FDA’s regulation continuum.

On the other hand, Alostad et al. (2018) report that in the European Union (EU), while regulation of herbal compounds can vary slightly from country to country, the EU has general standards and regulatory pathways for herbal medicinal products. In Germany, there is an established registration system for herbal medicine and “approximately 70% of German physicians have confidence in prescribing [herbal medicines] to their patients,” (p. 41). A quality that distinguishes EU regulations of herbal compounds from the U.S. is a more streamlined registration for herbal compounds that does not require qualifications as strict as those required for biomedical prescription drugs. This simplified registration process allows herbal medicines to become registered with “plausible efficacy as a result of established traditional use” (p. 44) and classifies them under “traditional herbal registration” (p.45). The EU also has a more rigorous option that has a full application which requires more robust empirical evidence. This stricter regulatory pathway is mainly used for products that have new active substances or are used for more serious conditions like cancer (Knoess & Wuesner, 2019; European Medicines Agency, 2021). Since research on herbal compounds is still a nascent field in comparison to the conventional drug industry, having a modified registration system that still ensures safety for consumers can maximize quality control while still being relatively accessible (Rabten, 2018).

Although this thesis only highlighted the U.S. and EU regulation pathways for herbal medicinal products, it is clear that there are distinctions in the registration processes which can lead to confusion on an international scale when additional countries are taken into consideration. If each country has its own regulations for herbal products, it can serve its national purposes well; however, it is crucial that proper communication and guidelines are set in place for the future so that uniformity can be achieved in this field on a global level.

### **Divorcing Traditional Medical Systems from Cultural Richness**

To increase empirical research quality, particularly for RCTs, experimental variables need to be well-defined to minimize bias and potential variation. This standard of practice presents challenges for traditional medical systems because they often incorporate a whole systems approach to patient care that is deeply based in cultures from hundreds to thousands of years ago. This frequently comes in the form of recommending several treatments rather than one treatment at a time, creating a synergistic interaction between treatments (Shekelle et al., 2005). By focusing on a single intervention in RCTs, patients are enrolled in a trial that limits the treatments they receive, posing an ethical issue if they are not given the highest quality of care with interventions that a traditional medicine practitioner may typically recommend (Institute of Medicine (US) Committee on the Use of Complementary and Alternative Medicine by the American Public, 2005). For example, if a mindfulness practice is combined with herbal medicinal products and diet recommendations, isolating only one of the treatments to study may not result in as impactful findings as compared to testing all recommended practices together.

Standard biomedical research methods not only pose ethical questions, but they also may not have results that can be meaningfully applicable to real-world clinical settings (Institute of Medicine (US) Committee on the Use of Complementary and Alternative Medicine by the

American Public, 2005). If there is a disconnect between how traditional medicine is studied in research and how it is practiced in real life, the literature will not be reliable. A way to combat this imbalance is by having “pragmatic trials” where participants are not assigned a specific treatment but rather a traditional medicine practitioner who will provide an individualized treatment recommendation for, ideally, the entire study population (Shekelle et al., 2005 p.1043). Although this approach would not allow methods of control such as double blinding, it would allow traditional medicine to be practiced as it would in a clinical setting and the effectiveness of individualized medicine could be investigated (Shekelle et al., 2005).

Besides the research application, traditional medical systems also face the risk of losing cultural richness through a difficulty in creating cross-cultural dialogue about traditional medical practices. The World Health Organization’s Traditional Medicine Strategy for 2014-2023 details how one strategic action for member states is to “encourage knowledge generation, translation and dissemination” (p. 47) of traditional medical systems and the cultural foundations that are integrated into their core (WHO, 2013). A major hindrance to this is when medical texts are written in a language that may not be accessible to everyone who is interested in the medical system (Lin et al., 2018). Often times, translation of these texts requires linguistic experts who can interpret the original piece and find an accurate way to express it in a universal language like English (Pritzker & Hui, 2014). Additionally, it is vital to adequately educate upcoming generations of traditional medical practitioners who are fluent in their native language to use original traditional texts as resources to refer to in their future practice.

