
**Health informatics — Information
model of combination of decoction
pieces in Chinese medicines**

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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 List of authorized representation of relationships for the combination of decoction pieces in Chinese medicines	3
5 Information model for representation of combination of Chinese medicines	4
5.1 Conformance principles	4
5.2 Overview	5
Bibliography	6

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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).

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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*.

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

Principles, methods, formulas and medicinals are four important parts of traditional Chinese medicine therapy, in which the importance of formulas cannot be underestimated.

As the fundamental rule to construct multi-herb prescriptions of Chinese Materia Medica (CMM), combination is the key to study the principles of CMM prescriptions. The key point in enhancing clinical efficacy is how to better achieve the combination of formulas.

However, the information on formulas in clinical reports tends to be insufficient for interpretation of heterogeneity, often causing difficulties for data synthesis in meta-analyses. This is due to three reasons: firstly, because an appropriate information model of formulas of Chinese medicines is not used, secondly, because some of the concepts in the traditional medicine practice in the western pacific-rim region originated from China and are not mentioned, and thirdly because semantic associations between concepts of formula combination of Chinese medicines need to be explicitly identified.

This document defines the information model within combination in order to address these problems. *Chinese medicines* means substance or combination of substances used under the guidance of Traditional Chinese Medicine (TCM) theory for medical care and the prevention and treatment of disease, which is different from TCM. TCM is the parent concept which includes Chinese medical treatment and Chinese medicines.

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Health informatics — Information model of combination of decoction pieces in Chinese medicines

1 Scope

This document specifies the information model within the subject field of combination of Chinese medicines. A set of domain constraints of sanctioned characteristics have been defined in the model. Domain constraints are achieved through a set of relationships.

This document does not apply to Kampo medicine.

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.

ISO 17115, *Health informatics — Vocabulary of compositional terminological systems*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

Chinese medicines

substance or *combination* (3.2) of substances used under the guidance of traditional Chinese medicine theory for medical care and the prevention and treatment of disease

3.2

combination

use of various medicinals jointly in a formula or prescription for producing the desired therapeutic effect and reducing toxic or side effects

Note 1 to entry: This definition is taken from Reference [12].

3.3

mutual reinforcement

two medicinals with similar properties used in *combination* (3.2) to reinforce each other's action

EXAMPLE Lonicera (LONICERAE JAPONICAE FLOS, Jin yin hua) and forsythia fruit (FORSYTHIAE FRUCTUS, Lian qiao) used together in a formula can release the exterior more effectively after decocting.

Note 1 to entry: This definition is taken from Reference [12].

3.4

mutual restraint

toxicity (3.6) or side effects of a medicinal being counteracted by another medicinal

EXAMPLE Pinellia tuber (PINELLIAE RHIZOMA, Ban xia) restraint fresh ginger rhizome (ZINGIBERIS RHIZOMA RECENS, Sheng jiang).

Note 1 to entry: This definition is taken from Reference [12].

**3.5
prohibited combination**

medicinals whose combined use is prohibited in a prescription

Note 1 to entry: This definition is taken from Reference [12].

**3.6
toxicity**

ability of a substance to produce an adverse effect upon a living organism

[SOURCE: ISO 472:2013, 2.767]

**3.7
effectiveness**

accuracy and completeness with which users achieve specified goals

[SOURCE: ISO/TS 20282-2:2013, 4.7]

**3.8
decoction pieces**

medicinal substances in small pieces or slices for decocting, mostly after appropriate processing

Note 1 to entry: This definition is taken from Reference [12].

Note 2 to entry: Decoction pieces are also called medicinal slices.

**3.9
constitution**

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

Note 1 to entry: This definition is derived from Reference [12].

