

附属 1) XML スキーマ

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edited with XMLSpy v2007 rel. 3 (http://www.altova.com) by Jun Nakaya (Tokyo
Medical and Dental University)
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Ⅲ. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

著者氏名	論文タイトル名	書籍全体の編集者名	書籍名	出版社名	出版地	出版年	ページ
Watanabe K, Sakiyama T and Ishino S.		渡辺賢治	漢方の証コード英語版	アシステ	東京	2009	1-26

雑誌

発表者名	論文タイトル名	発表誌名	巻号	ページ	出版年
Watanabe K, Matsuura K, Gao P, Hottenbacher L, Tokunaga H, Nishimura K, Imazu Y, Reissenweber H, Witt CM.	Traditional Japanese Kampo Medicine: Clinical Research between Modernity and Traditional Medicine—the State of Research and Methodological Suggestions for the Future.	eCAM	Advance Access published online on June 16, doi:10.1093/ecam/n eq067		2010
Nakaya J, Kimura M, Hiroi K, Ido K, Yang W, Tanaka H	Genomic Sequence Variation Markup Language (GSVML).	Int J Med Inform	79(2)	130-142	2010
渡辺賢治	今こそ日本型医療の創 生を	日本医事新 報	4468	1	2010
渡辺賢治	ICD-11 への改訂に向け ての東アジア伝統医学 分類作成	医学のあゆ み	231:4	311-312	2009
渡辺賢治	漢方医学をめぐる国際 的諸問題	医学のあゆ み	231:3	243-246	2009
渡辺賢治	渡辺賢治。伝統医学国際 化の潮流	医学のあゆ み	231:2	169-170	2009
渡辺賢治	西洋医学から見て分か りやすい漢方医学を目 指して	医療タイム ス	1925	34	2009

IV. 資 料

Traditional Medicine in Health Information Systems:

Integrating Traditional Medicine into the WHO Family of International Classifications

This background document summarizes why and how WHO will develop a standardized international system for classifying Traditional Medicine (TM) related health concepts, such as disease patterns and interventions and their associated features, including safety and effects. This classification will be based on existing practices of Traditional Medicine including Complementary and Alternative Medicine (CAM). Modern methods in terminology and classification sciences for uniquely identifying concepts will be utilized to capture existing national and regional TM practices. The resulting terminologies and classification will be extensively tested for relevance, applicability, quality and utility in practice and integrated into existing health information systems to produce appropriate statistics and reporting systems.

Background

The World Health Organization, in consultation with a large group of stakeholders in the areas of Traditional Medicine, including Complementary and Alternative Medicine, and Health Information Systems, has developed a collaborative project plan to produce an international standard terminology and classification system for Traditional Medicine. The rationale for this proposal is as follows:

1. *Traditional Medicine is a significant part of health care which is commonly used around the world;*
2. *Current health information systems about TM are not adequate: "Traditional Medicine does not count, unless we count Traditional Medicine";*
3. *Local Traditional Medicine knowledge exists, but there is a lack of international harmonization;*
4. *International Standardization of Traditional Medicine information is essential;*
5. *Unification of Traditional Medicine and conventional information will improve efficiency; and*
6. *Digitalization of health information provides an opportunity for Traditional Medicine.*

These points are briefly explained as follows:

1. ***Traditional Medicine is a significant part of health care which is commonly used around the world***

In many parts of the world, TM/CAM provides health care to a significant part of the population as part of general health services, especially in South East Asia, Africa, Latin America and the Western Pacific. In the so-called western world, TM is also on the rise and practices such as acupuncture, chiropractic, osteopathy, herbal medicines and/or homeopathy are utilized in general health services.

The Alma-Ata Declaration on Primary Health Care (1978) called on countries and governments to include the practice of traditional medicine within their primary health care approach. Thirty years later, traditional medicine grows even more widely available, affordable, and commonly used. For example, in some Asian and African countries, 80% of the population depends on TM for primary care.

Recent studies conducted in North America and Europe indicate that TM health care approaches tend to be used primarily in groups with higher levels of income and education. This is not the poor man's alternative to "western" medical care, and in many cases, the costs are not covered by medical insurance schemes. The use of these complementary and alternative medicine approaches has become a multi-billion dollar industry that is expected to continue its exponential growth. Case in point, 70% of the population in Canada and 80% in Germany have also used CAM.

