TECHNICAL SPECIFICATION

ISO/TS 5346

First edition
2022-06

Health informatics — Categorial structure for representation of traditional Chinese medicine clinical decision support system

Informatique de santé — Structure catégorielle pour la représentation du système d'aide à la décision clinique en médecine traditionnelle chinoise

Reference number
ISO/TS 5346:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
3.1 General 1
3.2 Characterizing categories 2
4 Categorial structure of TCM clinical decision support system **4**
4.1 Overview 4
4.2 semantic link 4
4.2.1 is the base of 4
4.2.2 is part of 4
4.2.3 produce 4
4.2.4 is applied with 4
4.2.5 optimize 4
4.2.6 affect 5
4.2.7 is processed by 5
Bibliography **7**

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The aim of traditional Chinese medicine clinical decision support systems (TCMCDSS) is to help prescribe Chinese materia medica (CMM) and other therapies that fit the patient's personal situation with respect to effectiveness and toxicity of the medicine. The imbalance between supply and demand of medical resources leads to a huge demand for TCMCDSS, through which TCM diagnosis and treatment schemes can be optimized and the effectiveness and safety of primary medical care can be improved. Hence the establishment of TCMCDSS is in line with clinical practice needs and it has the requirements of real application scenarios. However, different TCMCDSS lack a unified semantic information framework, which affects the data exchange and sharing among different institutions and databases.

In conclusion, a unified semantic classification framework will greatly enhance the completeness, accuracy of TCMCDSS, which will establish a solid foundation for the sharing and utilization of the data in the future.

Health informatics — Categorial structure for representation of traditional Chinese medicine clinical decision support system

1 Scope

This document specifies the categorial structure within the field of traditional Chinese medicine clinical decision support system by defining a set of domain constraints of sanctioned characteristics, each composed of a relationship and an applicable information model.

This document is not applicable to Western medicine and Japanese Kampo medicine. It is not applicable to the design and management of artificial intelligence diagnosis and treatment.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General

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

[SOURCE: ISO 1087:2019, 3.2.7, modified — Notes to entry deleted.]

3.1.2
entity
concrete or abstract thing of interest

Note 1 to entry: Some information modelling methods use entity for their main information modelling construct, whilst others use entity type.

3.1.3
relationship
association between two or more entities that is significant for some intended purpose

Note 1 to entry: Can also be known as an association when the information model is based upon object classes.

[SOURCE: ISO 19440:2020, 3.64, modified — Note to entry added.]

3.2 Characterizing categories

3.2.1
traditional Chinese medicine clinical decision support system
TCMCDSS
software designed to be a direct aid to TCM clinical decision-making, in which the characteristics of an individual patient are matched to a computerized TCM clinical knowledge base, where after patient-specific assessments or recommendations are presented to the TCM clinician or the patient to aid in the process of making evidence based clinical decisions

Note 1 to entry: These types of systems typically require input of patient-specific clinical variables and, as a result, recommendations are presented to the TCM clinician or the patient to aid in the process of making evidence based clinical decisions after patient-specific assessments.

Note 2 to entry: TCM clinical decision support system mainly provides the diagnosis support of TCM and the treatment scheme recommendation of TCM.

[SOURCE: ISO/TS 22756:2020, 3.2, modified — Reference to TCM added and Notes to entry added.]

3.2.1.1
constitution
characteristics, partly genetically determined, partly acquired, of an individual, including structural and functional characteristics, temperament, adaptability to environmental changes and susceptibility to disease

[SOURCE: ISO/TS 22835:2018, 3.9]

3.2.2
patient information
basic data which identifies the individual

Note 1 to entry: Patient information includes information such as name, gender, age and occupation, symptom and sign information obtained through the four diagnoses of traditional Chinese medicine (TCM), as well as the history of current illness and allergy.

3.2.3
four-diagnostic information
information obtained through the four diagnoses of traditional Chinese medicine (TCM) (including the four diagnoses of TCM and four-diagnosis equipment), including symptoms, signs and other signs of TCM

Note 1 to entry: "Four diagnoses" means a collective term for inspection, listening and smelling, inquiry, and palpation.

3.2.4
symptom and sign
bodily or mental phenomenon, circumstance or change of condition arising from and accompanying a disease or other pathological condition

Note 1 to entry: Subjective indications or behaviour disorder perceptible to the patient, and the abnormal signs discovered by a doctor, are included.

3.2.5
health history
patient's previous status and past illnesses, especially those closely related to the present illness

EXAMPLE 1 History of diabetes, history of trauma surgery, prophylaxis, allergies.

EXAMPLE 2 Smoking, drinking, occupational exposure.

