世界针灸学会联合会标准

WFAS 007.1—2023

针灸临床实践指南制定及其评估规范

Norms for formulation and evaluation of the clinical guidelines on acupuncture and moxibustion

2023-10-09 发布　　2023-12-31 实施

世界针灸学会联合会　　发 布

目　　次

Contents

针灸临床实践指南制定及其评估规范

1 前言

1.1 关于世界针灸学会联合会(WFAS)

世界针灸学会联合会(World Federation of Acupuncture-Moxibustion Societies,WFAS)是与世界卫生组织(World Health Organization,WHO)建立正式工作关系的、与国际标准化组织/中医药技术委员会(International Standardization Organization/Technical Committee 249, ISO/TC 249)建立A级联络关系的非政府性针灸团体的国际联合组织,WFAS针灸临床实践指南的制定遵行WHO提出的原则,同时遵循循证医学的理念和方法。

WFAS致力于把针灸科学、规范地推荐到世界各国,不断提高针灸医学在世界卫生保健工作中的地位和作用。针灸临床实践指南是实现这一目标的重要途径,WFAS针灸临床实践指南势必要紧紧围绕针灸医学特色和优势制定。

1.2 针灸在WFAS团体会员所在国家和地区的发展现状

截至2022年12月底,WFAS已有264个团体会员,遍及6大洲,70个国家和地区。根据WFAS调研结果显示,目前有65个国家和地区承认中医针灸合法地位,部分国家和地区已将针灸纳入主流医学体系。然而,不同国家和地区在针灸立法与管理、针灸教育情况等方面发展差别较大,如相比其他大洲,欧洲和南美洲将针灸纳入医疗保险的国家和地区数量及报销比例较低;有些国家在本国不同省份(地区)的针灸政策仍存在很大差异。在这种情况下,如何兼顾WFAS针灸临床实践指南的公平性、经济性、适用性,是WFAS指南制定的关键。

1.3 由针灸学科自身性质引发的证据困境和出路

1.3.1 制定针灸临床实践指南面临的证据困境

制定国际指南要求采用当前最佳临床研究证据,目前常采用临床研究设计等级最高的随机对照临床试验(Randomized Controlled Trial,RCT)对疗效进行评价。对于制定针灸指南而言,一方面,虽然针灸临床研究数据庞大,且近年有一定数量的重要针灸临床研究发表在高影响力期刊上,但整体来说,高质量证据仍旧非常缺乏。这一定程度影响了指南产生推荐意见的强度。另一方面,RCT需要设置严格的纳入、排除标准,排除诸多干扰,但实际上,针灸是一种多因素混杂的复杂干预,很难完全排除所谓的“干扰”,导致通过严格设计的临床研究与针灸真实临床实践并不完全一致。因此,若仅依靠临床研究证据制定指南,必然会出现指南临床适用性降低的窘境。

1.3.2 证据的解决出路

对于独特性和历史性极突出的传统针灸来说,其凝结着前人的智慧,蕴含着古人对千百年临床实践中确有效验的针灸技术、方法及治疗规律的总结。一项有效针灸治疗方案的形成,往往需经历早期对有效穴位(施术部位)或施术方法的发现,再经长期临床实践反复优化、验证的过程。在这样千百年的实践过程中,古人留下了大量含有经验总结的古代文献和广泛的医家经验,它们是当今针灸治疗方法的传承源头,与现代临床实践及临床研究中的治疗方案存在着不可分割的联系。因此,制定针灸临床实践指南,首先应该尊重针灸学本身依然存在的大量客观事实和规律,尊重历史经验,通过将古今医家经验与临床研究相参互验的转化应用,可作为形成针灸临床实践指南证据的重要组成部分。

2 规范简介

2.1 本规范的目的

《针灸临床实践指南制定及其评估规范》(以下简称本规范)旨在引导读者了解 WFAS 针灸临床实践指南的制定流程和评估方法;确保 WFAS 针灸临床实践指南在遵循循证医学理念和方法的同时,又能体现针灸临床的特点;保证高质量针灸临床实践指南的制定;最大限度地保证指南在 WFAS 团体会员所在国家和地区中的适用性。

2.2 本规范的适用人群

本规范适用于:

——希望制定针灸临床实践指南的 WFAS 团体会员和 WFAS 组织管理部门;

——制定 WFAS 针灸临床实践指南的起草组成员;

——制定 WFAS 针灸临床实践指南的专家组成员;

——制定 WFAS 针灸临床实践指南的评审组成员;

——开展针灸临床实践指南质量评估的人员;

——有兴趣了解 WFAS 针灸临床实践指南制定或评估方法的人员。

2.3 本规范的范围

本规范规定了 WFAS 针灸临床实践指南制定和评估的原则、方法、流程及要求。

2.4 WFAS 针灸临床实践指南的制定原则

WFAS 针灸临床实践指南遵循以下原则制定:

——针灸临床实践指南应反映 WFAS 以针灸促进“人人享有健康”的理念;

——针灸临床实践指南制定的提出应从针灸临床实践需求出发,符合必要性前提;

——针灸临床实践指南的制定过程应公开透明,即使用者可查看指南的制定原因、制定者、制定依据和方法;

——针灸临床实践指南临床问题的提出应以筛选对疾病有效、安全的针灸干预措施为出发点,以保证指南的适用性;

——根据针灸学特点,制定针灸临床实践指南采用的证据来源包括当前最佳研究证据,和(或)古代有记载、现在仍有应用的传统知识和经验,以及临床验证确实有效且有大量真实相关病例支持的医家经验;

——针灸临床实践指南制定的推荐意见应针对相关临床问题进行回答,明确推荐强度,此外,还应包含针灸疗效影响要素(如施术部位、施术方法,以及对施术者的教育背景、经验和技能的要求等),以保证其在针灸临床实践中的有效性和可操作性;

——制定针灸临床实践指南的每一步骤和方法应尽可能降低推荐意见中的偏倚风险;

——针灸临床实践指南的制定应考虑 WFAS 团体会员所在国家和地区的针灸使用环境和文化背景:如在指南规划阶段就应考虑指南实施中可能遇到的可及性或推广性问题;推荐意见除了要考虑证据质量因素外,还应尤其关注 WFAS 团体会员所在国家和地区医生或患者的价值观与意愿,卫生经济状况等;如有必要,可针对不同国家和地区或不同人群(包括但不限于针灸行业的公共卫生政策制定者、卫生保健提供者、患者、照护者等)发布不同版本。

2.5 针灸临床实践指南的分类

针灸临床实践指南的分类遵从国际指南的分类:可根据版本分为标准指南、汇编指南、临时指南、快

速指南、改编指南及更新指南等不同类型，本规范主要适用于标准指南；可根据用户分为专业版指南（医师版指南、护理版指南）、患者版指南，本规范主要适用于医师版指南。

针灸临床实践指南依据针灸学科特点，可根据主题分为疾病类针灸临床实践指南和常用针灸技术应用类针灸临床实践指南。

a) 疾病类针灸临床实践指南：是指关于某一具体疾病（症状）的一系列与针灸诊疗相关的指导性文件。应围绕“针灸干预可能适宜的人群”及“有效的针灸干预”，回答针灸干预可治疗的结局指标/症状，干预效果与安全性等问题，并形成相应适宜人群有效的针灸干预方案建议。

b) 常用针灸技术应用类针灸临床实践指南：是指针对某一临床常用针灸干预措施，围绕其在针灸实践中能够解决哪些优势病种等相关临床问题，系统研制的帮助指南使用者作出最佳临床决策的指导性文件。

本规范主要适用于疾病类针灸临床实践指南。

3 术语和定义

下列术语和定义适用于本规范。

3.1

WFAS 针灸临床实践指南 WFAS clinical guideline on acupuncture and moxibustion

由 WFAS 制定的，针对相关针灸临床问题，帮助指南使用者恰当选择和使用针灸干预措施、作出最佳临床决策的指导性文件。

注：指南中推荐意见应依据目前最佳临床研究证据，参照经转化的古今医家临床经验，综合考虑医生或患者价值观、意愿和卫生经济学等因素制定。

3.2

临床问题 clinical questions

针对特定疾病、体现针灸临床诊疗优势的临床情况，医生与患者关注的干预与预后、病因、诊断以及医疗成本等问题。

注 1：主要包括目标人群、针灸干预措施、针灸疗效、可改善的结局，以及针灸与其他疗法相比较的差异等方面。

注 2：临床问题是形成指南推荐意见的基础，制定指南以解决临床问题为目的。

［来源：GB/T 40972—2021，3.2，有修改］

3.3

证据 evidence

经过严格的质量评估，用于支持疾病病因、诊断、治疗和预后的文献。

注：与医学实践和决策相关的证据是多层次的。

［来源：GB/T 40972—2021，3.4，有修改］

3.4

推荐意见 recommendations

针对特定临床问题，依据相关证据，考虑利弊关系，以及特定资源、价值取向等因素，通过专家共识所形成的指导性意见。

［来源：GB/T 40972—2021，3.8，有修改］

3.5

推荐强度 the strength of recommendation

依据证据质量、与干预或结局指标相关的价值观和偏好、利弊平衡、资源影响、需解决问题的重要性、健康公平性、可接受性和可实施性等因素对推荐意见进行综合性、分级化描述。

注：对针灸临床实践指南而言，推荐意见的强度还与证据中的针灸治疗方案个体化程度及其在实施中产生变化的可能性相关。

4 指南制定前的规划和准备

4.1 是否真的有必要制定该指南？

在指南制定之前，指南起草组需要明确一个十分关键的问题：制定这个指南是否真的有必要？由于指南的制定是一件非常耗时、耗力、耗钱的事情，因此在指南制定之前需要认真思考以下问题。

4.1.1 何人需要这个指南？

是WFAS中某一个团体会员组织还是大部分团体会员组织提出的需求？按照WFAS标准工作委员会提出的制定要求，应至少有5个团体会员同时提出，且至少有2/3标准工作委员会委员通过（弃票不包括在内），提案才能被接受。鼓励项目提案者在指南制定之前，针对指南制定的必要性，向WFAS指南的使用者展开调研。

4.1.2 计划要制定的指南是否已经存在？

目前是否有某一国际组织或者某个国家已经发布了该主题的指南？该指南能否满足WFAS团体会员的需求？可以咨询WFAS团体会员、WFAS标准工作委员会秘书处、查询数据库等，以避免重复工作。若该主题已有相关指南发布，应检查其质量和对当前需求的适用性。若不符合当前需求，可考虑更新现有的WFAS指南。

4.1.3 是否有必要优先开展该指南的制定？

对于有紧急需求、有较成熟研究基础、有广泛临床实践基础、全球性流行且国际较为认可针灸治疗的病种，针灸临床从业者和患者关注的临床问题比较集中，但尚未形成针灸干预措施诊疗的共识性指导文件、未能满足当地诊疗需求的指南，将优先考虑制定。

4.2 指南的目的是什么？主要使用人群是谁？

4.2.1 指南想要达到什么目的？

指南除促进针灸推广之外，是否能够为针灸操作者提供更多的治疗思路和手段？是否能够解决一部分临床不确定的问题？

4.2.2 指南的主要使用人群？

指南的主要使用人群，它是指南的理想终端用户。一部指南的使用人群可以包含针灸从业者、患者、卫生管理人员等，但一般不建议一部指南将政策制定者、卫生部门管理者、患者、临床医生和其他卫生专业人员等同时作为指南的主要使用人群，因为这在实践中往往很难实现。

4.3 是否了解WFAS团体会员所在国家和地区的针灸使用环境和文化背景？

指南的最终意义需要通过指南实施来实现，WFAS作为一个国际组织，其团体会员所在国家和地区的针灸诊疗情况、使用针灸的社会/医疗环境和文化背景存在较大差异，因此建议在指南规划阶段要对以下情况有所掌握：

——团体会员所在国家和地区常用的针灸干预及其在各地应用情况；

——团体会员所在国家和地区针灸科常见病种；

——各地医疗体系将针灸纳入医疗保险范围、纳入医疗机构的情况；

——各地卫生管理系统对针灸从业人员的法规与管理政策；

——各地患者对针灸干预的接受程度等。

4.4 确定指南的范围

确定 WFAS 针灸临床实践指南的范围，需要起草组在前期对 WFAS 团体会员所在国家和地区中使用针灸的社会/医疗环境和文化背景有所了解的基础上，综合考虑时间、精力和资金等情况，以确保指南在可控范围之内，使指南既能适当突出重点，又能在指定的时间期限内通过现有资源加以完成。因此，在最终确定指南范围之前，需对文献进行预检索以确定相关信息，包括现有指南和系统评价、卫生技术评估报告和指南主题的经济评估，考虑制定该指南的证据基础。

确定 WFAS 针灸临床实践指南的范围，一般包括以下几个方面：

——明确要制定的指南类型，指南主要分为“疾病类针灸临床实践指南”和“常用针灸技术应用类针灸临床实践指南”(见 2.5)，本规范主要用于指导“疾病类针灸临床实践指南”的制定；

——确定指南的目标疾病，一般来说，WFAS 针灸临床实践指南所涉及的疾病应包含在针灸技术适宜病种范围内；

——明确与疾病相关的针灸干预措施。

4.5 指南工作组组成

4.5.1 组成概述

制定 WFAS 针灸临床实践指南时，会依据成员工作与职能的不同，成立不同的工作小组，以便指南制定工作能高效、科学地展开，具体包括：

——起草组；

——专家组；

——评审组。

建议指南在附录中提供所有指南工作组成员的所属组别、姓名、性别、职业、所属学会/团体与具体职责。指南制定的组织结构见附录 A 中的图 A.1。

4.5.2 起草组

起草组内设组长 1 名，负责指南项目的申报、组织实施、进度管理与利益冲突管理等工作。此外，还包含指南编写人员与证据筹备人员。

4.5.3 专家组

专家组为多学科团队，必须包括针灸临床专家与指南方法学家(循证医学专家)，同时还建议包括相关领域的临床专家、古籍文献专家、患者或患者家属、卫生经济学家、公共卫生管理人员等。其中，针灸临床专家的比例不应低于 60%。专家组成员除需具有学科代表性外，还应考虑地域与流派构成的合理性，建议至少包含 5 个不同国家和地区的团体会员代表，并尽量包含对针灸持不同政策(如是否立法、是否承认合法地位、是否将针灸纳入医保等)的国家和地区。专家组建议人数在 15 人～30 人，成员主要负责指导指南制定流程，参与指南制定过程中的共识决策。

4.5.4 评审组

评审组成员来自于 WFAS 标准工作委员会，主要负责审查指南项目建议书，对指南工作草案(working draft，WD)进行最终评议等。

4.6 指南的共识决策

指南制定过程中，临床问题的确定、结局指标及其重要程度的确定与推荐意见的形成需要进行共识

决策。共识参与者必须包括针灸临床专家与指南方法学家(循证医学专家)。

每个共识决策环节可能会进行多次共识会议或德尔菲法调查,考虑到时间、资源等因素的影响,专家组成员缺席的情况在所难免,为保证共识决策的可靠性,共识参与者应尽可能保持一定的稳定性。建议在指南专家组内设置核心专家组,由领域内具有一定学术影响力的专家构成,人数推荐在 8 人～10 人,选择成员时需要考虑地域与流派构成的合理性,每次共识决策必须包含 2/3 及其以上的核心专家组成员。同时,核心专家组还负责处理专家审查意见。

建议在指南中报告具体共识环节的共识参与者、所用的共识方法、达成共识的标准、具体共识流程、共识过程及共识结果。其中,形成推荐意见环节要求采用会议形式(包括线上会议形式)。

4.7 利益冲突声明与管理

利益冲突主要包括经济利益冲突和非经济利益冲突,在指南制定过程中对指南工作组的利益冲突管理,有助于指南的科学性与透明性。

在指南制定过程中,起草组与专家组的全体成员均需填写利益声明表,由起草组组长邀请 3 位～5 位专家一同对利益声明表进行评审,确定成员是否存在利益冲突(评价利益冲突严重性的标准可参见 WHO 指南制定手册),以及相应的处理方法,并在利益冲突声明表中报告处理方法及理由(见附录 B)。

对成员可采取的利益冲突管理方法如下。

——**不采取行动**:仅在利益声明表中作出报告,而不必采取其他措施。

——**参与受限**:个人被排除在部分会议和指南制定过程之外,可采取以下两种措施:

- 不可参与某些关键共识环节或步骤的决策,但可允许参与所有讨论;
- 禁止参与某些关键共识环节或步骤的决策与讨论。

——**不允许参与**:不允许成为起草组或专家组成员。

4.8 其他要考虑的关键问题

4.8.1 制定指南的资金是否充足?

为了制定出高质量的指南,需要有足够的资源用于完成系统评价、召开会议和支付制作成本等。但 WFAS 针灸临床实践指南制定过程中不能接受商业机构提供的资金支持。

4.8.2 时间能否合理安排?

制定指南需要充足的时间和精力投入,按照 WFAS 标准工作委员会规定,从确定立项到最终指南发布一般需要经历 18 个月～24 个月。因此,在指南制定之前,就应与参与指南制定的人员做好说明。

4.8.3 与有关法律法规和强制性标准的关系

需要明确指南与相关法律法规或强制性标准之间的关系,如与 WFAS 已发布的指南、WFAS 标准工作委员会章程、各地的法律法规等的关系。

4.8.4 考虑指南实施过程和可能遇到的障碍

是否所有的针灸干预都适合在指南中推荐?实施过程中需要具备的基本条件(对实施者的要求和对实施条件的要求)?指南应以什么样的形式发布?指南应以何种语言发布?这些问题应在规划阶段就纳入考虑,因为其会影响指南涉及人员、需要的资源和起草及提出推荐意见的方式。

4.9 提交指南建议书

制定 WFAS 针灸临床实践指南,需要向 WFAS 标准工作委员会秘书处提交建议书,在建议书“标

准起草单位和负责人介绍”部分，要写清楚核心专家组成员（见4.5.3）。按照WFAS标准工作委员会章程，若参与投票的标准工作委员会委员中有2/3委员同意立项，则立项通过。为了增加指南制定过程的透明性，避免重复，建议指南起草组在提交指南建议书的同时，在国际实践指南注册平台（http://guidelines-registry.cn/）进行指南注册。

5 临床问题的确定

在按照人群、干预、对照、结局（population，intervention，comparison，outcome；PICO）要素收集针灸临床问题时，需围绕某一具体“有一定疗效”的针灸干预，重点征集其“可治疗的人群”与“可缓解的结局指标”。在征集针灸临床问题前，对PICO每个要素可能涉及的重要信息可予以明确，并在确定临床问题时对其一一作出限定。

5.1 可形成临床问题的相关内容

根据针灸临床实践的特点和需求，可能形成针灸指南临床问题的内容，主要包括但不限于以下4个方面。

5.1.1 特定人群所适宜的具体针灸干预措施

针对针灸临床实践指南的目标人群，根据疾病的不同特点或对某一针灸疗法（方案）具有不同疗效反应的特定人群做进一步分类。起草组可结合前期对WFAS团体会员所在国家和地区开展的关于该疾病诊断和针灸治疗的调研结果，对指南目标人群进行分类（如疾病的分期、疾病轻重程度、中医辨证分型以及特定临床表现等），以提出特定人群可能适宜何种具体针灸疗法的问题。

示例5-1：

使用毫针和常规西药治疗急性期偏头痛患者，哪种疗法可使患者获益更多？

5.1.2 针灸干预措施的有效操作要点

根据疾病特点，收集可能有效的针灸干预（如针刺、电针、艾灸等），并明确其操作要点（如施术部位、施术方法、治疗时间等），以形成针灸干预措施操作相关的临床问题。

示例5-2：

对急性和亚急性非特异性腰痛患者，每周大于3次的针刺治疗，比每周3次的针刺治疗使患者获益更多吗？

5.1.3 针灸疗法与其他疗法的差异

提出针灸疗法单独使用或联合其他疗法使用，相对于其他疗法的疗效、安全性（不良反应）以及经济性等方面的差异，形成相关临床问题，包括但不限于以下内容：

——与目前公认的其他有效疗法的疗效、安全性（不良反应）以及经济性的差异；

——与空白对照（如安慰剂）疗效的差异，以及针灸疗法的不良反应与经济成本；

——与各针灸疗法之间的疗效、安全性（不良反应）以及经济性的差异；

——针灸疗法联合常规有效疗法，与该常规有效疗法之间的疗效、安全性（不良反应）以及经济性差异等。

5.1.4 针灸可改善的结局

根据疾病特点，提出针灸干预可解决何种结局的问题，如疼痛、生理或临床指标、生活质量等。

5.2 临床问题的形成

5.2.1 临床问题收集思路

针灸临床实践指南的临床问题宜围绕“有一定疗效的具体针灸干预措施”提出，首先收集治疗目标疾病的有一定疗效的具体针灸干预措施有哪些，然后针对每一种干预措施，收集以下内容：

——针对的适宜人群和治疗的适宜时机是什么？

——能解决哪些问题（包括结局指标或症状等）？

——安全性如何？

——使用范围和对诊疗环境有哪些要求？

5.2.2 临床问题的收集与确定

由起草组与指南方法学家（循证医学专家）共识后确定临床问题的收集方法与征集范围，可经过如下 3 个阶段形成临床问题，整个形成过程需要在指南中进行报告。

第 1 阶段：收集临床问题要素（即 PICO 要素）及相关临床问题

步骤 1：收集有一定疗效的针灸干预措施及其适宜的具体目标疾病人群。一方面，可由核心专家组确定与之相关的有一定疗效的针灸疗法；另一方面，可由起草组在 WFAS 团体会员所在国家和地区的针灸医患中发起调研，收集对目标疾病有一定疗效的针灸疗法。

步骤 2：针对以上收集结果，由核心专家组确定具体的有一定疗效的针灸干预措施，并将其作为临床问题中可限定的要素。

步骤 3：围绕核心专家组确定的有一定疗效的针灸干预措施，再从医患中广泛收集具体的临床问题（见 5.2.1）。调研范围应考虑代表不同团体会员、不同层级医疗机构等因素，调研对象数量的确定应符合流行病学调查样本量要求。在收集临床问题时，应关注针灸干预措施在 WFAS 团体会员所在国家和地区的不同使用情景，询问被调查者所处的诊疗环境。可采用如表 5-1 所示的半结构化收集表格。

表 5-1 围绕“有一定疗效的针灸干预措施”的临床问题收集问卷示例

请您从以下方面提出您关注“毫针治疗偏头痛的哪些问题”：毫针治疗**急性期偏头痛患者**（填人群）相比于**常规西药**（填其他干预措施）在**疼痛缓解强度、疼痛缓解时间、医疗花费**（填结局）方面有无差异？	
干预措施	如您有推荐的毫针治疗方案，请在此处填写：_____ 描述中应包括操作要点（如介入时机、选穴处方、针刺方法、治疗时间等） 如您没有推荐的治疗方案，此处默认为“毫针疗法相关的具体治疗方案”
可选人群	☑ 病期（☑ 急性期/□预防性治疗/□其他____） □疼痛程度（□轻度，请描述症状____/□中度，请描述症状____/□重度，请描述症状____/□其他____） □经络辨证分型（□少阳经头痛/□阳明经头痛/□其他____） □特殊人群（□伴抑郁/焦虑的偏头痛患者/□止痛药依赖的偏头痛患者/□处于哺乳期的急性期偏头痛患者/□月经期偏头痛患者/□其他____） □其他____
可选其他干预措施	□不治疗 ☑ 其他**常规西药**____

表 5-1　围绕“有一定疗效的针灸干预措施”的临床问题收集问卷示例（续）

可选结局	☑ 疗效类指标：**疼痛缓解强度、疼痛缓解时间** ☐安全类指标：_____ ☑ 卫生经济指标：**医疗花费** ☐其他：____
您所处的诊疗环境：**综合性医院**　（针灸专科医院/综合性医院等）	
关注的其他问题：**毫针操作是否安全**?	

