

A Comparative Case Review of Governance of Traditional, Complementary and Integrative Medicine (TCIM)

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Abstract

Many countries have invested significantly in the integration of traditional, complementary and integrative medicine into national health systems to improve accessibility of health services and achieve universal health coverage, expand and diversify health care markets, and protect and preserve cultural heritage, biodiversity, and intellectual property. Following the 2022 launch of the WHO Global Traditional Medicine Centre (GTMC) and the 2023 Traditional Medicine Global Summit (TMGS), an open policy window now exists to further support countries' attempts to strengthen governance around traditional medicine and its integration. This study presents findings from a set of case studies on the content of countries' traditional, complementary and integrative medicine (TCIM) governance documents. It describes how some countries are presently governing TCIM, explores the commonalities and differences in TCIM governance between countries, and then discusses the implications of these findings for initiatives targeting the TCIM space. The study found that case study countries have robust policy and regulatory landscapes governing TCIM, but that governance may not always translate into operationalization of policy and, in many (although not all) case study countries, TCIM is accessible primarily in the private sector and then only via out-of-pocket payments. Two key gaps in the TCIM governance landscape involve ensuring that mechanisms exist to monitor and evaluate, as well as finance, TCIM services and products and this, in part, involves dealing with improved oversight of the private sector. The study argues that, going forward, global technical support for TCIM should pivot toward translating governance into action to ensure that TCIM is able to contribute to each country's unique vision of the role that TCIM might play in its national health system. These conclusions strongly align with the direction of the new WHO Global Traditional Medicine Strategy, 2024-2035 and its planned Programme of Work.

Introduction

The governance of traditional medicine and its integration into health systems date back millennia. Multiple categories of professional and folk healers were on the royal payroll at Deir el Medina in Ancient Egypt (1550-1070 BCE), with policies enacted to enable workmen and their families to access sick leave and medical rations (1). Traditional Chinese Medicine (TCM) was first formally institutionalized during the Northern Song Dynasty (960-1200 AD), with policies launched establishing hospitals, centres of medical education, public health institutions, and medicinal product regulation (2). Ayurvedic and other traditional practitioners and products were integrated into India's pre-colonial and post-independence state health systems, and even conscripted for a short period into the colonial Indian Medical Services in the 19th century (3,4). Similarly, by the late Middle Ages, traditional midwives, healers, and medical practitioners throughout Europe were subject to ecclesiastical and municipal licensing and control (5).

Today, integrated multi-tiered governance of TCIM has been achieved on a massive scale in some countries. In India, the Ministry of Health established the Department of Indian Systems of Medicine and Homeopathy in 1995. In 2003, the department was renamed the Department of AYUSH (ayurveda, yoga, naturopathy, unani, siddha, and homoeopathy) and the National Rural Health Mission (NRHM) was used as a mainstreaming mechanism (6,7). In 2014, the Department was elevated to the Ministry of AYUSH, with the National AYUSH Mission launched as a fully budgeted platform of implementation working across institutionalized departments or programmes in most Indian states and union territories (6). Likewise, China has been strengthening policy frameworks for TCM since the 1950s, with the objective of ensuring the integration of TCM and Western medicine. Integration is embedded in China's Constitution and, since 1991, TCM has had equal status as Western medicine. TCM is embedded in national development strategy and all provinces, autonomous regions, and municipalities have TCM administrations (8,9).

The 1978 Alma-Ata Declaration recognized the historic and ongoing importance of traditional medicine as a key strategy in improving populations' access to health care, arguing that traditional medicine practitioners "can become important allies in organising efforts to improve the health of the community...it is therefore well worth exploring the possibilities of engaging them in primary health care and of training them accordingly"(10). WHO and its Member States and partners have since been developing an increasingly robust body of global, regional, and national policies and institutional mechanisms to improve the integration of TCIM within national health systems.

In recent years, these efforts have been accelerating. Since 2002, WHO member states have adopted subsequent iterations of the WHO Traditional Medicine Strategy (11,12) and numerous World Health Assembly resolutions and agenda items on traditional medicines (13,14). In 2019, WHO published its second Global Report on Traditional and Complementary Medicine to serve as a compendium of TCIM policy, regulation, and practice with contributions from 179 member states (9). In March 2022, WHO launched—with significant investment from the Government of India—its first Global Traditional Medicine Centre in Jamnagar, India as a global knowledge center with "a strategic focus on evidence and learning, data and analytics, sustainability and equity, and innovation and technology to optimize the contribution of traditional medicine to global health and sustainable development" (15). The Global Centre complements the core functions of WHO's Traditional, Complementary and Integrative (TCI) Unit, as well as work by WHO's six regional offices on TCIM (16).

Most recently, the first WHO Traditional Medicine Global Summit took place in August 2023 in Gandhinagar, India, held alongside the G20 health ministerial meeting to mobilize political commitment and evidence-based action on TCIM (17). The Summit saw the launch of the Gujarat Declaration that sets out an ambitious programme of work focused on strengthening global leadership and the TCIM research and evidence base, as well as on improving integration of TCIM into universal health coverage (UHC), primary health care (PHC), health systems, data and routine information systems, and digital health. At the heart of the Declaration is a commitment to biodiversity, sustainability, human rights, equity, and ethics (18). Both the Summit and the Declaration set the stage for WHO's newest iteration of the Traditional Medicine Strategy which will run from 2025-2034 (19).

These efforts create a policy window to study countries' governance approaches toward developing, operationalizing, financing, implementing, and monitoring and evaluating TCIM. How, if at all, are WHO Member States defining TCIM? What TCIM governance documents (e.g., policies, strategies, frameworks, roadmaps, guidance) exist and what topics do they cover? What mechanisms do these governance documents use to operationalize integration of TCIM? At the heart of these questions are issues of how countries govern the building blocks of both national health systems, and the role that TCIM plays within.

This review examines these questions and is based on set of 12 country case studies across five WHO regions on the content of WHO Member States' TCIM governance documents, as well as supplementary information from three countries in Europe. It describes how some countries are presently governing TCIM, explores the commonalities and differences in TCIM governance between countries, and then discusses the implications of these findings for initiatives targeting the TCIM space with advocacy, technical support, and financing.

Methods

Cases were drawn from a larger research study carried out in two phases. Phase I consisted of a policy landscape review of TCIM governance documents from a sample of WHO Member States (n=67). The review focused on publicly available search engines including Google, Google Scholar, World Health Organization Country Planning Cycle database, the Food and Agricultural Organization FAOLEX database, and PubMed, targeting grey literature from governments and technical agencies as a primary source. If this literature was not publicly available, databases were searched purposively for articles or books that specifically focused on country adoption of TCIM within national health systems governance. Search terms included: "traditional medicine" or "indigenous traditional medicine" or "alternative medicine" or "alternative therapies" or "complementary medicine" or "complementary therapies" or "integrative medicine" or "integrative healthcare" or "integrated medicine" or "integrative healthcare" or "herbal medicine." For inclusion, the document needed to be a policy, regulation, strategy, plan, or framework related to TCIM at the national level, either a standalone document specific to TCIM or integrated within other national policies. There were no restrictions on language or dates. Governance at the subnational level was not included.

