

Draft background note on integration of Traditional Medicine Chapter in ICD-11

What is the TM Chapter?

- A new Chapter within the ICD-11 MMS. It provides for the first time an internationally agreed standard list of diagnostic categories to identify and report on TM conditions.
- The scope of the chapter covers traditional medicine conditions which originated in ancient China and are now commonly used in China, Japan, Korea and elsewhere around the world (Module I).

This TM chapter (Module I) constitutes the formative step for the integration of TM into a classification with standards used in conventional medicine ICD. International classification on traditional medicine (ICTM) was proposed to be developed as a member of the WHO family of international classifications at the WHO-FIC annual meetings 2006 and 2007. Development of ICTM was officially implemented as a WHO project since 2010 and was integrated into the ICD-11 revision process as a new chapter on TM classifications. This development was performed based on existing international standards and national standards such as international standard terminology and national classifications of diseases, referring existing principle of classifications that have been applied to the ICD.

Additional modules classifying other prominent forms of TM (e.g. Ayurveda) may be developed in the future provided that certain requirements (e.g. existing national classification and terminology standards and use cases) are met.

- The Chapter is a mirror of clinical practice and reality. The TM Chapter categories were derived from:
 - National Clinical Modifications of ICD (i.e. Korean ICD version, KCD-7 Disease Codes of Korean Medicine);
 - National TM Classifications (e.g. Chinese TCM classification GB 95/97, Japanese Kampo Medicine Code Set);
 - Regional Terminologies (i.e. WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region);
 - The Chapter also represents the most common diagnoses used by TM practitioners in Europe and US (e.g. diagnostic categories related to the five element system).
 - Expert groups of TM clinicians using the existing classifications listed above to achieve consensus on standard terminology.
- The TM Chapter is being developed in parallel to the revision of other ICD-11 Chapters. The TM Chapter is using the same classification development principles and tools (e.g. Content Model,

iCAT, ICD-11 Browser) applied in other ICD Chapters. The TM Chapter is also undergoing translation in multiple languages, international peer review and pilot testing.

What is the TM Chapter not?

- As with other ICD chapters, the TM Chapter is neither judging nor endorsing the scientific validity of any TM practice or the efficacy of any TM intervention. It will assist research and evaluation to establish efficacy of TM.

DRAFT

How to respond to potential concerns & misperceptions?

- ❖ The ICD-11 Revision process should ignore TM, there are more pressing issues and needs in areas of conventional Western Medicine classification which the revision process has to address?
 - To ignore the inclusion of TM Chapter would be both to ignore the requests of Member States and to ignore a large section of the population that is using or providing Traditional Medicine. A large percentage of countries not providing information on mortality and morbidity include countries where TM is practised. This issue needs to be redressed with tools such as ICD, including the TM chapter.

Examples of global and national figures on TM usage:

- In general, the average prevalence of complementary and alternative medicine (CAM) was 32.2%.
- In Australia, of those randomly interviewed, 68.9% used at least one form of CAM in the past 12 months and 44.1% visited CAM practitioners.¹
- According to a national survey in China, the number of traditional Chinese medicine (TCM) visits was 907 million in 2009, which accounts for 18% of all medical visits to surveyed institutions; the number of TCM inpatients was 13.6 million, or 16% of the total in all hospitals surveyed. The output of Chinese Materia Medica was more than 100 billion USD in 2015.
- In Germany, where some forms of CAM are covered by insurance, cost for alternative therapies in 2000 accounted for about one-tenth of expenditure on general medical treatments.²
- In Singapore and the Republic of Korea where the conventional health-care system is quite well established, 76% and 86% of the respective populations still commonly use traditional medicine (TM).
- In US, a national health survey in 2007 revealed that more than \$34 billion is spent on CAM annually and almost 4 out of 10 adults had used CAM.³
- Traditional Chinese Medicine (TCM) is being part of health services in more than 160 countries and areas as of 2011. About 130 countries run medical, educational, and scientific institutions on TCM. There are 200,000 TCM practitioners providing its services in 80,000 medical institutions outside of China.⁴
- The national policy of Vietnam for development of TM till 2020 is to have TM hospitals in all provinces and central cities by 2015; TM department in all modern hospitals and TM units in all communes medical station by 2020. In China, all medical institutions should be able to provide traditional Chinese medicine services before 2020.

1 Complementary and Alternative Medicine Use in Australia: A National Population-based Survey. The Journal of Alternative and Complementary Medicine. Vol 13 No 6, 2007, pp.643-650.

2 Use and acceptance of Complementary and Alternative Medicine Among the General Population and Medical Personnel: A systematic Review. The Ochsner Journal 12:45-56, 2012.