**3.10
entity**

actual or abstract thing that exists, did exist, or might exist, including associations among these things

[SOURCE: ISO 41011:2017, 3.7.11]

**3.11
relationship**

association between two or more *entities* (3.10) that is significant for some intended purpose

[SOURCE: ISO 19440:2007, 3.1.66]

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

**3.12
information model**

graphical and textual representation of *entities* (3.10) and the *relationships* (3.11) between them

Note 1 to entry: Can also be known as a data model, a conceptual data model, a logical data model, an entity relationship model, an object class diagram, or a database definition.

[SOURCE: ISO/IEC 19763-12:2015, 4.2.24]

**3.13
combination rule**

principles governing the process of *combination* (3.2)

3.14**mutual assistance**

two or more medicinals used in *combination* (3.2), one being the principal substance and the others playing a subsidiary role, to reinforce the action of the former

EXAMPLE Tussilago flower (FARFARAE FLOS, Kuan dong hua) and bitter apricot seed (ARMENIACAE SEMEN AMARUM, Ku xing ren) used in a formula can suppress cough more effectively after decocting. The former is the leading Chinese medicine, the latter is the assistant.

Note 1 to entry: This definition is taken from Reference [12].

3.15**mutual suppression**

property of a medicinal to neutralize the *toxicity* (3.6) of another

EXAMPLE Fresh ginger rhizome (ZINGIBERIS RHIZOMA RECENS, Sheng jiang) suppresses jack-in-the-pulpit tuber (ARISAEMATIS RHIZOMA, Tian nan xing).

Note 1 to entry: This definition is taken from Reference [12].

3.16**mutual inhibition**

property of a medicinal to weaken the action of another

EXAMPLE Radish seed (RAPHANI SEMEN, Lai fu zi) weakens ginseng (GINSENG RADIX ET RHIZOMA, Ren shen).

Note 1 to entry: This definition is taken from Reference [12].

3.17**antagonism**

antagonistic combination of two medicinals where one can prevent the therapeutic effect of the other and/or there can be adverse effects

EXAMPLE Kan sui root (KANSUI RADIX, Gan sui) and licorice root (GLYCYRRHIZAE RADIX ET RHIZOMA, Gan cao) used together in a formula will reduce efficacy or produce side effects.

Note 1 to entry: This definition is taken from Reference [12].

3.18**five seasons**

collective term for spring, summer, late summer, autumn, and winter, as described in Traditional Chinese medicine literature

[SOURCE: ISO/TS 17938:2014, 3.2, modified]

4 List of authorized representation of relationships for the combination of decoction pieces in Chinese medicines

4.1 consist of

The relationship indicated by “consist of” indicates something that is structurally made up in whole or in part of some material or matter. This includes being composed of, made of, and formed of something.

Relationships: between decoction pieces, guiding herbs and combination.

EXAMPLE Ephedra (EPHEDRAE HERBA, Ma huang) consists of Ephedra soup (Mahuang soup).

4.2 enhance

The relationship indicated by “enhance” indicates an increase and an improvement. By increasing the leaching rate of the active ingredient of decoction pieces, the efficacy of Chinese materia medica is better than the original.

Relationships: between mutual reinforcement and effectiveness.

EXAMPLE Tussilago flower (FARFARAE FLOS, Kuan dong hua) used in combination with bitter apricot seed (ARMENIACAE SEMEN AMARUM, Ku xing ren) enhances the effectiveness of cough.

4.3 reduce

The relationship indicated by “reduce” indicates that something is less than before, a decrease. The inherent toxicity of Chinese materia medica can be reduced when used in a combination.

Relationships: between mutual restraint and toxicity.

EXAMPLE Fresh ginger rhizome (ZINGIBERIS RHIZOMA RECENS, Sheng jiang) can reduce the toxicity of pinellia tuber (PINELLIAE RHIZOMA, Ban xia).

4.4 affect

The relationship indicated by “affect” indicates something that produces a direct effect on, alters or influences an existing condition, state, situation, or entity.

Relationships: between constitution and combination.

EXAMPLE Combination is affected by the constitution of patients.

NOTE From Unified Medical Language System (UMLS).