In Phase II, researchers then purposively selected 12 countries within the sample across five of the WHO regions (AFR, AMR, EMR, SEAR and WPR) for in-depth case studies as to the integration of TCIM into countries' policy landscape. Countries chosen as case studies were those for which the initial policy

landscape review demonstrated a sufficient body of open access governance documents. The exception was DPR Korea which had very little open access documents but was nevertheless an interesting example of integration and one with which many readers will be unfamiliar. The countries ultimately selected for Phase II were Benin, Bhutan, Brazil, Cuba, Democratic People's Republic of Korea, Ghana, Iran, Malaysia, Republic of Korea, Saudi Arabia, Thailand, and Uganda.

While the policy review in Phase I did include cases from WHO's European Region (EUR), the case studies did not include EUR countries due to time constraints around translation and the risk of duplication since case studies of complementary and alternative medicine (CAM) governance and regulation in Europe have been comprehensively published by the EU-commissioned CAMbrella project (20). This review, however, has also included targeted information where relevant on Turkey, Germany, and Switzerland to ensure representation of European countries. These countries were selected purposively, based on suggestion by stakeholders of WHO GTMC. The total number of countries discussed in this review, then, is 15.

For case comparison, data were extracted from the country case studies by two researchers (BAP and LJF) and coded based on categories drawn from the WHO Global Core Indicator Framework for Traditional and Complementary Medicine. Deep-L and Google Translate were used to translate non-English governance documents. Each researcher analysed governance of TCIM for a set of the case study countries, and then met regularly to explore commonalities and differences between countries and regions, looking for themes related to the approaches taken by countries to TCIM across six governance categories. These categories were: 1) institutions and entities that serve as decision-making or oversight bodies around TCIM; 2) regulation of TCIM products and the assurance of product quality, safety, and efficacy, including consumer protection; 3) oversight of practitioners, including training, registration, and certification; 4) supervision of service delivery, including licensing of establishments and integration of quality services into conventional service delivery; 5) mechanisms for financing, whether from national and subnational budgets or public and private health insurance; 6) platforms for information and evidence generation, including routine health information systems and research and development around medicinal plants or TCIM products. Additionally, in a review of therapeutic pluralism in Latin America, Gallego-Perez et al. (2023) point out that the emphases that countries place on specific areas of governance are also guided by overarching logics for investing in TCIM, including commitments to biodiversity, indigenous knowledge and rights, cultural and medical sovereignty, Universal Health Coverage (UHC), and other key principles (21). This review, therefore, also took note of where a rationale for country commitment to TCIM could be identified either in governance documents or in supplementary materials.

Results

Overall, all case study countries have been working in earnest on the governance of TCIM for decades (and, in some, centuries). Often, countries' rationale for doing so is grounded in broader commitments to cultural heritage, medical sovereignty, universal access to health care, and protection of biodiversity and indigenous rights and systems of knowledge, with each country emphasizing certain aspects of these principles over others. For example, in Ghana, the legitimization of traditional medicine was promoted by then-President Nkrumah after independence in 1957 as a vital element of nation-building and as a means of recentring Ghanaian culture, tradition, and heritage following almost a century of colonial ordinances that banned indigenous expressions of healing and imposed a Western public health model as a means of

enforcing order on the local population (22,23). In another example, Cuba began to emphasize NTM practices in the period after the collapse of the Soviet bloc in 1989, with which the country had previously sourced raw materials for its pharmaceutical sector. Combined with the tightening of U.S. trade restrictions, Cuba experienced a serious shortage of pharmaceuticals and an increase in mortality, and so worked to reorganize its health care system, including an emphasis on NTM practices and domestic manufacturing and distribution of plant-based medicines (9,24,25).

Governance and Institutions

Governance

By governance, we mean legislative measures, policies, strategic plans and frameworks, and other documents originating either from a legislative body, a country's Ministry of Health (or equivalent), and/or other Ministries used to guide government decision-making and action around TCIM.

Some countries have embedded TCIM in legislation. For example, Malaysia's Law 775—The Traditional and Complementary Medicine Act 2016—provides for the establishment of the Traditional and Complementary Medicine Council to regulate traditional and complementary medicine (T&CM) services, and sets out numerous conditions for practitioners, including registration and certification (26). Ghana's Traditional Medicine Practice Act, 2000 establishes a Traditional Medicine Practice Council (TMPC) as the primary regulatory body for practitioners, directing the Council to work with the Food and Drug Board on regulation around traditional herbal medicine (27,28). Uganda passed the 2019 Traditional and Complementary Medicine Act to launch a multisectoral National Council of Traditional and Complementary Medicine Practitioners tasked with controlling, standardizing, regulating, and promoting traditional and complementary medicine (TCM) practice, with representation in district-level health administrative structures (29). In 2004, the Republic of Korea enacted the Traditional Korean Medicine and Pharmaceuticals Act to support the systematic development of traditional Korean medicine (TKM) in the country. The Act, since amended in 2008 and 2011, requires the government to create and enforce a mid-to-long term plan for TKM every 5 years (30). Traditional and complementary practices in Turkey are governed across multiple health sector legislation, including Supplementary Article 13 in Law No. 1219 on the Practice of Medicine and Medical Arts and articles and annexes within the country's Health Services Basic Law No. 3359 (31). In Germany, homeopathy is recognized as a special therapeutic system by the country's Medicines Act (*Arzneimittelgesetz*) and by its Social Code V (*Sozialgesetzbuch V*) (20).

In Bhutan, Thailand, and Switzerland, traditional medicine is, uniquely, built into the Constitution. Bhutan's *2008 Constitution* stipulates that "the state shall provide free access to basic public health services in both modern and traditional medicines" (32). In Thailand, the *2017 Constitution* specifies that the state is responsible for providing efficient and universal public health services, promoting basic knowledge about health promotion and disease control, and supporting the advancement of the wisdom of Traditional Thai Medicine (TTM) to maximise its benefits (33). Complementary medicine has been recognized in Switzerland's Federal Constitution Article 118a, 52 since 2009: "the Confederation and the Cantons shall within the scope of their powers ensure that consideration is given to complementary medicine" (20).