For traditional medical systems that have a small native population or rely on oral traditions to disseminate knowledge from one generation to the next, it is especially important to find ways to preserve as much information as possible. Ways to sustain a rich cultural base

include recording elders in a community and translating these oral histories to make them more accessible to those who are not fluent in the native tongue (Matusiake et al., 2017). Audio files can also be uploaded to an online database that can be accessible for anyone who is interested (Matusiake et al., 2017). Other solutions can be developed to minimize information lost in translation, keep traditional systems alive and prosperous as long as possible, and find avenues to expand reach by increasing accessibility to individuals outside of these communities.

Cultural depth is evident in traditional medical systems and is at risk of being diminished by both empirical research standards and loss of culturally relevant medical information through translation. Efforts need to be invested towards protecting these medical systems which define many communities to ensure that future generations still have access to rich global knowledge.

## **Discussion**

Throughout this literature review, evidence has been gathered which suggests that most of the Tibetan medical treatments studied are potentially effective and safe to use. However, more research is warranted and clearly needed.

As the TM research base grows, it is important to take a step back and look at the empirical developments in the complementary and integrative health (CIH) field as a whole. Although there have been efforts discussing CIH in the scientific community, there is still considerable uncertainty amongst researchers due to lack of robust evidence and unfamiliarity with the cultures behind frequently ancient practices. This skepticism is understandable; however, barriers like lower levels of funding for CIH projects often lead to a lower quality of research compared to heavily funded areas, and this perpetuates a belief that CIH is unreliable (Wardle & Adams, 2013; NIH, 2020). Multiple other challenges hinder CIH practices from

garnering proper footing in the scientific community such as inconsistent herbal product regulation and research methods that limit cultural richness (Alostad et al., 2018; Shekelle et al., 2005). Equity in empirical research opportunities needs to be taken into consideration when addressing these hindrances to CIH because it is through addressing these hurdles that CIH practices can begin to be studied to a greater extent and receive proper credibility.

## **Limitations**

Definitive conclusions from the current literature are not possible in this thesis because of limitations in the field of study. A primary setback is that there is heterogeneity in the studies done on Tibetan medicine in terms of the experimental design, the condition being studied, and the treatment modality of interest. This is best exemplified through the two systematic literature reviews that examined Tibetan medicine on a whole-system level (Luo et al., 2015; Reuter et al., 2013). Because of the broad but shallow depth of studies, clear-cut determinations cannot be made without additional research and improved methodological quality. Another inconsistency in the literature was that some experiments compared Tibetan medicine treatments to Western medicine treatments but lacked a negative control group (Ryan, 1997). Others only compared Tibetan medicine to a control with no treatment and did not include a Western medicine equivalent (Zhao et al., 2018; Fan et al., 2015).

In identifying challenges in studying Tibetan medicine, research on traditional Chinese medicine was also incorporated because there are more studies which have explored this system compared to Tibetan medicine. The primary objective of identifying these challenges was to raise awareness of the inequities that traditional medical systems face in terms of biomedical research and to find tangible ways to lessen these disparities.



## **Addressing the Challenges and Moving Forward**

### *Translational Research Strategy*

One of the key reasons that traditional medical systems are not as well-established in the West is the skepticism towards the effectiveness of the practices and a research base that needs further study to gain credibility. The “Hierarchy of Research Quality” section documented that for clinical treatment effectiveness, empirical studies are not regarded with the same confidence, with animal studies at the bottom of this hierarchy and systematic literature reviews at the top (Table 1). To parse out what areas of traditional medical systems are most salient in the research landscape, a translational research strategy can be especially useful to bridge the gap between basic science research and the clinical trials in the field (Woolf., 2008).

Translational research is a process which aims to apply basic science studies more efficiently in real-life interventions (Woolf, 2008). This can achieve the goal of producing high-quality, relevant research in the complementary health field because it caters to enhancing patient care in areas that are most prevalent (Keramaris et al., 2008). Clinical applications can also inform future clinical and basic science studies that may need to be explored, and thus, a bidirectional relationship can be established, and a two-pronged approach can be implemented. One approach can start from basic science research studies informing clinical trials. The second approach can translate observations made in real-world community clinical practice and find ways to form experimental hypotheses and define best practices of care (Hörig et al., 2005).

