世界中医药学会联合会国际组织标准

国际中医门诊病历书写规范

编制说明

一、工作简况

（一）任务背景

本标准项目拟研制中医门诊病历的记录内容的基本要求，以规范各国中医门诊病历书写和内容项目。

在中国，中医病历书写主要参照中国国家中医药管理局《中医病历书写基本规范》和原卫生部《病历书写基本规范》。其中《中医病历书写基本规范》基于中国国内中医发展的现状，包括了门诊、急诊和住院病历的书写内容规范，以对住院病历的规范要求为主。

在国际上，有个别中医药学术团体制定了内部使用的中医病历书写规范，尚缺乏相关国际组织标准。中国以外的中医临床以独立的门诊诊疗为主，参照这一规范指导临床病案书写不完全合适。由于各国中医发展水平不均衡，中医病案书写缺乏规范指导，随意性较强，不利于临床中医师临床经验的整理归纳分析，不利于国际中医诊疗工作质量的提升。

（二） 标准起草人及起草单位

主要起草单位：世界中医药学会联合会

参与起草单位：日本星火中医研究院、泰国中医科学院

主要起草人：李振吉、李昱、徐春波、刘强、申丹、郑跃先、姚乃礼、王映辉、张润顺、殷海波、胡镜清、顾晓静、李鹤白、王亚锋、林丹乾（泰国）、叶峰（泰国）、陈志清（日本）、秋本佳媛（日本）、赵俊萍（德国）。

参与起草人：

中　　国：陶有青、周亚男、穆倩倩、关梓桐；

日　　本：路京华、刘伶、邹大同、何晓霞、杨晓波、仝选甫、薛叶祥、韩笑、张成龙、尹倚艰、柯爱君；

新 西 兰：靖猛、肖煜晖、Amanda Liu、Shelly Tan、吴秀华、刘鹏、朱洵濡

泰　　国：杨秀专、张永发、蔡斌、谢进荣、孙智慧、杨真；

瑞　　典：国万春、周颖；

美　　国：王德辉；

加 拿 大：李维；

新 加 坡：黄玉华；

马来西亚：何秋月；

瑞　　士：李敬道。

二、标准起草过程简介

（如：何时启动，如何开展调研，如何征求各利益相关方的意见，召开了哪些审稿会，标准审定委员会讨论或投票情况等）

（一）标准文本起草

本标准起草过程主要遵循如下指导思想：（1）体现中医诊疗和临床思维特

色；（2）尽可能平衡标准要求的规范性和实用性；（3）适当加强对首诊记录的要求，简化对复诊的信息记录要求。

项目组参考了中国国家中医药管理局《中医病历书写基本规范》、原中国卫生部《病历书写基本规范》、十二五支撑计划名老中医课题病案采集系统（名老中医学术经验国家服务平台）、江西中医药大学岐黄中医门诊部门诊病案，以及日本中医药研究会《中成药应用症例百选》等，起草形成标准文本。

（二）专家研讨

标准起草初期，于2018年6月，组织中国境内专家在世界中联秘书处召开规范编制研讨会一次。到会专家包括李振吉、姚乃礼、王映辉、张润顺、殷海波、胡镜清、王亚锋、李鹤白。本次会议上，专家们主要意见包括：本标准制定的目标旨在通过规范病案支持国际中医职称评审、针灸国际合作及临床研究等；标准的起草需符合国际对病历的要求，还应结合国外法规、保险要求等；在内容方面应明确诊所信息、执业人、病史、脉诊等必填项，保证病历的可溯源性，保持一定灵活性（如舌像描述放宽），适当加入辨证分析；同时关注诊断编码、疗效评估等问题。针对门诊记录时间有限的问题，到会专家建议分两步实施：先出通用标准（统计病种、辨证、症状、干预方案及效果），再结合病种制定针对性要求。

