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Health informatics — Categorial 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

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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

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 guide-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

3.2.2
evaluation
action that assesses the value of traditional Chinese medicine clinical practice guidelines

Note 1 to entry: The rationality and accuracy of the contents of the guidelines and developing method, the coordination of guidelines and clinical practice.

Note 2 to entry: The application effect and the application conformity of the guidelines.

3.2.3
applicability evaluation
internal characteristics of the guideline elements, the specific scope of the external environment and the relationship between them

Note 1 to entry: The evaluation results determine whether a guideline should be used in whole or in part.

Note 2 to entry: It evaluates the applicability of the guidelines from technical level, coordination, structure and content, etc.

[SOURCE: Applicability evaluation tool of Medical Guidelines, 2013]

3.2.4
consistency evaluation
degree of implementation uniformity between clinical practice guidelines and real clinical practice scenarios in many conditions such as clinical diagnosis, syndrome differentiation, drug use

Note 1 to entry: Tools or other relevant resources to support the recommendations and evaluation criteria for monitoring or auditing provided by the guidelines can improve consistency.

Note 2 to entry: The promotion and impediment factors in the application could be described in the guideline.

3.2.5
technical level
accuracy, clarity and rigor of traditional Chinese medicine clinical practice guidelines in disease, syndrome diagnosis and suggestion of treatment

3.2.6
structure and contents
concrete clauses and details included in a traditional Chinese medicine clinical practice guideline

3.2.7
coordination and matching
not conflicting with other standard documents, enabling several documents to be used in conjunction with each other

3.2.8
clarity
property of being clear, unambiguous and operable

Note 1 to entry: Different health problems and different choices have been listed clearly.

Note 2 to entry: The diagnostic points are accurate.

Note 3 to entry: The physical and chemical examinations are reasonable.

Note 4 to entry: The scope of application of the guidelines is clear.

3.2.9
preciseness
quality of being reproducible in amount or performance

Note 1 to entry: Preciseness can be shown in development, application and revision.

3.2.10
matching degree
degree of coordination and integration between the technical level of the guidelines and the hospital itself

3.2.11
standardization
imposition of standards or regulations

3.2.12
integrity
completeness in content and structure

Note 1 to entry: Integrity means the guidelines meets the requirements of the clinical practice guidelines, whether it contains the core elements of the guidelines.

3.2.13
consistency
conformity of clinical practice guidelines in clinical use regarding the aspects of diagnosis, syndrome differentiation and intervention methods

3.2.14
diagnosis
identification of a health or disease state from its signs and/or symptoms, where the diagnostic process can involve examinations and tests for classification of an individual's condition into separate and distinct categories or subclasses that allow medical decisions about treatment and prognosis to be made

Note 1 to entry: It includes the diagnosis of diseases in TCM (traditional Chinese medicine) and the diagnosis of TCM syndromes.

[SOURCE: ISO 20184-1:2018, 3.6, modified — Note to entry added.]

3.2.15
intervention method
actions taken to maximize the prospects of achieving the patient's or providers' goals of care, including the removal of barriers to achieve better health

EXAMPLE Medication, physical therapy.

3.2.16
implementation effect
standardization effect and technical effect

3.2.17
standardization effect
effect of the wide utilization of the diagnostic and therapeutic technology that are included in the traditional Chinese medicine clinical practice guidelines

Note 1 to entry: Standardization effects can achieve the best overall benefit through unification, simplification, optimization and coordination.

EXAMPLE 1 The guidelines improve the application effect by adopting new diagnostic and therapeutic technology, optimizing scheme and eliminating low-efficiency technology.

EXAMPLE 2 The guidelines can reduce unnecessary differences in clinical practice by standardizing diagnostic and therapeutic behaviour, realizing unified simplification and improving application effect

EXAMPLE 3 The guidelines can promote the technical connection and improve the application effect through the coordination of internal and external technologies.

EXAMPLE 4 Through a wider range of popular application, to achieve the rapid spread of technology, the application of technology is increased.