第 2 阶段：整理与合并临床问题

由指南起草组对收集到的临床问题进行整理，形成包含“具体的人群”(P)、“具体的干预措施”(I)及“对照措施”(C)要素结构化表达且形式完整的临床问题，如“相比于不做治疗，应用耳针进行预防性治疗，是否可以使月经期偏头痛患者更加获益?”

对于针灸治疗方案相关问题，可以作为临床问题直接提出，也可将其和与之相关的临床问题整合提出。如，可将上述耳针预防性治疗月经期偏头痛临床问题与耳针治疗时机的临床问题“相比于不做治疗，应用耳针进行预防性治疗，适宜于何时开始?”合并为“相比于不做治疗，应用耳针进行预防性治疗，是否可以使月经期偏头痛患者更加获益？适宜于何时开始耳针治疗?”

第 3 阶段：筛选与确定临床问题

由专家组对整理合并后的临床问题进行进一步研讨，围绕针灸诊疗优势与特点，依据医患关注程度筛选出重要的针灸干预措施，由专家组对该种干预措施下的临床问题进行重要性打分，通过德尔菲法或其他共识方法遴选出优先被关注的临床问题。每类干预措施纳入的临床问题数量视医患对该类干预措施的关注程度而定，同时需综合考虑时间、资金，以及是否在已有指南中被回答等情况。

5.3　结局指标及其重要程度的确定

5.3.1　结局指标的确定

针对 5.2.2 第 1 阶段步骤 3 所收集临床问题涉及的结局和结局指标，经专家共识后，依据针灸干预措施的临床应用情况，确定某种针灸干预影响的具体目标人群(P)的结局和结局指标，如针刺治疗女性尿失禁的结局为漏尿的程度，对于混合性尿失禁人群可用 24 h 漏尿次数作为主要结局指标，而压力性尿失禁人群则用 1 h 尿垫试验作为主要结局指标。

专家组中临床专家、方法学专家、卫生经济学专家及患者代表可对其他影响医患决策的结局和结局指标进行补充，包括安全性指标、卫生经济学指标等。

5.3.2　结局和结局指标的重要程度分级

在每一类人群(P)下，起草组对所涉及的结局和结局指标进行整理。依据对针灸施术者或患者决策的影响程度，由共识专家对整理后的结局和结局指标按重要程度进行分级，分为第 1 类关键结局、第 2 类重要但非关键结局以及第 3 类不重要的结局：第 1 类是指影响决策的关键因素，包括 9 级～7 级；第 2 类是影响决策的重要但非关键因素，包括 6 级～4 级；第 3 类是对决策者和患者影响不大的因素，包括 3 级～1 级。同一干预措施对同一疾病不同类型人群(P)的结局指标及其重要程度不同(见表 5-2)。

表 5-2 《针灸临床实践指南　女性尿失禁》结局指标重要程度分级示例(节选)

结局指标	结局重要性评分	重要性评级
1. 24 h 尿失禁次数	8	关键结局
2. 用于评估尿失禁患者生活质量的相关问卷	7	关键结局
3. 急迫性尿失禁影响问卷(U-IIQ)、急迫性尿失禁量表(U-UDI)	7	关键结局
……	……	……
9. 24 h 漏尿量	6	重要结局
10. 1 h 尿垫试验漏尿量	6	重要结局
11. 用于评估泌尿系统问题的辅助检查	6	重要结局

5.4 临床问题的表述

5.4.1 临床问题的措辞

建议临床问题的措辞考虑以下 2 个方面。

——对完全包含 PIC 要素的临床问题,宜使用一般疑问句,减少使用特殊疑问句。建议使用“相比于……更好/较好”等程度副词,避免使用“最佳”“最好”“最优化”“最能反映”等程度副词。如“对于后遗症期面神经麻痹患者,WFAS 应该推荐毫针治疗还是不治疗?”

——针灸治疗方案相关临床问题,建议与相关临床问题合并提出后,采用一般疑问句与特殊疑问句相结合的方式表达。如“对于月经期偏头痛患者的耳针预防性治疗,适宜于何时开始治疗?”与“相比不做治疗,应用耳针进行预防性治疗,是否可以使月经期偏头痛患者更加获益?”可合并提出,即为“相比于不做治疗,应用耳针进行预防性治疗,是否可以使月经期偏头痛患者更加获益? 适宜于何时开始耳针治疗?”

5.4.2 临床问题的结构化分解

纳入的临床问题需按照 PICO 要素结构化分解(见示例 5-3)。

示例 5-3:

“伴抑郁/焦虑的偏头痛患者,毫针与西药联合应用进行预防性治疗,相比于单纯应用西药,患者受益是否更多?”可结构化分解为:

人群:伴抑郁/焦虑的偏头痛患者(未发作期)
干预措施:预防性治疗毫针联合西药
对照措施:西药
结局指标:临床疗效(发作天数、频率及强度的变化;有效率;与头痛相关的生活质量;功能健康状况和与健康相关的生活质量;症状改善、证候量表积分)
安全性结局(不良反应发生率)
卫生经济学评价指标(治疗费用、治疗时间成本)

5.5 临床问题的报告

最终确定的临床问题的报告采用结构化表格的形式(见表 5-3),报告内容包括:

a) 应对最终确定的临床问题,按 PICO 要素进行报告;

b） 对确定的所有临床问题是否被处理及其处理的结果(形成推荐意见/形成针灸治疗方案),应在指南正文中报告(见附录 C 中的 C.9.2)。

表 5-3 《针灸临床实践指南 偏头痛》中临床问题和推荐意见对应表报告示例(节选)

序号	临床问题内容	人群	干预措施	对照措施	结局指标	处理意见(推荐意见/针灸治疗方案)	备注
毫针							
1	对于急性期偏头痛患者,毫针相比于常规西药使患者获益更多吗?	急性期偏头痛患者	毫针	常规西药	头痛程度或强度(VAS、VRS等)[a];头痛持续时间[a];头痛缓解时间[a];2 h 内是否起效和头痛缓解程度[a];与头痛相关的生活质量[a];24 h 内的头痛缓解程度[a];严重不良反应发生率[a];功能健康状况和与健康相关的生活质量[b];症状改善、证候量表积分[b];头痛伴随症状的缓解程度[b];治疗费用[b];治疗时间成本[b]	形成推荐意见 R1	在综合性医院应用
耳针							
2	相比于不做治疗,应用耳针进行预防性治疗,是否可以使月经期偏头痛患者更加获益?适宜于何时开始耳针治疗?	月经期偏头痛患者	耳针	不做治疗	发作天数、频率及强度的变化[a];有效率[a];与头痛相关的生活质量[a];功能健康状况和与健康相关的生活质量[a];症状改善、证候量表积分[b]	形成推荐意见 R2,针灸治疗方案	在针灸专科医院应用

注:[a]表示关键指标;[b] 表示重要但非关键指标;R 为推荐意见简称。

6 证据的检索、评价与综合

6.1 证据来源

应包括来源于现代文献(系统评价与随机对照临床研究等)和古今医家临床经验(古代文献、近现代医家临床经验、观点著述、真实病历数据):

a） 系统评价,经筛选评价后,可直接用于形成推荐意见;

b） 现代临床研究,经系统评价后,用于形成推荐意见及其推荐的针灸治疗方案;

c） 古今医家临床经验,经转化评估后形成可用于推荐的针灸治疗方案内容,而不直接形成推荐意见。

6.2 证据检索与筛选

6.2.1 系统评价与现代临床研究证据检索

由起草组制定检索策略。文献检索策略包括检索工具、检索范围、检索词、检索式和文献纳入、排除

标准等。检索范围应包括中文、英文、日文及韩文等语种数据库。检索数据库如 Cochrane Library、Medline、EMBase、中国期刊全文数据库(China National Knowledge Infrastructure,CNKI)、中文生物医学期刊数据库(Chinese Medical Current Contents,CMCC)等。检索策略还应包括检索文献的年限。起草组根据确定的检索策略,采用电子检索和手工检索相结合的形式进行检索。

证据等级金字塔中包括系统评价与 Meta 分析、RCT、观察性研究等研究类型。对于现代文献证据的检索顺序,可根据临床问题的需要,按照证据金字塔"从高到低"进行逐级检索。

6.2.2 古今医家临床经验检索与收集

6.2.2.1 古代文献检索与收集

由指南专家组中的古籍专家,根据疾病特点确定古代文献检索词、古代文献检索书目范围及版本。古代文献检索书目需满足以下原则:

a) **广泛性**:包括成书年代从出土简帛医书至清代(A.D.1912)时间段内、世界范围内的针灸经络、腧穴、刺灸法、治疗相关针灸专书及综合书籍;
b) **代表性**:指在针灸学术史发展过程中影响较大且记录有较多针灸诊疗相关信息的古籍,可满足针灸临床实践指南对古籍信息资料的需求;
c) **可靠性**:古籍著者可考,能提供经校勘的版本,可为针灸临床实践指南充分借鉴与引用奠定基础;
d) **可获得性**:为公开发行的现存古籍,或经辑佚后公开出版的古籍文献,以保证古籍原始内容可获得。

由古籍专家根据以上原则制定检索策略,进行检索,并根据文献纳入、排除标准,筛选出符合条件的内容条目。

6.2.2.2 近现代医家临床经验资料检索与收集

包括(1912 年至今)医家临床经验、观点著述、真实病例数据等资料,收集步骤如下。

a) 确定纳入医家的范围。收集临床资料的医家人数由指南专家组确定,建议不超过 10 人。医家纳入标准如下:
   1) 对目标疾病治疗疗效显著;
   2) 长时间临证经验,有较为稳定的患者群体;
   3) 具有地域公认度(传承弟子人数较多、其思想具有影响力等)。
b) 由起草组收集医家临床经验,所纳入资料需同时符合以下标准:
   1) 病因病机、治则治法论述清晰,对目标疾病辨证有指导作用;或诊断明确,符合目标疾病诊断(疾病病因、病机、病位/部位、病性、病势等诊断明确,符合目标疾病诊断);或关键主症、全身兼症、舌象脉象描述清晰,符合目标疾病诊断;
   2) 施术部位、施术方法相关内容完整(例如,毫针的施术部位可包括腧穴、取穴方法;施术方法可包括刺法、操作手法、治疗时间等内容);或施术部位、施术方法描述清晰;
   3) 疗效/效果描述清晰;或有临床疗效效果描述、记录、解说等内容;
   4) 治疗方案与常规方法相比,具有独特性、特殊性。

   注:指或有特殊的治疗方法;或对某一类人群有特殊疗效;或取穴一致,但针刺方向、针感等不同;或施术方法、操作流程不同;或治疗频次、疗程不同等。

6.3 系统评价与现代临床研究证据评估

6.3.1 系统评价质量评估

系统评价采用系统评价/Meta 分析方法学质量评价工具(AMSTAR 2:A critical appraisal tool for

systematic reviews that include randomized or non-randomized studies of healthcare interventions, or both)评价工具进行质量评价(由 BMJ 出版集团有限公司出版,可访问网址 https://www.bmj.com/content/358/bmj.j4008.long,经授权后引用)。由起草组通过检索近年发表临床问题相关系统评价,近3年内有 RCT 发表但无系统评价更新,可考虑重新制定更新系统评价策略。无需更新的系统评价由起草组提取结果。如果临床问题缺乏相关系统评价,则由起草组收集现代临床研究证据,开展系统评价。

6.3.2 现代临床研究证据质量分级

6.3.2.1 现代临床研究证据质量分级方法

对现代文献证据质量的分级的评估采用推荐分级评估、制定与评价系统(Grading of Recommendations Assessment, Development and Evaluation, GRADE)软件系统。

6.3.2.2 现代临床研究证据体质量分级

现代临床研究证据体的评价方法与流程参见 WHO 指南制定手册。

现代临床研究的证据体质量由5个降级因素和3个升级因素决定,由起草组确定降级和升级的因素。在 GRADE 指南制定工具(GRADEpro GDT)中填入现代临床研究的降级和升级因素后,其证据体质量的级别将会自动出现。为达到透明和简化的目标,GRADE 系统将现代临床研究证据体强度分为高、中、低、极低4级。GRADE 为现代临床研究证据体强度提供了符号描述法、数字描述法和字母描述法。本规范建议采用字母描述法,用大写英文字母 A、B、C、D 分别表示高、中、低、极低4个等级。

6.4 不同来源证据中针灸治疗方案相关性评估

6.4.1 评估对象和评估内容

评估对象为现代临床研究和古今医家临床经验中针灸治疗方案,评估内容如下:

a) **疾病相关内容及治则治法**:可包括疾病诊断,病因、病机、病位、病性、病势,证候(主症、全身症状、舌象脉象等);治则治法、选穴原则、配穴方法等信息描述;

b) **施术部位相关内容**:可包括腧穴(经穴、经外奇穴)、微系统穴(区域穴,如头、耳、眼等)、病所和反应点/物(如阿是穴、敏化点、血络、结节等),以及取穴方法等信息描述;

c) **施术方法相关内容**:可包括针灸方法、操作方法(如针刺深度、针刺角度、针刺方向、施灸壮数等)和治疗时间(如治疗时间点、留针时间、间隔时间、疗程时间等)等信息描述。

6.4.2 相关性评估方法

由古籍文献专家和临床专家,依据疾病与针灸干预特征,通过对不同来源治疗方案中的评估内容是否一致,作出临床经验相关性判断。有相关性的古今医家临床经验,将作为临床研究中治疗方案的可靠性支持证据。不同来源针灸治疗方案相关性判断的具体内容如下:

a) 疾病病因、病机、病位、证型(阶段)、证候以及治则治法、选穴原则、配穴方法是否一致;

b) 选穴处方、施术部位、取穴方法是否一致;

c) 针灸方法、操作方法、治疗时间是否一致。

6.5 临床经验的转化应用

步骤 1:不同来源针灸治疗方案结构化提取和分析

由起草组对古今医家临床经验和现代临床研究中针灸治疗方案进行提取。当某一临床问题有多个临床研究时,需经综合考量治疗目标疾病的各临床研究的效应量、偏倚风险、安全性、合理性及可行性等

后，遴选出可供提取的针灸治疗方案。可采用结构化提取表对相关内容进行提取（见表 6-1）。

表 6-1　不同来源针灸治疗方案结构化提取示例表

条目 来源	著作（作者/ 年代）经验提供者	条目 内容	疾病相关 内容	治则 治法	施术 部位	施术方法 （注意事项）	效果
临床研究 1							
临床研究 2							
古今医家临床经验 1							
古今医家临床经验 2							

步骤 2：相关性评估

由古籍文献专家和临床专家对不同来源针灸治疗方案是否具有相关性进行评估，需要明确临床研究中治疗方案的哪些要素有古今医家经验支持。

步骤 3：临床价值评估

由临床专家对不同来源针灸治疗方案的临床价值进行评估。评估内容包括以下 4 个方面：

a）　方案的理法方穴术之间是否相对应；

b）　操作技术是否直观并且可重复，是否可推广在临床实施；

c）　较个人常用疗法是否更有应用价值；

d）　对临床诊疗是否具有启发或指导。

不同来源针灸治疗方案的评估过程见图 6-1，建议用表格形式呈现（见表 6-2）。

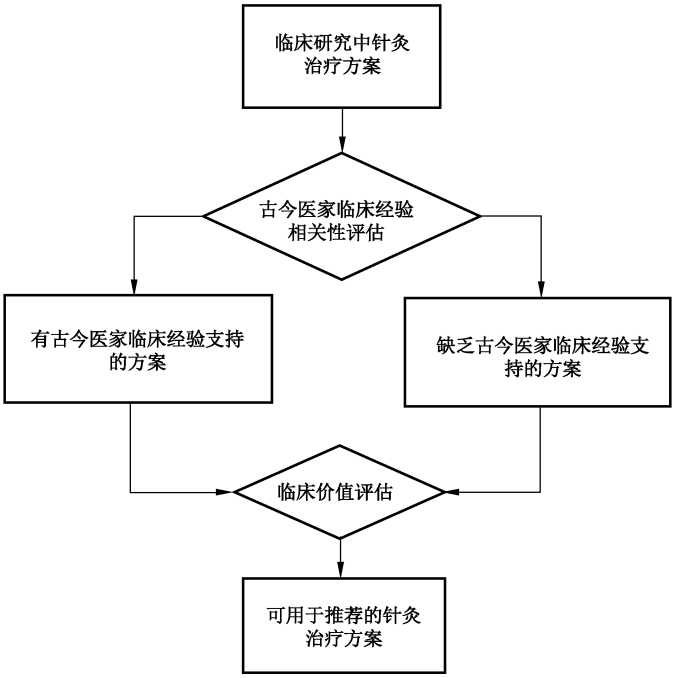

图 6-1　不同来源针灸治疗方案评估流程图

表 6-2　不同来源针灸治疗方案的评估过程示例表

<table>
<tr><td>临床问题内容</td><td colspan="7"></td></tr>
<tr><td rowspan="2"></td><td colspan="2">针灸方案及资料来源</td><td colspan="3">治疗方案信息</td><td colspan="2">相关内容</td></tr>
<tr><td>文献编号</td><td>资料来源(临床研究/古今医家临床经验)</td><td>疾病相关内容及治则治法</td><td>施术部位</td><td>施术方法</td><td colspan="2">临床研究与古今医家临床经验相关的内容</td></tr>
<tr><td rowspan="6">相关性评估</td><td rowspan="4">资料 1</td><td>临床研究</td><td></td><td></td><td></td><td colspan="2">—</td></tr>
<tr><td>古今医家临床经验 1</td><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td>古今医家临床经验 2</td><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td>……</td><td></td><td></td><td></td><td colspan="2"></td></tr>
<tr><td colspan="2">是否具有相关性</td><td></td><td></td><td></td><td colspan="2">—</td></tr>
<tr><td colspan="2">□有古今医家临床经验支持的方案
□缺乏古今医家临床经验支持的方案</td><td colspan="5">治疗方案 1：
取穴
主穴：
配穴(辨经/辨证/对症取穴)：
刺灸方法
针灸方法：
操作方法：
治疗时间：
注意事项</td></tr>
<tr><td colspan="2">□有古今医家临床经验支持的方案
□缺乏古今医家临床经验支持的方案</td><td colspan="5">治疗方案 2：
取穴
主穴：
配穴(辨经/辨证/对症取穴)：
刺灸方法
针灸方法：
操作方法：
治疗时间：
注意事项</td></tr>
<tr><td colspan="2">……</td><td colspan="5">……</td></tr>
<tr><td rowspan="3">临床价值评估</td><td colspan="2">评估内容</td><td>考虑因素</td><td>治疗方案 1</td><td>治疗方案 2</td><td>……</td><td>备注</td></tr>
<tr><td colspan="2">方案的理法方穴术(辨证分类、治则治法、选穴配穴、刺灸方法以及注意事项)之间是否相对应</td><td>a)　实践经验
b)　理论分析
c)　国内外资料
d)　直观感觉</td><td>□ 是
□ 否
□ 不确定</td><td>□ 是
□ 否
□ 不确定</td><td>□ 是
□ 否
□ 不确定</td><td></td></tr>
<tr><td colspan="2">操作技术是否直观并且可重复，是否可在临床推广实施</td><td>a)　自身实践经验
b)　他人实践经验
c)　直观感觉</td><td>□ 是
□ 否
□ 不确定</td><td>□ 是
□ 否
□ 不确定</td><td>□ 是
□ 否
□ 不确定</td><td></td></tr>
</table>

表 6-2　不同来源针灸治疗方案的评估过程示例表（续）

	评估内容	考虑因素	治疗 方案 1	治疗 方案 2	……	备注
临床价值评估	较个人常用疗法是否更有应用价值	a)　操作简便 b)　操作安全 c)　成本便宜(可获得) d)　短期疗效 e)　长期疗效	□ 是 □ 否 □ 不确定	□ 是 □ 否 □ 不确定	□ 是 □ 否 □ 不确定	
	对临床诊疗是否具有启发或指导意义	a)　诊断 b)　治则 c)　治法 d)　疗效评价方法	□ 是 □ 否 □ 不确定	□ 是 □ 否 □ 不确定	□ 是 □ 否 □ 不确定	
	临床价值评估结论	□ 有重要的临床价值 □ 有一定的临床价值 □ 临床价值不确定				