Applying a translational research strategy to traditional medicine would be extremely useful. Researchers could form relationships with traditional medical practitioners across the globe and obtain insight into the most prominent practices used in the clinic setting, which can positively shape bench and bedside research (Keramaris et al., 2008). Since there is currently not

enough basic science research to inform substantive clinical trials, this targeted approach could provide a more efficient manner of gathering evidence and disseminating it (Woolf, 2008).

*Improvement of Empirical Research Methods While Maintaining Cultural Integrity of TM*

Manualization, which entails the operationalization of a treatment framework that reflects the real-life practice of TM, provides a treatment heuristic that allows for both individualization and replicability of treatment interventions. Originally developed to operationalize cognitive behavioral therapy (CBT), manualization has been used extensively in CAM research (Schnyer & Allen, 2002). Manualization bridges the gap in traditional medicine research by asserting treatment interventions delivered in a standardized and replicable manner while also allowing flexibility for traditional medicine practitioners to maximize therapeutic effects (Institute of Medicine (US) Committee on the Use of Complementary and Alternative Medicine by the American Public, 2005).

Manualization has been used in acupuncture studies of repetitive stress injury, stroke, depression, and cerebral palsy, among others (Schnyer & Allen, 2002). Additionally, Ali et al. (2012) found significant treatment effects by manualizing a specific massage therapy for osteoarthritis in the knee. By communicating traditional medicine principles and including the necessary protocols relevant to each condition, these manuals can simultaneously facilitate more rigorous studies in CAM while also accurately depicting clinical practices in literature.

A way that manualization can be applied to Tibetan medicine, for instance, is by systematically creating different treatment frameworks for each possible humoral constitution that a person could have. If an RCT was conducted under a standard biomedical framework, then all human participants in the experimental group would be provided the same intervention to determine its effectiveness. An issue with this approach is that in Tibetan medicine, each person

has one of seven possibilities of humoral constitutions; as a result, their body's natural tendencies towards interventions can be varied, so having a single treatment could have mixed results (Tibetan Medicine Education Center, 2020b). Instead, a reputable TM practitioner can be recruited for the RCT to have individual consultations with each study participant and identify each patient's humoral constitution. Using a manual with specific recommendations for each humoral constitution, principal investigators can then have individuals of each humoral constitution implement the practitioner's interventions for the condition that is under study. When analyzing results, participants of each humoral constitution can be compared to each other in addition to the control group, which would minimize overall variability and gives more specific data to later interpret.

Ultimately, manualization can be a way to improve empirical research methods while also maintaining a sense of cultural richness for other traditional medical systems such as Tibetan medicine, Chinese medicine, Ayurveda, and others. Expanding the potential of this approach and standardizing it for major traditional medical systems is another way that research on traditional medical systems can improve their credibility in the scientific community.

#### *Universal Definition of Herbal Medicines*

As outlined in the "Herbal Compound Complexities and Regulation" section, the categorization of herbal compounds is inconsistent depending on a particular country's classification. Because herbal compounds play an integral role in traditional medicine, their regulation can be more efficiently handled if there is a universal classification system.

When deciding what classification would best suit herbal compounds, characteristics of current categorization and regulation can be used as a starting point. In the United States, the FDA's practice of grouping almost all herbal compounds in the dietary supplement category

leaves little room for proper quality control and opportunity to build trust with consumers. However, the second option of registration for herbal compounds, the botanical drug pathway, is extremely selective and requires strong evidence from clinical studies to support registration (Alostad et al., 2018). Because traditional medicine is an understudied field, there is subsequently a gap in robust pharmaceutical research of herbal compounds which limits most compounds from becoming registered as botanical drugs. Additionally, an IND is required from the FDA and IRB to pursue any clinical research on herbal products to determine their efficacy, and this is difficult to obtain without extensive prior research in the subject area (FDA, 2013). The botanical drug pathway will make more sense as a classification system in the long-run once there is more research available on herbal compounds. Although some argue that keeping herbal compounds as dietary supplements has the benefit of increased accessibility, conventional physicians may be skeptical of their efficacy since the FDA review process is not required and as a result may not recommend them to patients.