3.2.18
technical effect
effects of the diagnostic and therapeutic technology itself

3.2.19
compliance evaluation
extent to which something complies with relevant laws and regulations, in line with the public interest of the society

3.2.20
source evaluation
methods for developing traditional Chinese medicine clinical practice guidelines

Note 1 to entry: Evidence-based clinical practice guidelines or expert consensus are the main manifestations of source evaluation.

Note 2 to entry: If evidence-based, it is based on literature evidence or clinical trials.

Note 3 to entry: If it is an expert consensus, it is necessary to evaluate whether it is widely representative and authoritative.

3.2.21
evidence-based clinical practice guidelines
set of systematically developed statements to assist the decisions made by healthcare actors about healthcare activities to perform with regard to specified health issues

[SOURCE: ISO 13131:2021, 3.3.5]

3.2.22
expert consensus
guidance document to guide clinicians to engage in prevention, diagnosis, treatment, rehabilitation, health care and management through formal consensus method

Note 1 to entry: When a clinical problem needs to be solved urgently with no best evidence or low-quality evidence, expert consensus is recommended.

Note 2 to entry: Expert consensus accounts for a large proportion of traditional Chinese medicine clinical practice guidelines.

3.2.23
evidence-based literature
document that supports the establishment of traditional Chinese medicine clinical practice guidelines

Note 1 to entry: Evidence in this document mainly refers to evidence from ancient books. They are important sources for the decision-making process of clinicians.

3.2.24
convenience evaluation
operability of traditional Chinese medicine clinical practice guidelines in application and promotion

Note 1 to entry: Suggestions and/or supporting tools are provided.

Note 2 to entry: Potential resource investment in the application of recommendation is considered.

3.2.25
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]

3.2.26
physical therapy
non-drug interventions including other therapies besides traditional Chinese medicine and Western medicine

EXAMPLE Massage, laser therapy, etc.

3.2.27
clinical trial
any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational medicinal product(s), and/or to study absorption, distribution, metabolism and excretion of investigational medicinal product(s) with the object of ascertaining its safety and/or efficacy

[SOURCE: ISO 11616:2017, 3.1.3, modified — Note to entry deleted.]

3.2.28
diagnostic criteria
basis for diagnosing a disease

Note 1 to entry: It is divided into international diagnostic standard, national diagnostic standard, professional conference standard and regional diagnostic standard according to the authority of the standard.

3.2.29
therapeutic principle and method of treatment
general rule method of treatment followed when treating disease

4 Categorial structure of TCMCPG evaluation

4.1 Overview

The formal concept representation system in the field of TCMCPG evaluation 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 evaluated of

Action that assesses the value of something.

It expresses the semantic link between traditional Chinese medicine clinical practice guidelines (see 3.2.1) and applicability evaluation (see 3.2.3) whose relevant parameters are evaluated.

EXAMPLE <TCMCPG> is evaluated of <applicability evaluation>.

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 (UMLS).

It expresses the semantic link between standardization effect (see 3.2.17) and implementation effect (see 3.2.16).

EXAMPLE <standardization effect> is part of <implementation effect>.

4.2.3 is manifested of

Part of a phenomenon that is directly observable or concretely or visibly expressed, or which gives evidence to the underlying process. This includes expression of, display of, and exhibition of (UMLS).

It expresses the semantic link between clarity (see 3.2.8) and technical effect (see 3.2.18).

EXAMPLE <technical effect >is manifested of<clarity>.

4.2.4 is preceded by

Happen or exist before something or someone.

It expresses the semantic link between applicability evaluation (see 3.2.3) and consistency evaluation (see 3.2.4).

EXAMPLE <applicability evaluation> is preceded by <consistency evaluation>.

4.2.5 is based on

To use something as the thing from which something else is developed.

It expresses the semantic link between evidence-based clinical practice guidelines (see 3.2.21) and clinical trial (see 3.2.27).

EXAMPLE <evidence-based clinical practice guidelines> is based on<clinical trial>.

4.2.6 according to

In a way that agrees with a system or plan, or obeys a set of rules.

It expresses the semantic link between diagnosis (see 3.2.14) and diagnostic criteria (see 3.2.28).

EXAMPLE <diagnosis> according to <diagnostic criteria>.