（三）意见征询

针对初步的标准文本，项目团队组织中国境外的中医师开展意见征询一次，涉及加拿大、瑞典、瑞士、新西兰、日本、泰国、新加坡、马来西亚8个国家的30名中医从业人员。部分专家认为目前需进一步精简；可简化年轻、病情简单患者的首诊病历；结合各国学会现有标准等。一些具体条款修改建议还包括将“证候诊断”改为“辨证诊断”；“治疗目的”改为“治疗原则”，删去“需要以及患者本人意愿”；在“治疗原则”后补充“根据治疗原则，采取的具体的治疗”等。

（四）修改优化

完成专家研讨和初步意见征询后，基于专家研讨和征询反馈意见对草案内容进行初步修改，具体修改意见及回复处理结果见“四、重大分歧意见的处理经过和依据”中表1。

三、主要技术内容介绍

（如：技术指标、参数、公式、性能要求、实验方法、检验规则等）的论据（包括试验、统计数据），修订标准时，应增加新、旧标准的对比。

标准草案术语部分对“病历”“中医门诊病历书写”“首诊”“复诊”“随访”“刻下症”“临床评估”“患者依从性”进行了定义，主体内容主要包括一般规范、首诊记录、复诊记录、随访记录四部分要求。其中：

在一般规范部分，明确提出了对病历记录的要求，以及门诊病历首页、首诊记录、复诊记录、随访记录的病历内容基本要求。

对于首诊记录，要求的信息主要包括：主诉、现病史、既往史、个人史、婚育月经史、家族史等病史信息；一般情况、望闻切诊等体格检查、专科检查、临床评估、辅助检查（包括阳性和有鉴别诊断价值的阴性信息）、辨证分析；中医疾病、证候诊断等诊查情况；治则治法、处置的中成药、汤药、针刺、其他治疗以及针对调护的医嘱等治疗方案。

对于复诊记录，要求的信息主要包括：上次就诊或随访后至本次复诊期间

患者依从治疗的情况、治疗后的反应、刻下症情况、患者在随访中补充报告的病史信息，以及复诊诊查情况和治疗方案。

对于随访记录，要求的信息主要包括：患者上次就诊后至本次随访期间的情况；针对患者反馈信息，对治疗方案的调整；对患者依从治疗和疾病调护的医嘱信息等。

四、重大分歧意见的处理经过和依据

标准编制研讨会和国际专家意见征询意见过程中无重大分歧意见，共处理专家意见 22 条，采纳 10 条，部分采纳 4 条，不采纳 6 条，其他情况 2 条。汇总处理意见表见表 1。

表 1-标准研制阶段专家意见汇总处理表

序号 No.	标准条文号 Standard Clause	意 见 内 容 Comments	提出单位/个人 Proposed Unit/ Individuals	处理意见（由起草单位填写）Proposed Comments (Filled by Draft Unit)
1	综合	标准制定要与国外当地管理机构沟通。	李维（加拿大）	未采纳，与各国管理机构沟通与协调工作量较大，不利于标准指定顺利推荐。相关沟通协调工作可考虑在推广应用及制定不同语种的过程中进行，必要时根据要求进行修订。
2	综合	非常全面，但需要相当长的时间来完成首诊病历，可否略简化一点的。	吴秀华（新西兰）	采纳，在原有基础上尽量精简相关内容。
3	综合	建议结合各国学会现有病历标准。	靖猛（新西兰）	采纳，标准起草过程中初步参考了日本中医药研究会《中成药应用症例百选》的内容，考虑到目前海外各国中医学会出台相关标准较少，还将进一步收集参考相关标准。
4	综合	希望能多听取老中医师们的意见。	杨真（泰国）	采纳，意见征询过程中安排了对海外多位年纪较大中医师的征询。标准研发过程中考虑进一步征询。
5	综合	作为门诊病历太过繁琐。	蔡斌（泰国）	采纳，在原有基础上尽量精简相关内容。
6	前言	标准起草人建议增加美国专家。	张润顺	采纳，联系并增加了美国专家王德辉作为起草人。
7	3	术语中补充“临床评估、患者依从性”等。	张润顺	采纳，已补充相关内容。
8	4.1	补充书写时间；错字改动要求等。	张润顺	已采纳，在 4.1.3 和 4.1.4 部分补充相关内容。
9	5.3.5	脉诊建议改为“切诊”。	张润顺	部分采纳。将“脉诊”内容作为“切诊”下一级内容。
10	5.3.9	“证候诊断”改为“辨证诊断”。	路京华（日本）	未采纳。“证候诊断”为名词，“辨证诊断”可理解为动词，“证候诊断”表述更准确。