Besides legislation, all case study countries had one or more standalone traditional medicine policy instruments. Uganda, for instance, embedded a *Policy Framework for Partnership with Traditional and Complementary Medicine Practitioners* as an annex to its 2005 *National Policy on Public Private Partnership in Health*. This framework urges the creation of a national TCM policy and calls for the development of legislation, standards, regulations, and oversight around practitioners and products (34). Benin has multiple TCIH-specific governance documents dating back to 1985, the most important of which are 1) *Décret No. 2001-036 du 15 Février 2001 (Decree No. 2001-036 of 15 February 2002)* which seeks the development of professional and integrated class of traditional medicine practitioners, along with strengthened research, training, and protection of biodiversity, and 2) the *Politique Nationale de la Pharmacopée et de la Médecine Traditionnelles 2013 (National Policy on Pharmacopoeia and Traditional Medicine)* which aims to improve traditional medicines coverage by operationalizing policy goals around traditional medicine products, practitioners, and practice (35,36).

In 2006, Brazil approved the *National Policy on Integrative and Complementary Practices* with a focus on safety, effectiveness, and quality which, along with ordinances in 2017 and 2018, recognized a total of 29 integrative and complementary practices (PICS) (37–39). Iran's *Doctrines of Revival and Indication* were published in 1996 to ensure the integration of traditional Persian medicine into Iran's health system (9). In 2014, the Supreme Council of the Cultural Revolution further approved the *National Document of Medicinal Plants and Traditional Medicine* which sought to guide the revitalization and development of medicinal plants and traditional medicine in the country (40). In 2007, Thailand's *National Strategic Plan on the Development of "Tai" Wisdom, "Tai" Ways of Health 2007-2011* was approved, consisting of strategies around knowledge and information, health services, human resources, development of TTM and herbal medicines, and protection of Thai traditional knowledge (41). Malaysia's *National Policy of Traditional and Complementary Medicine* was adopted in August 2001 and revised in 2007, with a vision to 'integrate' T&CM into the health system, particularly in primary health care (42,43). Turkey's 2014 *Presidential Decree No. 1, Traditional and Complementary Medicine Practices Regulation* sets forth 15 recognized practice areas and stipulates the qualifications requirements for both practitioners and practice centres (31).

Additionally, all case study countries have integrated TCIM into broader national health policies, strategies, and other health governance frameworks. Bhutan's *National Health Policy 2011* states that the government shall "continue to preserve and promote the traditional medicine system by effectively integrating it into the overall national health care delivery system" (44). Thailand's *Twenty-Year National Strategic Plan for Public Health (2017-2036)* has as a key objective the integration and increased access to TTM services (45). Additionally, the country's 2019 *National Reform Plan in Public Health* includes a TTM service reform plan, an educational reform plan, and an herbal products reform plan (33). Consecutive health policies in Ghana include traditional medicine as a key element of improving equity of access including the *National Health Policy 2020* which embeds TCIM in a UHC framework, using a "whole-of-government and a whole-of-society" approach to deliver comprehensive, equitable, affordable, and responsive health services towards a better quality of life, with respect for "other traditional systems" of care (46). In 2014, the Supreme Leader of Iran included traditional medicine in the 12th clause of Iran's *General Policies for Health* which aimed to standardize and update Persian medicine services and improve cooperation with modern medicine (47). In 2016, Iran's *Sixth Five-Year Development Plan (2016-2021)*

required the Ministry of Health and Medical Education (MoHME) to integrate approved Persian and complementary medicine into the health system (48). Turkey includes regulation of traditional, complementary and alternative medicine practices into its Law on Organization and Duties of the Ministry of Health and Its Affiliates, 2011, including specifying the role that Turkey's Directorate General for Health Services should have in regulation (49).

Institutions

By institutions, we refer to the establishment of institutional mechanisms embedded within a country's Ministry of Health (or equivalent), and/or other Ministries to plan, oversee, and implement TCIM in the country.

Case study countries had formally established institutional mechanisms for governing TCIM, although these mechanisms vary with respect to the level at which they are located and have often evolved over time. Some countries place traditional medicine within the Ministry of Health (MoH) at directorate, division, or department level. For example, Benin established a Directorate of Research, Medicine, and Traditional Pharmacopoeia under the MoH in 1985 which situated the governance of traditional pharmacopoeia on equal footing with the governance of other medicines (36,50). In 1990, Benin's *National Health Development Plan* established a National Program of Traditional Pharmacopoeia and Medicine sitting under the Directorate of Public Health (36). Today, traditional medicine sits as an independent Directorate under the MoH's Department of Research, Training and Traditional Medicine alongside the other two ministerial technical directorates. Ghana launched the Traditional Medicine Unit in 1991 to institutionalize policy development around traditional medicine, and then elevated the Unit in 2002 to the level of Directorate, expanding its mandate (51,52). Ghana's Traditional and Alternative Medicine Directorate (TAMD) is organised around a Traditional and Alternative Medicine Policy and Regulations Unit, a Research and Monitoring and Evaluation Unit, and an Information Communication Unit (53).

Iran's National Office of Traditional Medicine was established in 1981 and, in 2004, the Secretariat for the Educational Council of Iranian Traditional and Complementary Medicine was established under the MoHME (48). In 2016, the Secretariat was elevated to a General Directorate called the Persian and Complementary Medicine Office (40). The Republic of Korea created the Division of Traditional Korean Medicine in 1993 under the then-Ministry of Health and Social Affairs which was later elevated to become the Office of the Director General for Korean Medicine and now includes two divisions: the Division of Traditional Korean Medicine Policy and the Division of Traditional Korean Medicine Industry (9). Malaysia began formally integrating T&CM into its health system in 1996 with the establishment of a special T&CM Unit within the MoH. In 2004, the Unit was elevated to divisional status with subdivisions for Policy and Development, T&CM Practice, T&CM Council, Inspectorate and Enforcement, and Professional Development, under each of which further units sit (54,55). Saudi Arabia established the National Center for Complementary and Alternative Medicine (NCCAM) in 2008 with the intention of creating a centre embedded within the MoH to serve as a regional reference centre and leader in the field of complementary and alternative medicine (CAM) (56–58). Turkey's Ministry of Health has embedded the Department of Traditional, Complementary and Functional Medicine Practices under its General Directorate of Health Services. The Department is charged with determining standards and qualifications

for traditional and complementary medicine practitioners and practices, issuing and revoking licenses, documenting the educational institutions providing traditional and complementary medicine training, and monitoring practitioners, practices, and developments in the sector (31).

In addition to Ministerial Departments, other high-level institutional entities serve as platforms for TCIM medicine, including national councils, commissions, or committees. For example, Malaysia's T&CM Council was established under the *National Policy on Traditional/Complementary Medicine 2001*, with appointed membership and the Director General of Health acting as chair. Initially serving as an advisory committee for policy direction, the Council's role expanded to include regulatory functions in 2013 after the gazetting of *The Traditional and Complementary Medicine Act (26,59)*. In Cuba, before the development of a specialized department, the government issued a national mandate in 1992 to integrate natural and traditional medicine (NTM) into Cuba's health sector (60), and its formalization began in 1995 with a directive that established a National Commission for directing and coordinating activities related to NTM, chaired by the Minister of Public Health and including the Ministries of Agriculture, as well as Science, Technology, and Environment, and the pharmaceutical industry (61).