Examining the processes that herbal compounds undergo to become registered in the European Union, specifically Germany, provides a more practical expectation for herbal compounds and how they can be registered and regulated. In the EU, the modified registration for herbal compounds allows a long tradition of use, plausibility in efficacy, and some empirical evidence as requirements to be classified as a traditional herb (Alostad et al., 2018). The EU also has another tier of herbal product registration called the “Well-established use marketing authorization” which requires more stringent scientific evidence before approval (European Medicines Agency, 2021).

It would be beneficial for traditional medical systems in the U.S. if an herbal compound registration system similar to the European one was adopted, especially since a multitude of

traditional medical systems are practiced in the U.S. A point of difference between the U.S. and EU systems, even though both have two tiers, is that the regulations for the U.S. are either too lax or too restrictive given the current state of herbal products. The EU system has more practical guidelines and a smaller gap in requirements between tiers. If the U.S. cannot currently adopt an herbal classification system that mirrors the EU's, then creating a universal categorization of herbal compounds should be considered for the near future. Requiring moderate empirical evidence and having an appropriate, attainable tiered system for herbal medicinal products will reduce misunderstanding, increase the validity of herbal compounds, and expand the reach of traditional medical systems in a scientifically-supported manner (Rabten, 2018).

#### *Increased Integration of Complementary Medicine in Medical Training*

At their core, traditional medical systems are closely intertwined with the cultures and countries where they originate from, and this is one of the contributing factors why these practices are not discussed as often as mainstream allopathic medicine. With an increasingly diverse and globalized society, it is critical for current and upcoming generations of healthcare practitioners to be understanding of their patients and have some familiarity with complementary and integrative health practices.

Looking at medical education currently, there are inconsistencies in terms of CAM inclusion in medical school curriculum. According to a systematic analysis of 125 United States medical schools done by Cowen and Cyr (2015), 59 of the included schools (45.4%) had no CAM didactic or clerkship courses offered to students while only five schools required students to take a CAM course. This difference in course offerings across medical schools can impact the attitudes and opinions that medical students have towards CAM when they graduate and transition to training in their specialties. As a result, some physicians have an additional

knowledge base which was not available for others. Looking towards the future, having at least one CAM course offered at all medical schools can provide all incoming students with an equal opportunity to learn more about the practices. Making it mandatory to take a CAM course before graduation can be up to each school's discretion; students should certainly not feel coerced into taking CAM courses. Even though the research base for CAM is in the early stages compared to conventional Western medicine, important non-scientific skills such as inter-professional communication and patient-centered care can undoubtedly be learned and improved on through CAM courses as well (Cowen & Cyr, 2015).

A literature review by Joyce, Wardle, and Zaslowski (2016) discusses the perceptions that allopathic medical students have towards the CAM field, with many students increasing their likelihood of recommending a future patient to a CAM practitioner. Additionally, medical students in general have positive thoughts about CAM, especially in the preclinical years (typically the first two years in a traditional four-year medical education). A potential reason for this is that exposure to CAM early in the medical training process helps students become more informed on CAM principles and treatments available while also having greater interaction with CAM practitioners. This finding exemplifies the necessity to introduce CAM starting in the preclinical years when possible, because there may be less receptiveness later in medical school.

Despite the finding that preclinical medical students have a more positive view towards CAM than clinical medical students, any introduction to CAM can be beneficial, especially for students who are going into the primary care field. Primary care, which encompasses the medical specialties of family medicine, internal medicine, and pediatrics, allows physicians to have long-term relationships with patients and act as the first line of defense when patients have physical ailments (Lebensohn et al., 2012). Likewise, preventive medicine specialties take a similar

perspective in prioritizing balanced lifestyles in individual patients in addition to addressing larger, public health level concerns (Chiaramonte et al., 2015). For both primary care and preventive medicine, CAM exposure can be a helpful tool when considering all interventions that may best suit a patient's health needs, particularly with chronic conditions and pain management.

When the University of Maryland's preventive medicine residency program partnered with a center for integrative medicine to adapt more components of integrative medicine into the curriculum between 2012 and 2014, residents in the program rated it positively and recommended that it be widely adapted for more specialties (Chiaramonte et al., 2015). Over 60 hours of instruction were provided to residents, and modes of teaching varied from traditional lectures, self-care retreats, and skill-based workshops, with topics spanning from nutrition, herbal medicine, acupuncture, mind-body medicine, and different traditional medical systems. Having these various subject areas covered in the residency curriculum equips these preventive medicine residents with a more comprehensive view of health when they are treating patients or studying communities on a larger scale.