[SOURCE: Big dictionary of diagnostics, 2004]

3.2.6
algorithm
step-by-step procedure for solving a mathematical problem, also used to describe step-by-step procedures for making a series of choices among alternative decisions to reach a calculated result or decision

Note 1 to entry: TCM (traditional Chinese medicine) disease and syndrome diagnosis and treatment scheme can be recommended based on algorithm and knowledge base.

EXAMPLE Support Vector Machine (SVM), Convolutional Neural Networks (CNN).

3.2.7
knowledge base
facts, information and skills on a specific topic as a set of declarative, hierarchical organization of such statements, and relationships between declarative statements

Note 1 to entry: Which serves as the underpinning of TCMCDSS.

[SOURCE: ISO/TS 22756:2020, 3.9, modified]

3.2.8
diagnosis recommendation
traditional Chinese medicine diagnosis suggestion to someone, which is produced by TCM clinical decision support system

3.2.9
traditional Chinese medicine disease diagnosis
TCM disease diagnosis
judgment of the nature of illness with someone, by examining them closely

3.2.10
traditional Chinese medicine pattern diagnosis
TCM pattern diagnosis
diagnostic conclusion of the pathological changes at a certain stage of a disease, including the location, cause and nature of the disease as well as the trend of development, which suggest appropriate treatment

Note 1 to entry: TCM pattern is specific to the individual.

[SOURCE: World Health Organization (2007) International standard terminology for traditional medicine in Western Pacific Region]

3.2.11
intervention recommendation
activity including medication and other therapies proposed to maximize the prospects of achieving the patient's goals of care

3.2.12
medication
substance that has an intended therapeutic effect on a patient and can influence the medication safety of a patient

Note 1 to entry: This would include prescribed, but also non-prescribed medication such as cough syrups. A placebo has the intent of a therapeutic effect and is thus considered medication. Alcoholic beverages however also influence medication safety but are not considered to be medication because they do not have the intent of giving therapy.

[SOURCE: ISO/TR 20831:2017, 3.5]

3.2.13
physical therapy
non-medication treatments

Note 1 to entry: Some physical factors such as electricity, light, sound, temperature, magnetism, water and mechanical stimulation act on the body surface

EXAMPLE Acupuncture, massage, cold compress.

4 Categorial structure of TCM clinical decision support system

4.1 Overview

The formal concept representation system in the field of TCMCDSS includes characterizing categories (see 3.2) and semantic links (see 4.2). The outline of those characterizing categories and semantic links is illustrated in a concept diagram in Figure 1.

4.2 semantic link

4.2.1 is the base of

Use something as the thing from which something else is developed

It expresses the semantic link between knowledge base (see 3.2.7) and algorithm (see 3.2.6).

EXAMPLE <Knowledge base> is the base of<algorithm>.

4.2.2 is part of

Composes, with one or more other physical units, some larger whole. This includes component of, division of, portion of, fragment of, section of, and layer of.

It expresses the semantic link between physical therapy (see 3.2.13) and intervention recommendation (see 3.2.11).

EXAMPLE <physical therapy> is part of <intervention recommendation>.

4.2.3 produce

Brings forth, generates or creates.

It expresses the semantic link between TCMCDSS (see 3.2.1) and intervention recommendation (see 3.2.11).

EXAMPLE <TCMCDSS> produce <intervention recommendation>.

4.2.4 is applied with

Something used in a particular situation, activity, or process such as a method, idea, or material.

It expresses the semantic link between algorithm (see 3.2.6) and TCMCDSS (see 3.2.1).

EXAMPLE <algorithm> is applied with <TCMCDSS>.

4.2.5 optimize

Improve the way that something is done or used so that it is as effective as possible.

It expresses the semantic link between diagnosis recommendation (see 3.2.8) and TCMCDSS (see 3.2.1).

EXAMPLE <TCMCDSS> optimize <diagnosis recommendation>.

4.2.6 affect

Produces a direct effect on. Implied here is the altering or influencing of an existing condition, state, situation, or entity. This includes has a role in, alters, influences, predisposes, catalyses, stimulates, regulates, depresses, impedes, enhances, to, leads to and modifies.

It expresses the semantic link between diagnosis recommendation (see 3.2.8) and intervention recommendation (see 3.2.11).

EXAMPLE <diagnosis recommendation> affects <intervention recommendation>.

4.2.7 is processed by

The action of certain standard traditional pharmaceutical technologies, which changes CMM into decoction pieces.

It expresses the semantic link between patient information (see 3.2.2) and TCMCDSS (see 3.2.1).

EXAMPLE <patient information> is processed by <TCMCDSS>.

Figure 1 illustrates the categorial structure for TCM clinical decision system in the formal concept representation system.