Products

By products, we refer to both regulation and governance around regulatory institutions providing oversight of TCIM products, such as herbal medicines.

Across all case study countries, national drug regulatory authorities have primary responsibility for the regulation of TCIM products. For example, the Malaysian National Pharmaceutical Regulatory Agency (NPRA)—and, under this, the country's Drug Control Authority—oversees all regulation of herbal and traditional medicinal products including registration, manufacturing, importing, distributing, prescribing, and post-marketing surveillance (54). In Saudi Arabia, medicines regulation is the responsibility of the Saudi Food and Drug Authority (SFDA) which regulates, oversees, sets specifications and policies for, and monitors and evaluates all locally manufactured or imported foods, drugs, and medical devices, including all herbal medicines and other complementary and alternative medicine (CAM) products and devices (9,62). In Brazil, the National Health Surveillance Agency (ANVISA) coordinates the National Sanitary Surveillance System and among its responsibilities are the registration and inspection of herbal medicine production, as well as surveillance related to the marketing, dispensing, and distribution of plant-based materials (63).

The study was able to identify separate divisions, offices, or committees specific to TCIM products in some countries. For example, in Iran, the General Directorate of Natural, Traditional and Complementary Products sits within the country's Food and Drug Administration at the MoHME (40). In the Republic of Korea, the Division of Herbal Medicine Policy is located within the Ministry of Food and Drug Safety's Biopharmaceuticals Herbal Medicine Bureau [2]. In Saudi Arabia, several TCIM-specific committees sit under the SFDA, including the Registration Committee of Manufacturers of Herbal and Health Products which is separate from the committee that handles the registration of allopathic pharmaceuticals (64). Countries take several different approaches to the regulation of TCIM products.

Some countries have developed standalone regulations that are specific to TCIM products. Cuba's Regulatory Authority for Medicines, Equipment and Medical Devices, for instance, issued four normative

documents specific to NTM products that make up the regulatory framework to support their development and ensure their safety and efficacy (65–68). In Thailand, the existing Drug Act and Food Act was seen as insufficient for the registration of traditional medicines and herbal dietary supplements, so an *Herbal Products Act* was drafted in 2016 and put into effect in 2019, under the responsibility of the Thai Food and Drug Administration and the Department for the Development of Thai Traditional and Alternative Medicine (DTAM) within the Ministry of Public Health (MoPH) (33).

Other countries primarily embed regulations on TCIM products fully within national pharmaceutical policy. This is the case in Bhutan where traditional medicine products are regulated by the Drug Regulatory Authority, using the same criteria as conventional pharmaceuticals. Traditional medicine is integrated into both the *Medicines Act 2003* in which all “medicinal products,” from both allopathic or traditional medicine, follow the same criteria for production, inspection, registration, and advertisement (69) and the *Medicines Rules and Regulation 2012* which outlines requirements for Good Manufacturing Practice (GMP) (70). Bhutan’s *National Drug Policy 2007* also covers both allopathic and traditional medicines (71). In Malaysia, T&CM is embedded in the *Control of Drugs and Cosmetics Regulations (1984)* that require all T&CM products to be registered, with an exception made for traditional preparations of herbal medicines produced only through drying in the absence of other treatment or processing (9,72). Malaysia has required T&CM products to adhere to GMP and various ISO requirements since 1997 and T&CM product manufacturers to be licensed since 1999 (9,54,72).

Still other countries have mixed regulations, with some specific to TCIM medicines and some embedded in national pharmaceutical policies. Benin has specific regulations that authorize traditional health practitioners to prepare, package, and sell traditional medicine products as long as they have been submitted to rigorous safety testing, empower a national committee to be in charge of oversight around authorization of traditional medicine promotion centres, describe procedures for the approval of herbal medicinal products, and regulate the advertizing of traditional medicine (36,73). However, regulations are also embedded in national pharmaceutical policy, with traditional medicine integrated into general pharmaceutical regulation such as on registration of medicines meant for human use and approval procedures for pharmaceutical products for human use (74). Likewise in Brazil, ANVISA regulates the production of herbal medicine products through a resolution that sets out two categories of products for registration: herbal medicines and traditional herbal products (63,75). Regulation of GMP for the manufacturing of herbal medicines, however, is covered under a 2010 resolution which regulates all pharmaceuticals broadly (76).

In the Republic of Korea, the *Traditional Korean Medicine and Pharmaceuticals Act* of 2004 supports the systematic development of TKM and requires the government to create and enforce a mid-to-long term plan for TKM every 5 years (77). In 1995, the *Regulation on Quality Control of Herbal Materials and Distribution* was developed, under which the regulatory system for quality control of herbal materials was established a year later (9). The government strengthened the system in 2012 by ensuring that all herbal materials used in TKM must be processed by manufacturers certified in GMP (9). Herbal medicine products must obtain market authorization from the Ministry of Food and Drug Safety, which has a Division of Herbal Medicine Policy within its Biopharmaceuticals Herbal Medicine Bureau (9). In Ghana, herbal products are regulated in Ghana’s first *Food and Drug Act, 1992*, and the main guiding policy for

traditional medicine products are consecutive versions of its *National Medicines Policy* with the third version relaunched in 2017 (78–80). However, Ghana also has standalone documents on herbal products with the *2005 Policy Guidelines on Traditional Medicines Development* setting forth policies around research and development of traditional medicine products, as well as GMP, quality assurance, protection of biodiversity, and intellectual property protections (51). Finally, the *Public Health Act, 2012 (Act 851)* also outlines the role of Ghana’s Food and Drug Authority in relation to standards and regulation of all food and drug products, including herbal and homeopathic medicine products (81).

In Europe, countries such as Germany frequently cite **the European Directive on Traditional Herbal Medicinal Products (THMPD) as the most vital regulation with respect to herbal and complementary medicine products**, as differing regulatory procedures across member states would otherwise impede trade in products across the European Union. THMPD, or Directive 2004/24/EC, was established in March 2004 as an amendment to Directive 2001/83/EC which states codes on medicinal products for human use. THMPD seeks to harmonize guidance, create a single committee for product review embedded within the European Medicines Agency (EMA), and greatly simplify authorization and registration. The Directive is unique in that it recognizes that most EU member states’ have long, culturally-relevant histories of T&CM and notes the desire of states to ensure their citizens have access to traditional products (82).

Practitioners

By practitioners, we refer to governance around the TCIM health workforce, including the training, registration, licensing, and certification of providers of TCIM services.