针对临床价值评估结论，经专家组共识，最终确定是否推荐该针灸治疗方案的内容。

6.6　基于多源证据的综合性评估

针灸指南证据综合包括推荐意见的证据综合和推荐意见中的针灸治疗方案的综合性评估：

——**推荐意见**的证据综合过程，由起草组应用系统评价、现代临床研究等各类型证据评价的结果，对临床问题中涉及的“疗效差异”“安全性”等问题进行回答的过程；

——**针灸治疗方案**的综合性评估过程，由指南专家组对临床研究及古今医家临床经验中的治疗方案进行临床经验相关性评估后，将有相关性的古今医家临床经验作为临床研究中治疗方案的可靠性支持证据，再通过对临床研究中治疗方案进行临床价值评估后，经专家共识形成针灸治疗方案的过程。

7　推荐意见的形成

7.1　指南推荐意见框架和内容

推荐意见应包含以下内容，并在指南正文中进行报告（见 C.9.3）。

7.1.1　临床问题

报告确定的最终临床问题。

7.1.2　推荐意见内容

推荐意见应包括是否推荐干预措施（疗法）治疗特定人群或目标疾病患者，能否改善关键结局指标，以及证据等级、推荐强度。报告与相应临床问题相关的推荐意见。若推荐强度为有条件的推荐（即弱推荐），应陈述推荐意见使用的特定条件。

推荐意见应包括针灸治疗方案，其内容可包括针灸干预的适用人群、介入时机、治则治法、施术部位（包括主穴、配穴等）、施术方法（包括针灸方法、操作方法、治疗时间）、注意事项，以及该方案可改善的结局指标（症状）。

7.1.3 判断依据

应对以下方面作出说明：

——概述证据来源及不同来源的证据质量、数量等情况；

——可包括证据中反映的针灸可治疗的具体特定人群或不适宜的特定人群，如证据中无特定人群区分也需作出说明；证据中反映的有效干预措施包括哪些针灸方法，及其取效的操作方法、治疗时间等刺灸方法要点；

——干预措施利弊关系的权衡；

——患者价值观和意愿的分析或直接和间接成本情况。

7.1.4 实施的注意事项

可包括以下内容：

——与该推荐意见密切相关的操作注意事项等；

——该推荐意见可应用的使用环境，需考虑的政策法规；

——对施术者资质和水平的要求；

——对患者的健康教育和使用说明。

7.1.5 从证据到推荐的共识决策过程

推荐意见（含推荐的针灸治疗方案）形成时考虑的关键因素及共识过程。若有专家组成员对某项决策或共识结果持强烈反对意见，可记录异议及其观点。

7.1.6 参考文献

需报告推荐意见形成过程用到的临床研究参考文献和古今医家临床经验资料。

7.2 从证据到推荐需考虑的因素

证据质量和利弊平衡将影响推荐意见的强度。同时，推荐的强度还与目标疾病人群的偏好与价值观，以及推荐的干预措施对资源的利用、公平性、可行性有关（见 GRADE 网址 EtD 框架：http://www.gradeworkinggroup.org/）。

证据形成决策过程应考虑以下 12 个维度的内容：

——问题优先性（该临床问题是否应当被优先解决）；

——有利效果；

——不利效果；

——整体证据质量；

——结局指标的重要性；

——利弊平衡；

——资源利用；

——资源利用的证据质量；

——成本效益比；

——健康公平性；

——（干预的）可接受性；

——（干预的）可行性。

7.3 形成推荐意见中的针灸治疗方案需考虑的因素

若推荐意见中包含针灸治疗方案，在对不同来源针灸治疗方案的相关性和临床价值进行评估后，专

家组需对针灸治疗方案的方案合理性、利弊平衡、所需资源、公平性、可接受性及可推广性等方面进行综合性考虑，优选推荐的针灸治疗方案，建议考虑以下 9 个维度的内容：

——有利效果；

——不利效果；

——证据质量；

——方案合理性；

注：此维度建议从方案“是否有不同来源证据支持？”“方案的理法方穴术（辨证分类、治则治法、选穴配穴、刺灸方法以及注意事项）之间是否相对应？”等方面考虑。

——成本需求；

——健康公平性；

——（方案的）患者可接受度；

——（方案的）操作者可接受度；

——（方案的）可推广性。

7.4 推荐方向与强度

推荐方向与强度包括以下 5 个选项：

——强烈反对此干预；

——有条件地反对此干预；

——有条件地推荐干预或对照；

——有条件地推荐此干预；

——强烈推荐此干预。

在形成推荐意见时，需考虑“证据总结”“亚组人群说明”“实施说明”“监测与评估”“需优先研究的问题”等因素（见 GRADE 网址推荐强度表格：http://www.grade workinggroup.org/）。

8 未来可开展的研究

在指南的制定过程中，会遇到某一临床问题可能没有相关临床研究或者古籍上有明确记载、现代也在应用，但目前临床研究尚未关注。可以将这些问题单独整理列为独立的章节，这为以后的研究提供了思路和方向（具体内容应在 C.14 和 C.18.4 中报告）。

常见的可为未来研究提供方向指导的内容可能有：

——临床比较关注，但缺乏现代研究（如不同病情、亚组人群缺乏充分研究，某些重要结局指标缺乏探索，卫生经济学相关研究空缺等），同时古今医家临床经验中也无明确对应记载的问题；

——古今医家经验中有记载，临床也较为常用，但没有现代研究证据的操作或者经验；

——其他虽然目前不在临床研究热点之列，但有潜在价值的内容。

9 WFAS 针灸临床实践指南的共识决策

9.1 何人在何时需要进行共识决策？

本规范 4.6 中所描述的共识决策，主要涉及 WFAS 针灸临床实践指南的 3 个制定环节，分别为临床问题的确定、结局指标及其重要程度的确定以及推荐意见的形成。

9.2 何为共识？

共识是指群体内部或不同群体之间要达成普遍一致。然而，当临床问题情境较为复杂、证据不足或

相互矛盾、部分共识参与者有强烈不同观点时，共识参与者的讨论通常很难直接达成一致。因此，普遍一致并不意味着没有异议，重要的是对如何协调各方观点设置科学的指标。本章的目标是：

——为 WFAS 针灸临床实践指南工作组提供指导，提出可用于共识决策的共识方法；

——概述选择特定共识方法时的相关考虑；

——提出 WFAS 针灸临床实践指南制定中记录共识决策过程的最低要求。

9.3 达成共识的方法与标准

目前国内外有多种达成共识的方法与标准，依据共识内容的不同可采用正式和/或非正式的共识方法。正式共识法包含德尔菲法(Delphi)、共识会议法、名义群体法等，每种都有许多衍变形式，也有多种“混合”方案在临床使用，目前并无证据表明何种方法更优(不同共识方法的介绍及使用说明可参见 WHO 指南制定手册)。

WFAS 针灸临床实践指南制定中使用何种共识方法受若干因素影响，包括共识参与者的地域性(国家、地区或不同团体会员)、指南主题与相关临床问题、推荐意见的目标人群、证据质量以及时间或资源的限制等。WFAS 指南工作组可根据实际情况对共识方法进行选择，但需要在指南文本的相应环节或方法学部分进行报告，并解释选择该方法的相关考虑。

最终确定是否达成共识所需的一致程度称为达成共识的标准，当共识参与者的观点差异较大时，可采用投票法作为替代方案来达成最终结果，WFAS 针灸临床实践指南对“普遍一致通过”的标准建议最低不能低于 60%，并对反对意见及其理由在指南中进行报告。

9.4 WFAS 针灸临床实践指南的共识要求

9.4.1 共识前规划

根据不同共识内容确定以下内容：

——确定共识参与者(包括地域、专业等方面的要求)以及选择共识参与者的方式，并对共识参与者进行利益冲突管理；

——确定所使用的共识方法、达成共识的标准，对强烈反对意见的处理方式，以及在无法达成共识情况下的处理方法(若采用投票法作为替代方案需提前确定投票规则)，并对共识程序进行模拟；

——系统整理并合理设计共识材料，与相关背景资料一起提前发送给每位共识参与者；

——若有必要，对共识参与者进行共识方法的培训；

——若采用共识会议法或名义群体法，还应确定主持人。

9.4.2 共识时的注意事项

共识进行时应注意以下内容：

——向共识参与者宣读所使用的共识方法、达成共识的标准、预计的共识流程，以及共识参与者的利益冲突声明(见附录 B)；

——严格按照预先制定好的流程有序进行，注意时间管理。若采用共识会议法或名义群体法，主持人应做好进度和时间的把控，并防止某些成员的不当行为对会议产生影响；

——对共识人员、共识方法、共识过程、共识结果进行详细记录，保存相关材料及影音文件。

9.4.3 共识报告要求

在对 WFAS 针灸临床实践指南共识决策过程进行报告时，可包括目的与内容、参与者、方法与标准、材料与背景、过程、结果、利益冲突等方面。报告指南共识决策过程的要素和内容见附录 D。该部分

内容在指南文本中呈现的详细程度视具体情况而定，最终目的是提升共识决策过程的透明度，以便指南使用者清楚了解每项决策背后所考虑的因素以及实施每项推荐意见所需的信息。不同共识决策环节的报告要求有共性部分，也有个性部分。

9.4.3.1 共性部分

共识参与者、所用的共识方法、达成共识的标准、具体共识流程在不同环节的报告要求较为一致，具体如下：

——选择共识参与者的方式、共识参与者的人数与基本信息、共识参与者的专业与地域的分布情况、共识参与者的利益冲突情况及处理方式；

——所使用的共识方法以及选择该方法所考虑的原因，对强烈反对意见的处理方式，以及在无法达成共识情况下的处理方法；

——共识参与者意见的统计与综合方式、达成共识的标准以及确定该标准的方式和人员；

——经过的共识轮次、每一轮的共识结果，以及每位共识参与者在本环节的总体参与情况。

9.4.3.2 个性部分

共识过程、共识材料与共识结果在不同环节的报告要求存在不同，具体如下。

a) 临床问题的确定。需要报告以下两方面的内容：
   - 临床问题的收集过程概述、整理合并后的临床问题清单、共识参与者的意见处理过程；
   - 最终确定的临床问题。

b) 结局指标及其重要程度的确定。需要报告以下两方面的内容：
   - 结局指标的收集过程概述、整理合并后的结局指标清单、共识参与者的意见处理过程；
   - 结局指标重要程度分级（见表 5-2）。

c) 推荐意见的形成。需要报告以下 3 个方面的内容：
   - 证据概要表及相关解释说明，若推荐意见中包含针灸治疗方案，建议以表格形式报告可用于推荐的针灸治疗方案的形成过程（见 6.5）；
   - 证据形成推荐意见决策表，若推荐意见中包含针灸治疗方案，建议报告推荐的针灸治疗方案的形成过程；
   - 依据推荐意见框架形成的推荐意见（见 7.1）。

9.4.4 在指南中报告的位置

不同环节的共识过程在指南中报告位置不同，具体如下：

a) “临床问题的确定”环节，最终确定的临床问题和推荐意见对应表在指南正文中进行报告（见 C.9.2），其他与共识过程相关的内容于指南附录中进行报告（见 C.18.2）；

b) “结局指标及其重要程度的确定”环节的共识相关内容于指南附录中进行报告（见 C.18.2）；

c) “推荐意见的形成”环节的共识相关内容包括：
   - 共识参与者、所用共识方法、达成共识的标准、对强烈反对意见的处理方式，以及在无法达成共识情况下的处理方法、具体共识流程可在“形成推荐意见”章节段首统一报告；
   - 每个推荐意见（含推荐的针灸治疗方案）形成时考虑的关键因素及共识过程在推荐意见框架中的“共识过程”中进行报告（见 C.9.3）；
   - 证据形成推荐意见决策表（参见 GRADE 网站）及形成推荐的针灸治疗方案的过程在指南附录中进行报告（见 C.18.4）。

10 指南的形成和方法

10.1 指南的内容和体例

指南内容应包括封面、目次、正文和附录。正文部分包括前言，引言，摘要，简介，疾病概述，针灸治疗概况，针灸治疗与推荐意见，本指南利益冲突声明，本指南获取途径及将推荐意见应用于实践的方式，本指南实施中的有利因素和不利因素，未来可开展的研究，本指南的局限和不足，本指南更新计划和参考文献。附录部分包括：指南工作组成员，指南临床问题的确定，检索范围、检索策略及结果，推荐意见（含推荐的针灸治疗方案）的形成过程，专家意见征集过程、结果汇总及处理和指南编制过程中召开的历次会议[可以附录的形式提供和（或）按照电子版发表，这样可以降低主要指南的印刷和发行成本]。指南的内容和体例见附录 C。

10.2 指南的撰写与评审

10.2.1 形成工作草案

由起草组根据共识后的推荐意见与指南内容和体例要求撰写指南初稿。由核心专家组对指南初稿进行审核，起草组再根据核心专家组的建议对初稿进行修改，形成 WD。

10.2.2 征求意见

对 WD 进行广泛的同行意见征集，起草组整理、汇总广泛征求的意见，形成征求意见汇总处理表（见 C.18.5），提交核心专家组审定。

10.2.3 形成标准草案

起草组按照核心专家组的结论修改 WD，形成标准草案（draft of WFAS standard，DS）。

10.2.4 审核

起草组将 DS 提交至 WFAS 标准工作委员会，WFAS 标准工作委员会委员投票决定是否通过，并形成审查意见。详细投票规则见 WFAS 标准工作委员会章程。

指南制定的流程图见附录 E 中的图 E.1。

11 指南的发布与实施

11.1 指南的发布

核心专家组对审查意见进行审定，由起草组修改形成 WFAS 指南，经 WFAS 标准工作委员会提请 WFAS 秘书处报送 WFAS 执委会批准发布。语言以英文和中文为主，如有特殊需求，可与 WFAS 秘书处协商联系。

11.2 指南的实施

在实施过程中，以下本土化策略可供参考：

——安排当地发布会、讲座或者学术交流会，传播理念获得更多认可；

——与当地政府或相关协会、组织机构等合作，协助建立当地实施小组；

——和当地的专业教育结合；

——和患者健康教育结合：可以印发针对患者的指南版本，并由专业人士定期讲解。

12 免责声明

指南中应写明指南仅作为推荐性文件，不具备法律效应，针灸操作者需经过临床专业知识和判断，根据当地卫生系统的背景选择使用。

13 指南的版本、修订与更新

13.1 指南的版本

考虑到指南的实施，指南在发布的时候可以面对不同的受众发布多个版本，如患者版本，针对亚洲地区团体会员所在国家和地区的版本等。指南标准草案的文本规定见附录 F。

13.2 指南的修订与更新

13.2.1 修订或更新的条件

相关管理机构根据针灸临床实际需求与发展情况，对现行指南组织复审，复审周期一般不超过 5 年。经复审决议确定复审的指南如被管理部门列入标准修订计划，其修订程序与制定程序相同。

在发生以下变化时，应对指南及时进行更新：

a） 产生了新的高质量干预措施；

b） 产生了证明现有干预措施有利/有弊的新的证据；

c） 产生了新的重要结论，该结论带来了新的意义和价值；

d） 在治疗方面产生了新的医疗资源。

出现上述情况，相关管理机构将责成工作组重新对文献进行再搜集评价，更新指南。

13.2.2 由谁修订或更新

一般来讲，起草组组长应同样负责该指南的修订和更新，如果原起草组组长因故不能负责指南的修订和更新，应由世界针灸学会联合会指定人员进行修订或更新。

14 关于指南重大问题变更

包含指南名称和内容的重大调整，指南的延期申请等问题。一般由立项机构来决定，如 WFAS 标准工作委员会立项，应向 WFAS 标准工作委员会申请报备。

15 针灸临床实践指南的评估

15.1 评估针灸临床实践指南的工具

采用《临床指南研究与评价系统Ⅱ》(Appraisal of Guidelines for Research and Evaluation Ⅱ，AGREEⅡ)进行指南的评估。

15.2 针灸临床实践指南领域和条目的评估

评估针灸临床实践指南包括范围和目的、参与人员、制定的严谨性、清晰性、应用性、编辑的独立性 6 个领域共 23 个条目。评估针灸临床实践指南的领域和条目见附录 G。评估方法如下。

a） 由指南工作组负责针灸临床实践指南的评估组织工作，由 2 名～4 名指南方法学人员对指南

进行评价。

b) 评分等级的确定。每个条目均以 7 分表评价(1:很不同意;7:很同意)。如果没有与条目相关的信息或者报告得非常差,则为 1 分;如果报告的质量很高,有完整的标准和清楚的理由,则为 7 分;当条目报道不能满足全部标准或理由,则根据不同情况给予 2 分～6 分。分值分配取决于信息的完整性和质量。

c) 计算各领域得分。对每个质量领域的评分分别进行计算,6 个领域评分是独立的,不能合并为一个单一的质量评分。每个领域得分等于该领域中每一个条目分数的总和,并标准化为该领域可能的最高分数的百分比。

d) 指南的总体评价。指南的总体评价包括对指南总体质量评分(判断)和是否将推荐使用这个指南。也可以针对指南提出具体的修正意见。

附　录　A
（资料性）
指南制定的组织结构图

指南制定的组织结构图见图 A.1。

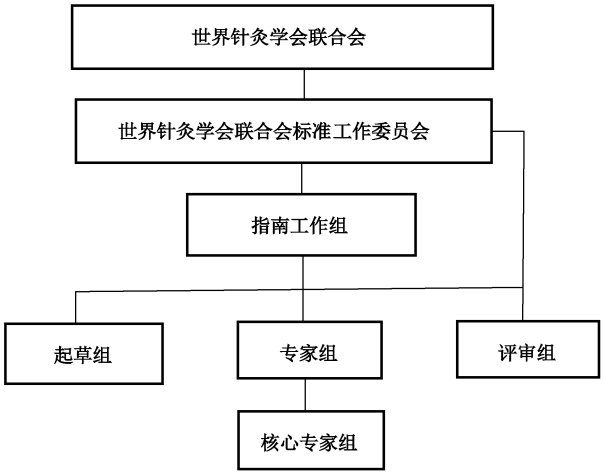

图 A.1　指南制定的组织结构图

附 录 B
（规范性）
利益冲突声明

- 成员基本信息

姓名		所属学会/团体	
所在组别		专业领域	
联系电话		邮箱	
通信地址			

- 所有指南工作组成员必须声明所有潜在的利益冲突，您必须在这张利益冲突声明表上声明与本指南主题相关的任何经济、非经济或其他方面的利益冲突。

过去 3 年间可能存在的经济利益冲突	
我或我的配偶接受与本指南有利益关系的企业支付的综合大于 1.5 万元人民币费用（如咨询费、劳务费、礼物和差旅费等）	□是 □否
我或我的配偶持有与本指南有利益关系的企业股份或股票	□是 □否
我或我的配偶持有与本指南有利益关系的企业相关的个人专利	□是 □否
我或我的配偶接受过与本指南有利益关系的企业提供的研究经费	□是 □否
我或我的配偶接受过与本指南有利益关系的企业资助的设备或仪器等	□是 □否
过去 3 年间可能存在的非经济利益冲突	
我或我的配偶参与本指南的相关研究或发表本指南制定过程中涉及的研究，如系统评价	□是 □否
我或我的配偶公开发表与本指南相关的观点或立场，如参与制定其他组织机构相关指南	□是 □否
我或我的配偶与本指南的推荐意见存在学术利益，如为相关领域针灸疗法或流派的创始人或主要传承人	□是 □否
注：与指南有利益关系的企业包括生产、销售相关针具、药物或设备的公司。	

- 除上述内容，在过去 3 年里，您还有什么需要声明的内容，请于下框填写：

- 如果上述任何问题您的答案为“是”，请在下框中予以简要的说明：

- **利益声明发表知情**：我同意将上述内容公开给其他指南工作组成员，并同意该利益声明表在指南中发表。
- **声明**：我承诺我所声明的内容是真实而完整的，如果上述我所声明的信息在任何时间发生任何变动，我将第一时间告知指南起草组组长，并完成 1 份新的利益声明表。

签名：_____ 日期：_____

- **评审后填写**：

基于上述利益冲突声明，该成员的利益冲突级别判定为：　□严重　□不严重　□无

处理方式及理由：

附 录 C
（规范性）
指南的内容和体例

C.1 封面

C.1.1 名称：指南名称采用两段式表达方式，即主体要素和补充要素。主体要素为：针灸临床实践指南；补充要素为疾病名称。

C.1.2 版本：如果文件代替了一个或多个文件，在封面中应标明被代替文件的编号。

C.1.3 发布日期：××××（年）-××（月）-××（日）。

C.1.4 实施日期：××××（年）-××（月）-××（日）。

C.2 目次

目次用自动生成的形式，一般显示二级或者三级目次。

C.3 前言

该部分主要给出诸如文件起草依据的其他文件，与其他文件的关系，文件与代替文件的关系，文件及其所代替或废止文件的历代版本发布情况，有关专利的说明等文件自身内容之外的信息。

