ISO/TS 5118:2022(E)

2022-04-20

ISO TC 215

Secretariat: ANSI

Health ~~Informatics —~~ informatics — Categorial ~~Structure~~structure for ~~Representation~~representation for ~~Evaluation~~evaluation of ~~Clinical Practice Guidelines~~clinical practice guidelines in ~~Traditional~~traditional Chinese ~~Medicine~~medicine

~~Publication~~

ISO copyright office

Case postale 56 ●● CH-1211 Geneva 20

Tel.+ 41 22 749 01 11

Fax+ 41 22 749 09 47

E-mailcopyright@iso.org

Webwww.iso.org

Published in Switzerland.

Contents

Foreword 5iv

Introduction 6v

1 Scope 71

2 Normative references 71

3 Terms and definitions 71

4 List of authorized representation of relationships for TCM guideline evaluation 126

Bibliography 38

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*.

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 ~~relatively proven.~~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 ~~6~~six quality assessment areas~~ and be~~. It is widely used for the quality assessment of clinical practice guidelines. ~~But~~However, AGREE doesn't cover the application evaluation of CPG.

Traditional Chinese ~~Medicine Clinical~~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. ~~Of~~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 ~~vital~~necessary, which will greatly improve the effect of the application evaluation of TCMCPG, establish a communication platform for the research of TCMCPG~~ and international standards~~, and lay a solid foundation for future sharing and utilization.

Health Informaticsinformatics — Categorial structure for representation of the evaluation of clinical practice guidelines in traditional Chinese medicine

1 Scope

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

The development ofclinical practice guidelines is outside the guideline is outscope of this scope.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 terminologicalterminology databases for use in standardization at the following addresses:

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

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

3.1General

3.1 General terms

3.1.1
concept

internal conception of something; general notion or idea of something

[SOURCE: ISO/TS 18876-21:2003, 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 — Note to entry added].]

3.13.2 3.2CharacterizingCharacterizing categories

3.2.1
Clinical Practice Guidelines of Traditional3.2.1

traditional Chinese ~~Medicine~~ medicine clinical practice guidelines
TCMCPG
set of systematically developed statements to assist the decisions made by healthcare actors of TCM about healthcare activities ~~to be~~ performed with regard to specified health issues

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

Note 1 to entry: ~~the~~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~~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 ~~the guidelines~~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 ~~(Guozuo Dengzi-~~, 2013~~-A00103587)]~~]

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

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

Note ~~2to~~ 2 to entry:~~whether they describe the~~ The promotion and impediment factors in the application

~~Note 3 to entry: whether they consider the relevant resources that may~~ could be ~~needed~~described in the ~~application of recommendations~~guideline.

~~Note 4 to entry: whether they provide evaluation criteria for monitoring or auditing.~~

3.2.5
technical level
accuracy, clarity and rigor of ~~TCM~~clinical practice guidelines 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 ~~which~~included in a ~~TCMCPG should have~~ traditional Chinese medicine clinical practice guideline

3.2.7
coordination and matching

not ~~contradict or conflict~~conflicting with other standard documents, ~~can~~ 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~~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
normalization
imposition of standards or regulations

Note 1 to entry: Normalization is manifested in the process of making the guideline.

3.2.12
integrity

~~undivided or unbroken~~ completeness ~~or totality with nothing wanting~~ in content and structure

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

3.2.13
consistency
conformity of clinical practice guidelines in clinical use ~~from~~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~~— 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 success

EXAMPLE ~~medication~~Medication, physical therapy

~~[SOURCE: SKMT]~~

3.2.16
implementation effect
standardization effect and technical effect

3.2.17
standardization effect
effect of the ~~widely~~wide utilization of the diagnostic and therapeutic technology ~~after which is~~that are included in the ~~TCMCPG~~traditional Chinese medicine clinical practice guidelines

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

~~EXAMPLE1~~EXAMPLE 1 The ~~guideline improves~~guidelines improve the application effect by adopting new diagnostic and therapeutic technology, optimizing scheme and eliminating low-efficiency technology.

~~EXAMPLE2~~EXAMPLE 2 The ~~guideline~~guidelines can reduce unnecessary differences in clinical practice by standardizing diagnostic and therapeutic behaviour, realizing unified simplification and improving application effect

~~EXAMPLE3~~ EXAMPLE 3 The ~~guide~~guidelines can promote the technical connection and improve the application effect through the coordination of internal and external technologies.

~~EXAMPLE4~~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
~~**degree of acting according**~~
extent to ~~certain accepted standards~~ which something complies with relevant laws and regulations, in line with the public interest of the society

3.2.20
source evaluation
~~**basis**~~
methods of ~~the foundation of TCMCPG~~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 ~~from~~based on literature evidence or clinical trials.