All the case study countries regulate standards and require licensing for at least some categories of TCIM practitioners, with regulations found across many different types of governance documents. In some countries, practitioners are regulated in acts passed by legislative bodies. In the Republic of Korea, the *National Medical Act 1951* acknowledged TKM alongside Western medicine with the bill guaranteeing equal status for doctors of Western medicine and TKM and providing legal protection through licences (77,83). The Act led to regulation of TKM services, standards for licensing of practitioners, rules for TKM institutions, and qualifications for specialists (77). In Malaysia, the *Traditional and Complementary Medicine Act 2016* sets out conditions of registration and certification, liabilities, and penalties (as well as processes to appeal these), and obligations for referral to biomedical practitioners in instances in which conditions cannot be treated through T&CM (26). In Ghana, the *Traditional Medicine Practice Act 575* of 2000 required all practitioners to register with the TMPC to ensure standardization and professionalization—including in traditional medicine training and curriculum development—and establish a code of ethics (27). In Bhutan, the *Medical and Health Council Act 2002* regulates standards for traditional medicine, academic qualifications, and government-granted practitioner licences (84). Traditional medicine practitioners have similar civil services grades and entitlements as allopathic physicians, and only those practitioners registered by the Council are allowed to practice (33). In October 2014, Turkey approved the Regulation on Traditional and Complementary Medicine Practices, which included regulation around *hijama/cupping* and bloodletting (49).

In other countries, standards for TCIM practitioners are articulated in national TCIM policies and plans. In Benin, *Decree N° 2001-036* states that traditional medicine must only be practiced by registered

practitioners from Benin (or countries with reciprocal agreements with Benin) who have passed a test of competence with proven ability to treat at least four conditions. Registration grants these practitioners the right to access the traditional Beninese pharmacopoeia, binds practitioners to a code of ethics, and requires practitioners' preparation of traditional medicine products to be regulated by the MoH (35). In Uganda, governance of TCM practitioners was first set forth in 2005's *Policy Framework for Partnership with Traditional and Complementary Medicine Practitioners* (34). It creates accountability mechanisms for TCM practitioners and services with strategies such as registration, monitoring, and oversight of all TCM practitioners and practices, establishment of certification criteria for both practitioners and facilities, and encouragement of practitioners to belong to accreditation bodies (34). In Cuba, in 2002 the Executive Committee of the Council of Ministers adopted *Agreement 4282* to consolidate the strategy and development of NTM, including a framework for the training and accreditation of NTM practitioners which was most recently updated in 2015 (9,85). *Agreement 4282* established academic institutions to issue relevant licences or certificates required for NTM practice (85). Cuba has no separate register for NTM practitioners as they are included in the general practitioner register under the national health system (9). Saudi Arabia is, meanwhile, taking a stepwise approach to bringing the regulation of CAM practice under a common umbrella. In 2015, the NCCAM regulated *hijama* practitioners, issuing licences to those who did a week-long NCCAM training course followed by a series of examinations (including clinical practice exams) and stipulating that they work from within a licensed *hijama* facility, and then only with approved *hijama* equipment (86,87). *Hijama* regulation was intended as the first phase of CAM licensing and regulation in the country with further regulations issued in 2017 (86,87). Germany has been regulating T&CM practitioners since 1939 via the *Heilpraktikergesetz*, which established and formalized the *Heilpraktiker* profession for practitioners of homeopathy, naturopathy, and other medical treatments that do not involve medical accreditation; however, it also stipulates that all those who would engage in T&CM practice are required to be trained, certified, and licensed (20).

Services

By services, we mean the governance of TCIM practices as embedded within healthcare establishments and the steps taken within policies, strategies, and frameworks to ensure that quality care is widely accessible.

In only five countries—Bhutan, Republic of Korea, DPR Korea, Cuba, and Thailand—was TCIM being offered in the public sector regularly and at scale (that is, neither as a pilot or a unique service within a designated hospital). For example, Bhutan's public sector governs traditional medicine services through the same window as allopathic services. While traditional medicine services are available through the specialist National Traditional Medicine Hospital, policy also allows for the public sector to offer traditional medicine units co-located in all of the country's 20 district hospitals and within 29 basic health units, allowing cross-referrals of patients between allopathic and traditional medicine and offering patients the choice of services in one setting (33,88,89). Bhutan implements two quality criteria for traditional medicine services—*smen-pai-ju-druug* (quality of practitioner) and *che-pai-yen-lag-bduen* (quality of practice)—and continues to improve these dimensions of quality through developing skilled practitioners at the Faculty of Traditional Medicine, establishing traditional medicine facilities, providing free traditional medicine services throughout the country, and manufacturing quality medicines (90). In DPR Korea, policy

enables Koryo medicine and allopathic medicine to be integrated into service delivery at the central level, in 20 provincial Koryo traditional medicine hospitals, and at the county level through the household doctor system (33,91). In Cuba, policy enables NTM services approved for use to be made available throughout all three levels of the national health system, including at the community level in neighbourhood *consultorios* (small clinics) that place an emphasis on both preventive and curative primary care and at which 88% of NTM utilisation presently occurs (92).

Elsewhere, TCIM is only partially integrated into public sector services. In Malaysia, the MoH conducted a phased launch of T&CM units at public sector hospitals in 2006 in order to integrate certain T&CM practices into service delivery; as of December 2022, 15 public hospitals throughout the country provide different packages of T&CM services for designated health conditions (93). Malaysia's Traditional and Complementary Medicine Division has a Quality Policy and Quality Objectives for T&CM services, both of which commit the Division to comply with existing regulations, be responsive to client needs, complaints, and feedback, and carry out monitoring and evaluation and continuous quality improvement, including via a Client Charter (94–96). Training programs in T&CM must also be approved by the Malaysian Qualifications Agency under the Malaysian Qualifications Agency Act 2007 (97,98). In Germany, as specified practices are available via social health insurance, certain public sector hospitals – in particular, specialist hospitals – offer complementary medicine services for designated health issues; for example, Germany's Havelhöhe hospital offers whole-person complementary approaches to care across 14 specialist departments (99).

In Ghana in 2010, a pilot integrating herbal medicine into approximately 18 government hospital facilities was launched and, by 2022, had scaled to 53 public sector hospitals around the country (100,101). Herbal medicine programmes are staffed by medical herbalist graduates of the Kwame Nkrumah University of Science and Technology who work with conventional medical practitioners using traditional medicines locally manufactured by the Center for Scientific Research into Plant Medicine. Many of these continue to exist as part of hospital service delivery, but it is not apparent if there exist plans to either permanently embed herbal medicine as a standard hospital service (22,102–105). In Iran, by the end of 2015, there were 20 public clinics providing Persian medicine services, as well as two hospitals that admitted patients for hospitalization for Persian medicine therapies (48). The Office of Persian and Complementary Medicine and the Deputy of Health launched a pilot study in 2020 to scale up primary health care coverage of Persian medicine services which led to the integration of Persian medicine into primary health care in 15 faculties and universities in November 2022, with a plan for further scale up in the future (40,106).