C.4 引言

用以说明与文件自身内容相关的背景信息，如编制该文件的原因、文件技术内容的特殊信息或说明等。

C.5 摘要

包括治疗原则与推荐意见。

治疗原则不需要写推荐强度等级；推荐意见以表格形式列出推荐意见、推荐强度等级和证据等级（见表 C.1）。

表 C.1 推荐意见

推荐意见	推荐等级/证据等级

C.6 简介

C.6.1 指南制定的目标

C.6.2 指南制定的目的

C.6.3 指南适用的疾病范围

包括指南适用的疾病/病症范畴、具体的或特定的患者人群。

C.6.4 指南的适用人群

针对目标疾病，提出指南所应用的具体人群、目标环境和条件等。

示例：如腰痛指南，其使用人群可为从事腰痛治疗的针灸师、护士、西医医生；计划接受或者已经接受针灸治疗的腰痛患者；有诊疗培训计划的医护人员和医院管理者等。

C.7 疾病概述

C.7.1 定义

包括该疾病的西医、中医概念定义。

C.7.2 发病率与患病人群特点

C.7.3 临床特点

包括病史、症状及体征等。

C.7.4 诊断标准

包括西医诊断标准与分型、中医诊断标准与分型。诊断分型应包含指南推荐的针灸治疗方案中涉及的类型，针灸治疗方案中若涉及特殊人群，也应明确该人群的诊断标准。

C.8 针灸治疗概况

包括古今治疗目标疾病的针灸使用情况、影响针灸疗效的常见因素、针灸治疗的通常注意事项以及针灸治疗中需要患者配合的调护事宜等。

C.9 针灸治疗与推荐意见

C.9.1 针灸治疗的原则与特点

C.9.2 临床问题和推荐意见对应表

C.9.3 推荐意见

推荐意见中应注明对应的临床问题、最终形成的推荐意见、判断依据、实施的注意事项、共识过程及参考文献(见 7.1)。具体共识过程的报告及要求见 9.4.4。

C.10 本指南利益冲突声明

C.11 本指南获取途径及将推荐意见应用于实践的方式

C.12 免责声明

C.13 本指南实施中的有利因素和不利因素

包括报告实施本指南推荐意见后的监察与评估内容，如本指南发布之后，应当如何监测指南的推荐意见是否被采纳，以及通过监察、评估哪些结果或结局以判断推荐意见的结果符合预期等。

C.14 未来可开展的研究

C.15 本指南的局限和不足

应描述本指南制定过程中的所有局限性。

C.16 本指南更新计划

应提供详细的更新过程，包括是否会被更新、更新的方法、更新时间和周期。

C.17 参考文献

C.18 附录

C.18.1 指南工作组成员

包括起草组、专家组和评审组成员，并对各成员的专业（学科/专长）、机构、职责和分工加以说明。

C.18.2 指南临床问题的确定

包括临床问题形成、结局指标排序及其共识流程的报告。具体要求参见第5章“临床问题的确定”和第9章“WFAS针灸临床实践指南的共识决策”。

C.18.3 检索范围、检索策略及结果

C.18.4 推荐意见（含推荐的针灸治疗方案）的形成过程

C.18.5 专家意见征集过程、结果汇总及处理

在指南工作草案初稿撰写完成，至标准获批，起草组应广泛征求意见，并完整呈现从“工作草案（WD）→征求意见→标准草案（DS）送审→报批”各环节中的专家意见征集过程、结果汇总及处理，用意见汇总处理表表达即可，见表C.2。

表C.2 本指南征求意见汇总处理表

文件名称： 时间：

负责起草单位： 阶段：（WD/DS）

序号	章条编号	意见内容	所属团体会员（所在国家或地区）	处理意见（接受/不接受）	备注（处理后的结果）

注：WD——工作草案，DS——草案标准。

C.18.6 指南编制过程中召开的历次主要会议

应列出时间、地点、主题、人物、决议。

附 录 D
（规范性）
报告指南共识决策过程的要素和内容

D.1 目的与内容

D.1.1 描述使用共识法的目的。

D.1.2 描述在本环节需要达成共识的内容及其来源，并将共识内容依据共识目的分解为结构清晰、可被共识的内容要素。

D.2 参与者

D.2.1 描述共识参与者的基本情况，如地域分布、专业领域分布等。

D.2.2 描述共识参与者的遴选标准。

D.2.3 描述共识参与者的选择过程。

D.2.4 描述共识参与者在指南制定中的参与情况。

D.3 方法与标准

D.3.1 明确提出所使用的具体共识方法，并对其核心要素特征进行合理、清晰的描述。

D.3.2 描述共识方法在指南制定中应用的具体环节。

D.3.3 描述达成/终止共识的标准。

D.3.4 描述共识参与者在本环节作出决策时需考虑的主要因素。

D.4 材料与背景

D.4.1 描述共识材料的来源、形成方法与综合过程，以及其与共识内容的相关程度。

D.4.2 （可选内容）描述指南制定的视角，以及指南对干预措施的分类方法和每种干预措施及对照措施在不同情境下的内涵。

D.5 过程

D.5.1 描述共识方法的实际实施过程，若实施时对共识内容或规划的程序（规则）进行修改，应描述修改后的内容/程序与修改理由。

D.5.2 描述对共识决策进行质量控制的方法与过程。

D.6 结果

D.6.1 清晰报告每一轮的共识结果与最终的共识结果。

D.6.2 应对共识结果进行全面解释，报告共识决策过程中出现的分歧，并描述分歧双方各自的立场和原因。

D.6.3 描述本次共识决策过程的潜在局限性。

D.7 利益冲突

描述共识参与者利益冲突情况，若存在利益冲突，应描述利益冲突类型与管理方式。

附 录 E
（规范性）
指南制定的流程图

指南制定的流程图见图 E.1 和图 E.2。

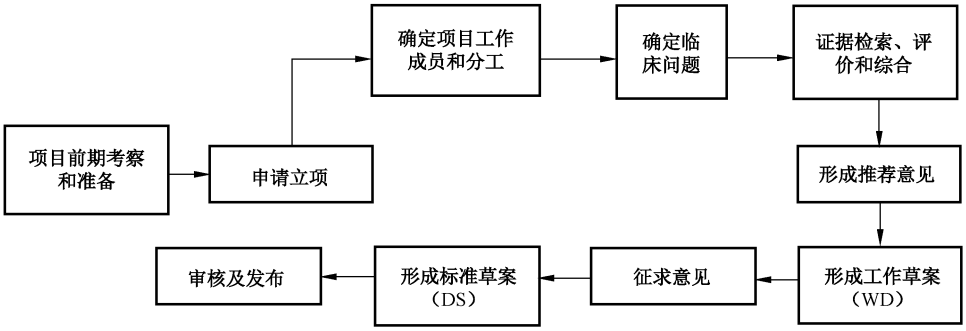

图 E.1 指南制定流程图

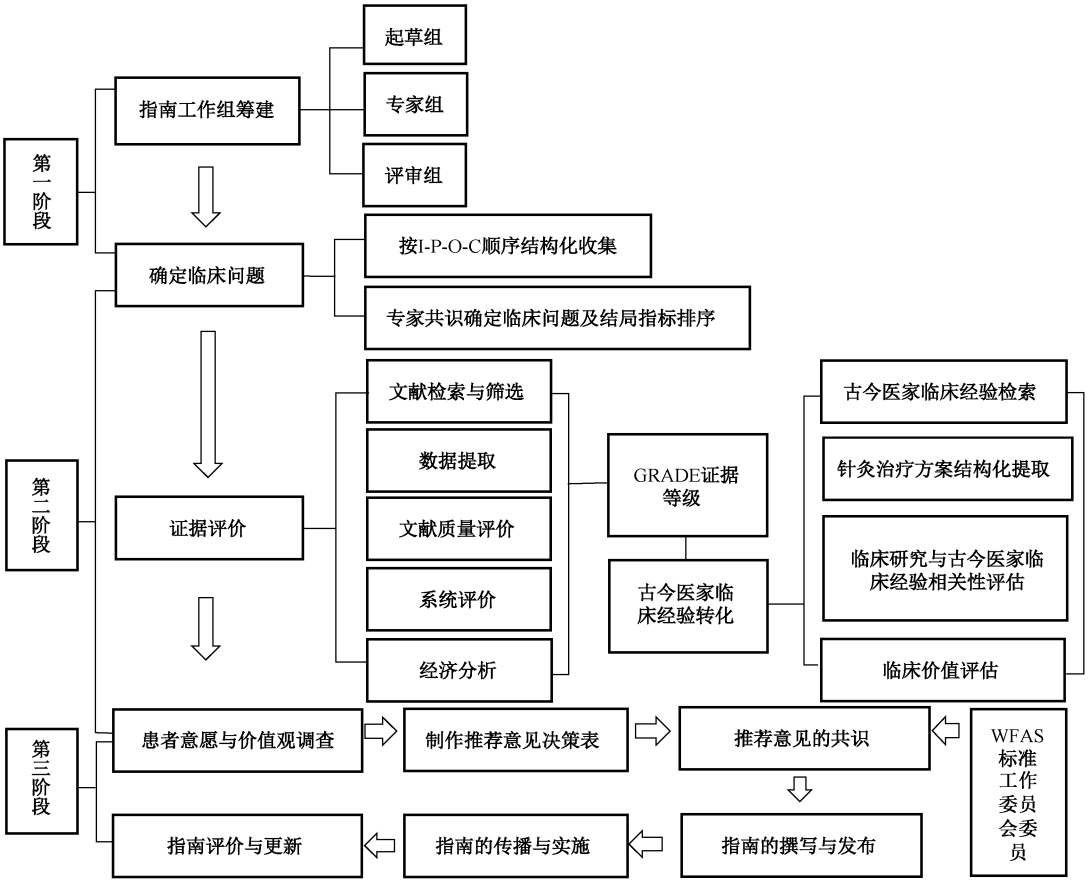

图 E.2 指南制定方法流程图

附 录 F
（规范性）
指南标准草案的文本规定

世界针灸学会联合会工作语言为中文、英文。WFAS针灸临床实践指南标准文本以中文、英文发布。

F.1 中文格式

F.1.1 题目格式

黑体，一号，居中。采用A4幅面，页边距上10 mm，下25 mm，左25 mm，右15 mm。

F.1.2 标题格式

文中一级标题用黑体，五号，左对齐。一级标题下的相关内容若需要二级标题时，应按照：

1

1.1

1.1.1

F.1.3 正文格式

正文采用宋体，五号。无序号的正文首行缩进2字符，有序号的正文左对齐。

正文中引用参考文献时，要在相关内容后以上标形式进行标注，如：××××××[1]。

F.2 英文格式

F.2.1 题目格式

黑体，小四号，左对齐，采用A4幅面。

F.2.2 标题格式

文中一级标题用黑体，小四号，左对齐。一级标题下的相关内容若需要二级标题时，应按照：

1

1.1

1.1.1

F.2.3 正文格式

正文采用黑体，五号。正文均为首行左对齐。

正文中引用参考文献时，要在相关内容后以上标形式进行标注，如：××××××[1]。

附 录 G
（规范性）
评估针灸临床实践指南的领域和条目

评估针灸临床实践指南，主要依据临床指南研究与评估系统Ⅱ（AGREE Ⅱ）的领域和条目，包括以下内容。

G.1 领域 1.范围和目的

G.1.1 明确描述针灸临床实践指南的总目的。
G.1.2 明确描述针灸临床实践指南涵盖的卫生问题。
G.1.3 明确描述针灸临床实践指南应用的人群（包括患者和公众等）。

G.2 领域 2.参与人员

G.2.1 指南制定小组包括来自于所有相关专业小组的个人。
G.2.2 收集目标人群（患者和公众等）的观点和优先选择。
G.2.3 明确界定针灸临床实践指南的目标使用者。

G.3 领域 3.制定的严谨性

G.3.1 应用系统方法学检索证据。
G.3.2 清楚描述检索证据的标准。
G.3.3 清楚描述证据质量评价的方法。
G.3.4 清楚描述形成推荐建议的方法。
G.3.5 形成推荐建议时考虑对健康的利弊关系、患者意愿和卫生经济学。
G.3.6 推荐建议和支持证据之间有明确联系。
G.3.7 指南发表前已经过外部专家评审。
G.3.8 提供指南更新的步骤。

G.4 领域 4.清晰性

G.4.1 推荐建议明确，且不含糊，能够体现针灸对该疾病治疗的疗效特点，明确针灸治疗能够解决哪些临床问题。
G.4.2 明确列出不同的选择或临床问题。
G.4.3 重要的推荐建议容易识别。

G.5 领域 5.应用性

G.5.1 在指南中描述应用过程中的促进和阻碍因素。
G.5.2 在指南中提供如何应用于实践的推荐建议和（或）工具。
G.5.3 考虑推荐建议应用中可能需要的相关资源和技术的可行性。
G.5.4 指南提供监测和（或）稽查标准。

G.6 领域 6.编辑的独立性

G.6.1 赞助单位的观点不影响指南的内容。
G.6.2 记录并公开指南制定小组成员的利益冲突。

致　谢

世界针灸学会联合会表示：感谢所有为本规范的研制作出贡献的人员以及组织机构。

本规范的研究与编制工作主要由武晓冬（中国中医科学院针灸研究所）、刘保延（中国中医科学院）、赵楠琦（中国中医科学院针灸研究所）、袁静云（北京中医药大学）、丁楠（中国中医科学院针灸研究所）完成。赵京生（中国中医科学院针灸研究所）、刘雅莉（首都医科大学附属北京儿童医院）、张誉清（加拿大麦克马斯特大学）、黄龙祥（中国中医科学院针灸研究所）、杨宇洋（世界针灸学会联合会）、姚晨（北京大学第一医院）在本规范研制过程中提供了研究方法与路径建议及技术指导。

以下人员对本规范提供了同行评审意见（按照字母顺序致谢）：陈耀龙（兰州大学）、费宇彤（北京中医药大学）、金荣奭（韩国庆熙大学）、刘建平（北京中医药大学）、夏君（宁波诺丁汉大学）。以下人员承担了本规范的翻译任务（按照字母顺序致谢）：陈业孟（美国纽约中医学院）、刘竞元（世界针灸学会联合会）、王慧珠（中国中医科学院针灸研究所）、余敏（中国中医科学院针灸研究所）、张誉清（加拿大麦克马斯特大学）。世界针灸学会联合会标准工作委员会成员对本规范进行了审查与评议。

中国中医科学院针灸研究所为本规范的研究工作提供了科研平台与保障。

资助方：国家重点研发计划“中医药现代化研究”重点专项项目“国际针灸临床实践指南、技术操作规范和服务标准的研制”（项目编号：2019YFC1712200）为本规范的制定提供资金支持。

参 考 文 献

[1] GB/T 40972—2021 针灸临床实践指南制定及其评估规范

[2] ISO/IEC Directives,Part 2 Principles and rules for the structure and drafting of ISO and IEC documents (2018)

[3] WHO Handbook for Guideline Development(2015)

[4] 世界针灸学会联合会针灸标准化委员会第二届技术规程(草案)(Technical Procedure for the 2nd term of the Acupuncture Standardization Committee of World Federation of Acupuncture Societies)

[5] AMSTAR 2:A critical appraisal tool for systematic reviews that include randomized or non-randomized studies of healthcare interventions,or both

网址:https://www.bmj.com/content/358/bmj.j4008.long

[6] 临床指南研究与评估系统Ⅱ(AGREE Ⅱ)

网址:http://www.agreetrust.org/

http://www.agreetrust.org/resource-centre/agree-ii-translations/

[7] 国际临床实践指南报告规范针刺扩展版(RIGHT for Acupuncture)

网址:http://www.right-statement.org/extensions/12

Norms for formulation and evaluation of the clinical guidelines on acupuncture and moxibustion

1 Foreword

1.1 About the World Federation of Acupuncture-Moxibustion Societies (WFAS)

The World Federation of Acupuncture-Moxibustion Societies (WFAS) is an international non-governmental organization uniting acupuncture-moxibustion associations, which is in official relations with the World Health Organization (WHO) and in A-level liaison relationship with the International Standardization Organization/Technical Committee 249 (ISO/TC 249). The formulation of the WFAS clinical guidelines on acupuncture-moxibustion shall follow the principles proposed by WHO and meanwhile the concept and methods of evidence-based medicine.

WFAS is devoted to promoting acupuncture-moxibustion to various countries in the world in a scientific and standardized way and enhancing the status and role of acupuncture-moxibustion in global health care. Being an important approach to achieving this goal, the development of WFAS clinical guidelines on acupuncture-moxibustion should be closely based on the features and advantages of acupuncture-moxibustion discipline.

1.2 The development status of acupuncture-moxibustion in the countries and regions where WFAS member societies are located

Until the end of December 2022, WFAS has 264 member societies covering 6 continents, and 70 countries and regions. According to WFAS survey results, 65 countries and regions have recognized the legal status of Chinese acupuncture-moxibustion, and some countries and regions have incorporated it into the mainstream medical system. However, there are big differences in acupuncture-moxibustion legislation and administration, acupuncture-moxibustion education and other aspects in different countries and regions. For example, compared with other continents, there are fewer countries and regions in Europe and South America that cover acupuncture-moxibustion in medical insurances and the reimbursement ratio is lower; in some countries there are still great differences in acupuncture-moxibustion policies among different provinces (regions). In this circumstance, how to take into account the equity, cost-effectiveness and applicability of the clinical guidelines on acupuncture-moxibustion is the key for WFAS guidelines development.

1.3 Evidence dilemma due to the nature of acupuncture-moxibustion discipline and its solution

1.3.1 The evidence dilemma faced with the development of clinical guidelines on acupuncture-moxibustion

The development of international guidelines requires use of the best available clinical research evidence. Currently, randomized controlled trials (RCT) with the highest level of clinical study design are often used to evaluate the therapeutic effect. When developing clinical guidelines, on the one hand, although there are a large number of clinical studies on acupuncture-moxibustion, and a number of important clinical studies on acupuncture-moxibustion have been published in influential journals in recent years, the high-quality evidence is still very scarce in generally speaking. This has impaired, to a certain extent, the strength of recommendations generated by the guidelines. On the other hand, RCTs need to set strict inclusion and exclusion criteria to exclude interferences. However, the fact that acupuncture-moxibustion is a complex intervention involving many factors and it is difficult to completely eliminate the so-called "interferences" lead to inconsistency between the strictly designed clinical researches and the real clinical practice of acupuncture-moxibustion. Therefore, if a guideline is developed solely on the basis of clinical studies evidence, there will inevitably be a dilemma of reduced clinical applicability of the guideline.

1.3.2 Solution to the evidence dilemma

Traditional acupuncture-moxibustion is unique and historic, which has integrated the wisdom of the predecessors and summarized the effective techniques, methods and treatment rules of the ancient doctors' experience of acupuncture-moxibustion in clinical practice for thousands of years. The development of an effective treatment protocol of acupuncture-moxibustion often requires early discovery of the effective acupoints (treatment sites) or methods, followed by repeated optimization and verification in long-term clinical practice. In the practice of acupuncture-moxibustion for thousands of years, there have been a great deal of ancient documents containing extensive medical experience summaries of acupuncturists. They are the source of the inheritance for today's acupuncture treatment methods and are closely associated with the treatment protocol of acupuncture-moxibustion in modern clinical practice and clinical studies. To develop clinical guidelines on acupuncture-moxibustion, we shall first respect the large number of objective facts and laws still existing in the science of acupuncture-moxibustion, and respect historical experience as well. To transform and utilize both ancient and modern acupuncturists' experience and clinical studies through cross reference and verification can be an important part of evidence generating in the development of clinical guidelines on acupuncture-moxibustion.

2 Introduction of the *Norms*

2.1 Purposes of the *Norms*

The purposes of the *Norms* are to guide readers to understand the formulation process and evaluation methods of the WFAS clinical guidelines on acupuncture-moxibustion; to ensure that the WFAS

clinical guidelines on acupuncture-moxibustion can reflect the characteristics of clinical practice of acupuncture-moxibustion and at the same time follow the concept and methods of evidence-based medicine; to ensure high-quality formulation of the clinical guidelines on acupuncture-moxibustion; and guarantee the highest possible applicability of the guidelines in the countries and regions of WFAS member societies.

2.2 Users of the *Norms*

The *Norms* will be applied to:

—WFAS member societies and WFAS administrative departments that wish to formulate a clinical guideline on acupuncture-moxibustion;

—members of the drafting group in formulating a WFAS clinical guideline on acupuncture-moxibustion;

—members of the expert group in formulating a WFAS clinical guideline on acupuncture-moxibustion;

—members of the review group in formulating a WFAS clinical guideline on acupuncture-moxibustion;

—persons who carry out quality evaluation of a clinical guideline on acupuncture-moxibustion;

—those who are interested in learning about the formulation methodology or evaluation of the WFAS clinical guidelines on acupuncture-moxibustion.

2.3 Scope of the *Norms*

The *Norms* stipulate the principles, methods, procedures and requirements for the formulation and evaluation of the WFAS clinical guidelines on acupuncture-moxibustion.

2.4 Principles of formulating WFAS clinical guidelines on acupuncture-moxibustion

The WFAS clinical guidelines on acupuncture-moxibustion are formulated according to the following principles.

—The guidelines shall reflect the WFAS concept of promoting “health for all” by acupuncture-moxibustion.

—The formulation of the clinical guidelines on acupuncture-moxibustion shall be proposed out of the needs of acupuncture-moxibustion clinical practice and in accordance with the premise of necessity.

—The process of formulating the guidelines shall be open and transparent, namely the users can see why and who made the guideline and the basis on which it has been formulated.

—Clinical questions in the clinical guidelines on acupuncture-moxibustion shall be put forward for selecting safe and effective acupuncture-moxibustion interventions to diseases so as to ensure the applicability of the guidelines.

—According to the characteristics of acupuncture-moxibustion, the sources of evidence applicable in the formulation of the clinical guidelines include the best current research evidence, and/or traditional knowledge and experience recorded in ancient times and still applied today, as well as the acupuncturists' experience which has been proven effective in clinical practice and supported by a large number of relevant real cases.

—The recommendations formulated in the guideline shall answer relevant clinical questions and the strength of recommendations shall be clarified. Also, important factors related with the therapeutic result of acupuncture-moxibustion (such as treatment sites, methods, and requirements in terms of the operator's educational background, experience and skills etc.) to guarantee the effectiveness and operability of acupuncture-moxibustion clinical practice.

—The risk of bias in recommendations shall be reduced as much as possible in each process and method of formulating the guideline.

—The formulation of the guideline shall take into account the application environment of acupuncture-moxibustion and cultural background in the countries and regions where the WFAS member societies are located; for example at the planning stage of the guideline, the issues of accessibility or promotion which may be encountered in the implementing the guideline shall be considered; in addition to the quality of evidence, special attention shall be paid to other factors such as the values and willingness of practitioners or patients, and the health-economic situation in the countries and regions where WFAS member societies are located. If necessary, different editions may be published for different countries and regions or different groups of people (including but not limited to public health policy makers, health care providers, patients, and caregivers of acupuncture-moxibustion profession).