11	5.4.1	“治疗目的”改为“治疗原则”；删去“需要以及患者本人意愿”。	路京华（日本）	为精简内容，删去了相关要求。
12	5.4.1	治疗方案中，删除“治疗目的”相关内容。	王映辉	采纳，删去了本部分内容。
13	5.4.2	在“治疗原则”后补充“根据治疗原则，采取的具体的治疗”。	路京华（日本）	部分采纳，将“治疗原则”后的“方法”修改为“计划采取的治疗方法”。
14	5.4.3	处方（包括处方的出处、方剂名称）。	路京华（日本）	部分采纳，补充了“中药汤药处方应包括方剂名称”的要求。
15	5.4.3	处方改为“干预措施”。	张润顺	未采纳。此处提出对“处方”内容的要求，并非针对干预措施。具体文字中已提及“干预方案”。
16	5.4.4	调护医嘱中，补充“必要时，给出其他检查和治疗的建议”。	王映辉	采纳，已补充。
17	5、6	建议补充：合并治疗情况、辨证分析、按语。	张润顺	未采纳。相关内容并非必须，为保持内容精简，未补充。
18	6、7	明确随访/回访，或统一表达。	王映辉	采纳，已统一为“随访”，并在术语部分补充了定义。
19	7	建议补充病情分析、健康记录。	张润顺	未采纳。相关内容并非必须，为保持内容精简，未补充。
20	附件	模板修订：诊次信息不容易定义，首复诊要明确定义；随访记录增加临床评估。	张润顺	部分采纳。术语中增加了对首诊、复诊的定义。为保持灵活性，删去了附件模板。
21	附件	模板的随访记录中，补充“临床评估”。	王映辉	为保持灵活性，删去了附件模板。
22	其他	补充按语。	王映辉	未采纳。按语并非门诊工作内容，为保持内容精简，未补充。

五、其他应说明的事项

无。

International Standard of World Federation of Chinese Medicine Societies
Standard for Medical Records in the International Clinic of Chinese Medicine
Formulation Explanations

I. Work Profile

(I) Background

This standard aims to establish basic requirements for the content of outpatient medical records in Chinese medicine, in order to standardize the writing and content items of Chinese medicine outpatient medical records across various countries.

In China, the writing of Chinese medicine medical records primarily follows the "*Basic Rules for Writing TCM Medical Records*" issued by the National Administration of Traditional Chinese Medicine of China and the "*Basic Rules for Writing Medical Records*" issued by the former Ministry of Health of China. The "*Basic Norms for Writing TCM Medical Records*" are based on the current development status of Chinese medicine in China and encompass the writing content norms for outpatient, emergency, and inpatient medical records, with a focus on the normative requirements for inpatient medical records.

Internationally, some individual academic groups of Chinese medicine have developed internal standards for writing Chinese medicine medical records, but there is still a lack of relevant international organizational standards. Most of the Chinese medicine clinics outside of China are independent. Therefore, referring to this standard to guide clinical medical record writing is not entirely appropriate. Due to the uneven development of Chinese medicine in different countries, there is a lack of standardized guidance for Chinese medicine medical record writing, which leads to a high degree of arbitrariness. This is not conducive to the collation, induction, and analysis of clinical experience of Chinese medicine practitioners, nor is it conducive to improving the quality of international Chinese medicine diagnosis and treatment work.