3 Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007. National Health Statistics Reports No 12 Dec 10, 2008.

4 Ya, Y., Han, X., Xie, Y., Wang, Y., & Lu, A. (2011). Analysis and thinking on the current status of traditional Chinese medicine standardization. World Science & Technology, 13(3), 445-449.

- The inclusion of the TM Chapter **makes ICD truly “international”**.
 - Quality and Safety. Having a TM chapter within ICD-11 allows TM practitioners to use other parts of ICD which allow capture of data on complications of care and external cause of injury as well as co-morbid conditions.
- ❖ TM Chapter is not scientific or evidence based, but consensus based. The inclusion of TM in ICD-11 will be an unwanted endorsement and advocacy tool for Traditional Medicine.
- The TM Chapter is not an endorsement of the scientific validity of any TM practice or the efficacy of any TM intervention, but a tool for classifying, diagnosing, counting, communicating and comparing TM conditions.
 - Epidemiology needs to record what is being done. TM is being used extensively and often without being noted, documented and reported.
 - Historically, ICD was created by consensus of selected experts.
 - TM Chapter is created in parallel to the revision of other ICD-11 Chapters. TM Chapter has to follow the same classification rules and meet the same requirements as other ICD Chapters.
- ❖ TM Chapter is representing the Chinese, Japanese and Korea perspective of TM and ignores European or US views of TM.
- All uses of the ICD-11 TM Chapter ultimately depend upon a shared notion of what the ICD means by a TM condition. Different understandings, and uses of TM conditions are reflected and balanced in the final version of the TM Chapter through various means and processes:
 - The Chapter development, the peer review and field testing is organized as an international process involving traditional medicine clinicians, researchers, academics and classification experts from around the world.
 - As a new feature, ICD-11 (including the TM Chapter) provides textual definitions, which precisely clarify the meaning of individual ICD entries, across cultures, languages, levels of technological sophistication, and application purposes. As such, ICD-11 TM Chapter categories like other ICD categories represent a scientific consensus about their meanings, and can be regarded as the world consensus view about high-level, clinical phenotype.

Why is a TM Chapter within ICD-11 MMS needed?

Standardized and international comparable data on TM diagnosis and encounters is needed because currently such data is not available despite the following facts:

- Utilization of TM is on the rise globally.
 - 80% of the population in some Asian and African countries depend on traditional medicine for primary care (Source: WHO Global Atlas on TM 2005).
 - 70-80% of the population in developed countries has used some form of TM (Source: WHO Global Atlas on TM 2005). In the US for example the number of visits to acupuncturists tripled between 1997 and 2007 (Source: National Health Interview Survey NHIS).
 - In the European Union, approximately 145,000 medical practitioners and 160,000 non-medical practitioners are providing traditional and complementary (T&CM) services. Over 100 million Europeans are currently T&CM users, with one-fifth regularly using T&CM and preferring health care which includes T&CM.
 - In Australia, there was total of 11,266 TM/CAM registered practitioners as of 2014. According to the Australian Medicare DB, the total benefits of acupuncture services rebated by the government between July 2013 and June 2014 was A\$ 24,672,468.
 - In China, 81 institutions provide university level TCM education. There are also 229 vocational schools providing TCM training and education.
 - In the Hong Kong healthcare system, TM private practitioner consultation reaches 18% of all out-patient consultations.
 - In Japan, according to the Annual Health, Labour and Welfare Report 2011 – 2012, the number of registered medical doctors who are sole prescribers of Kampo medicine is 295,046. There were 276,517 registered pharmacists who are sole dispensers of Kampo medicines.
 - In Malaysia, there was total of 12,139 registered T&CM local practitioners as of 2013
 - In Saudi Arabia, a recent study showed that individuals pay 560 USD per annum out-of-pocket for T&CM services.
 - In the Rep of Korea, patients had total of 138,185,477 visits to TM health facilities as of 2012.
- TM products and practice are a global phenomenon with growing economic importance. Traditional Medicines are often manufactured locally and increasingly sold globally, generating billions of dollars in revenue annually and accounting for XX%??? of health expenditure.
 - The market on CAM products are on increase. In China, there are 3,813 TCM manufacturers as of 2014 with revenue of approximately 114.1 billion USD as of 2014. The production of TCM cultivation in China will grow at an average annual rate of 10%. China trade figure of TCM products is 4.795 billion USD in 2015. In US, sales of herbal dietary supplements also increased by 6.8% in 2014, reaching an estimated total of more than 6.4 billion USD.