Likewise, Lebensohn et al. (2012) implemented a 200-hour web-based Integrative Medicine in Residency (IMR) initiative in eight family medicine residency programs across the United States, from New York to Minnesota to Arizona. This program spanned three graduating classes and consisted of a primarily online module system which also incorporated longitudinal aspects and in-person learning experiences. Similar to Chiaramonte et al. (2015), Lebensohn et al.'s IMR program covered a number of topics within integrative medicine, and residents overwhelmingly rated the program as having high clinical utility, with an average rating of 89.7 out of 100. Both these pilot programs demonstrate that there is definite potential for implementation of some CAM and integrative medicine topics throughout residency training.

The primary benefit of CAM exposure that medical students and residents alike cited was an increased confidence in discussing CAM in future clinical practice, acknowledging CAM as a highly relevant field given its growing use (Lebensohn et al., 2012). Students were open to increased integration of CAM into medical school education and residency programs through elective courses and workshops interspersed during the semesters. However, 18 out of the 21 papers included in Joyce et al.'s review had a high preference for there to be a wider and deeper CAM evidence base established prior to increased inclusion in medical education (2016). Again, this desire for increased literature reiterates the importance of more empirically supported, reliable research.

## **Conclusion**

Tibetan medicine, like other traditional medical systems, has undergone adaptations to fit into a modern society. Nevertheless, the increased exposure to more individuals around the world has amplified the need to conduct scientific research to ensure that these practices are safe.

With globalization, utilization of traditional medical systems has increased and there are promising results in published literature on treatment safety and efficacy for various medical conditions. Nevertheless, several issues arise in the pursuit of empirical research in the field of complementary and integrative health (CIH). Lower funding dedicated towards CIH plays a role in fewer, smaller-scale studies, often leading to these studies being classified as lower quality when compared to their conventional biomedical counterparts. Additionally, heterogenous classification of herbal medicinal compounds in different countries makes it difficult to keep the quality of herbal compounds internationally uniform. Lastly, standard conventional research



methods, though effective for minimizing variation and bias, often simplify traditional medical treatments in ways that are not culturally accurate.

An objective of this thesis is to advocate for ways the scientific community can address these obstacles and improve research on these medical systems. By increasing funding towards CIH and involving more traditional medical practitioners in the research process, study methodologies that are more culturally accurate can be created. Using a translational research strategy can help scientists understand what areas of research are most relevant to real-world clinical practice. Also, by creating a universal classification system for herbal compounds, regulation can be streamlined. Lastly, by increasing CAM offerings throughout the medical training process, students who are interested in expanding their understanding of more treatment avenues can become better informed healthcare practitioners.

Throughout this thesis, the importance of non-judgment and openness towards traditional medical practices has been emphasized. By taking the appropriate steps and dedicating time and effort towards researching traditional medical systems, the scientific community can begin to have a deeper understanding of these practices. Moreover, the potential findings of this research can further develop the literature base of traditional medicine and increase its integration in mainstream healthcare.

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## **Author Biography**

Tenzin was born in Los Angeles, California and moved to the greater Houston area early in her childhood. After graduating high school in 2017, she began her undergraduate career at the University of Texas at Austin as part of the Health Science Scholars Program. During her time at UT, Tenzin was involved with on-campus activities like the Freshman Research Initiative, American Medical Student Association, Health Careers Mentorship Program, club golf team, and The Project. Off campus, she spent time as a Girlstart STEM CREW intern, a hospital and free clinic volunteer, and a volunteer for the American Tibetan Medical Association. It was during her time interacting with Tibetan medicine practitioners that Tenzin developed an interest in exploring the topic of complementary and integrative health for her thesis. Tenzin will be graduating in May 2021 with degrees in Biology and Psychology, a minor in Sociology, and a pre-health professions certificate. Her post-graduation plan is to matriculate into medical school and become a physician who cares for her patients and the surrounding community as well.