(II) Drafters and drafting units

Main Drafting Unit: World Federation of Chinese Medicine Societies

Participating Drafting Units: ISKRA Research Institute of TCM, Japan; Thailand Academy of Chinese Medical Sciences, Thailand.

Main Drafters: Li Zhenji, Li Yu, Xu Chunbo, Liu Qiang, Shen Dan, Zheng Yuexian, Yao Naili, Wang Yinghui, Zhang Runshun, Yin Haibo, Hu Jingqing, Gu Xiaojing, Li Hebai, Wang Yafeng, Lin Danqian (Thailand), Ye Feng (Thailand), Chen Zhiqing (Japan), Akimoto Yoshimoto (Japan) and Zhao Junping (Germany).

Participating Drafters:

China: Tao Youqing, Zhou Yanan, Mu Qianqian, Guan Zitong

Japan: Lu Jinghua, Liu ling, Zou Datong, He Xiaoxia, Yang Xiaobo, Tong Xuanfu, Xue Yexiang, Han Xiao, Zhang Chenglong, Yin Yijian, Ke Aijun

New Zealand: Jing Meng, Xiao Yuhui, Amanda Liu, Shelly Tan, Wu Xiuhua, Liu Peng, Zhu Xunru

Thailand: Yang Xiuzhuan, Zhang Yongfa, Cai Bin, Xie Jinrong, Sun Zhihui, Yang Zhen

Sweden: Guo Wanchun, Zhou Ying
United States: Wang Dehui
Canada: Li Wei
Singapore: Huang Yuhua
Malaysia: He Qiuyue
Swiss: Li Jingdao

II. Brief Introduction to the Standard Drafting Process

(I)Drafting of standard text

The drafting process of this standard primarily follows the following guiding ideologies: (a) Reflecting the characteristics of Chinese medicine diagnosis and clinical thoughts. (b) Balancing the standardization and practicality of the standard requirements as much as possible. (c) Appropriately strengthening the requirements for first visit records and simplifying the information recording requirements for return visit records.

The project team drafted a standard text by referring to the "*Basic Rules for the Writing TCM Medical Records*" issued by the National Administration of Traditional Chinese Medicine of China, the "*Basic Rules for the Writing of Medical Records*" issued by the former Ministry of Health of China, the "Medical Record Collection System for Experienced Chinese Medicine Masters" project under the "Twelfth Five-Year Support Plan" (National Service Platform for Academic Experience of Experienced Chinese Medicine Masters), outpatient medical records from the Qihuang Chinese Medicine Clinic, Department of Jiangxi University of Traditional Chinese Medicine, and "*Hundred Selected Application Cases of Chinese Patent Medicines*" issued by the Japan TCM Research Association.

(II)Expert seminar

During the standard drafting process, in June 2018, a seminar on standard preparation was organized by experts within China at the WFCMS Secretariat. The experts attending the meeting include Li Zhenji, Yao Naili, Wang Yinghui, Zhang Runshun, Yin Haibo, Hu Jingqing, Wang Yafeng, and Li Hebai. At this meeting, the main opinions of the experts are as follows. The goal of this standard is to support international professional title evaluation of Chinese medicine, international cooperation in acupuncture and moxibustion, and clinical research through the standardization of medical records. The drafting of the standards should comply with international requirements for medical records and should also incorporate foreign regulations, insurance requirements, etc. In terms of content, it is necessary to specify required items such as clinic information, practitioners, medical history, and pulse diagnosis to ensure the traceability of medical records, while maintaining a certain degree of flexibility (such as relaxing the description of tongue images). Appropriate inclusion of dialectical analysis is also recommended, while paying attention to issues such as diagnostic coding and efficacy evaluation. In response to the issue of limited recording time in outpatient clinics, the experts present suggested implementing a two-step approach. First, develop general standards (including statistics of disease types, syndrome differentiation, symptoms, intervention plans, and effects), and then formulate targeted requirements based on specific disease types.