For other case study countries, TCIM is mainly delivered via private sector service provision (either standalone or integrated into diversified private practice). For instance, Uganda's 2005 *Policy Framework for Partnership with Traditional and Complementary Medicine Practitioners* aims for integration of traditional medicine practitioners and practice into the health care system (34) while its *Traditional and Complementary Health Act* aims to promote collaboration and integration of TCM with conventional medicine (29). TCIM services, however, remain largely standalone and unregulated, with no data on the extent of integration with either private allopathic or public sector practice. Benin's *Decree N° 2001-036* set forth criteria for traditional medicine practice and establishment of places of business, with the former overseen by the national professional body for traditional medicine and the latter by a newly established

National Committee for the Support and Monitoring of Activities for the Promotion of Pharmacopoeia and Traditional Medicine located within the MoH (35). The goal of the country's 2013 Policy on Traditional Medicine of Benin (36) was to "improve the coverage of the population's health needs by effectively and efficiently integrating traditional medicine and pharmacopoeia into the national health system" (p. 25). It is unclear how—as a country with a decentralised system of both health and governance—traditional medicine service delivery intersects with local government, although the WHO 2019 Report also states that "T&CM providers practice only in private sector clinics and hospitals" (p.61), albeit ones licensed by government (9).

Financing

By financing, we refer to policy or regulation around how TCIM programmes and services are financed, whether through government health spending, prepaid private spending (such as private health insurance), out-of-pocket spending, or some combination of these financing arrangements.

In countries with significant integration of TCIM in the national health system and a non-existent or minimal private health insurance market, government health spending is a critical source of financing for TCIM services. In Bhutan, where the right to free access to basic services in both traditional and allopathic medicine is enshrined in its *2008 Constitution*, the government health system provides services free of charge, including for traditional *gSo-ba Rig-pa* services (32,107). In Cuba, the national health system provides free of charge the eleven NTM services that were approved within the Cuban health system in 2015 and 2019 (108,109). Likewise, in DPR Korea, the government health system provides free services for both traditional (Koryo) and allopathic medicine, as well as acupuncture, chiropractic, herbal medicines, and naturopathy (9). In Germany, homeopathy, naturopathy, acupuncture, and different types of "manual medicine" (chiropractic, massage, osteopathy) are covered by Germany's social health insurance scheme (20). In Switzerland, reimbursement by insurance companies also depends on where T&CM is administered (by registered doctors or by non-medical professionals) and whether the particular company recognizes non-medical professionals' certification on the private registry of experience medicine ("*Erfahrungsmedizinisches Register*") (20).

In several countries, universal coverage schemes cover select TCIM services, and services that are not covered are instead financed through prepaid private or out-of-pocket spending. In the Republic of Korea, the government piloted coverage of TKM services in its National Health Insurance (NHI) in 1984, expanding nationwide in 1987 (110). Today, the NHI covers select TKM consultations and treatments and research suggests that by decreasing out-of-pocket payments, the NHI has improved health equity and increased the use of TKM services (77,110,111). For TKM services not covered by the NHI, the patient must pay 100% of costs out-of-pocket unless they have private health insurance coverage (112). In Thailand, TTM was added in 2007 to the benefit package of the country's tax-based Universal Coverage Scheme (UCS) which covers almost 75% of the Thai population and provides free health care at the point of service (113). Coverage of and access to TTM medicines and services has increased over the years and UCS now covers Traditional Thai herbal massage, postpartum care, herbal medicines listed on the National List of Essential Medicines (NLEM), and acupuncture for stroke patients (113). TTM and complementary medicine services not covered under the UCS are paid through private insurance or out-of-pocket. In Turkey, traditional and complementary medicine practices are not covered by general health insurance,

although some parallel practices (rehabilitation, manual therapies, spa practices) are covered if provided by a qualified practitioner (31), while in Iran, herbal medicines on the national essential medicines list and a few complementary practices (hijama/cupping and bloodletting) are covered by national health insurance (114).

In Brazil, the country's decentralized, universal public health system—used by around 75% of the population—is financed by tax revenues and social contributions and offers the 29 recognized PICS services free of charge. Though the use of PICS services in the public health system is increasing, it is still relatively low due to a number of implementation issues, including lack of sufficient funding (108–112). The other 25% of Brazilians, primarily from middle- and high-income households, have private health insurance, regulated by the National Health Supplementary Agency, with coverage only for homeopathy and acupuncture (116,120). In Iran, herbal drugs on the national essential medicines list (NEML), as well as a limited number of Persian and complementary services (i.e., hijama/cupping, phlebotomy) are covered by public insurance (40,48,114,121). Financing of Persian medicine in Iran has been challenged by lack of dedicated budget lines in national budgets, and continued lack of clarity about payment methods for traditional medicine services (122).

In Ghana, traditional medicine is, in theory, included within the National Health Insurance Service (NHIS) benefits package, dating back to the MoH's *2004 National Health Insurance Policy Framework* which states that benefits for medication should include approved traditional medicines, specifically within outpatient services (123). Since then, the benefit package has expanded and the NHIS now states that Ghana's minimum benefits package includes reimbursements for consultations by practitioners within "accredited integrated service settings" and for "traditional medicines approved both by the Food and Drugs Board and prescribed by accredited medical and traditional medicine practitioners within both out-patient and in-patient settings" (124). In practice, however, it is often not possible for services or products to meet the qualifications stipulated within these benefit descriptions, and benefits from consultation and/or medication are rarely encouraged, filed for, or claimed (indeed, reimbursement codes for traditional medicines have been slow to be developed hence there is no practical means to file a claim for traditional products) (125–127).

In some of the case study countries, including those with UHC schemes, TCIM services rely on private financing. In Saudi Arabia, CAM is not covered under national health insurance (87,128). CAM practices are mostly practised in the private sector as parallel services, funded by out-of-pocket payments (56,87). In Malaysia, T&CM services provided in the 15 public hospitals participating in the MoH's integrated service delivery project are fully subsidized; however, most T&CM services are obtained in the private sector (97). Some private health insurance companies cover categories of T&CM (such as chiropractic and Traditional Chinese Medicine) (129,130). The country's *National Policy of Traditional and Complementary Medicine* urges practitioners to ensure their clients have sufficient health insurance coverage and the 2019 T&CM Consumer Guidelines notes that private T&CM service prices are unregulated, with the proportion of out-of-pocket spending on T&CM differing depending on the condition for which a T&CM treatment is sought and sometimes may lead to catastrophic health expenditures (43,95,131).