The most recent WHO resolution on traditional medicine (2009) urges its Member States to formulate national policies, regulations and standards, as part of comprehensive national health systems, to promote appropriate, safe and effective use of traditional medicine to strengthen health system ability to provide primary care.

2. Current health information systems about TM are not adequate: "Traditional Medicine does not count, unless we count Traditional Medicine"

Currently, the data collection practices for TM are frequently not integrated within national or international health information systems. This lack of integration hinders quality data collection on the form, frequency, effectiveness, safety, quality, outcomes and cost of TM interventions. Additionally, insurance and billing procedures for TM are not always integrated into general service procedures, with the result that much of the global health statistics do not include services, practitioners, or economic parameters of, and around, TM. This is an issue, as TM should be included in international health statistics.

3. Local Traditional Medicine knowledge exists, but there is a lack of international harmonization

Given the long history of TM use, there have been national and regional developments to set policies, regulate practices, and to perform research. In some countries, significant efforts exist to capture this information in national standards. However, these efforts have remained largely fragmented and disparate, and are not harmonized internationally.

4. International Standardization of Traditional Medicine information is essential

To enable global knowledge exchange and facilitate efficient and effective use of TM, it is essential to produce international health information standards on TM terminologies and classifications. Such standards will allow various stakeholders to gather data on form, frequency, and outcomes of TM, and to meaningfully exchange information globally. In order to include TM in health systems, TM should be included in the health information systems

5. *Unification of Traditional Medicine and conventional information systems will improve efficiency*

It is also essential that these data collection, monitoring, and evaluation systems for TM are unified with those used in conventional (or so-called 'western') medical services, in order to ensure efficiency of data collection. Such unification will be possible through integration of the TM terminologies and classification with the WHO Family of International Classifications (WHO-FIC).

6. *Digitalization of health information provides an opportunity for Traditional Medicine*

An additional major driver for this work is the movement towards digitalization of health information. Health information systems are being computerized at a great pace. These initiatives focus on electronic health records and standardization of information, including terminology and classifications. This provides an opportunity to harmonize the TM-related information with computerized health information systems.

Specific Aims:

WHO proposes to coordinate various streams of work to develop a standardized traditional medicine terminology and classification system which will allow for regular data collection and comparisons with conventional health information systems.

This proposal aims to harness the potential from two key drivers, namely: (i) development of health information standards, and (ii) digitalization of health information systems.

The proposal specifically aims:

1. To create an international standard TM terminology and classification that is based on modern information sciences providing a representation format to identify each TM entity with its defining characteristics.
2. To enable tools for compiling health statistics and information related to TM practices serving both analogue and digital health information systems, including electronic health records, accounting, insurance, billing, and reimbursement systems

These specific aims will be built on already existing national, regional and international work. It will add value to current work through establishment of common standards to exchange information in a meaningful way, in particular the following ways:

1. *Standardization of the clinical terms used by TM practices internationally*

WHO has important standardization work already started in the Western Pacific Regional Office and Headquarters in Geneva that reflects various aspects of standardization, such as the Traditional Medicine Thesaurus including terms used in acupuncture, and terms used in the traditional medicine of China, Japan and Korea. Additional potential resources are listed in the text box below:

China uses the 1995 Classification and Codes of Diseases and ZHENG (pattern/syndrome) of traditional Chinese medicine, which has disease and pattern names. It is a national standard and is distributed electronically. Patterns/Syndromes are groups of presenting signs and symptoms that determine the prescribing formulae.

Japan uses the ICD disease description for western and Kampo medicine and government insurance claims. It has also developed disease patterns for prescribing 148 formulae within Kampo medicine. Kampo medicine is traditional medicine developed in Japan during the last 1500 years from practices with Chinese origin. The practice of Kampo medicine is now integrated with the practice of western medicine by all doctors.

Korea uses the KCD4 (2004) based on the ICD-10 for western medicine. The KCDOM-2 (1994) has disease names used for traditional medicine insurance claims and pattern names, and the KCDOM 2004 focuses on disease patterns. A newly released KCDOM-3 has also recently come into use including ICD information in a dual coding resource.