2.5 Classification of the clinical guidelines on acupuncture-moxibustion

The clinical guidelines on acupuncture-moxibustion can be classified based on the classification of international guidelines: when classified by groups of formulation or updated versions of the standard guidelines, compilations of guidelines, interim guidelines, rapid guidelines and adaptations of guidelines, this *Norms* is mainly applicable to the standard guidelines; and if classified by users into professional guidelines (physicians/acupuncturists' guidelines, nurses' guidelines) and patients' guidelines, this *Norms* is mainly applicable to the physicians/acupuncturists' guidelines.

According to the characteristics of acupuncture-moxibustion, the clinical guidelines on acupuncture-

moxibustion can be divided into disease-related guidelines and guidelines for applying common acupuncture-moxibustion techniques.

a) Disease-related guidelines: a series of guiding documents related to acupuncture-moxibustion diagnosis and treatment for a specific disease (symptom). Focusing on "population possibly appropriate to acupuncture-moxibustion intervention" and "effective acupuncture-moxibustion intervention", questions such as the outcome indicators/symptoms, and efficacy and safety of intervention shall be answered based on which the effective treatment protocol of acupuncture-moxibustion intervention recommended for that population are formulated.

b) Guidelines for applying common acupuncture-moxibustion techniques: referring to the guiding documents systematically developed, each focusing on a commonly used acupuncture-moxibustion intervention measure and what diseases are suitable for that measure, to help users make the best decision in solving relevant clinical problems.

This *Norms* is mainly applicable to the disease-related clinical guidelines on acupuncture-moxibustion.

3 Terms and definition

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

3.1
WFAS clinical guideline on acupuncture and moxibustion

A guiding document formulated by WFAS to help guideline users choose and use acupuncture-moxibustion intervention appropriately and make the best clinical decision for acupuncture-moxibustion related clinical questions.

NOTE Recommendations in the guideline shall be formulated based on the best current clinical research evidence, referring to the transformed clinical experience of ancient and modern acupuncturists, and comprehensively considering factors such as values and wishes of doctors or patients and health economics, etc.

3.2
clinical questions

Clinical conditions that reflect the clinical advantage of acupuncture-moxibustion in diagnosis and treatment for a specific disease, and the questions that practitioners and patients concern including the intervention and prognosis, cause of disease, diagnosis, medical costs and so on.

NOTE 1 Main factors include the target population, intervention measures and efficacy of acupuncture-moxibustion, improvable outcomes, and difference in acupuncture-moxibustion compared with other therapies.

NOTE 2 Clinical questions are the basis for forming guideline recommendations, and the guidelines are formulated to solve clinical questions.

[SOURCE GB/T 40972—2021, 3.2, adapted]

3.3
evidence

The literature, after rigorous quality assessment, used to support the etiology, diagnosis, treatment and prognosis of disease.

NOTE The evidence relevant to medical practice and decision making is multilayered.

[SOURCE GB/T 40972—2021, 3.4, adapted]

3.4
recommendations

Guiding suggestions formed through expert consensus for specific clinical questions based on relevant evidence and considering the balance of benefits versus harms as well as resources, value preferences, and other factors.

[SOURCE GB/T 40972—2021, 3.8, adapted]

3.5
the strength of recommendation

Recommendations shall be described comprehensively and graded based on factors such as quality of evidence, values and preferences related to interventions or outcomes, balance of benefits and harms, resource impact, importance of the problem to be solved, health equity, acceptability, and practical implementation.

NOTE For the clinical guidelines on acupuncture-moxibustion, the strength of recommendation is also related to the degree of individualization of the treatment protocol of acupuncture-moxibustion in evidence and the possibility of change in the implementation.

4 Planning and preparation before the guideline formulation

4.1 Is it really necessary to formulate this guideline?

Before the guideline is formulated, the guideline drafting group needs to be clear about a very important question: Is it really necessary to work out this guideline? Since the formulation of guidelines consumes much time, labor and money, the following questions need to be carefully considered before the guideline is formulated.

4.1.1 Who needs this guideline?

Is it a demand from one member society or the majority of member societies in WFAS? According to the formulation requirements put forward by the WFAS Standardization Working Committee, a guideline proposal shall only be accepted when put forward jointly by at least 5 member societies and approved by at least 2/3 of the Standardization Working Committee members (abstentions are not included). Those who intend to propose a project are encouraged to carry out a survey in terms of the necessity for guideline development to the users of the WFAS guideline.

4.1.2 Does the guideline to be developed already exist?

Is there a guideline on the same subject already published by any international organization or country? Does this guideline meet the needs of WFAS member societies? You may consult the WFAS member societies, the secretariat of the WFAS Standardization Working Committee, and search through database to avoid duplicating existing work. If any guideline of this subject has been published, examine its quality and applicability to current needs. If it does not meet the present needs, consider updating the existing WFAS guidelines.

4.1.3 Is it necessary to prioritize the development of this guideline?

Priority will be given to formulate guidelines for diseases with urgent need, relatively mature research basis, extensive clinical practice basis, global prevalence and to which acupuncture-moxibustion treatment is internationally accepted, on basis that both acupuncture-moxibustion practitioners and patients share common concern to a certain range of clinical questions but consensus guiding documents of acupuncture-moxibustion intervention measures have not been developed, or the existing guidelines fail to meet local needs for diagnosis and treatment.

4.2 What is the purpose of the guideline? Who are the main users?

4.2.1 What does the guideline want to achieve?

In addition to promotion of acupuncture-moxibustion, can the guideline provide more therapeutic clues and methods for acupuncture-moxibustion practitioners? Or can it solve certain unsettled clinical problems?

4.2.2 Who are the main users of the guideline?

The main users of the guideline mean the ideal end-users. The users of a guideline can include acupuncture-moxibustion practitioners, patients, health administrative staff, etc. However normally it doesn't recommend to target policy makers, health administrators, patients, doctors and other health professionals to be the main users of a guideline simultaneously because this is hardly the real case in practice.

4.3 The application environment of acupuncture-moxibustion, and cultural background in the countries and regions where WFAS member societies locate

The ultimate goal of the guideline needs to be achieved through the implementation of the guideline. For WFAS as an international organization, there have been great differences in diagnosis and treatment conditions of acupuncture-moxibustion, as well as application environment and cultural background in the countries and regions where the member societies are located. Therefore, in the planning stage of a guideline, the following conditions should be observed:

—the commonly used acupuncture-moxibustion intervention in the countries and regions where the member societies are located and the application of acupuncture-moxibustion in various places;

—common diseases treated by acupuncture-moxibustion in the countries and regions where the member societies are located;

—the coverage of acupuncture-moxibustion in local medical insurance and l medical institutions;

—rules and administrative policies for acupuncture-moxibustion practitioners by local health administration systems;

—patients' acceptance of acupuncture-moxibustion intervention in various regions, etc.

4.4 Determination of the scope of the guideline

In order to determine the scope of a WFAS clinical guideline on acupuncture-moxibustion, in the early stage the drafting group needs to take overall account of the amount of time, effort and funds based on the understanding of the application environment of acupuncture-moxibustion and cultural background in the countries and regions where the WFAS member societies are located so as to ensure that the guideline is within the controllable scope and can be both appropriately concentrated and completed in a limited period of time by using resources available. Therefore, prior to finally deciding the scope of the guideline, a pre-search of literature is needed to identify relevant information including existing guidelines and systematic reviews, health technology evaluation reports and economic assessment of guideline topics and to see the evidence basis for the guideline development.

Determining the scope of a WFAS clinical guideline on acupuncture-moxibustion usually includes the following aspects.

—To determine the type of the guideline to be formulated. The guidelines are mainly divided into "disease-related guidelines" and "guidelines for applying common acupuncture-moxibustion techniques" (see 2.5). This *Norms* is mainly used to guide the formulation of the "disease-related clinical guidelines".

—To determine the target diseases of the guideline. Generally speaking, the diseases covered by the

WFAS clinical guidelines on acupuncture-moxibustion shall fall into the range of diseases suitable for acupuncture-moxibustion techniques.

—To identify the disease-related intervention measures of acupuncture-moxibustion.

4.5 Composition of the guideline working groups

4.5.1 Composition overview

When developing a WFAS clinical guideline on acupuncture-moxibustion, different working groups will be set up according to the different work and functions of members, so that the guidelines can be developed efficiently and scientifically. The working groups include:

—drafting group;

—expert group;

—review group.

It is suggested that the group category, name, gender occupation, affiliated association/organization, and detailed responsibility of all members of guideline working groups are listed in the annex. The organizational structure of guideline development, see Annex A-Figure A.1.

4.5.2 Drafting group

The drafting group shall have a group leader, who is responsible for proposing and organizing the guideline project, and managing the overall schedule and conflicts of interest, etc. The group shall also consist of guideline writers and evidence preparers.

4.5.3 Expert group

As a multidisciplinary team, the expert group must include clinical experts in acupuncture-moxibustion and guideline methodologists (evidence-based medicine experts). It is also suggested to include clinical experts in related fields, experts in ancient literature, patients or their family members, health economists, public health administrators etc. Among them, the proportion of clinical experts in acupuncture-moxibustion shall not be less than 60%. In terms of the composition, the members of the expert group need to have subject representativeness, in addition, the rationality of regions and academic schools shall also be considered. The suggestion is that, the WFAS member societies representatives from at least five different countries and regions should be contained, and those countries and regions holding different policies about acupuncture-moxibustion, (whether there is legislation on acupuncture-moxibustion, whether its legal status is recognized, whether it is included in medical insurance, and the government's attitude towards the acupuncture-moxibustion, etc.), should be included as much as possible. The recommended number of the expert group members is 15 to 30. The

members are mainly responsible for guiding the formulation process and consensus decision-making during the guideline formulation process.

4.5.4 Review group

Members of the review group are from the WFAS Standardization Working Committee. They are mainly responsible for reviewing the guideline project proposals and making final comments on the Working Drafts (WD) of the guideline.

4.6 Consensus decision-making of the guidelines

In the process of guideline development, consensus decision is needed to determine the clinical questions, outcome indicators and their importance, and to formulate recommendations. Consensus participants shall include clinical experts in acupuncture-moxibustion and guideline methodologists (evidence-based medicine experts).

Each consensus decision-making process may need to go through several consensus meetings or Delphi surveys. Considering the time, resources and other factors might be irreconcilable among all members, the absence of some members of the expert group is inevitable. In order to ensure the reliability of consensus decision-making, consensus participants should be consistent to as much extent as possible. It is recommended to set up a core expert group in the guideline expert group. The core expert group is composed of those experts who have certain academic influence in the field, with the number of experts recommended to be 8 to 10 and a reasonable composition of members representing different regions and academic schools according to needs. Each consensus decision must be made with participation by 2/3 or more members of the core expert group. At the same time, the core expert group is also responsible for handling the expert review comments.

It is suggested to report in the guideline the consensus participants, method for reaching consensus, threshold for consensus, process for consensus and result of consensus for each consensus proceedings. Among them, the process of formulating recommendations requires to be in meeting form (including online meetings).

4.7 Declaration and management of conflicts of interest

Conflicts of interest may be economic or non-economic. Managing conflicts of interest in the guideline working groups during the guideline formulation is conducive to the guidelines' scientificity and transparency.

It is suggested that in the guideline development process, all members of the drafting and expert groups fill in the interest declaration form. The leader of drafting group invites 3 to 5 experts to review these forms together, to determine whether there is a conflict of interest (refer to the *WHO Handbook for Guideline Development* for the criteria of assessing the severity of a conflict of interest) and the corresponding managing method. The method and reason of management shall be repor-

ted in the conflict of the interest declaration form(see Annex B).

The methods to manage conflicts of interest for the members are as follows.

—**No action**:Only report in the interest declaration form,but without taking other measures.

—**Limited participation**: He/she is excluded from some meetings and guideline development process.May take the following two measures:

- not allowed to participate in key consensus decisions or steps,but allowed to participate in all discussions;
- prohibited from participating in any decision-making or discussion of key.

—**Not allowed to participate**: Not allowed to be a member of the drafting group or the expert group.

4.8 Other key issues

4.8.1 Is the guideline development adequately funded?

In order to produce high-quality guidelines,sufficient resources are needed to complete systematic reviews,convene meetings,and payment for production costs.However,the formulation process of WFAS clinical guidelines on acupuncture-moxibustion is not allowed to be financially supported by any commercial organizations.

4.8.2 Is the time reasonably arranged?

The guideline formulation requires sufficient time and energy input.According to the regulations of WFAS Standardization Working Committee,it usually takes 18 to 24 months from project approval to final guideline release.Therefore,such clarification should be given in advance to those who are involved in the work.

4.8.3 Clarification of the relationship with the relevant laws,regulations,and mandatory standards

The relationship between the guidelines and relevant laws,regulations,or mandatory standards,such as the relationship with the published WFAS guidelines,with the WFAS Standardization Working Committee constitution,with the local laws and regulations,etc.,should be clarified.

4.8.4 Consideration of the implementation process and possible obstacles

Are all acupuncture-moxibustion interventions suitable for recommendation in the guideline? What

are the basic conditions required in the implementation process (the requirements for the implementer and the requirements of the implementation conditions)? In what form should the guideline be published? In what language should the guideline be published? These issues should be taken into account at the planning stage as they affect who would be involved in the guideline making, the resources required, and the way in which the recommendations are drafted and presented.

4.9 Submission of guideline proposals

A proposal should be submitted to the Secretariat of the WFAS Standardization Working Committee for developing a clinical guideline on acupuncture-moxibustion. The members of the core expert group should be listed in the "Introduction to the drafting organization and principals" of the guideline (see 4.5.3). According to the regulations of the WFAS Standardization Working Committee, if 2/3 of the voting members of Standardization Working Committee agree to approve the project, the project will be approved. In order to increase the transparency of guideline development process and avoid duplication, it is recommended that the guideline drafting group register the guideline on the *Practice Guideline Registry Platform* (http://guidelines-registry.cn/) at the same time when submitting the guideline proposal.

5 Formulation of the clinical questions

When collecting clinical questions in accordance with the Population, Intervention, Comparison and Outcomes (PICO) elements, it is necessary to collect around a specific acupuncture-moxibustion Intervention "with certain therapeutic effect". It's emphasized for collecting "the treatable population" and "the outcome indicators can be alleviated". Before collecting clinical questions about acupuncture-moxibustion, important information that may be involved in each P-I-C-O element should be clarified, and each of them be defined when formulating clinical questions.

5.1 Issues may be formulated as clinical questions

According to the characteristics and demands of acupuncture-moxibustion clinical practice, the contents of the clinical questions of acupuncture-moxibustion guidelines may include but not limited to the following 4 aspects.

5.1.1 Specific acupuncture-moxibustion intervention measures suitable for particular groups of population

The target population of a clinical guideline on acupuncture-moxibustion need to be further classified by different therapeutic responses to a certain kind of acupuncture-moxibustion therapy (treatment protocols) according to the different characteristics of diseases. The drafting group can classify the target population (by the stage of disease, the severity of disease, TCM syndrome differentiation,

specific clinical manifestations, etc.) based on the previous survey results on the diagnosis and acupuncture-moxibustion treatment of this disease in the countries and regions where WFAS member societies are located, so as to raise specific questions of what target population might be suitable for which acupuncture-moxibustion therapy.

EXAMPLE 5-1:

Comparing acupuncture by filiform needles and conventional western medicine in treating acute migraine, which of them benefits patients more?

5.1.2 Essentials of effective manipulations of acupuncture-moxibustion intervention measures

According to the characteristics of disease, collect the possible effective acupuncture-moxibustion intervention (such as acupuncture, electro-acupuncture, moxibustion, etc.) and clarify key points of manipulations (such as the treatment sites, treatment method, treatment time, etc.) to form the key clinical questions related to the manipulations of acupuncture-moxibustion intervention measures.

EXAMPLE 5-2:

For acute and subacute nonspecific low back pain patients, does it benefit more from acupuncture for 3 plus times per week than 3 times per week?

5.1.3 Differences between acupuncture-moxibustion therapy and other therapies

Put forward the differences in efficacy, safety (adverse reactions) and economics of acupuncture-moxibustion therapy used alone or in combination compared with other therapies to form the related clinical questions, including but not limited to:

—differences from other commonly recognized effective therapies;

—differences in efficacy compared with blank controls (e.g., placebo);

—differences among various acupuncture-moxibustion therapies;

—differences between acupuncture-moxibustion therapy combined with other conventional effective therapies and such conventional effective therapies.

5.1.4 Outcomes and symptoms that acupuncture-moxibustion can improve

According to the characteristics of the disease, propose which outcomes can be resolved by acupuncture-moxibustion intervention, such as pain, physiological or clinical indicators, quality of life, etc.

5.2 Development of the clinical questions

5.2.1 Clues for collecting clinical questions

The clinical questions of clinical guidelines on acupuncture-moxibustion should be raised around specific acupuncture-moxibustion interventions "with certain therapeutic effect". First collect the specific acupuncture-moxibustion interventions with certain therapeutic effect to the target disease and then for each intervention, the following contents should be collected:

—What are the appropriate target population and appropriate timing of treatment?

—What problems (including outcome indicators or symptoms) can be addressed?

—How about safety?

—Range of application and what are the requirements for the diagnosis and treatment environment?

5.2.2 Collection and formulation of clinical questions

The drafting group and guideline methodologists (evidence-based medicine experts) determine after consensus the collecting method and solicitation scope of clinical questions. Clinical questions can be formulated in the following 3 stages, and the whole formation process needs to be reported in the guideline.

First stage: To collect clinical question elements (PICO elements) and related clinical questions

Step 1: Collect acupuncture-moxibustion intervention measures with certain therapeutic effect and appropriate target population. On the one hand, the core expert group could determine the relevant acupuncture-moxibustion therapy with certain therapeutic effects. On the other hand, the drafting group could initiate a survey among acupuncture acupuncturists and patients in countries and regions of WFAS member societies to collect acupuncture-moxibustion therapies with certain therapeutic effects on the target diseases.

Step 2: According to the above collected results, the core expert group determine specific acupuncture-moxibustion intervention measures with certain therapeutic effects, and determine it as the definable clinical question elements.

Step 3: Focusing on the acupuncture-moxibustion intervention measures identified by the core expert group as having certain therapeutic effects, specific clinical questions are collected extensively from doctors and patients (see 5.2.1). The scope of survey should consider factors such as representativeness of different member societies and medical institutions at various levels, and the number of respondents should meet the requirements of sample size in epidemiological investigations. When

collecting clinical questions, attention should be paid to the different usage scenarios of acupuncture-moxibustion interventions in the countries and regions of WFAS member societies, and the clinical environment of the respondents should be asked. The following semi-structured survey form can be used (see Table 5-1).

Table 5-1—Questionnaire for collecting clinical questions of acupuncture-moxibustion intervention measures with certain therapeutic effects example chart

What are your concerns about "migraine treatment with acupuncture-moxibustion" from the following aspects: when using acupuncture by filiform needling to treat patients with acute migraine (fill in population), if compared with conventional western medicine (fill in other interventions), is there any difference in relieving intensity of pain, duration of pain, and medical costs (fill in outcomes)?	
Intervention	If you recommend any treatment protocol of acupuncture by filiform needling, please fill it here: _____ The description should include key points for operation (such as timing of intervention, point prescription, needling method, treatment time, etc.) If you do not recommend any treatment protocol, the default is "a specific treatment protocol related to filiform needle therapy"
Optional population	☑ Stage(☑ acute stage/☐ prophylactic treatment /☐ other____) ☐ Pain degree(☐ mild, please describe the symptoms____/☐ moderate, please describe the symptoms____/☐ severe, please describe the symptoms____/☐ other____) ☐ Meridian syndrome differentiation and classification(☐Shaoyang meridian headache /☐Yangming meridian headache /☐ other____) ☐ Special population(☐ migraine sufferers with depression/anxiety /☐migraine sufferers who are dependent on painkillers /☐patients with acute migraine during lactation /☐menstrual migraine patients/☐ other____) ☐ Other____
Other optional comparison	☐ No treatment ☑ Other conventional western medicine
Optional outcome	☑ Efficacy indicator: extent of pain relief, time of pain relief ☐ Safety Indicators: _____ ☑ Health-economic indicators: medical costs ☐ Other____
The clinical setting you are in: general hospital (hospital specialized on acupuncture-moxibustion/general hospital, etc.)	
Other issues of concern: Is acupuncture by filiform needles safe?	

Second stage: To sort and summarize clinical questions

Drafting group of guidelines eventually sorts through the collected clinical questions to form the clinical questions in a complete structure which contains specific population (P), specific interventions

(I)and comparisons (C), such as "For menstrual migraine patients, does it benefit more from prophylactic treatment with ear acupuncture than from no treatment?"

Questions related to treatment protocols of acupuncture-moxibustion can be asked directly as a clinical question, or integrated with related clinical questions. For example, the above clinical questions of prophylactic treatment for menstrual migraine with ear acupuncture may be compared with the clinical questions of the timing of ear acupuncture treatment— "Compared with no treatment, when is it appropriate to start prophylactic treatment with ear acupuncture?" The clinical question may be merged to "For menstrual migraines patients, does it benefit more from prophylactic treatment with ear acupuncture than from no treatment? When is it appropriate to start?"

Third stage: To screen and formulate clinical questions

The expert group further discuss the clinical questions after consolidation, select important acupuncture-moxibustion intervention measures based on the advantages and characteristics of acupuncture-moxibustion on diagnosis and treatment, and screen the important intervention measures according to the attention degree of doctors and patients. The expert group grade the importance of the clinical questions associated with the intervention, and determine the clinical questions with priority concern through the Delphi method or other consensus method. The number of clinical questions included in each type of intervention depends on the level of concern of doctors and patients. Meanwhile, time, funding, and whether it has been answered in the existing guidelines should be considered comprehensively.

