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Health informatics — Categorial structures of clinical findings in traditional medicine —

Part 1: **Traditional Chinese, Japanese and Korean medicine iTeh STANDARD PREVIEW**

> S Informatique de santé — Structures catégorielles des recherches cliniques en médecine traditionnelle —

Partie 1: Médecine traditionnelle de l'Asie de l'est

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

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Introduction

In most countries there are many types of traditional medicine that are distinct from the health care system based on biomedicine. In some countries this traditional medicine has been institutionalized; in other countries it may have a significant role in health care as an alternative medicine. One type of traditional medicine is traditional Chinese, traditional Japanese, and traditional Korean medicine (TM-CJK), which has spread from ancient China to other East Asian regions over thousands of years. TM-CJK is now relatively homogenous in terms of theory and practice including: disease classification; diagnostic methods; and treatment modalities such as acupuncture and use of herbs.

As in biomedicine, health care professionals specializing in this clinical discipline use specific terminologies in their clinical records and documentations as well as in their practice, research and education. There will be several standard TM-CJK terminologies used around the world in Electronic Health Record (EHR) systems both in separate systems supporting TM-CJK practice and in systems combining TM-CJK and biomedicine content. Interoperability of health record systems is a core objective of informatics standards; this can be supported by standards for terminologies such as those used in TM-CJK and biomedicine.

This Technical Specification provides categorial structures of clinical findings in TM-CJK for the requirements. An essential requirement for sematic interoperability of TM-CJK health records is a categorial-structure driven terminology system for TM-CJK diagnosis. Although there are many terminological resources in TM-CJK in electronic format and also some International Standard TM-CJK terminologies, there are none that meet the requirements of health informatics such as interoperability between systems and machine readability. However, the ICD-11 Traditional Medicine (TM) chapter and ICTM are being developed by the World Health Organization (WHO) and will meet this criteria with their formal content model which identifies TM diagnostic entities, their properties and value sets.^[15] Hence This Technical Specification refers to the ICTM content model.

This Technical Specification describes the core underlying components of terminological expressions (i.e. the Categorial Structure) of clinical findings in TM-CJK. It is aligned with ISO/TS 22789:2010 *Health informatics — Conceptual framework for patient findings and problems in terminologies,* which deals with the same domain in biomedicine. It specifies a concept system detailing the categories of the domain (clinical findings in TM-CJK) and a domain constraint of sanctioned characteristics, each composed of a semantic link and an applicable characterizing category. An item enclosed by single brackets <> refers to a category of domain or a characterizing category that can be specialized to various concepts as required. An item enclosed within the text by single accolades { } identifies a semantic link.

The Technical Specification does not specify the names of individual TM-CJK concepts in the definitions. However, when it is necessary to give examples with names of concepts in TM-CJK, the WHO International Standard Terminologies on Traditional Medicine in the Western Pacific Region is used. [1] Also current ICD-11 Traditional Medicine chapter(Beta Draft), which is the global reference point, will serve as a repository for examples in the next revision.^[15] International Standard Chinese-English Basic Nomenclature of Chinese Medicine of World Federation of Chinese Medicine Societies (WFCMS) was accessible and considerable for the Technical Specification.^[13] A future revision of this Technical Specification will incorporate examples from other authorized standards when they are fully established.

When a unique category is introduced and its name is already used in biomedicine, the '-TM' after the name is used to indicate that the term has a different concept in TM-CJK, for example, 'disorder-TM' is a different concept from 'disorder' in the biomedicine field.

Comparison and alignment with ISO/TS 22789:2010 is presented in <u>Annex A</u>. In <u>Annex B</u>, an informative description of Categorial Structures and their implementation in terms of intersection between terminology models and information models is provided.

The building methodology of the categorial structure in this Technical Specification is the one that was defined by CEN in EN 12264 and applied to different domains, from surgical procedures (EN 1828^[2]) to nursing care (ISO 18104^[3]) and clinical findings of the biomedicine area (ISO/TS 22789).

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The potential uses for this categorial structure are to:

- provide a core model to describe the structure of TM-CJK, and facilitate improved semantic correspondence with information models;
- facilitate the representation of TM-CJK using a standard core model in a manner suitable for computer processing;
- support developers of new terminology systems concerning TM-CJK clinical findings;
- support developers of new detailed content areas of existing terminology systems concerning TM-CJK clinical findings;
- facilitate the mapping or integration between TM-CJK terminologies and biomedicine terminological systems.

The direct users for this Technical Specification are:

- developers of terminology systems concerning TM-CJK patient findings;
- developers of information systems that require a structured framework of concepts of TM-CJK patient findings to facilitate implementation.