India has developed English equivalents of Ayurvedic clinical conditions and diseases, which translate directly into modern allopathic ICD equivalents.

Some complementary and alternative medical systems, such as **osteopathy** and **chiropractic** are already integrated within the allopathic classification systems, particularly with respect to diagnostics. Therapeutic interventions, however, may not yet be included in internationally accepted standards.

International Standard Terminologies on Traditional Medicine in the Western Pacific Region is a terminology developed in the WHO Western Pacific Region. It is intended for use in clinical practice, for clinical guidelines, and for information (inclusion in MeSH and UMLS), education, and research in, or with, evidence based traditional medicine purposes. The current draft is in English.

Text Box 1 - Some existing resources for traditional medicine classification and terminology

We propose that all these elements and other possible sources identified should be brought together in a "Health Information Model" for TM. This health information model will be ontology-based, and identify each entity with its defining characteristics. This structure will enable integration into the WHO Family of Classifications and Terminologies, as all family classifications on disease, disability and interventions are based on this standard methodology. In this way, integration of TM terminologies and classification into general health information systems will be possible.

2. *Representation of TM knowledge in digital information systems*

Standardized TM terminologies and classification will serve as building blocks for uniform data generation and collection concerning traditional medicine practice and utilization, and will be formatted for use in electronic health records and digital health information systems, including accounting, insurance, billing, and reimbursement systems.

Such standardization will enable users to examine volume and flow of patients, as well as reporting needs, outcomes and costs. In addition, safety and quality of traditional medicines can be more easily reported on.

Deliverables:

Deliverable 1:

International Classification of Traditional Medicine (ICTM)

This is the creation of an ICTM that will include disease terms submitted from various TM systems. ICTM will have different modules, for example (1) East Asian / Chinese based traditional medicine (2) Ayurveda, (3) Homeopathy, or (4) other TM systems with independent diagnostic conditions included in a similar fashion. The purpose of the classification is to allow reporting on the various practices of traditional medicine in a useful manner to improve clinical care and resource allocation. The scope of the ICTM covers disease names, disease patterns, symptoms, signs, indications for treatment, and interventions within the selected TM systems. The ICTM can be used as an independent, stand-alone classification and could also be included as an additional chapter within the ICD, in part or as a whole. This will enable unification of the conventional and traditional medicine classifications for diagnosis and interventions. The project will establish links with the WHO-FIC Network to enable the membership of ICTM as a derived classification of the WHO Family.

Similarly TM treatments or procedures could be included in the health interventions classifications of the WHO-FIC: namely, International Classifications of Health Interventions (ICHI), or in other WHO-FIC classifications as appropriate.

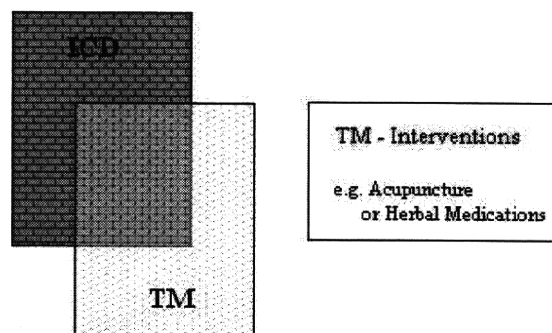


FIGURE 1: Place of Traditional Medicine in relation to WHO-FIC

Deliverable 2:

International Standard Terminologies of Traditional Medicine

An international, multilingual terminology of TM will be developed in line with standard clinical terminology work as a foundational piece of the project. This work will have the same ontology foundation identified in methodology step 1 with a software tool similar to Protégé. The terminology will utilize common elements from the international health terminologies wherever applicable, and the same ontological structure and software will be used for different types of TM conventions.

Deliverable 3:***A Web Portal on TM that links ICTM and TM terminology to WHO-FIC***

A knowledge management portal will be compiled with various tools to enable computerized generation and maintenance of the classification work using:

1. A Collaborative Authoring Tool (a Wiki-like internet-based tool with semantic linkages) as a user interface
2. An ontology tool (i.e. Collaborative Protégé) for identifying and linking the underlying terminology /ontology to classification concepts
3. Multilingual representation for ICTM in languages that are relevant for the practice of TM in WHO Member States

Timelines:

The bulk of the project work is expected to take place within four years.