5.3 Determination of outcome indicators and their importance

5.3.1 Determination of outcome indicators

According to the outcomes and their indicators related to the clinical questions collected in the Step 3 of the First stage indexed as 5.2.2, the outcomes and their indicators of specific target population (P) resulted from a particular acupuncture-moxibustion intervention are to be determined according to the clinical application of such acupuncture-moxibustion intervention and by expert consensus. For example, the outcome of female urinary incontinence treated by acupuncture is the degree of urine leakage. So, 24-hour urine leakage can be used as the primary outcome (indicator) for patients with mixed urinary incontinence, and 1-hour pad test can be used as the primary outcome (indicator) for patients with stress incontinence.

Clinical experts, methodological experts, health economics experts, and patient representatives in the expert group may supplement other outcomes and indicators that influence doctor-patient decision-making, including safety indicators, health economics indicators, etc.

5.3.2 Importance rating of outcomes and indicators

For each group of population (P), the drafting group sort out the outcomes and outcome indicators

involved.Considering how much it will influence the decision making of the acupuncture-moxibustion operators or the, the expert group rank the outcomes and indicators according to their importance and classify them into Category 1 critical, Category 2 important but non-critical and Category 3 not important.Category 1 outcomes refer to the key factors in decision making, including rates 9 to 7.Category 2 outcomes are important but not critical factors in decision making, including rates 6 to 4.Category 3 covers factors that have little influence on decision makers and patients which includes rates 3 to 1.The same intervention has different outcome indicators and importance for different groups of population with the same disease (P)(see Table 5-2).

Table 5-2—Importance grading of outcome indicators form of the *Clinical guideline on acupuncture and moxibustion—Female urinary incontinence* example chart (Excerpt)

Outcome indicator	Outcome importance score	Importance rating
1. 24 hours of urinary incontinence	8	Critical
2. A questionnaire to assess quality of life in patients with urinary incontinence	7	Critical
3. Urge-Incontinence Impact Questionnaire (U-IIQ), Urge—Urinary Distress Inventory (U-UDI)	7	Critical
……	……	……
9. 24 hours urine leakage	6	Important
10. 1 hour pad test urine leakage	6	Important
11. An adjunctive test used to assess urinary problems	6	Important

5.4 Presentation of clinical questions

5.4.1 Phrasing of clinical questions

It is recommended that the phrasing of clinical questions consider the following 2 aspects.

—Yes-no questions should be used instead of wh-questions for clinical questions that contain all PIC elements.We suggest use "For × × × patients should × × × recommend or", and avoid using degree adverbs such as "best", "optimal", "perfect" and "most reflective".For example, "For facial paralysis patients in sequelae period, should WFAS recommend acupuncture by filiform needles or no treatment?"

—Yes-no questions and wh-questions are combined to express the clinical questions related to acupuncture-moxibustion treatment protocols.For example, questions such as "If to the ear acupuncture prophylactic treatment of migraine patient of menstrual period, when to begin to treat appropriately?", "Does prophylactic therapy with ear acupuncture benefit patients with menstrual migraine more than no therapy?" It may be concomitant to ask "whether prophylactic treatment with ear acupuncture, as compared to no treatment, can benefit patients with menstrual migraine more?

When is it appropriate to start ear acupuncture?"

5.4.2 Structural breakdown of clinical questions

Included clinical questions need to be structurally breakdown according to PICO elements.(see Example 5-3).

EXAMPLE 5-3:

"Do migraine patients with depression/anxiety benefit more from a combination of acupuncture by filiform needles and western medicine as a preventive treatment than from western medicine alone?"
May be structured into:

Population:Migraine patients with depression/anxiety (non-attack phase)
Intervention measures:Preventive treatment of acupuncture by filiform needles combined with western medicine
Comparisons:Western medicine
Outcome indicators:Clinical efficacy (days of headache, changes in frequency and intensity; effective rate; quality of life associated with headache; functional health status and health-related quality of life; symptom improvement and syndrome scale score)
Safety outcome (incidence of s adverse reactions)
Indicators of health economics evaluation (costs and time cost for treatment)

5.5 Report of clinical questions

The finalized clinical questions are reported in a structured form (see Table 5-3)and the content include:

a) should report on PICO elements for the clinical questions eventual determined;

b) report in the main body of the guideline whether or not all clinical questions determined were addressed and the results of handling the questions (recommendations formulated/ treatment protocols of acupuncture-moxibustion formulated)(see Annex C-C.9.2).

Table 5-3—Sample report on the corresponding table of clinical questions and recommendations in *Clinical guideline on acupuncture and moxibustion—Migraine* example chart (Excerpt)

No.	Content of clinical questions	Population	Intervention measures	Comparisons	Outcome indicators	Handling results (recommendations/ treatment protocols)	Remarks
Filiform needle acupuncture							
1	Do patients with acute migraine get benefit more from acupuncture than from conventional western medicine?	Patients with acute migraine	Filiform needle acupuncture	Conventional western medicine	The degree or intensity of the headache (VAS, VRS, etc.)[a]; duration of headache[a]; headache relief time[a]; effectiveness and headache relief within 2 hours[a]; quality of life associated with headache[a]; headache relief over 24 hours[a]; incidence of serious adverse reactions[a]; functional health status and health-related quality of life[b]; symptom improvement and syndrome scale score[b]; degree of relief of headache concomitant symptoms[b]; the time cost of treatment[b]; treatment expense[b]	Forming recommendations R1	Application in general hospitals
Auricular acupuncture							
2	For menstrual migraines patients, does it benefit more from prophylactic treatment with ear acupuncture than from no treatment? When is it appropriate to start?	Patients with menstrual migraine	Auricular acupuncture	No treatment	Changes in duration, frequency and intensity of headache[a]; effective rate[a]; quality of life associated with headache[a]; functional health status and health-related quality of life[a]; symptom improvement and syndrome scale score[b]	Forming recommendations R2, treatment protocols of acupuncture-moxibustion	Application in hospitals specialized on acupuncture-moxibustion

NOTE [a] refers to critical outcome indicators; [b] refers to important but not critical outcome indicators; R is short for recommend.

6 Retrieval, evaluation and synthesis of the evidence

6.1 Sources of evidence

The evidence shall be from the modern literature (systematic review and RCTs, etc.) and the clinical experiences of ancient and modern acupuncturists (ancient literature, clinical experiences, viewpoints and books, and real cases):

a) systematic reviews: those data may be directly used to form recommendations after screening and evaluation;

b) modern clinical studies: those are used to form recommendations and recommended treatment protocols of acupuncture-moxibustion after systemic review;

c) clinical experiences of ancient and modern acupuncturists: those are formed into the contents of recommended therapeutic protocols of acupuncture-moxibustion, instead of directly forming the recommendations, after translational evaluation.

6.2 Retrieving and screening of evidence

6.2.1 Systematic review and evidence retrieval of modern clinical researches

The retrieval strategy is made by the drafting group. Literature search strategies includes search tools, search scoping, search words, search formulas, inclusion and exclusion criteria, etc. Retrieval scope should include databases in Chinese, English, Japanese, and Korean languages. Databases, such as *Cochrane Library*, *Medline*, *EMBase*, *China National Knowledge Infrastructure* (CNKI) *Database*, *Chinese Medical Current Contents* (CMCC) *Database*, etc., are used. The retrieval strategy shall also include limited range of years of literature. According to the determined retrieval strategy, the drafting group adopts the combination of electronic retrieval with manual retrieval.

The pyramid of evidence levels includes systematic reviews and meta-analysis, RCTs, observational studies and other research types. For the retrieval order of modern literature evidence, according to the needs of clinical questions, the evidence pyramid "from high to low" may be searched step by step.

6.2.2 Retrieval and collection of clinical experiences of ancient and modern acupuncturists

6.2.2.1 Retrieving and collecting ancient literature

According to the characteristics of diseases, the ancient literature search words, the scope and edition of the ancient literature are determined by the ancient literature experts of the guideline expert group. The retrieval bibliography of ancient literature should meet the following principles:

a) **universality**: it includes the books whether or not specialized on acupuncture-moxibustion which contain content of meridians, acupoints, techniques of needling and moxibustion, and treatment dating from as early as the unearthed silk medical books through to the Qing Dynasty (A.D.1912);

b) **representativeness**: it refers to those ancient books greatly influenced the academic history of acupuncture-moxibustion and with a lot of informative records related to acupuncture-moxibustion treatment, which meet the need for ancient information in making clinical guidelines on acupuncture-moxibustion;

c) **reliability**: with the authors that can be verified and the collated editions available, a foundation is laid for full reference and citation in developing the clinical guidelines on acupuncture-moxibustion;

d) **availability**: retrieve the publicly released ancient books in existence or the ancient books with their lost parts re-compiled, to ensure that their original contents can be obtained.

According to the above principles, ancient literature experts determine the bibliography for literature retrieval and develop a search strategy. In the retrieval, the qualified contents are screened out according to the inclusion and exclusion criteria of literature.

6.2.2.2 Retrieval and collection of clinical experience of modern acupuncturists

It includes the acupuncturists' (1912-present) clinical experiences, viewpoints and books, and real cases. The collection procedure is as follows.

a) Determine the scope of acupuncturists to be included: The expert group decides the number of acupuncturists whose clinical data to be collected. It is suggested that the number of acupuncturists is not more than 10. The inclusion criteria of acupuncturists are as follows:

   1) those who achieved significant therapeutic effect on the target disease;

   2) those who have rich clinical experience and have relatively stable patient populations;

   3) those who are well recognized in their regions (having many inheritors and whose academic thoughts are influential, etc.).

b) The drafting group collects the clinical experience of acupuncturists, and the data included should meet all the following criteria:

   1) the exposition for etiology, pathogenesis, treatment principles and methods is clear and playing a guiding role in syndrome differentiation of the target diseases; or the diagnosis is clear and in line with the diagnosis for target disease (the diagnosis for etiology, pathogene-

sis, disease location/site, disease nature, and disease developing trend is clear and consistent with the diagnosis for target disease); or the description for main symptoms, accompanied symptoms, tongue and pulse manifestations is clear, meeting the diagnosis for target disease;

2) the contents about treatment sites and methods are complete (for example, in the filiform needle acupuncture, it includes the selected points, and locating method of selected points; it also includes the method of needling, the manipulation method, the treatment time, etc.); or the description for treatment sites and methods is clear;

3) the description for efficacy/effect is clear; or there are contents about the clinical efficacy or effects descriptions, recordings, explanations;

4) the treatment protocols are unique and special, which are compared with conventional methods in treatment protocols.

NOTE It refers to special diagnostic and therapeutic method; or having a special effect on a certain group of people; or the point selection is the same, but the direction or the sensation of needling is different; or the treatment methods and procedures are different; or the treatment frequency and courses are different, etc.

6.3 Systematic review and evidence evaluation of clinical studies

6.3.1 Quality evaluation of systematic reviews

Evaluate the quality of systematic reviews using systematic evaluation/Meta-analysis methodological assessment tools (*AMSTAR 2: A critical appraisal tool for systematic reviews that include randomized or non-randomized studies of healthcare Interventions, or both*) (published by the BMJ publishing group co., LTD., visit https://www.bmj.com/content/358/bmj.j4008.long, cited with authorization). The drafting group retrieves the systematic reviews published in recent years answering the clinical questions. For those RCTs published in the last 3 years but without updated systematic reviews, it is suggested to update the strategy for systematic review. For the system reviews with no need to be updated, the results will be extracted by the drafting group. If there is a lack of systematic review of clinical questions, the drafting group need to collect evidence from modern clinical studies and make a systematic review.

6.3.2 Rating the quality of evidence from modern clinical studies

6.3.2.1 Method of rating the quality of evidence from modern clinical studies

The software system *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) is used to rate the quality of evidence from modern literature.

6.3.2.2 Rating the quality of evidence body from modern clinical studies

The evaluation methods and procedures of evidence body from modern clinical studies refer to the *WHO Handbook for Guideline Development*.

The quality of evidence body from modern clinical studies is determined by 5 reasons to rating down and 3 reasons to rating up, and the drafting group decides on such reasons. After filling the rating down and rating up reasons in the *GRADE Guideline Development Tool* (GRADEpro GDT) the rating of quality of evidence body from modern clinical studies will be automatically presented. To achieve transparency and simplification, the GRADE system classifies the strength of evidence body from modern clinical studies into four levels: high, moderate, low, and very low. GRADE provides symbolic, numerical, and alphabetical descriptions of the evidence strength for modern clinical studies. Here the *Norms* recommends the use of alphabetical description method, using capital English letters A, B, C, D to represent the 4 levels, ie high, moderate, low, and very low, respectively.

6.4 Correlation assessment of acupuncture-moxibustion treatment protocols (including therapeutic elements) from different sources of evidence

6.4.1 Objects and contents of assessment

The objects for assessment are those treatment protocols of acupuncture-moxibustion in modern clinical studies and clinical experiences of ancient and modern acupuncturists. The contents are as follows:

a) **disease-related background, treatment principles and treatment methods**: including diagnosis, etiology, pathogenesis, disease location, nature, developing trend, and syndrome(s) (main symptoms, systemic symptoms, tongue and pulse manifestations, etc.); descriptions of treatment principles and methods, point selection principles, point prescription methods, and so on;

b) **contents about treatment sites**: including descriptions of points (regular points, extra points), points of microsystems (regional points, such as on the head, ear, eye, etc.), disease locations, and reaction points/objects (such as Ashi points, sensitive points, superficial venules, nodules, etc.), as well as methods to locate points;

c) **contents about treatment methods**: it may include the information description of the operation method of acupuncture-moxibustion (such as the depth of acupuncture, the angle of acupuncture, the direction of acupuncture, the quantity of moxibustion operation/ZHUANG, etc.), the treatment time (such as treatment time point, the time of needle retention, the time interval between treatments, the duration and course of treatment) and so on.

6.4.2 Correlation assessment methods

Based on the characteristics of diseases and acupuncture-moxibustion interventions, ancient literature experts and clinical experts judge whether the clinical experiences are correlated and consistent

with the treatment protocols from different sources. Those correlated clinical experiences of ancient and modern acupuncturists will be used as evidence to support the reliability of treatment protocols of acupuncture-moxibustion in clinical studies. The specific contents of correlation assessment of acupuncture-moxibustion treatment protocols from different sources are as follows:

a) whether the etiology, pathogenesis, location, syndrome type (stage), syndrome, and treatment principles and methods, point selection principles, and point prescription methods are consistent;

b) whether the point prescription, treatment sites, and method of locating points are consistent;

c) whether the method and operation of acupuncture-moxibustion, and the treatment time are consistent.

6.5 Translational application of clinical experiences

Step 1: Structured extraction and analysis of treatment protocols of acupuncture-moxibustion from different sources of evidence

Firstly, the drafting group extract the treatment protocols of acupuncture-moxibustion from clinical experiences of ancient and modern acupuncturists as well as modern clinical studies. When there are multiple clinical studies on a certain clinical question, the sample size, indirectness, effect size, and safety of each clinical study should be comprehensively considered to select the treatment protocols of acupuncture-moxibustion that can be extracted. Then, the related content can be extracted by using the structured extraction table (see Table 6-1).

Table 6-1—Example table of structured extraction of treatment protocols of acupuncture-moxibustion from different sources of evidence example chart

Source	Provider of literature (author/year)/ experience	Contents	Disease-related content	Treating principles and methods	Treatment sites	Treatment methods (precautions)	Effects
Clinical study 1							
Clinical study 2							
Clinical experience of ancient and modern acupuncturists 1							
Clinical experience of ancient and modern acupuncturists 2							

Step 2: Correlation assessment

Ancient literature experts and clinical experts are required to evaluate whether acupuncture-moxibustion treatment protocols from different sources are correlated. Meanwhile, it is necessary to fur-

ther clarify which elements of the treatment protocols in clinical studies are supported by the experience of ancient and modern acupuncturists.

Step 3:Clinical value evaluation

The clinical value of acupuncture-moxibustion treatment protocols from different sources is evaluated by clinical experts.The contents of evaluation include the following four aspects:

a) whether the theory, methods, prescription, acupoints selection and operation technique of the treatment protocol correspond to each other;

b) whether the manipulation is intuitive and repeatable, and whether the treatment protocol can be spread for clinical implementation;

c) whether it is more useful than commonly used individual therapies;

d) whether it can inspire or guide the clinical diagnosis and treatment.

The evaluation process of acupuncture-moxibustion treatment protocols from different sources is shown in Figure 6-1, and it is recommended to be presented in table format (see Table 6-2).

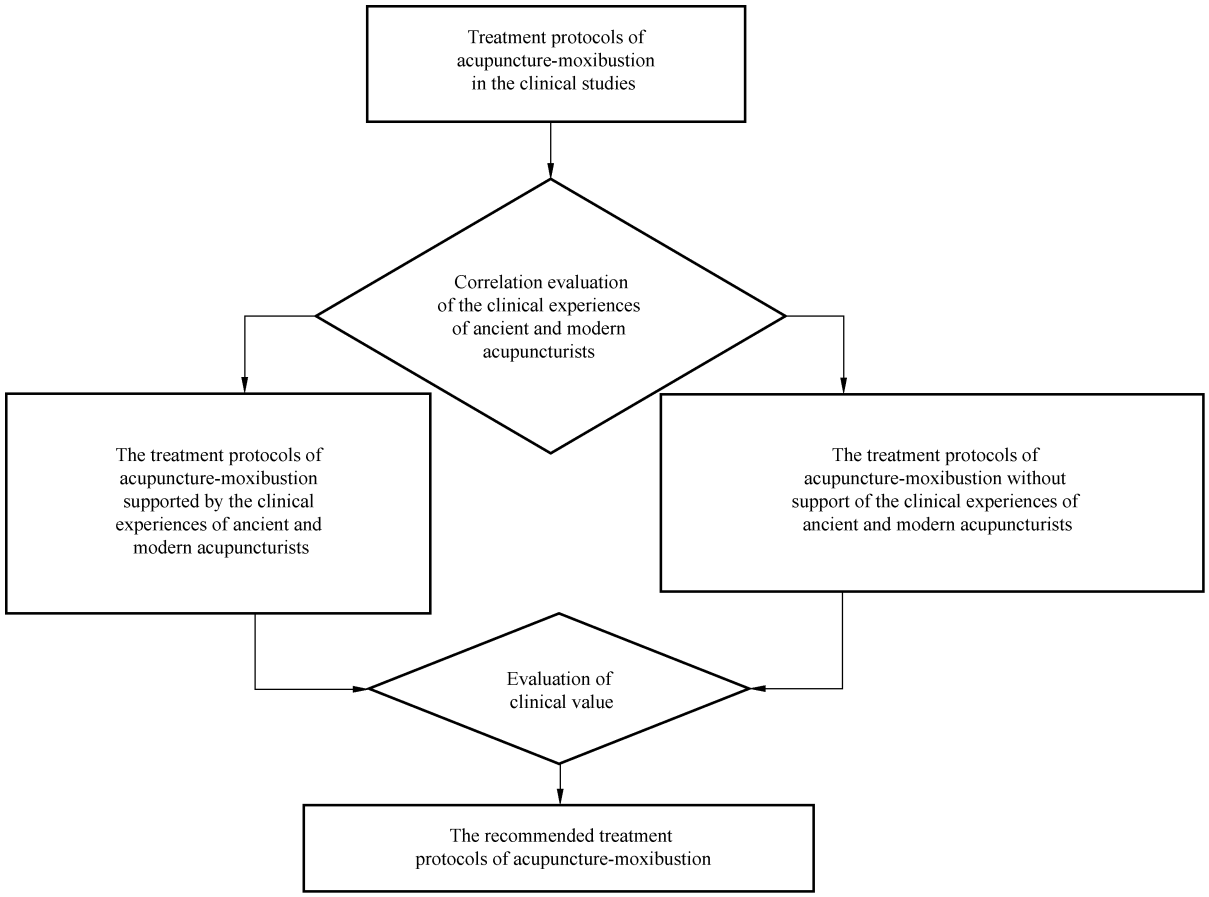

Figure 6-1—Flowchart for evaluating the of treatment protocols of acupuncture-moxibustion from different sources

Table 6-2—Table of evaluation process of acupuncture-moxibustion treatment protocols from different sources example chart

<table>
<tr><td>Clinical questions</td><td colspan="6"></td></tr>
<tr><td rowspan="2"></td><td colspan="2">Acupuncture-moxibustion treatment protocols and source of data</td><td colspan="3">Information of treatment protocols</td><td>Related contents</td></tr>
<tr><td>Literature No.</td><td>Data source（Clinical studies/Clinical experiences of ancient and modern acupuncturists）</td><td>Disease-related background，treatment principles and methods</td><td>Treatment sites</td><td>Treatment methods</td><td>Clinical studies and clinical experiences of ancient and modern acupuncturists</td></tr>
<tr><td rowspan="6">Correlation assessment</td><td rowspan="4">Material 1</td><td>Clinical study</td><td></td><td></td><td></td><td>—</td></tr>
<tr><td>Clinical experience of ancient and modern doctors 1</td><td></td><td></td><td></td><td></td></tr>
<tr><td>Clinical experience of ancient and modern doctors 2</td><td></td><td></td><td></td><td></td></tr>
<tr><td>……</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Any correlation?</td><td></td><td></td><td></td><td>—</td></tr>
<tr><td colspan="2">☐ The treatment protocol of acupuncture-moxibustion in clinical studies supported by the clinical experiences of ancient and modern acupuncturists
☐ The treatment protocol of acupuncture-moxibustion in clinical studies without support of the clinical experiences of ancient and modern acupuncturists</td><td colspan="4">Treatment protocol 1：
Points selection
Main points：
Supplementary points（point selection based on meridian differentiation/syndrome differentiation/symptomatic differentiation）
Method of needling and moxibustion
Acupuncture-moxibustion method
Operation method
Treatment time
Precautions</td></tr>
<tr><td colspan="2">☐The treatment protocol of acupuncture-moxibustion in clinical studies supported by the clinical experiences of ancient and modern acupuncturists
☐The treatment protocol of acupuncture-moxibustion in clinical studies without support of the clinical experiences of ancient and modern acupuncturists</td><td colspan="4">Treatment protocol 2：
Points selection
Main points：
Supplementary points（point selection based on meridian differentiation/syndrome differentiation/symptomatic differentiation）
Method of needling and moxibustion
Acupuncture-moxibustion method
Operation method
Treatment time
Precautions：</td></tr>
<tr><td colspan="2">……</td><td colspan="4">……</td></tr>
</table>

Table 6-2—Table of evaluation process of acupuncture-moxibustion treatment protocols from different sources example chart（*continued*）

	Evaluation contents	Factors to consider	Treatment protocol 1	Treatment protocol 2	……	Remarks
Evaluation of clinical value	Whether there is a correspondence between the theory, methods, prescription, acupoints selection and operation technique of the treatment protocol（the method of syndrome differentiation and classification, the principle and method of treatment, the selection of points and supplementary points, the method of needling and moxibustion, and precautions）	a） Experience from practice b） Theoretical analysis c） Data from various countries d） Intuitive perception	☐ Yes ☐ No ☐ Unclear	☐ Yes ☐ No ☐Unclear	☐ Yes ☐ No ☐Unclear	
	whether the manipulation is intuitive and repeatable, and whether the treatment protocol can be spread for clinical implementation	a） Experience from your own practice b） Experience of other people c） Intuitive perception	☐ Yes ☐ No ☐ Unclear	☐ Yes ☐ No ☐Unclear	☐ Yes ☐ No ☐Unclear	
	whether it is more useful than commonly used individual therapies	a） Easy to operate b） Safe to operate c） Inexpensive（available） d） Short-term efficacy e） Long-term efficacy	☐ Yes ☐ No ☐ Unclear	☐ Yes ☐ No ☐Unclear	☐ Yes ☐ No ☐Unclear	
	Whether it can inspire or guide the clinical diagnosis and treatment	a） Diagnosis b） Treating principle c） Treatment methods d） Efficacy evaluation methods	☐ Yes ☐ No ☐ Unclear	☐ Yes ☐ No ☐Unclear	☐ Yes ☐ No ☐Unclear	
	Conclusion of clinical value evaluation	☐ This treatment protocol has important clinical value ☐ This treatment protocol has certain clinical value ☐ The clinical value is uncertain				

According to the conclusion of clinical value evaluation, whether to recommend the content of treat-

ment protocols of acupuncture-moxibustion are finally decided by consensus of the expert group.