The following will benefit from this Technical Specification;

- informaticians, analysts and epidemiologists who require common models of knowledge to facilitate analysis of current and legacy data from one or more information systems;
- clinicians and coders, to provide greater consistency in structure and organization when entering and retrieving data using one or more terminology systems.

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Health informatics — Categorial structures of clinical findings in traditional medicine —

Part 1: **Traditional Chinese, Japanese and Korean medicine**

1 Scope

This Technical Specification defines a categorial structure for clinical findings in terminological systems for Traditional Chinese Medicine, Traditional Japanese Medicine, and Traditional Korean Medicine (TM-CIK). This Technical Specification defines three subcategories: pattern-TM, disorder-TM and sign&symptom-TM. Concept representations within these three categories are used to describe the states of patients in clinical records and communications.

This Technical Specification is not applicable to:

- a comprehensive categorial structure for TM-CJK;
- an exhaustive list of all possible characterizing concepts that could be used to describe clinical findings; $\mathbf{K}\mathbf{F}$
- terms/descriptions for individual TM-CJK concepts;
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- a detailed terminology of clinical findings in TM-CJK;
- categorical structure of diagnosis and treatment on clinical findings in TM-CJK.

NOTE This Technical Specification7is limited to a subpopulation of clinical findings in traditional medicine. Other types of clinical findings are represented in ISO/TS 22789 although it has not been tested for this purpose.

Normative references 2

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies

ISO/TS 22789:2010, Health informatics — Conceptual framework for patient findings and problems in terminologies

Terms and definitions 3

For the purposes of this document, the following terms and definitions apply.

3.1 General

3.1.1 concept unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, definition 3.2.1]

3.1.2

categorial structure

minimal set of *categories* (3.1.4) and the valid relationships between them for representing **concept**s (3.1.1) in terminological systems for a specified subject field

[SOURCE: ISO 18104, definition 3.1.2]

3.1.3

characterizing category

category (3.1.4) which is allowed by a domain constraint (3.1.7) to specialise a concept (3.1.1) in a particular domain

EXAMPLE in {performedUsing} <instrument>; {hasLocation} <bodyPartOrImplantedDevice>, "<instrument>" and "<bodyPartOrImplantedDevice>" is the *characterizing category* (<u>3.1.3</u>).

Note 1 to entry: (<u>3.1.1</u>).

3.1.4

category

type of *entity* (3.1.8) shared by all the individual instances in existence in the present, past and future

EXAMPLE The *category* (3.1.4) <Route> is instantiated by *oral route* and all other routes that meet the defining **characteristic**s (3.5) for <Route>.

Note 1 to entry: category (3.1.4) is usually described by a superordinate and generic concept (3.1.1).

Note 2 to entry: **categor**ies (3.1.4) may be more or less general. Where one *category* (3.1.4) is subsumed by another, the *isA* relation is asserted to obtain a hierarchy between the more specific or subsumed *category* (3.1.4) and the more general or subsuming *category* (3.1.4). For example, *parenteral-route* is more general than *intravenous route*.

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Note 3 to entry: Each *entity* (<u>3.1.8</u>) instantiates some *category* (<u>3.1.4</u>).

ISO/TS 16277-1:2015 [SOURCE: ISO 18104, definition/3a13] ds.iteh.ai/catalog/standards/sist/c60d91f9-f78a-44be-a65b-

3.1.5

characteristic

abstraction of a property of an object or of a set of objects

[SOURCE: ISO 1087-1:2000, definition 3.2.4]

EXAMPLE Red and gold are the *characteristic* (3.1.5) colours of autumn.

Note 1 to entry: **Characteristics** (<u>3.5</u>) are used for describing **concept**s (<u>3.1.1</u>).

3.1.6

clinical findings-TM

any state observed directly or indirectly concerning a patient and their relationship with the environment according to TM-CJK theories

Note 1 to entry: Modified from ISO/TS 22789 for TM-CJK theories.

3.1.7

domain constraint

rule prescribing the set of **sanctioned characteristic**s(<u>3.1.9</u>) that are valid to specialise a concept representation in a certain subject field

EXAMPLE "Infection possibly hasLocation SkeletalStructure" explains that an infection in a certain context can be located in a structure that is a kind of skeletal structure.

[SOURCE: ISO 17115:2007, definition 2.3.2]

Note 1 to entry: The rule describes the set of **sanctioned characteristic**s (3.1.9) by combining the *semantic link* (3.1.10) and the *characterizing category* (3.1.3)

3.1.8

entity

any concrete or abstract thing of interest

EXAMPLE Aspirin, environment, parent, symptom, mobility.