Year 0: Preparation and initial start-up

Year 1: Development

Year 2: Alpha testing

Year 3: Beta testing

Year 4: Finalization and maintenance setup.

Planned actions for developing ICTM:

2009: Finalization of detailed Project Plan with identified partners showing the development phases and milestones

2010: Development of relevant terminologies and classifications; workgroups

2011: Peer review, and alpha testing

2012: Beta testing for relevance and utility

2013: Finalization and integration in the WHO-FIC

Costs

The overall costs of the project will amount to US\$ 5.5 million dollars over 5 years; approximately US\$1.3 million for each of the next 4 years (2010 - 2013).

These costs would be required to support:

1. drafting and revision of the ICTM Modules content - managing collaborative editing;

2. the creation and maintenance of the software platform (collaborative Protégé platform in multiple languages, identified semantic model and daily maintenance tools, networking);
3. TAG and Work Group meetings, (2 meetings per year);
4. Contracts: will be issued to generate content, link databases, review proposals; conduct field trials and publish results;
5. Personnel to run the specified activities: This project will require a full-time Project Manager to run the specified activities within the CTS team and an administrative assistant to arrange for activities, budgeting and reporting. TRM will also require a professional staff member and one general support staff member while QSM requires one professional staff member for technical support. Each of the latter positions will be hired at 0.5 FTE.

Methodology:

To achieve these specific aims several steps of work are necessary:

1. **Recording all TM terminology in ontology software** (i.e. Protégé) to precisely describe the content of each term, which will allow for the most appropriate knowledge representation and possible multilingual equivalents. This should have a modular structure for different groupings of TM practices such as East Asian/Chinese-based TM, Homeopathy, or Chiropractic etc. Ayurveda could be added if additional resources become available.
2. **Establishing links to the current ICD and using a common base for terms when possible**, such as in infectious disease names, common signs and symptoms, and other common terminology.
3. **Production of an International Classification of Traditional Medicine** that will cover:
 - (a) Main diagnostic entities
 - (b) Main TM interventions
 with proper, logical groupings and explicit operational characteristics for describing the content of each entity and group.
4. **Linkage of the TM ontology/terminology and classification with other WHO-FIC products**
 - (a) cross-links to International Classification of Diseases (ICD)
 - (b) cross-links to International Classification of Health Interventions (ICHI)
 - (c) cross-links to Classifications for Drug Utilization Studies
 - (d) cross-links to International Classification for Patient Safety Classification (ICPS)
 - (e) incorporation of TM terms in standardized clinical terminologies (e.g. SNOMED-CT, etc.)

These linkages will primarily be accomplished through shared terms (e.g. infectious disease names, common signs and symptoms, and other terminology). This is essential to enable unique

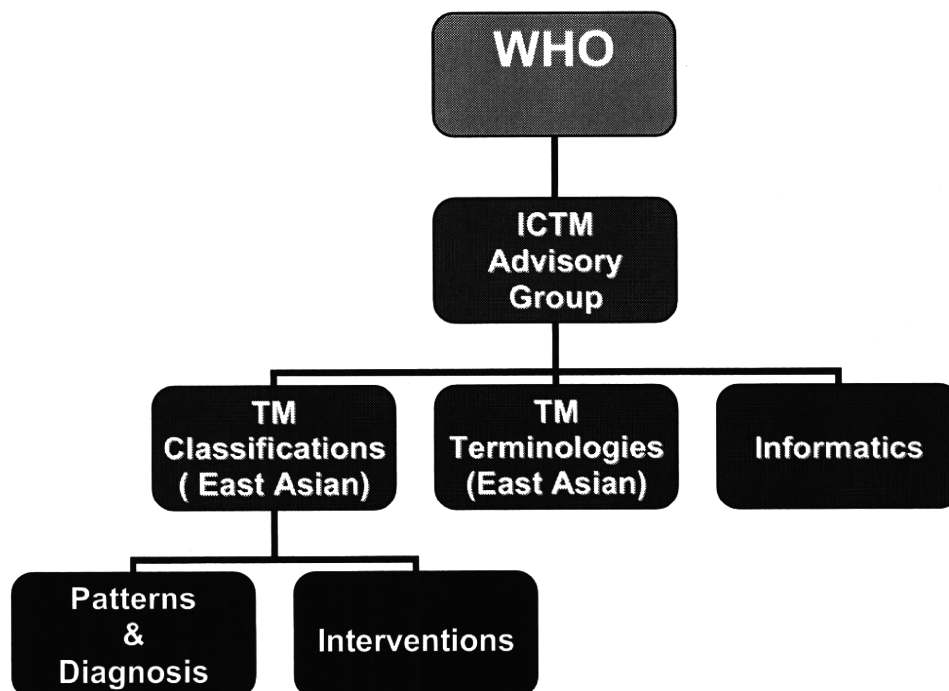
identification of each concept and to avoid redundancy in health information systems and electronic records.