6.6 Comprehensive assessment of evidence from multiple sources

The comprehensive assessment of evidence includes synthesizing evidence for recommendations, and the comprehensive assessment of treatment protocols of acupuncture-moxibustion in recommendations:

—evidence synthesizing for **recommendations** is the process that the drafting group answers the clinical questions of "difference in efficacy" and "safety", etc. by applying the results of all types of evidence evaluation in systematic review, modern clinical studies, and so on;

—the comprehensive assessment process of **treatment protocols of acupuncture-moxibustion** is the process that the guideline expert group performs the correlation evaluation of treatment protocols from the clinical studies and the clinical experiences of ancient and modern acupuncturists, then, those clinical experiences of ancient and modern acupuncturists having correlations will be used as the supporting evidences for the treatment protocols of clinical studies, and then, after the clinical value evaluation, those treatment protocols of clinical studies having clinical value will be formed as recommended treatment protocols of acupuncture-moxibustion through consensus of the expert group.

7 Formulation of recommendations

7.1 Framework and contents of recommendations in guidelines

Recommendations should include the following and be reported in the body text of the guidelines (see C.9.3).

7.1.1 Clinical question

The clinical questions finally determined in the report.

7.1.2 Contents of recommendations

Recommendations shall include whether to recommend intervention measures (treatments) to treat certain population or patients with target diseases, whether the key outcome indicators can be improved, and the level of evidence and strength of recommendation. Recommendations should be reported to the related clinical question. If the strength of recommendation is conditional (i.e., weak recommendation), the conditions to use the recommendation shall be stated.

The recommendation shall include the treatment protocols of acupuncture-moxibustion, including the

acupuncture intervention for the applicable population, the timing of intervention, the treatment principle and method, treatment sites (including the main points, supplementary points, etc.), the treatment method (including the method of acupuncture-moxibustion, the operation method, treatment time, etc.), precautions, and the outcome indicators (symptoms) that can be improved by the treatment protocol.

7.1.3 Judgment basis

The followings shall be explained:

—overall description of the sources of evidence and the quality, quantity and others of evidence from different sources;

—this may include descriptions of population to whom acupuncture-moxibustion treatments are applicable or not applicable reflected by the evidence, and the situation that the evidence not indicating distinction between groups of population need to be stated nonetheless; the effective intervention measures reflected by the evidence including the method of acupuncture-moxibustion, as well as the effective operation methods, treatment time and other key points in the method of needling and moxibustion;

—desirable and undesirable consequences of intervention measures should be weighted;

—analysis of patients' values and willingness, or direct and indirect costs.

7.1.4 Precautions in operation

The followings may be included:

—precautions in operation closely related to the recommendation;

—the environment wherein the recommendation is applicable and the policies, laws and regulations need to be considered;

—requirements for the qualification and proficiency of the operator;

—health education and instructions for the patients.

7.1.5 Consensus decision-making process from evidence to recommendation

The key factors are taken into consideration during the formulation of recommendations (including recommended treatment protocols of acupuncture-moxibustion) as well as the consensus process. If any member of the expert group holds strong objection to any decision or consensus, the objection and its standpoints may be recorded.

7.1.6 References

It is necessary to provide references on both modern and ancient literatures used to support the formulation of recommendations.

7.2 Factors in formulating recommendations from evidence

Quality of evidence and balance between desirable and undesirable consequences will affect the strength of recommendation. Meanwhile, the strength of recommendation is also related with the preferences and values of the population with target disease, as well as the resources use, equity and feasibility of the recommended intervention measures (see *EtD Framework* on GRADE website: http://www.gradeworkinggroup.org/).

The following 12 factors shall be considered in formulating recommendations from evidence:

—priority of question (whether this clinical question shall be resolved in priority);

—beneficial effects;

—adverse effects;

—overall quality of evidence;

—importance of outcomes;

—balance between desirable and undesirable consequences;

—resource use;

—quality of evidence on resource use;

—cost-benefit ratio;

—health equity;

—acceptability (of intervention);

—feasibility (of intervention).

7.3 Factors in formulating treatment protocols of acupuncture-moxibustion

If the treatment protocols of acupuncture-moxibustion are included in recommendations, the assessing the correlations and clinical value of the treatment protocol from different sources, the expert

group members need to consider of rationality of the treatment protocol, balance between desirable and undesirable consequences, resources needed, equity, acceptability and generalizability to recommend treatment protocol of acupuncture-moxibustion in priority. The following 9 factors should be considered:

—beneficial effects;

—adverse effect;

—quality of evidence;

—rationality of the treatment protocol;

NOTE In this factor it is suggested to consider "whether the treatment protocol is supported by evidence from different sources", "whether there is a correspondence between the theory, methods, prescription, acupoints selection and operation technique of the treatment protocol (the method of syndrome differentiation and classification, the principle and method of treatment, the selection of points and supplementary points, the method of needling and moxibustion, and precautions)".

—cost demand;

—health equity;

—acceptability of the treatment protocol to the patients;

—acceptability of the treatment protocol to the operators;

—generalizability of the treatment protocol.

7.4 Direction and strength of recommendations

Direction and strength of recommendations include the following 5 options:

—strong against this intervention;

—conditional against this intervention;

—conditional recommendation for either the intervention or the comparison;

—conditional recommendation of the intervention;

—strong recommendation for the intervention.

In formulating recommendations, it is necessary to take into account of the summary of evidence, subgroups of population, implementation, monitoring and evaluation, etc. (see the figure of strength of recommendation on GRADE website: http://www.grade workinggroup.org/)

8 Directions for future studies

In developing guidelines, there might encounter certain clinical questions that not clearly recorded in any studies or ancient books, being used nowadays but have not yet been paid attention to by clinical researches. These issues may be sort out in separate chapters which would provide ideas and directions for future researches (detailed contents shall be reported in C.14 and C.18.4).

Common issues which can provide directions for future researches may include:

—issues with high clinical attention but lack modern studies (such as inadequate researches on different diseases and subgroups of population, lack of exploitation in certain key outcome indicators, absence of related researches on health-economics, etc.) or clear corresponding records in clinical experience of ancient and modern acupuncturists;

—manipulations or experience that are recorded in clinical experience of ancient and modern acupuncturists and are commonly used in clinical practice but with no evidence from modern studies;

—other issues that are not among current research hotspots but with potential values.

9 Consensus decision-making in WFAS clinical guidelines on acupuncture-moxibustion

9.1 Who and when need consensus decision-making?

The consensus decision-making process stated in the term 4.6 in this *Norms* involves 3 procedures in formulating a WFAS clinical guideline on acupuncture-moxibustion, namely determining clinical questions, deciding outcome indicators and their importance, and formulating the recommendations.

9.2 What does consensus mean?

The term consensus means general agreement within a group or between different groups. However, it is often difficult to reach agreement in a straightforward manner during discussions among consensus participants when the clinical questions are complex, the evidence is insufficient or conflicting, or some consensus participants bear strong and diverse viewpoints. Therefore, general agreement does not mean to have no diverse viewpoints. One important thing is to set scientific indicators based on coordination among viewpoints of all parties. The objectives of this chapter are to:

—provide guidance to working groups of WFAS clinical guidelines on acupuncture-moxibustion on the methods for consensus decision-making;

—outline the relevant considerations when selecting a method for consensus decision-making;

—propose the minimum requirements for documenting the process of consensus decision-making in formulating WFAS clinical guidelines on acupuncture-moxibustion.

9.3 Methods and threshold for consensus

There are a number of methods and thresholds for consensus in existence, and formal and/or informal methods may be used based on the varied content of consensus. Formal methods for reaching consensus include the Delphi method, the consensus development conference and the nominal group technique, with many variations of each of these methods and many hybrid approaches used in clinical practice that incorporate elements from more than one method. There has been no evidence yet to prove which of the methods is the best (refer to *WHO Handbook for Guideline Development* for introductions and instructions of these methods).

The consensus method used in a WFAS guideline on clinical practice of acupuncture-moxibustion will depend on several factors, including the geographical features of consensus participants (national, regional or of different member societies), the focus and the clinical questions of the guideline, the target population of the recommendations, the quality of evidence, and the time and resource constraints involved. Working groups for WFAS guidelines may choose the most suitable method in accordance with practical contexts, but it is suggested to report such decision in the relevant part or the chapter of methodology in the guideline, and explain the considerations in choosing such method.

The level of agreement necessary to finalize whether a consensus is reached is called the threshold for consensus. When there are great differences in the viewpoints of consensus participants, voting may be used as an alternative method to reach final decision. Any recommendation in WFAS clinical guidelines on acupuncture-moxibustion to be "approved by general agreement" must win no less 60% of votes, and the objective viewpoints and their rationale shall be reported in the guidelines.

9.4 Requirements of consensus in WFAS clinical guidelines on acupuncture-moxibustion

9.4.1 Pre consensus planning

Determine the following issues based on content of consensus:

—determine the consensus participants (including requirements for geography, major and so on) and the criteria for choosing the consensus participants, and manage the conflict of interest of the consensus participants;

—define the method for reaching consensus, the threshold for consensus, the way to deal with strong

objective opinions and the method as how to proceed if consensus cannot be achieved (the specific rules for taking a vote need to be made in advance if voting is used as an alternative method), and rehearse the proceedings;

—systematically sort out and rationally design the consensus materials, and send them to each consensus participant together with the background materials;

—train the consensus participants with methods for reaching consensus if necessary;

—determine a chair if the consensus development conference or the nominal group technique is adopted.

9.4.2 Precautions for achieving consensus

Pay attention to the followings in reaching consensus:

—read out to consensus participants the method for reaching consensus, threshold for consensus, expected process of consensus, and conflict of interest declaration of the consensus participants (see Annex B);

—follow the pre-established process in a strict and orderly manner while paying attention to time management; if the consensus development conference or the nominal group technique is adopted, the chair shall make good control over the progress and the time, and shall prevent undesired results due to improper behavior of group members;

—make detailed records of the consensus participants, method for reaching consensus, process for consensus and result of consensus, and save relevant materials as well as audio-visual documents.

9.4.3 Requirements for reporting consensus

In reporting the consensus process of the WFAS clinical guidelines on acupuncture-moxibustion, there are certain aspects under purpose and content, participant, method and standard, material and background, process, result, and conflict of interest. See Annex D for the elements and contents for reporting the consensus process of clinical guidelines on acupuncture-moxibustion. How detailed this part to be presented in the guidelines will depend on practical circumstances and the ultimate goal is to increase transparency of the consensus decision-making process so that the guideline users will have a clear understanding of the factors taken into account in every decision as well as the information needed to implement each recommendation. There are both common and characteristic parts in reporting different proceedings of consensus decision-making.

9.4.3.1 Common parts

The requirements for reporting consensus participants, method for reaching consensus, threshold for

consensus and process of consensus are more or less the same in different proceedings.Details are as the followings:

—criteria for selecting consensus participants, number of consensus participants and their basic information, distribution of majors and geological regions, conflict of interest and management of interests;

—method for reaching consensus and its rationale, the way to deal with strong objective opinions and the method as how to proceed if consensus cannot be achieved;

—way to add up and sum up viewpoints from consensus participants, threshold for consensus as well as how and by whom such threshold is determined;

—number of rounds for achieving consensus and the result of each round, and the overall description of participation by every consensus participant in each procedure.

9.4.3.2 Characteristic parts

The requirements for reporting process of consensus, materials of consensus and result of consensus are varied for different procedures.Details are as the followings.

a) Determining clinical questions.The following 2 aspects should be reported:

- general description of how clinical questions are collected, a synthesized list of clinical questions, and how viewpoints of consensus participants are dealt with;
- the finally determined clinical questions.

b) Determining outcome indicators and rating of their importance.The following 2 aspects should be reported:

- general description of how outcome indicators are collected, a synthesized list of outcome indicators, and how viewpoints of consensus participants are dealt with;
- rating of the importance of outcome indicators (see Table 5-2).

c) Formulating recommendations.The following 3 aspects should be reported:

- summary of evidence and relevant explanations, if the recommendation contains treatment protocols of acupuncture-moxibustion, the process of formulating the optional treatment protocols of acupuncture-moxibustion should be reported in table (see 6.5);
- table of Evidence-to-Decision, if the recommendation contains treatment protocols of acupuncture-moxibustion, the process of formulating the recommended treatment protocols of

acupuncture-moxibustion should be reported;

- recommendations formulated according to the framework of recommendations (see 7.1).

9.4.4 Place of reporting in guidelines

The consensus process of different procedures is reported in different parts in the guidelines, with details as follows:

a) for "determining the clinical questions", the finally determined clinical question and its corresponding table of recommendations shall be reported in the main body of the guideline (see C.9.2); other contents related to the process of consensus shall be reported in the annex (see C.18.2);

b) for "outcome indicators and rating of their importance", contents related to consensus shall be reported in the annex of the guideline (see C.18.2);

c) for contents related to consensus in "formulating recommendations", including:

- the consensus participants, method for reaching consensus, threshold for consensus, the way to deal with strong objective opinions, the method as how to proceed if consensus cannot be achieved, and the proceedings for achieving consensus may be reported in whole in the first paragraph of the chapter "formulating recommendations";

- key factors taken into consideration in formulating each recommendation (including the recommended treatment protocols of acupuncture-moxibustion) and the process of consensus shall be reported in the section "process of consensus" in the framework of recommendations (see C.9.3);

- the table of Evidence-to-Decision (refer to GRADE website) and the process of formulating the recommended treatment protocols of acupuncture-moxibustion shall be reported in the annex of the guideline (see C.18.4).

10 Production of the guideline

10.1 Contents and format of guidelines

A guideline shall consist of the title page, a table of contents, a main body and annexes. The main body shall include foreword, introduction, summary, general description, overview of disease, overview of acupuncture-moxibustion treatments, acupuncture-moxibustion treatment and recommendations, conflict of interest declaration of this guideline, ways to access this guideline, ways to implement the recommendations in this guideline, beneficial and adverse effects in implementing this

guideline, directions for future studies, limitations and deficiencies of this guideline, update planning of this guideline and references. The annexes shall include members of working groups of the guideline; determination of clinical questions of the guideline; retrieval scope, strategy and results; process of formulating recommendations (including the recommended treatment protocols of acupuncture-moxibustion); process of soliciting, summing up and handling expert comments; and all meetings convened for formulating the guideline (may be provided in annexes and/or published in digital form so as to reduce the cost of printing and publishing the main part of the guideline). See Annex C for the contents and format of guidelines.

10.2 Composition and review of the guideline

10.2.1 Formulation of a Working Draft

The drafting group shall write a preliminary draft guideline in accordance with the consensus-based recommendations and the required contents and format of guidelines. The preliminary draft is to be revised by the drafting group after reviewed by and based on advises from the core expert group in order to form the Working Draft (WD).

10.2.2 Solicitation of comments

The drafting group sort out and sum up comments collected from an extensive peer review to the WD, form a table of comments and handlings (see C.18.5) which is to be submitted to the core expert group for review and decision.

10.2.3 Formulation a Draft Standard

The drafting group revises the WD in line with the decision by the core expert group to form the draft of WFAS standard (DS).

10.2.4 Review

The drafting group submits the DS to the WFAS Standardization Working Committee, who will vote to decide whether to approve and also provide review comments. See the constitution of WFAS Standardization Working Committee for voting rules.

See Annex E-Figure E.1 in for the flowcharts of formulating a guideline.

11 Publication and implementation of the guideline

11.1 Publication of the guideline

The core expert group decides over the review comments and the drafting group revises the text ac-

cordingly to form the WFAS guideline. The WFAS Standardization Working Committee then proposes to the Secretariat of WFAS to submit the guideline to the Executive Committee of WFAS for approval. The final guideline will be published after approved by the Executive Committee of WFAS. The languages are preferred to be English and Chinese, while it is possible to consult with the Secretariat of WFAS if there are additional demands.

11.2 Implementation of the guideline

The following localization strategies may be referred to in implementing the guideline:

—organizing local press conferences, lectures, or academic symposiums to disseminate the ideas and obtain more recognition;

—cooperating with local governments and relevant associations, organizations and institutions, and assisting the establishment of local implementation groups;

—integrating with local professional education;

—integrating with patient health education: a patient targeted edition of the guideline may be printed and spread out, and interpreted by professionals on regular basis.

12 Disclaimer

It shall be clearly stated in the guideline that it is only a recommendatory document without any legal effect. The operator of acupuncture-moxibustion needs to choose whether to use it based on his/her own judgment out of his/her clinical expertise and knowledge as well as the contextual circumstances of local health system.

13 Editions, revision and update of the guideline

13.1 Editions of the guideline

Considering implementation of the guideline, several editions targeted to varied audience may be published such as the patients' edition, Asian editions for countries and regions where member societies are located and so on. See Annex F for textual specifications of the draft of WFAS standard.

13.2 Revision and update of the guideline

13.2.1 Conditions to revise or update the guideline

The relevant managerial body shall organize to review the existing guidelines based on practical clini-

cal demand and the development of acupuncture-moxibustion, with a time interval usually not exceeding 5 years. If a guideline is listed into revision plan by the managerial body after review, the revising process is the same as the formulating process.

The guideline shall be updated in time when the followings occur:

a) new high quality intervention measures have emerged;

b) new evidence has emerged to prove the benefits or harms of existing intervention measures;

c) new significant conclusions have emerged, which brought new meaning and value;

d) new medical resources have emerged in treatment.

In case of the above stated circumstances, the managerial body will urge the working group to recollect and reevaluate the literature and to update the guideline.

13.2.2 Who will revise or update the guideline

Usually, the leader of drafting group shall also be responsible to lead revising and updating the guideline. If the leader of drafting group cannot take lead in revising and updating the guideline, the person designated by WFAS shall lead revising and updating the guideline.

14 Major changes in terms of the guideline

This includes major changes to the name and contents of the guideline, postponed application for the guideline and others. The decision is usually made by the project approval body. For example, such application or report shall be filled to the WFAS Standardization Working Committee if it is the project approval body.

15 Evaluation of the clinical guidelines on acupuncture-moxibustion

15.1 Tools for evaluating the clinical guidelines on acupuncture-moxibustion

Use the *Appraisal of Guidelines for Research and Evaluation II* (*AGREE II*) to evaluate the guidelines.

15.2 Domains and items for evaluating the clinical guidelines on acupuncture-moxibustion

In evaluating the clinical guidelines on acupuncture-moxibustion there are 6 domains covering 23 items under scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability and editorial independence. See Annex G for the domains and items for evaluating

the clinical guidelines on acupuncture-moxibustion.Steps of evaluation are as the followings.

a) The guideline working group is responsible for organizing evaluation of the guideline,and each guideline shall be assessed by 2 to 4 guideline methodologists.

b) Ratings.Each item is rated on a 7-point scale (1:Strongly Disagree;7:Strongly Agree).A score 1 should be given when there is no information that is relevant to the item or if the concept is very poorly reported;a score of 7 should be given if the quality of reporting is exceptional with full criteria and clear rationale;a score between 2 and 6 is assigned when the reporting of the item does not meet the full criteria or considerations.A score is assigned depending on the completeness and quality of reporting.

c) Calculating domain scores.A quality score is calculated for each of the domains.The 6 domain scores are independent and should not be aggregated into a single quality score.Domain scores are calculated by summing up all the scores of the individual items in a domain and by scaling the total as a percentage of the maximum possible score for that domain.

d) Overall assessment of the guideline.The overall assessment includes scoring (a judgment)of the quality of the guideline and whether the appraiser would recommend use of the guideline.Advices to amendments may also be proposed.

Annex A
(informative)
Organizational structure for formulating a guideline

See Figure A.1 for the organizational structure for formulating a guideline.