Note 1 to entry: While in general the word entity can be used to refer to anything, in the context of modelling it is reserved to refer to things in the universe of discourse being modelled.

Note 2 to entry: This definition is similar to that for *object* in ISO:1087–1[4] which is: *anything perceivable or* conceivable. ISO 1087-1 notes that Objects may be material (e.g. an engine, a sheet of paper, a diamond), immaterial (e.g. conversion ratio, a project plan) or imagined (e.g. a unicorn). However, the term object is normally interpreted as representing a material thing, therefore *entity* is preferred.

3.1.9

sanctioned characteristic

formal representation of a type of *characteristic* (3.1.5)

[SOURCE: ISO 17115:2007, definition 2.3.1]

EXAMPLE {performedUsing} <Instrument>; {hasLocation} <BodyPartOrImplantedDevice>, where "{performedUsing}" and "{hasLocation}" are the *semantic links* (<u>3.1.10</u>), and "<Instrument>" and "<BodyPartOrImplantedDevice>" is the *characterizing category* (<u>3.1.3</u>).

Note 1 to entry: A sanctioned characteristic (3.1.9) is typically made up of a combination of a semantic link (3.1.10)and a *characterizing category* (3.1.3), and can be used in **domain constraints** (3.1.7).

iTeh STANDARD PREVIEW 3.1.10

semantic link

formal representation of a directed associative relation or partitive relation between two concepts (3.1.1)

[SOURCE: ISO 17115:2007, definition 2.2.3] TS 16277-1:2015

{hasLocation} {with inverse {isLocationOf} and {isCauseOf} (with inverse {hasCause}). EXAMPLE

Note 1 to entry: A semantic link (3.1.10) always has an inverse, i.e. another semantic link (3.1.10) with the opposite direction. The inverse may or may not be explicitly stated.

3.2 Core categories

3.2.1

pattern-TM

condition which represents a typical constellation of symptoms or complete clinical presentation of patients including symptoms at a given moment in time and is a known or assumed dysfunction of body function-TM(3.3.3.2), body structure-TM(3.3.1) or body substance-TM(3.3.2.1)

EXAMPLE <heart yang collapse pattern> is a pattern marked by sudden profuse sweating and cold skin, reversal cold of limbs, feeble breathing, palpitations, clouding or loss of consciousness, pale complexion and hardly perceptible pulse.^[1] <greater yang cold damage pattern> is a pattern caused by pathogenic cold attacking the greater yang meridian, chiefly manifested by fever, chills, absence of sweat and floating pulse, also called the greater yang cold damage.^[1]

Note 1 to entry: *pattern-TM* (3.2.1) indicates a set of signs and symptoms at a given moment in time that can be captured by body system-TM (3.3.1.1) and their derivatives based on TM-CJK.

Note 2 to entry: This concept (3.1.1) may be expressed by pattern, syndrome, or disease pattern in English, if or 證 in Chinese and Japanese and 증 in Korean in TM-CJK related literature.

Note 3 to entry: This concept (3.1.1) is subcategories of clinical findings-TM and it can be used for characterizing category (3.1.3) with semantic link(3.1.10) such as hasAssociatedPattern-TM(3.4.5) and hasAssociatedFinding-TM(3.4.6).

3.2.2

disorder-TM

condition which represents a set of dysfunction with associated manifestations and is often defined by typical chief symptom, sequential pathological process-TM (3.3.3.3), body state-TM (3.3.3.1), or aetiology according to TM-CJK theories

EXAMPLE <consumptive disorder>, <lung distention>, <heat wheezing>, <plum-pit qi>, <water distention>, <qi strangury>.

Note 1 to entry: Disorder-TM may have multiple underlying causes, corresponding multiple patterns-TM (3.2.1), and consequently multiple different treatments.

Note 2 to entry: It is useful to capture an individual health condition over time using a fixed concept (3.1.1) in disorder-TM while pattern-TM may change over time.

Note 3 to entry: This concept (3.1.1) may be expressed by disease or disorder in English, \overline{R} in Chinese and Japanese, and in Korean in TM-CJK related literature.

Note 4 to entry: This concept (3.1.1) is subcategories of clinical findings-TM and it can be used for characterizing category (3.1.3) with semantic link (3.1.10) such as hasAssociatedPattern-TM (3.4.5) and hasAssociatedFinding-TM (3.4.6).