5. Testing of the TM terminology and classification for:

- (a) Relevance: fitness-for-purpose, completeness, accuracy, etc.
- (b) Applicability: in different settings: at country level, in primary care, etc.
- (c) Utility: use cases and outputs that are shown to be beneficial for identified purposes

Testing will be structured in an alpha phase that will focus more on relevance; and beta phase that will focus more on applicability and utility.

Structural Organization for Advisory Group and Workgroups:



1. ICTM Advisory Group:

A group of selected technical experts will serve as an Advisory Group and oversee several potential Topic Advisory Groups (TAGs) for the project. This group will assist in determining which TM disciplines should be selected for inclusion; agreeing upon standards relating to the terminology and knowledge representation; as well as generating for possible multilingual equivalents and creating and overseeing the other groups.

2. Topic Advisory Groups (TAGs):

Depending on the scope of work several TAGs will be formed to represent expertise from different TM disciplines who will undertake the relevant work.

The selected disciplines would be developed within four years, and can then be included into the 11th revision of the ICD. The ICTM-AG and TAGs may advise WHO to set up workgroups to develop the modules for the ICTM, as necessary.

Identified potential candidates for TM modules include, but are not limited to:

- a. East Asian / Chinese based TM including the variations developed in: China, Japan, Korea, Mongolia, and other areas.
- b. Ayurveda, including the varieties from India, Sri Lanka, Bangladesh, Nepal, and other areas.
- c. Homeopathy: as utilized in Germany, UK, France, and other areas.

3. Linkage to the WHO-FIC Network; ICD, ICHI or other WHO-FIC products, as appropriate

The conceptual relations and overlapping content will be explored by joint workgroups between the existing WHO Classifications and proposed TM terminologies and classification. It will be essential to explore the linkages, develop a common methodology to represent them to the WHO-FIC community, and present the case. This working method will be essential for identifying the TM modules that will be represented in the 11th revision of the International Classification of Diseases.

Benefits of the Project:

This proposal, when implemented, will link Traditional Medicine practices with global norms and standard development activities for health information systems through the WHO Family of International Classifications. Incorporation in WHO classifications will enhance international public health tasks on global statistics, surveillance and patient safety. It will also enhance basic and clinical research around TM, which will facilitate enhanced acceptance.

These project activities will also create an International Platform and a Network for sharing knowledge and securing cultural sensitivity.

The end products of the project will ensure equal access to global public goods for all WHO Member States.

Development of a linguistic platform for adequate representation of clinical concepts in different cultures and languages will be extremely useful for knowledge sharing and service provision in a world with mobile citizens.

Inclusion of these terminologies and classification in the WHO Family of International Classifications will provide the basis for inclusion of TM/CAM treatment services under insurance schemes, many of which already use the ICD diagnostic codes, and will do so through a structured, standardized and unified approach.

This project will also facilitate training programmes in collaboration with WHO basic training guidelines for acupuncture, chiropractic, and others to be developed. Both the number of TM practitioners and the availability of education facilities are expanding worldwide.

The maintenance costs for the ICTM and Terminology will be low, as the system will be incorporated in the WHO Family of International Classifications.