(III)Request for Comments

Regarding the preliminary standard text, the project team organized a consultation with Chinese medicine practitioners outside China, involving 30 practitioners from 8 countries: Canada, Sweden, Switzerland, New Zealand, Japan, Thailand, Singapore, and Malaysia. Some experts believe that further simplification is necessary at present. The first visit records for young patients with simple conditions can be simplified. And existing standards of various national societies should be taken into account. Some specific suggestions for revising the terms include changing "syndrome diagnosis" to "differential diagnosis", changing "treatment purpose" to "treatment principles", deleting "needs and patient's willingness", and after "treatment principles", supplementing with "specific treatments adopted according to the treatment principles", etc.

(IV)Modification and optimization

After completing the expert seminar and preliminary opinion consultation, preliminary revisions were made to the draft content. For specific modification suggestions and the handling results of replies, see Table 1 in "IV. Handling Process and Basis for Major Divergent Opinions".

III. Introduction to Main Technical Content

The terminology section of the draft standard defines terms such as "Medical record", "TCM outpatient medical records writing", "First visit", "Return visit", "Follow-up", "Present symptoms", "Clinical assessment", and "Patient compliance". The main content primarily encompasses four requirements: general specifications, records of first visit, records of return visit and records of follow-up.

In the general specifications section, the requirements for medical record keeping are clearly outlined, as well as the basic content requirements for the records of first visit, return visit, and follow-up.

For the records of first visit, the required information mainly includes: complaint, history of present illness, history of past illness, personal history, history of marriage, childbearing and menstrual, family history and other medical history information; general situation, looking, listening & smelling, asking, pulse feeling & palpation physical examination, speciality check-up, clinical evaluation, auxiliary examination (including positive and negative information of differential diagnosis), syndrome differentiation analysis; diagnosis of Chinese medicine diseases and syndromes; therapeutic principle, therapeutic method, prescription of Chinese patent medicine, soup medicine, acupuncture, other treatments and advice for adjusting and nursing.

For records of return visit, the required information mainly includes: Patient status since the last visit or follow-up, Including compliance, response, present symptoms and more medical history reported by the patient in the follow-up, as well as the follow-up diagnosis, examination and treatment.

For records of follow-up, the required information mainly includes: patient status since the last visit or follow-up, the adjustment of the treatment according to the feedback of

the patient and advice for compliance, adjusting and nursing.

IV. Handling Process and Basis for Major Divergent Opinions

During the standard preparation seminar and the process of soliciting opinions from international experts, there were no major divergences. A total of 22 expert opinions were processed, with 10 adopted, 4 partially adopted, 6 not adopted, and 2 for others. The summary of the processing opinions is shown in Table 1.

Table 1. Summary and Processing of Expert Opinions during the Standard Development

No.	Standard Clause	Comments	Proposed Unit/ Individuals	Proposed Comments (Filled by Draft Unit)
1	Entirety	The formulation of standards should be communicated with local regulatory agencies abroad	Li Wei (Canada)	Not adopted. The workload of communication and coordination with regulatory agencies from various countries is significant, which is not conducive to the smooth recommendation of standard specifications. Relevant communication and coordination work can be considered during the promotion, application, and development of different languages, and revisions can be made as necessary according to requirements.
2	Entirety	It's very comprehensive, but it takes quite a long time to complete the first visit record. Could it be simplified a bit.	Wu Xiuhua (New Zealand)	Adopted. Try to simplify the relevant content on the existing basis.
3	Entirety	Combine the existing medical record standards of various national societies.	Jing Meng (New Zealand)	Adopted. During the drafting process, the content of "*Hundred Selected Application Cases of Chinese Patent Medicines*" published by the Japan TCM Research Association was initially referenced. Considering the limited number of relevant standards issued by Chinese medicine associations overseas, further efforts will be made to collect and reference relevant standards.