4.5 be avoided

The relationship indicated by “be avoided” indicates deliberately not doing something, especially something wrong, dangerous, or harmful.

Relationships: between prohibited combination and combination.

EXAMPLE The combination of kan sui root (KANSUI RADIX, Gan sui) with licorice root (GLYCYRRHIZAE RADIX ET RHIZOMA, Gan cao) needs to be avoided in formulas.

5 Information model for representation of combination of Chinese medicines

5.1 Conformance principles

Any information model for representation of formulas of Chinese medicines in a terminological system shall conform to the requirements specified in ISO 17115 and shall provide the following information:

- a) an information model that organizes the healthcare entities for representation of formula combination of Chinese medicines in the terminology and subdivides their representation in the domain;
- b) a list of the representation relations authorized by domain constraints;
- c) the goal (purpose and scope) of the terminology for which the information model is set;
- d) a list of minimal domain constraints required by the goal of the information model. The information model that organizes the healthcare entities and the representation relations for representation of formula combination of Chinese medicines in terminological systems is defined in [Clause 4](#).

5.2 Overview

The formal concept representation system for the subject field of the formulas of Chinese medicines has relationships to the following information model.

Relationships among them are specified in [Clause 4](#).

The outline of those information model including relationships is illustrated in a concept diagram in [Figure 1](#).

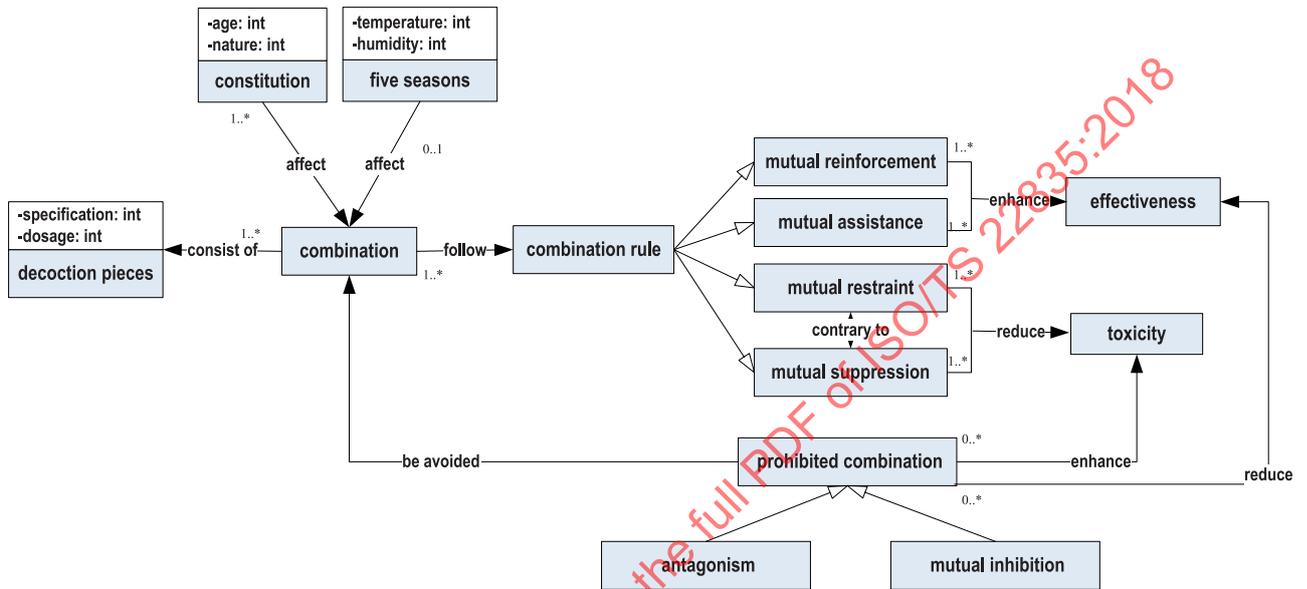


Figure 1 — Information model of representation of combination