3.2.3

sign&symptom-TM

manifestation of a dysfunction classified only by TM-CJK

<night sweating>, <cold sweating>, <floating pulse>, <slippery pulse>, <relaxed pulse>, <hollow **EXAMPLE** pulse>, <pale tongue>, <red tongue>, <yellow fur tongue>.

Note 1 to entry: *sign&symptom* (3.2.3) may be identifiable by the affected person or the health worker.^[6]

Note 2 to entry: This concept (3.1.1) is subcategories of clinical findings-TM and it can be used for characterizing category (3.1.3) with semantic link(3.1.10) such as has Associated Pattern-TM (3.4.5) and hasAssociatedFinding-TM (3.4.6) 3ff76cda5488/iso-ts-16277-1-2015

Characterizing categories 3.3

3.3.1

body structure-TM

abstract or physical arrangement of parts of the body for explanatory framework according to TM-CJK

3.3.1.1

body system-TM

body structure-TM (3.3.1) that works to perform a certain task as a part of a whole in intimate interconnection according to TM-CJK

EXAMPLE 1 eliver-TM>, <heart-TM>, and <lung-TM>.

<liver meridian-TM>, <heart meridian-TM> and <lung meridian-TM> of meridian system and also EXAMPLE 2 <exterior-TM> and <interior-TM>.

Note 1 to entry: A body system-TM (3.3.1.1) can include anatomical structure, functional system and abstract notion for its constituents. They are mutually independent as well as complementary because they may reflect different aspects of body and health problems and are also closely related to each other.

Note 2 to entry: Body system-TM (3.3.1.1) may have subcategories according to different needs of the terminology system. Meridian system, Sanjiao system and Four constitutional system could be examples.

3.3.1.2

body part-TM

body structure-TM (3.3.1) that is physical anatomical *entity* (3.1.8), has a spatial dimension, and is uniquely used in TM-CJK

EXAMPLE 1 Any acupuncture points.

EXAMPLE 2 <high bone-TM> that is the bony area including the styloid process of the radius.

EXAMPLE 3 <upper orifices-TM> that refers to the eyes, ears, mouth and nose.

3.3.2

substance-TM

continuous abstract or physical entity (3.1.8) that has no inherent shape according to TM-CJK

3.3.2.1

body substance-TM

substance-TM (3.3.2) that is originated in body

Note 1 to entry: This refers to an entity (3.1.8) which is contained by body structure-TM (3.3.1). Because the body structure-TM (3.3.1) is abstract as well as physical, the body substance (3.3.2.1) is abstract or physical.

EXAMPLE 1 <essence-TM>, <vitality-TM>, <qi, <blood-TM>.

EXAMPLE 2 <phlegm-TM>, < static blood-TM>, <yang of yang collapse pattern>, <deficiency fire> which deficiency of yin fluid give rise to, <stagnant qi>.

3.3.2.2 **iTeh STANDARD PREVIEW non-body substance-TM** substance-TM (3.3.2) that is not originated in body iteh.ai)

EXAMPLE Cold of < greater yang cold damage pattern

3.3.3 https://standards.iteh.ai/catalog/standards/sist/c60d91f9-f78a-44be-a65bstate-TM 3ff76cda5488/iso-ts-16277-1-2015

series of abstract or physical actions over time or condition in certain time in body according to TM-CJK

Note 1 to entry: While

body system-TM> (3.3.1.1) has an explanatory framework for human body and health problems, many individual findings also can be related to <state-TM> (3.3.3). It includes functional aspects like

body state-TM> (3.3.3.1) among entities of

body system-TM> (3.3.1.1) and also <pathological process-TM> (3.3.3.3) impairing the normal

body function-TM> (3.3.3.2) in TM-CJK.

3.3.3.1

body state-TM

normal or abnormal condition of body structure-TM (3.3.1) or body substance-TM (3.3.2.1)

EXAMPLE 1 <cold state-TM>, <heat state-TM>, <deficiency state-TM>, <excess state-TM> in eight principle.

EXAMPLE 2 <lung sector excessiveness> of four constitutional medicine, <yin deficiency constitution>.

Note 1 to entry: There can be more specific or subsumed category (3.1.4) like normal *body state-TM* (3.3.3.1) or abnormal *body state-TM* (3.3.3.1) if needed.

Note 2 to entry: *body state-TM* (3.3.3.1) refers to relatively static condition of body and sometimes refers to consequence of body function-TM (3.3.3.2). Dynamic change in body is described by pathological process-TM (3.3.3.3).

Note 3 to entry: *body state-TM* (3.3.3.1) includes constitutional characteristics of patients, which are the characteristics of an individual, including structural and functional characteristics, temperament, capability of adapting to environments. See Example 2.