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**Health informatics — Categorical  
structure of representation for  
evaluation of clinical practice  
guidelines of traditional Chinese  
medicine**

*Informatique de santé — Structure catégorielle de représentation  
pour l'évaluation des lignes directrices de pratique clinique en  
médecine traditionnelle chinoise*

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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](http://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](http://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](http://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](http://www.iso.org/members.html).

## Introduction

Clinical practice guideline (CPG) is one of the important measures to improve the quality of medical services and standardize of diagnosis and treatment. The evaluation of clinical practice guidelines for biomedicine has been shown to be useful. The appraisal of guidelines for research and evaluation (AGREE) tool was published in 2003 and upgraded in 2009, which includes 23 items and covers six quality assessment areas. It is widely used for the quality assessment of clinical practice guidelines. However, AGREE doesn't cover the application evaluation of CPG.

Traditional Chinese medicine clinical practice guideline (TCMCPG) is mainly divided into consensus-based guideline and evidence-based guideline. Consensus guideline is the main body of TCM Clinical practice guidelines and evidence-based guideline is still in its infancy. Out of the 527 TCM and acupuncture clinical practice guidelines/consensuses issued by December 2019, 403 (76,47 %) were based on the expert consensus approach and 124 (23,53 %) were based on the evidence-based guideline-making approach. Different from evidence-based guidelines of biomedicine, the clinical promotion and application effects of a large number of expert consensus-based guidelines need to be evaluated.

Furthermore, the application evaluation of the guidelines is an indispensable basic work, which is different from the evaluation of the quality of guideline. No unified semantic information framework exists in the application evaluation of TCMCPG, which affects the data exchange and sharing among different institutions and databases. From the perspective of categorical structure, an overall framework involving the whole process of application evaluation of the guidelines is needed so that the exchange and utilization of data can be more convenient. Categorical structure of application evaluation of TCMCPG is an essential part among this process. This document was developed to standardize the effect of application evaluation of CPG in order to promote the implementation, popularization, further revision and perfection of TCMCPG.

To sum up, evaluating the application effect of clinical practice guidelines can provide a basis for the implementation, promotion and revision of the guidelines, which can promote the application effect of TCMCPG and is beneficial to developers and practitioners of clinical guidelines. The establishment of a unified categorial structure for the application evaluation of TCMCPG is necessary, which will greatly improve the effect of the application evaluation of TCMCPG, establish a communication platform for the research of TCMCPG, and lay a solid foundation for future sharing and utilization.



# Health informatics — Categorial structure of representation for evaluation of clinical practice guidelines of traditional Chinese medicine

## 1 Scope

This document specifies the categorial structure within the field of TCMCPG application evaluation by defining a set of domain constraints of sanctioned characteristics each composed of a relationship.

The development clinical practice guidelines is outside the scope of this document.

## 2 Normative references

There are no normative references in this document.

## 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 terms

#### 3.1.1

##### **concept**

general notion or idea of something

[SOURCE: ISO/TS 18876-1:2003, 3.1.3]

#### 3.1.2

##### **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 practice guidelines**

##### **TCMCPG**

set of systematically developed statements to assist the decisions made by healthcare actors of TCM about healthcare activities performed with regard to specified health issues