In Benin, the research found no recent assessment of central or municipal budgets for financing of traditional medicine, nor governance stipulating the source of financing. WHO's 2019 Report states that,

from 2010 to 2016, annual government or public research funding for traditional and complementary medicine in Benin varied between USD \$100,000 and \$300,000 and financial support was a key strategic target within its 2013 strategic plan for traditional medicine (9,132). A 2020 progress report from WHO's Regional Office for Africa (AFRO) on the implementation of AFRO's 10-year *Regional Strategy on Enhancing the Role of Traditional Medicine in Health Systems* states that, since 2012, twelve AFRO Member States, including Benin, had research institutes investing in research and development through public fund allocations since 2012 (133). Similarly, in Uganda, the *Policy Framework for Partnership with Traditional and Complementary Medicine Practitioners* included advocacy around the inclusion of TCM into national planning and budgeting activities (34). Only Uganda's *Health Strategic Plan (HSP), 2020/21-2024/25* includes costed activities for traditional medicine, coming to less than 150,000 UGX spread out over 5 years (134).

Information and Research

By information, we refer to the integration of TCIM service coverage, utilization, and human resources for health into a country's health information system. This includes routine health information systems (RHIS) that collect and aggregate data on a daily, weekly, or monthly basis, and periodic surveys. Research refers to either the prioritization of TCIM research in governance documents or the existence of institutions to conduct pharmaceutical, biomedical, or agronomic research into herbal medicinal plants or other TCIM products and practices.

Information

Countries that routinely capture coverage or utilization data within their RHIS were countries that had policy enabling TCIM integration at scale within, specifically, public sector service delivery. For example, Bhutan's MoH collects and publishes annual data on traditional medicine in parallel with data on allopathic medicine in its *Annual Health Bulletin* (135). Services are monitored and evaluated through the hospital management information system and there are multiple indicators in place for monitoring performance (136). In the Republic of Korea, data is collected annually on the prevalence of TKM service use and health expenditure, including national health insurance reimbursement data, and these provide the basis for policy decisions (111). The *National Survey for Usage and Consumption of Traditional Korean Medicine* was first conducted in 2008 and has since been carried out every three years (137). Thailand has a real-time monitoring system on the performance of traditional medicine services and the MoPH prepares monthly reports based on data from 76 provinces across 13 health service areas (33). In Brazil, the implementation of PICS in the country's health system is monitored through continuous data collection as part of RHIS for primary care in order to evaluate the adoption of practices at state, municipal, and district levels (138).

Other case study countries provide for monitoring and evaluation (M&E) of TCIM data in national TCIM governance documents but there is no clear indication of routine data collection. Saudi Arabia, for example, has a national patient Electronic Medical Records (EMR) system and the country's CAM Regulations 2019 state that CAM establishments should have EMR in place (139); however, Saudi Arabia utilizes more than 10 digital health platforms to collect, link, and integrate EMR data from facilities across the country and this multiplicity of platforms creates challenges in assessing routine health data (140). It is unclear how CAM utilization and service delivery data is being captured, aside from special utilization

surveys. Ghana has a dedicated indicator on TCIM within Medium-Term Health Sector Development Plans (100,141) but it is unclear the data source used to measure this indicator, although the numbers are presented in Health Sector Annual Programme of Work: Holistic Assessment Reports (101). As registries exist for traditional medicine practitioners, practitioner numbers should be easily available, but publicly available data is extremely dated. Uganda has been working to integrate the private sector into the country's DHIS-2 system, but this effort is tied to indicators that are focused on services offered in the public sector, all of which are allopathic. The *Policy Framework for Partnership with Traditional and Complementary Medicine Practitioners* tasks the MoH with the responsibility to plan, mobilize resources for, and carry out M&E including creating appropriate indicators, carrying out routine impact assessments, and ensuring data is accessible within an information system (34).

Research

Some case study countries clearly embedded research into TCIM governance documents. National TCIM policies may have provision for the development of a national TCIM research agenda, the strengthening of TCIM research and research institutions, the dissemination of evidence, or the utilization of research to help secure indigenous cultural and intellectual property, reach national biodiversity aims, or advance a country's economic development goals. For example, Uganda's 2005 *Policy Framework for Partnership with Traditional and Complementary Medicine Practitioners* has the promotion of research and use of appropriate methods and technologies in the TCM sector, as well as the protection and conservation of indigenous knowledge and genetic resources, as its objectives (34). Article 30 of DPR Korea's *People's Public Health Law 1980* states, "public health institutions and medical scientific research institutions must strengthen research work to scientize traditional medicine, shall theoretically systematise traditional medicine and folk medicine and must further develop them" (142). In 2015, Brazil's *Law No. 13,123/2015* regulates access to genetic heritage, as well as protection of traditional knowledge and fair and equitable sharing of benefits for the conservation and sustainable use of Brazil's biodiversity, with a Genetic Heritage Management Council established for oversight and governance (143). Thailand's *Protection and Promotion of TTM Knowledge Act 1999* was passed to improve public awareness of the value of TTM knowledge and plants, as well as their conservation, development, and sustainable use (144). The Act enabled the MoPH to consolidate information on TTM knowledge and designate herbs which are valuable for research, have economic value, or are endangered, as "controlled herbs" (144). Turkey passed the Regulation on Clinical Research of Traditional and Complementary Practices in March 2019, which includes control and oversight around how and by whom clinical research into traditional medicine will be conducted in the country (49).

All case study countries had government- or university-based TCIM research institutions which supported the generation of evidence on TCIM products and practices. Uganda's Natural Chemotherapeutics Research Laboratory, for example, was launched in 1964 and elevated in 2011 to one of only two public sector medical research institutes in the country under the MoH with a focus on research around claims of efficacy and safety of natural products (145). In 1975-76, Ghana established the Centre for Scientific Research into Plant Medicine to conduct scientific research and evaluation into the safety and efficacy of traditional medicinal products (146,147) and has since been joined by other university-based research institutes across the country (148). Saudi Arabia's NCCAM has a strong CAM

research agenda and partnerships with King Saud and Umm al Qura universities, including King Saud's Medicinal Aromatic and Poisonous Plants Research Center (9,128). Iran has 15 research centres, offices, and institutes belonging to medical universities around the country that work on Persian and complementary medicine and the history of Persian medicine, including the Institute for Studies in Medical History, Persian and Complementary Medicine established in 1997, and the Traditional Medicine and Materia Medica Research Centre founded in 1999 (9,149). The Turkish Institute of Traditional and Complementary Medicine (T&CM Institute) sits under the Turkish Directorate of Health Institutes to serve as a means of generating interdisciplinary evidence on traditional and complementary medicine practices in the country and to promote evidence-based Anatolian medicine (49). In Germany and Switzerland, a number of research institutes exist embedded within universities and university hospitals, including Havelhöhe Community Hospital, which serves as both an integrated acute care hospital and an academic teaching hospital affiliated with Berlin University of Medicine's Charité Hospital and The Institute for Complementary and Integrative Medicine (IKIM) at Switzerland's University of Bern (99,150).

Discussion

Case countries, then, had an abundance of TCIM governance in place, either TCIM-specific, embedded within broader health sector governance documents, or both. In Bhutan, Republic of Korea, DPR Korea, Cuba, and Thailand, the robust policy environment has resulted in TCIM being broadly integrated and implemented into free or low-cost public sector health services, while countries like Ghana and Malaysia have made targeted efforts at public sector integration even if TCIM remains primarily available in the private sector.