- Growing demands for more and better integration of TM in mainstream health care.
 - The number of countries with health insurance coverage of certain TM practices is growing even in countries and regions with partial integration of TM in the Health system.
 - Switzerland was the first country in Europe to have TM practices covered by the compulsory health insurance programme since 1999. The compulsory health insurance (AOS, basic insurance) reimburses benefits of anthroposophic medicine, traditional Chinese medicine, homeopathy and herbal medicine since 2012.
 - By 2005 63% of the Countries in the WHO Europe region have public and/or private insurance coverage of certain TM practices (Source: WHO Global Atlas on TM 2005).
 - Under the affordable care act in the US a number of states recognize acupuncture as an “essential health benefit” and every insurance company has to pay for acupuncture care (Source: American Acupuncture Council, ACC).
 - Increased regulatory efforts of TM products, practices, and practitioners. For example:
 - The number of Member States with TM policy regulations increased 2.7 fold within 13 years (from 25 MS in 1999 to 69 MS in 2012) (Source: WHO TM Strategy 2014-2023).
 - The number of Member States with Herbal medicines regulations increased by almost 2 fold within 13 years (from 65 MS in 1999 to 119 MS in 2012) (Source: WHO TM Strategy 2014-2023).
- TM is a center piece of people-centered integrated services.
- There is a significant increase of TM related research activities.
 - The number of peer review publishes research articles increased from XXXX in YYYY to XXXX in. YYYY [REF???].
 - The number of Member States reporting the establishment of National TM Research institutes increased by almost 4 fold from 19 National Institutes in 1999 to 73 National Institutes in 2012 [Source: WHO TM Strategy 2014-2023]. TM research is becoming increasingly international [REF???].

What are the potential benefits of having a TM Chapter in ICD?

- Enable counting of traditional medicine health services and encounters and measure their form, frequency, effectiveness, safety, quality, outcomes and cost nationally and internationally.
- International comparability of practice, research and reporting of morbidity in traditional medicine.

- Digitization of TM diagnoses data with facilitated integration into Electronic Health Record (EHR) systems.
- Joint use of ICD-11 TM Chapter and other ICD-11 Chapter (e.g. Neoplasm, Patient Safety, Injuries) can enhance adverse-event reporting and enable integration of TM into insurance coverage and reimbursement systems, in line with larger WHO objectives relating to universal health coverage.
- Link Traditional Medicine practices with global norms and standard development.
- International network of traditional medicine clinicians, researchers, academics and classification experts

Uses of ICD-11 TM Chapter

The TM Chapter can be used as a coding tool for statistical and administrative purposes as well as a tool for facilitating clinical decision making, research and education.

- Reporting TM conditions. The ICD-11 TM Chapter will allow enumeration of incidence and prevalence of TM conditions and their trends, systematically classified by mutually exclusive and exhaustive categories.

Countries with integrated health care systems already use national diagnostic classification standards for coding of TM conditions in hospitals and primary care settings.

In China, for example, over 2500 TCM Hospitals and most of PHC Units report in- and outpatients TM diagnosis with GB95/97 codes. Since the 90s the nationwide recommended medical record template is using an integrated approach whereby coding conventional medicine diagnosis is done with ICD-10 and TM diagnosis with the national GB95/97 standard. Based on data from the national monitoring of TCM services, the top five diseases for admission to TCM hospitals in 2008 were: cerebrovascular accident, intervertebral disc displacement, haemorrhoids, ischaemic heart disease and essential hypertension.

Reporting of TM conditions in Korea is ICD based using TM specific ICD codes which are part of the Korean ICD 10 version (i.e. KCD-7). For these countries the use of the ICD-11 TM Chapter as an international standard is of particular importance in the context of enhancing statistical comparability of hospital activity analysis. The 2013 Hospital Status Data from Health Insurance Review and Assessment Service allowed assessing the medical performance of collaborative practice between traditional Korean medicine and conventional medicine in stroke patients. The claim data showed that collaborative practice decreased the intermediate and long term death rates in stroke patient with prolonged day of hospitalization, and increased total cost.⁵

5 Performance of collaboration between Korean medicine and Western medicine – utilization and quality of care for stroke patients. Department of Health Care Management and Policy, Graduate School of Public Health, Seoul National University.

- In countries which are moving towards TM integration the use of the ICD-11 TM Chapter will offer the first ever opportunity to count traditional medicine health services and encounters

In France, chronic musculoskeletal disorders patients made up a greater proportion of visit to physicians who offered alternatives to conventional medicine

An extensive number of patients with multiple sclerosis resort to CAM treatments: prevalence of use ranges from 41% in Spain to 70% in Canada and 82% in Australia.

- Reimbursement. The ICD-11 TM Chapter Code sets can be used for reimbursement of TM treatment under health insurance schemes. In the absence of a global TM specific classification countries have currently different arrangements for TM reimbursement in place.