4	Entirety	Hope to listen more to the opinions of experienced Chinese medicine practitioners.	Yang Zhen (Thailand)	Adopted. During the opinion solicitation process, consultations were arranged with several elderly overseas Chinese medicine practitioners. Further consultations are being considered in the standard research and development process.
5	Entirety	As an outpatient medical record, it is overly cumbersome.	Cai Bin (Thailand)	Adopted. Try to simplify relevant content on the existing basis.
6	Foreword	Among the standard drafters, it is suggested to include American experts.	Zhang Runshun	Adopted. We contacted and added American expert Wang Dehui as a drafter.
7	3	Supplement the terminology with "clinical evaluation, patient compliance", etc	Zhang Runshun	Adopted. Relevant content has been supplemented.
8	4.1	Supplement writing time, requirements for correcting typos, etc.	Zhang Runshun	Adopted. Add related content to sections 4.1.3 and 4.1.4..
9	5.3.5	The term "Pulse feeling"（脉诊） should be changed to "Pulse feeling and palpation"（切诊）.	Zhang Runshun	Partially adopted. Move the content of "Pulse diagnosis"（脉诊） to be a sub-level content under "Pulse feeling and palpation"（切诊）.
10	5.3.9	"Syndrome diagnosis" （证候诊断）should be changed to "Syndrome differentiation and diagnosis"（辨证诊断）.	Lu Jinghua (Japan)	Not adopted. "Syndrome diagnosis"（证候诊断） is a noun, while "Syndrome differentiation and diagnosis"（辨证诊断）can be understood as a verb. Considering the context, "Syndrome diagnosis" is a more accurate expression.
11	5.4.1	"Therapeutic objectives" should be changed to "therapeutic principles". Delete "needs and the patient's own wishes."	Lu Jinghua (Japan)	To simplify the content, relevant requirements have been removed.

12	5.4.1	In the treatment plan, delete the content related to "treatment objectives"	Wang Yinghui	Adopted. The content of this section has been deleted.
13	5.4.2	After the "treatment principles", add "the specific treatments adopted based on the treatment principles".	Lu Jinghua (Japan)	Partially adopted. Replace "methods" after "treatment principles" with "planned treatment methods".
14	5.4.3	Prescription (including the source of the prescription and the name of the prescription).	Lu Jinghua (Japan)	Partially adopted. The requirement that "prescriptions for Chinese medicine decoctions should include the name of the formula" has been added.
15	5.4.3	Change the prescription to "intervention measures".	Zhang Runshun	Not adopted. The requirements for the content of the "prescription" proposed here are not targeted at intervention measures. The specific text has already mentioned "intervention plan".
16	5.4.4	In the “Advice for adjusting and nursing”, add "If necessary, provide suggestions for additional examinations and treatments."	Wang Yinghui	Adopted. It has been supplemented.
17	5, 6	It is recommended to supplement the following content: consolidated treatment details, dialectical analysis, and remarks.	Zhang Runshun	Not adopted. The relevant content is not essential, and to keep the content concise, it has not been supplemented.
18	6, 7	Clarify “follow-up” & “return visit”, or express in a unified way.	Wang Yinghui	Adopted. It has been unified as "follow-up" and a definition has been added in the terminology section.
19	7	It is recommended to supplement with disease analysis and health records.	Zhang Runshun	Not adopted. The relevant content is not essential, and to keep the content concise, it has not been supplemented.

20	Attachment	Template revision: The number of visits is not easily defined, and “first visit” and “follow-up visits” should be clearly defined. Clinical assessments should be added to follow-up records.	Zhang Runshun	Partially adopted. The definitions of first visit and follow-up have been added to the terminology. To maintain flexibility, the attachment template has been removed.
21	Attachment	In the follow-up record of the template, add "clinical evaluation".	Wang Yinghui	To maintain flexibility, the attachment template has been removed.
22	Others	Add remarks.	Wang Yinghui	Not adopted. "Remarks" is not part of outpatient work content, and to keep the content concise, no additional information has been provided.

V. Other Matters Needing Explanation

None.