Driving forces for business cases do exist:

1. The harmonization between "western" medicine and traditional medicine is strongly promoted in China, Korea, and Japan. Governments, professional organizations, and health care administrators, as well as the insurance sector, will benefit from this harmonization.
2. Incorporation of TM in health information systems is forthcoming. China and Korea already use their TM classifications in health information systems, and there is a significant need to register information on traditional medicine practice in the USA.

Appendix 1:

Plan Details:

The specific details of each major task and the development process from start to finish will include:

1. *Project Commencement*

The project will commence with situational analysis, a planning step that will facilitate implementation of the project through examination of existing traditional medicine terminologies and classifications. It will involve, among other tasks, investigating, analyzing, identifying, and cataloguing the work that has already been completed and which may be used as a foundation, or in support of the ICTM project, as well as identification of user needs to more appropriately tailor the project design.

The formulation of use cases will both support and direct the progression of the ICTM project, and be based on information gathered through the situational analysis. The ICTM must be designed to be functional for clinicians in the field, while also maintaining the established standard that is useful for statisticians and, by extension, governments and other health systems governance organizations. The use cases will include a synopsis of how this information will be used, for what, and by whom. Examples of use cases might be mortality, morbidity, primary care, or public health.

The draft project plan is a blueprint which will give structure and focus to the task of creating the ICTM, while allowing for the flexibility required in a project of this magnitude. The project plan will also support transparency and accountability by dividing the tasks and outlining timelines and milestones.

Milestone 1: Project plan formed

Another component of project commencement will be the formation of ICTM entities, the groups responsible for the on-the-ground work of the ICTM. These include the ICTM Topic Advisory Group, composed of a variety of experts and Working Group representatives who will be responsible for guiding and evaluating ICTM development through providing input directly to WHO. Other ICTM entities will include Working Groups and, potentially, sub-Working Groups, responsible for specific areas of technical content.

Meeting 1: Joint ICTM coordination meeting

2. *Tools Development*

Like any building project, we must have the appropriate tools developed to accomplish our goals. For the ICTM, these tools will include, but not be limited to, content models, a TM portal, a map for cross linking, and various ontology tools.

Each content model is a blank template, waiting to be populated with information. One of the content models will be formulated to accommodate diagnostic entities, including diseases, conditions, syndromes, patterns, etc. The other content model will be designed to accommodate standardized data on interventions. First, the project must select parameters for each content model, and then select the value sets for each parameter.

Meeting 2: Development of Content Models

Milestone 2a: Content Models formed

Ontology tools are those which will allow for the formal representation of information and include a set of standards to guide the identification and categorization of each potential entity, whether diagnostic or interventional, with its defining characteristics in the ICTM. Another such tool will be the collaborative authoring tool (CAT), which will allow the ICTM to draw upon the expertise of anyone at any time, without requiring the time and expense of constant travel. Other types of ontology tool will be web-based content model templates that will be used in the CAT. Further tools will include, a revision specific workflow, which will outline the timelines and processes through which the ICTM will integrate all of these components, weaving the completed work together and establishing the coding rules.

Milestone 2b: Information model created

Meeting 3: Information and Content Model discussion

The TM Portal will be built in three layers, namely the terminologies, the classification, and the development of knowledge on interventions. Each of these three components will require that we compile existing and available work already completed to use as references and resources, while simultaneously programming the system to accommodate for the intricacies of the compiled information. The system must also be designed to include commenting and structure editing features, to accommodate translational/multilingual generation, and be rigorously tested to ensure the software functions fully to support the project as designed.

Meeting 4: Working meeting on Tools, including Software

In order for the ICTM to be fully integrated and usable, as well as effective for including traditional medicine into health statistics, it will be necessary to establish cross links between the entire TM Portal and the Information Model, as well as to establish cross-ref-links with ICD and WHO-FIC, including ICHI and the Patient Safety classification, among others. Due to the fact that this will be a cooperative linkage between multiple projects and classifications, it will be necessary to program the software to accommodate the linkages using a common base for terms, when possible. Linkages will primarily be accomplished through these shared terms, an essential feature to enable unique identification of each concept and to avoid redundancy. To maintain the integrity and usefulness of the project, this will be followed by testing the mapping, both antero- and retrograde.

Milestone3: Software tools developed

Milestone4: TM Portal Developed and launched