Elsewhere, however, the existence of policies on paper or the institutionalization of TCIM within or parallel to MoHs, however, has not always resulted in operationalized, well-resourced, integrated TCIM services equitably available to all. For example, Benin's 2013 National Traditional Medicine Policy noted that, after almost three decades of policy work in the traditional medicine sector, "the various mechanisms for promoting traditional medicine that have been put in place in Benin have not achieved the desired results due to insufficient resources and the lack of timeline implementation planning at the health zone level" (p.21) (36). Likewise, despite a favourable policy, regulatory, and legislative environment, the use of PICS services in Brazil's public sector is still relatively low with stakeholders pointing to the need to improve funding, training of health professionals, knowledge, management, access to PICS services, and M&E (115–119). Meanwhile, Iran's Deputy Health Minister has stated that, although there is political commitment for Persian medicine, Iran's public sector is still not fully benefiting, with researchers noting that this is partly due to a lack of dedicated budget lines, unclear payment methods for services, weak regulatory and monitoring systems for products, and other challenges (106,122).

When TCIM remains primarily in the domain of the private sector—whether siloed/standalone or integrated with allopathic services—its governance is partly dependent on policy and regulation of the private sector more generally. Countries like Iran, Malaysia, and Saudi Arabia which, as described in this review, have more strongly developed institutional infrastructure for governance and regulation of practitioners and products have the capacity to govern the private sector, with the sort of resourced infrastructure that enables enforceable licensing, accreditation, certification, and regulation of products

and practitioners, even if 1) integration of TCIM and allopathic services is less well developed, and 2) people's access to TCIM services is determined by access to the means to pay for them (151–153). By contrast, other case study countries with under-resourced regulatory infrastructure may have less capacity to govern private sector health entities (154,155). Regardless of how rigorous their TCIM policy landscape is, if such countries have limited capacity to govern the private allopathic health sector, they will likewise not have the capacity to govern privately provided TCIM.

Two critical weak links between governance and operationalization of TCIM are the lack of provision within national policy instruments for dedicated national and subnational financing and the integration of TCIM data for decision-making into routine health information systems. An understanding of how TCIM is being used—by whom, for what, how often, and to what outcome—is essential to the creation of the operational scaffolding that links ideas to resources to action (i.e., costed implementation plans, budget lines in programme-, activity-, or performance-based budgets, actuarial statistics, etc.). This review has found that the barriers to collecting information on TCIM service coverage and utilization and to funding TCIM services (whether publicly or privately) remain formidable, even in countries with historically strong TCIM medical systems running parallel to allopathic care.

Countries that are routinely collecting data—such as Bhutan, Republic of Korea, and Thailand—were more likely to see no- or low-cost TCIM services financed, integrated, and widely available within the public sector and, thus, the operationalization of their many TCIM policy instruments. By contrast, in case study countries in which TCIM is primarily available in the private sector, review findings were mixed and partly dependent on the degree to which the national RHIS was collecting data on both TCIM and the private sector more generally, as well as the extent to which TCIM services were covered either by national health insurance, private health insurance, or out-of-pocket.

In the case of Saudi Arabia, for example, while there is UHC, health governance reform aimed at greatly expanding private service provision, and strong government commitment to TCIM health governance, a patchwork of information systems makes it difficult to assess routine data on TCIM and TCIM is not financed under national health insurance (140). In Malaysia, although there exists robust governance of the TCIM sector, routine data on TCIM is not as readily available. TCIM is not funded under UHC and only intermittently under private insurance plans. TCIM utilization is assumed to be high based on special surveys but has been linked to catastrophic out-of-pocket health expenditure (156).

These bottlenecks in tying governance of TCIM to operationalization and access to services raise larger questions on the value of standalone TCIM policies in the absence of integration into more general health governance, as such standalone policies imply the need for a siloed stream of financing which may not exist. Countries' national health budgets are tied to national health strategic plans which, in turn, are tied to both costed implementation plans, budgets, and monitoring and evaluation frameworks. While it is clear from many of the case study countries that the integration of TCIM into national health governance does not guarantee that TCIM will be successfully monitored or equitably and/or sufficiently financed, nevertheless, if the aim of countries is to achieve integrated, accessible service delivery, integration starting at the level of governance and regulation is vital. TCIM health services are simply health services, and should be financed, monitored, and made available in the same way that allopathic health services

are financed, monitored, and made available. By contrast, case study countries with only standalone TCIM policies may be more likely to struggle in financing, regulating, monitoring, and ensuring their availability.

Going forward, then, it is vital that global stakeholders pivot from strengthening countries' governance landscape toward supporting them in translating governance into action. This includes helping countries understand the importance of integrating TCIM data into the national RHIS or of carrying out more regular, periodic health services surveys so that data for decision making is available to policymakers, planners, and service providers. It involves transforming data into costed implementation plans to guide national and subnational planning. It considers advocacy for TCIM's inclusion in national or subnational budgets and in national or private health insurance plans. Lastly, it requires supporting countries to make a perceptual shift away from viewing TCIM as a specialized silo to one in which evidence-based TCIM services sit alongside all other essential health services as part of an accepted package of care. These conclusions align strongly with the objectives of the new WHO Traditional Medicine Strategy, 2024-2035 and its expected Programme of Work, and provide a strong body of supporting evidence justifying the new Strategy's approach.

Limitations

Case comparison findings are dependent on the set of case study countries that were used, most of which had fairly rich policy and regulatory landscapes on TCIM which is not the case in all countries. Additionally, the review only was able to draw upon literature that was open access. Therefore, the review is necessarily biased towards countries where information was most extensive and readily available. Many of the case study countries had TCIM documents that the authors were unable to review due to either 1) the unavailability of online documents, or 2) the presence of documents that were not in a language that machine translation could accommodate. Thus, a comprehensive review of the entirety of each country's governance landscape was not always possible. In these instances, it was necessary to review summaries of primary sources in secondary articles. The authors cannot attest to the accuracy of these secondary sources.

Conclusion

Most case study countries included in this review have a robust policy and regulatory landscape governing TCIM practitioners, practices, and/or products. Governance, however, does not always translate into the operationalization of policy, enforcement of regulation, or equitable access to services. Operationalization requires data, financing, and improved oversight of the private sector if, indeed, the private sector is where TCIM services are most likely to be found. In particular, costed implementation plans at national and subnational levels are vital to secure financing. Each country in this review had a strong vision of the role that TCIM might play in its national health system, such as its contribution to UHC, the advancement of national medical sovereignty, or the elevation and protection of indigenous ways of knowing. Whatever this vision, however, it will not be realized if TCIM governance continues to remain on paper, thus supporting the approach taken by WHO within its next 10-year Global Traditional Medicine Strategy.

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