The Korean national medical insurance has been using TM specific ICD codes for many years. The coding has enabled the tracing of total health expenditure for traditional medicine under scheme of Universal Health Coverage. The total expense represents 3.9% of the total cost of National Health Insurance treatments in 2010.⁶ The claim data showed musculoskeletal diseases accounted for a large part of traditional medicine utilization in Korea.⁷

In Japan, 84% of Japanese physicians use Kampo in daily practice. As of April 2000, the National Health Insurance Reimbursement List included 147 prescription Kampo formulae and 192 herbal materials used in prescription Kampo formula.

In China the national Standard GB95/97 is used and exploration of using TM specific codes sets in Casemix systems have started.

In the US and some European countries therapist or TM trained physicians have to use ICD-10 codes.

- Patient safety and pharmacovigilance. The ICD-11 TM Chapter can be used in conjunction with other ICD-11 chapters to capture issues relating to patient safety and complications of care. This already happens for recording sequelae of care in the Western Medicine milieu. The ICD-11 will provide enhanced coding possibilities for capturing adverse events.

This will be of particular relevance to countries such as the US where due to the growing popularity of TM the number of malpractice cases against acupuncturists (primarily for

6 Korean medicine coverage in the National Health Insurance in Korea: present situation and critical issues. Integrative Medicine Research. 2 (2013) 81-88.

7 Translation of Korean Medicine Use to ICD-Codes Using National Health Insurance Service-National Sample Cohort. Evidence-Based Complementary and Alternative Medicine. Vol. 2016.
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pneumothorax and burns) also increased significantly. According to American Acupuncture Council a prototypical Malpractice Insurance company is currently handling 5 to 12 cases against acupuncturist per week while in the late 80s they were handling in average 2 cases per month.

The State Food and Drug Administration (SFDA) approved 81 TCM products in 2010, reaching 8% of all drugs approved in China.⁸ SFDA also operates National Adverse Drug Reaction and TCM drugs represent 13.8% of total reported cases. Expected and serious TCM drugs case reports represent 12.2% of total unexpected and serious reports in 2010.⁹

Since 2004 EU countries use a common regulatory framework for registration of Traditional Herbal Medicinal Products (THMP) in the EU (Dir. 2004/24/EC). One of the challenges in the THMP Registration is the lack a TM specific international diagnostic classification system which would allow provide more structured and international comparable information regarding the efficacy of the THMP.

- Research, policy making and education.

In China, the State Administration of Traditional Chinese Medicine promotes TCM clinical pathways of 304 diseases. Its diagnoses are referred to GB95/97. TCM clinical pathway means a set of standardized diagnostic and treatment models for TCM disease in order to enhance medical quality and control its cost.

[NOTE: *Add info on 'clinical utility' from pilot testing in Europe*, describe on provide data on which treatment of modern medicine conditions (e.g. cancer, musculoskeletal, MH) go hand in hand with treatment of TM conditions, give info on how a joint ICD-11 TM and WM code set will facilitate cost-effectiveness research.]

8 ZHIGUO XU (2011) One step at a time The repertoire of traditional Chinese medicine could offer rich pickings for modern drug developers, but researchers must first define and test herbal concoctions, TRADITIONAL ASIAN MEDICINE, Vol.480(7378), p.S90(3).

9 Li, Z., Yan, J., Liu, X., Ye, Z., Yang, X., & Meyboom, R., et al. (2012). Pharmacovigilance practice and risk control of traditional chinese medicine drugs in china: current status and future perspective. Journal of Ethnopharmacology, 140(3), 519–525.

How is WHO planning to use the TM Chapter within its TCM strategy and program?

- Universal Health Coverage (UHC) ensures everyone has access to the health services without suffering financial hardship. Traditional medicine services have been functioning as primary health care, people centred care, and integrated care in many health care setting of the Member States. Thus documentation and monitoring the access to its services composites the essential information to monitoring progress towards UHC.
- WHO TCM Unit in the Service Delivery and Safety Department is planning, in cooperation with relevant teams to:
 - Use the TM Chapter as a tool to conduct projects in monitoring and assessing TM morbidity and services at the global context;
 - Facilitate the projects on safety, quality and effectiveness in T&CM services;
 - Facilitate the projects on clinical research;
 - Be included into relevant training and clinical documents. (e.g. benchmarks for training and for practice documents in T&CM);
 - Facilitate the integration of T&CM service with national healthcare systems
 - Monitoring how T&CM services contributes to the progress toward UHC

Conclusion: Including a classification of TM in ICD-11 will allow greater visibility of TM worldwide. Such focus can only be a positive contribution to our knowledge, promote discussion amongst TM practitioners regarding standards of practice and allow exposure to rigorous examination of TM efficacy and efficiency.