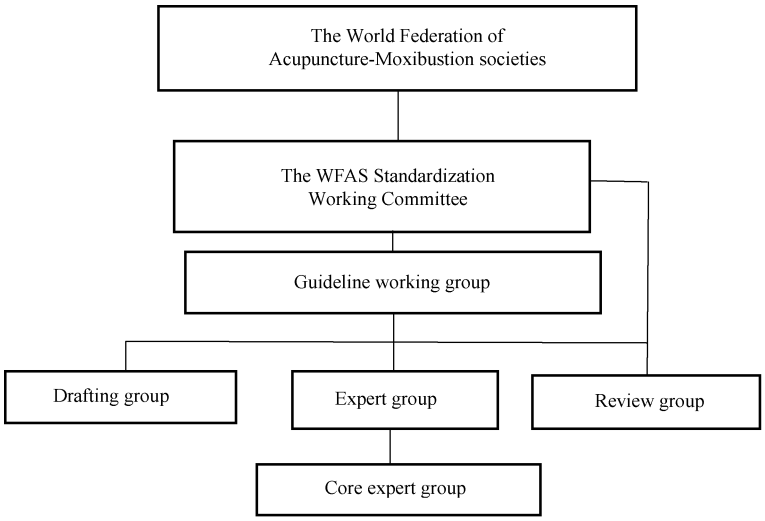

Figure A.1—The organizational structure for formulating a guideline

Annex B
(normative)
Conflict of interest declaration

- Basic information

Name		Name of association/organization	
Group		Major	
Contact phone number		Email	
Postal address			

- All members of the guideline working group should declare all potential conflicts of interest. You should declare any economic, non-economic or other conflicts of interest related to the subject of this guideline in this conflict of the interest declaration form.

Potential conflicts of economic interests during the past 3 years	
I or my spouse have accepted a total sum of more than 150,000 RMB yuan payment (such as payment for consultation, labors, gifts and travel expenses) from any enterprise that has an interest in this guideline	☐Yes ☐No
I or my spouse hold shares or stocks of any enterprise that has an interest in this guideline.	☐Yes ☐No
I or my spouse hold personal patent(s) related to any enterprise that has an interest in this guideline	☐Yes ☐No
I or my spouse have accepted research funds from any enterprise that has an interest in this guideline	☐Yes ☐No
I or my spouse have accepted equipment or instruments funded by any enterprise that has an interest in this guideline	☐Yes ☐No
Potential conflicts of non-economic interests during the past 3 years	
I or my spouse participated in any research related to this guideline or published results of any research involved in formulating this guideline, for example the systematic review	☐Yes ☐No
I or my spouse publicly expressed views or positions related to this guideline, for example by participating the work formulating similar guidelines for any other organization	☐Yes ☐No
I or my spouse have academic interest(s) in the recommendations of this guideline, for example being the founder or main inheritor of the acupuncture-moxibustion therapy or school which is relevant to this guideline	☐Yes ☐No
NOTE The enterprises having interests in this guideline includes those produce and sell acupuncture needles, medicines or equipment.	

- In addition to the above, please write in the box below any other conflict of interest during the past 3 years you would like to declare:

- Please give a brief description in the box below if you have checked "Yes" to any of the above questions:

- **Informed disclosure of conflict of the interest declaration:** I agree to disclose the above content to other guideline working group members, and I agree to publish this Conflict of the Interest Declaration form in the guideline.

- **Declaration:** I commit that the content I declared is true and complete. Should any of the information I declared above change in any form at any time, I will immediately inform the head of drafting group and complete a new Conflict of Interest Declaration form.

Signature:_____ date:_____

- **Fill in after review:**

Based on the Conflict of the Interest Declaration above, the severity of conflict of interest of this group member is judged as: □severe □not severe □none

Conclusion and reasons:

Annex C
(normative)
Contents and format of the guideline

C.1 Title page

C.1.1 Title: The title of the guideline is composed of two sections, namely the main section and the supplementary section. The main section is: *Clinical guideline on acupuncture and moxibustion*; and the supplementary section is made of the name of disease.

C.1.2 Edition: If the document replaces one or more documents, the number of the replaced document shall be indicated on the cover.

C.1.3 Issue date: ××××(year)-××(month)-××(day).

C.1.4 Implementation date: ××××(year)-××(month)-××(day).

C.2 Table of contents

Use automatic table to generate the Table of contents which normally cover Heading 2 or 3.

C.3 Foreword

This part mainly gives information beyond the contents of this document, such as other documents used as references for drafting this document, the relations between this and other documents, the relations between this document and the replaced document, publishing information of previous editions of this document and any replaced or abolished document, the description of patents, etc.

C.4 Introduction

This part is for presenting background information about the contents of this document, such as reasons for formulating the document, special information or introduction of the technical contents of this document.

C.5 Summary

This part includes treatment principle as well as recommendations.

There is no need to specify strength of recommendation in treatment principle; the recommendations as well as the strength of recommendation and evidence shall be presented in a table(see Table C.1).

Table C.1—Recommendations

Recommendations	Strength of recommendation/evidence

C.6 General description

C.6.1 Objectives of this guideline

C.6.2 Purposes of this guideline

C.6.3 Range of diseases this guideline is applicable to

This part presents range of diseases/symptoms and the population with the specific or particular disease to whom this guideline is applicable.

C.6.4 Intended users of this guideline

Propose the intended users, environment and requirements to apply this guideline.

EXAMPLE The intended users of the guideline for low back pain may be acupuncturists, nurses and physicians/acupuncturists who are engaged in treating low back pain; patients with low back pain who are planning to or have received acupuncture-moxibustion treatments; medical professionals and hospital administrators who are making diagnosis and treatment training plans.

C.7 Overview of disease

C.7.1 Definition

The definition of the disease in both western and Chinese medical contexts.

C.7.2 Incidence rate and the characteristics of the patients

C.7.3 Clinical characteristics

Medical history, symptoms and signs.

C.7.4 Diagnostic criteria

Diagnostic criteria and classification based on western medical theories and those based on Chinese medical theories. Diagnostic classification shall include that involved in the treatment protocol of acupuncture-moxibustion recommended in this guideline. In the case that any special population is involved in the treatment protocol of acupuncture-moxibustion, the diagnostic criteria for that special

population shall be clarified.

C.8 Overview of acupuncture-moxibustion treatments

This part includes overview of the use of acupuncture-moxibustion in treating the target disease in ancient and modern times, common factors affecting the efficacy of acupuncture-moxibustion, common precautions in implementing acupuncture-moxibustion treatment as well as the appropriate nursing and care management needing cooperation from the patients.

C.9 Acupuncture-moxibustion treatment and recommendations

C.9.1 The principle and characteristics of acupuncture-moxibustion treatment

C.9.2 Table of clinical questions and corresponding recommendations

C.9.3 Recommendations

In this part the clinical questions, the corresponding recommendations, judgment basis, precautions in operation, process of consensus and bibliography shall be noted (see 7.1). See 9.4.4 for requirements for reporting the process of consensus.

C.10 Conflict of interest declaration of this guideline

C.11 Ways to access this guideline and ways to implement the recommendations in this guideline

C.12 Disclaimer

C.13 Beneficial and adverse effects in implementing this guideline

This part includes content in terms of monitoring and evaluation of the recommendations in this guideline. For example, how to monitor whether the recommendations have been adopted, what results or outcomes to be monitored or evaluated to judge whether the effect of recommendations meets expectations after this guideline is issued.

C.14 Directions for future studies

C.15 Limitations and deficiencies of this guideline

Describe all limitations in formulating this guideline.

C.16 Update planning of this guideline

Present detailed update proceedings including whether the guideline will be updated, and the method,

time and term for updating.

C.17 References

C.18 Annexes

C.18.1 Members of working group of the guideline

This part specifies members of the drafting group, the expert group and the review group and describes the major (discipline/specialty), affiliation, responsibilities and tasks of each member.

C.18.2 Determination of clinical questions of the guideline

This part includes generating clinical questions, ranking outcomes and reporting process of consensus. See Chapter 5 Formulating of the clinical questions and Chapter 9 Consensus decision-making in WFAS clinical guidelines on acupuncture-moxibustion.

C.18.3 Retrieval scope, strategy and results

C.18.4 Process of formulating recommendations (including the recommended treatment protocol of acupuncture-moxibustion)

C.18.5 Process of soliciting, summing up and handling expert comments

From completion of first working draft until approval of standard, the drafting group shall widely solicit comments and present the whole process of soliciting, summing up and managing expert comments in each procedure in "working draft (WD)→ soliciting comments → submitting draft of the WFAS standard (DS)→ submission for approval". The comments and their handlings can be presented in a table as Table C.2.

Table C.2—Table of comments and handlings of the guideline

Name of document: Date:

Drafting organization: Stage: (WD/DS)

No.	No.of Chapter/term	Comments	Name of member society (country/region)	Handlings (accepted/rejected)	Remarks (results after handling)

NOTE WD—Working Draft, DS—Draft of the WFAS Standard.

C.18.6 Important meetings held in formulating the guideline

The time, location, subject, participants and resolutions shall be listed.

Annex D
(normative)
Elements and contents in reporting the consensus process of clinical guidelines on acupuncture-moxibustion

D.1 Purpose and content

D.1.1 Describe the purpose(s)of using the consensus method.

D.1.2 Describe the content(s)and its source(s)that need achieve consensus,and decompose the content(s) into clearly structured content component(s) which could achieve consensus.

D.2 Participants

D.2.1 Describe the basic situation of consensus participants (distribution of majors and geological regions,etc.).

D.2.2 Describe the criteria for the selection of consensus participants.

D.2.3 Describe the process of consensus participants selection.

D.2.4 Describe the participation of consensus participants in the development of the guidelines.

D.3 Method and threshold for consensus

D.3.1 Explicitly propose the specific consensus method(s),and describe the characteristics of its core elements reasonably and clearly.

D.3.2 Describe the specific procedure which use consensus method(s)in the development of guidelines.

D.3.3 Describe the threshold for reaching/ending consensus.

D.3.4 Describe the key factors that consensus participants need to consider when they are making decisions in a specific procedure.

D.4 Material and background

D.4.1 Describe the sources,methods of formation and synthesis of consensus materials,and how well correlated with the consensus content.

D.4.2 (Optional content)Describe the perspective of the guideline development (the health system perspective,the individual patient perspective,etc.).

D.5 Process

D.5.1 Describe the actual implementation process of the consensus method.If the consensus content or planned procedures (rules)are modified during implementation,the modified content/procedures and reasons for modification should be described.

D.5.2 Describe the quality control method and process of consensus decision-making.

D.6 Result

D.6.1 Report the result(s)for each round and the final result(s)clearly.

D.6.2 Explain the consensus results comprehensively,report the divergences arising from consensus decision-making process,and describe the respective positions and reasons of the two sides.

D.6.3 Describe the potential limitations of the consensus decision-making.

D.7 Conflict of interest

Describe conflicts of interest of consensus participants.If there is a conflict of interest,describe the type and the method to manage conflicts of interest.

Annex E
（normative）
Flowcharts of formulating a guideline

See Figure E.1 and Figure E.2 for the flowcharts of formulating a guideline.

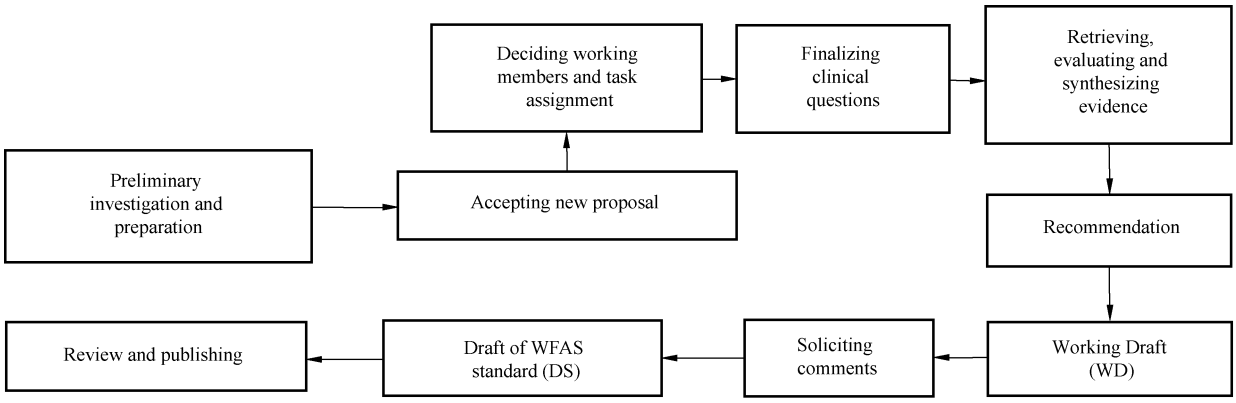

Figure E.1—Flowchart of formulating a guideline

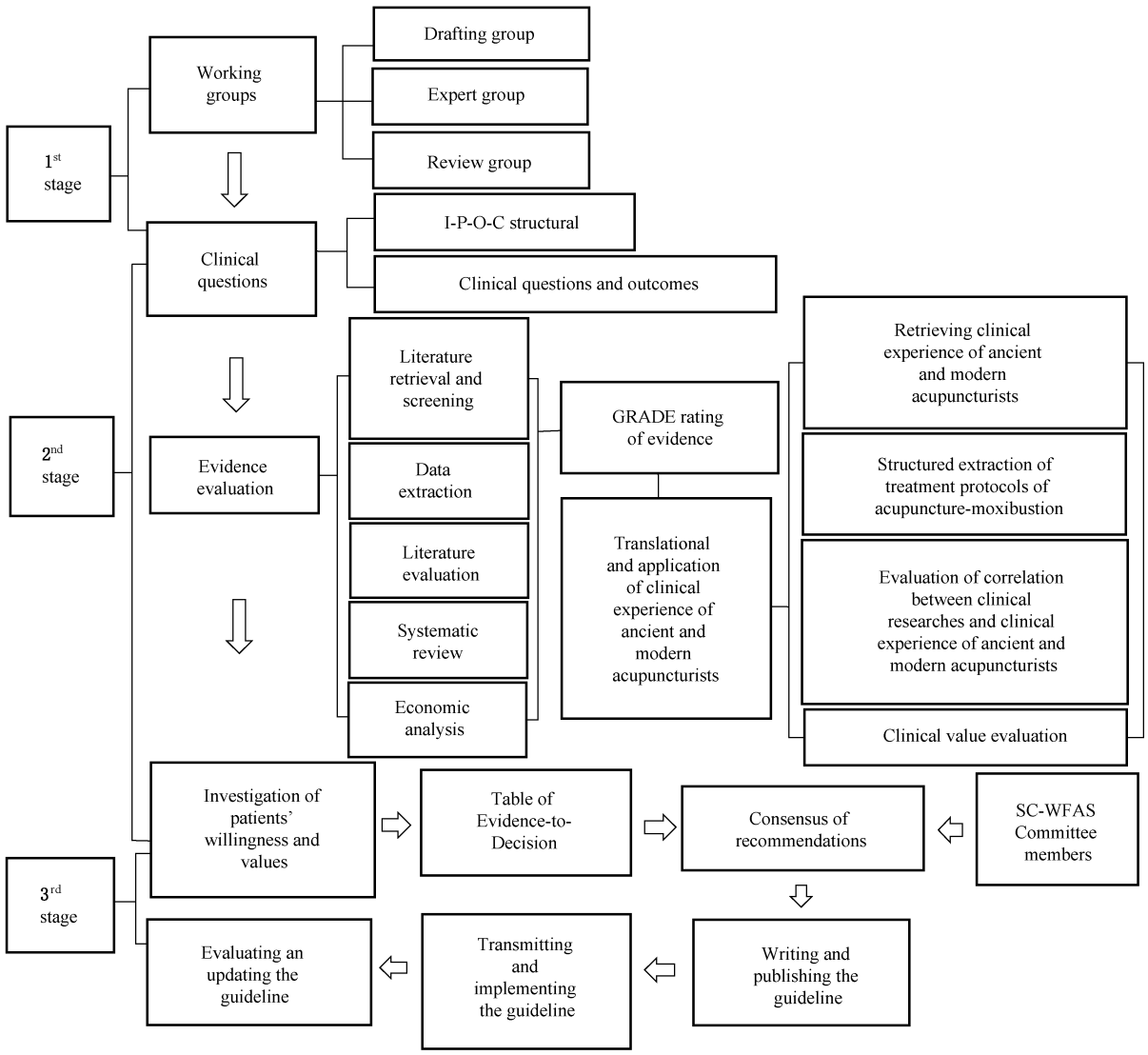

Figure E.2—Flowchart for method of formulating a guideline

Annex F
（normative）
Textual Specifications of the draft of WFAS standards

The working languages of the World Federation of Acupuncture-Moxibustion Societies（WFAS）are Chinese and English.The texts of WFAS clinical guidelines on acupuncture-moxibustion are issued in Chinese and English.

F.1 Format of the Chinese version

F.1.1 Format of the title

Font SimHei，size 26，center text.Use A4 sized page with 10 mm top and 25 mm bottom margins，and 25 mm left and 15 mm right margins.

F.1.2 Format of headings

Font SimHei，size 10.5 and aligned to the left for all first-level headings.Headings of and below the second level，if there is any，shall be presented in the format：

1

1.1

1.1.1

F.1.3 Format of the main text

The texts shall be written in Font SimSun and size 10.5.For the texts without numbering the first line of each paragraph shall be indented by 2 characters，and the texts with numbering shall be aligned to the left.

When quoting references in the text，it is necessary to mark the relevant contents in the form of superscript，such as：××××××[1].

F.2 Format of the English version

F.2.1 Format of the title

Font SimHei，Size 14，aligned to the left，and page size A4.

F.2.2 Format of headings

Use Font SimHei,Size 12 and align to the left for all first-level headings.Headings of and below the second level,if there is any,shall be presented in the format:

1

1.1

1.1.1

F.2.3 Format of text

The texts shall be written in Font SimHei,Size 10.5.The first line of each paragraph is aligned to the left.

When quoting references in the text,it is necessary to mark the relevant contents in the form of superscript,such as: ××××××[1].

Annex G
(normative)
Domains and items in evaluating the clinical guidelines on acupuncture-moxibustion

Clinical guidelines on acupuncture-moxibustion are evaluated based primarily on the domains and items of the *Appraisal of Guidelines for Research and Evaluation II* (*AGREE II*), including:

G.1 Domain 1.Scope and purpose

G.1.1 The overall objective(s)of the clinical guidelines on acupuncture-moxibustion is (are)specifically described.

G.1.2 The health question(s)covered by the clinical guidelines on acupuncture-moxibustion is (are) specifically described.

G.1.3 The population (patients, public, etc.)to whom the clinical guidelines on acupuncture-moxibustion is meant to apply is specifically described.

G.2 Domain 2.Participants

G.2.1 The guideline development group includes individuals from all relevant professional groups.

G.2.2 The views and preferences of the target population (patients, public, etc.)have been sought.

G.2.3 The target users of the clinical guidelines on acupuncture-moxibustion are clearly defined.

G.3 Domain 3.Rigor of development

G.3.1 Systematic methods were used to search for evidence.

G.3.2 The criteria for selecting the evidence are clearly described.

G.3.3 The methods for evaluating the quality of evidence are clearly described.

G.3.4 The methods for formulating the recommendations are clearly described.

G.3.5 The desirable and undesirable consequences to health benefits, patients' willingness, and health economic factors have been considered in formulating the recommendations.

G.3.6 There is an explicit link between the recommendations and the supporting evidence.

G.3.7 The guideline has been externally reviewed by experts prior to its publication.

G.3.8 A procedure for updating the guideline is provided.

G.4 Domain 4. Clarity of presentation

G.4.1 The recommendations are specific and unambiguous, can present the efficacy characteristics of acupuncture-moxibustion in treating this disease, and clearly present the clinical questions which acupuncture-moxibustion treatment can solve.

G.4.2 The different options or clinical questions are clearly presented.

G.4.3 Key recommendations are easily identifiable.

G.5 Domain 5.Applicability

G.5.1 The guideline describes facilitators and barriers to its application.

G.5.2 The guideline provides advice and/or tools on how the recommendations can be put into practice.

G.5.3 The potential resource and technical feasibility of applying the recommendations have been considered.

G.5.4 The guideline presents monitoring and/or auditing criteria.

G.6 Domain 6.Editorial independence

G.6.1 The views of the funding body have not influenced the content of the guideline.

G.6.2 Conflict of interests of guideline development group members have been recorded and publicized.

Acknowledgements

World Federation of Acupuncture-Moxibustion Societies appreciate all the staff and organizations that contribute to the development of this standard.

Throughout the research and compiling, the main contributors were Xiaodong Wu (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China), Baoyan Liu (China Academy of Chinese Medical Sciences, Beijing, China), Nanqi Zhao (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China), Jingyun Yuan (Beijing University of Chinese Medicine, Beijing, China), and Nan Ding (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China). The following individuals provided study method, approach advice and technical support: Jingsheng Zhao (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China), Yali Liu (Beijing Children's Hospital, Capital Medical University, Beijing, China), Yuqing Zhang (McMaster University, Hamilton, Canada), Longxiang Huang (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China), Yuyang Yang (World Federation of Acupuncture-Moxibustion Societies, Beijing, China), and Chen Yao (Peking University First Hospital, Beijing, China).

Peer review were received from (acknowledged in alphabetical order): Yaolong Chen (Lanzhou University, Lanzhou, China), Yutong Fei (Beijing University of Chinese Medicine, Beijing, China), Yong-Suk Kim (Kyung Hee University, Seoul, South Korea), Jianping Liu (Beijing University of Chinese Medicine, Beijing, China), Jun Xia (University of Nottingham Ningbo, Ningbo, China). Translations were undertaken by (acknowledged in alphabetical order): Yemeng Chen (New York College of Traditional Chinese Medicine, Mineola, New York, the United Stated of America), Jingyuan Liu (World Federation of Acupuncture-Moxibustion Societies, Beijing, China), Huizhu Wang (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China), Min Yu (Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, Beijing, China), and Yuqing Zhang (McMaster University, Hamilton, Canada). The standard was censored and reviewed by the standardization committee of World Federation of Acupuncture-Moxibustion Societies.

The institute of acupuncture and moxibustion (China Academy of Chinese Medical Sciences) provided scientific research platforms and guarantees.

Funding: The standard was financially supported by *National Key Research and Development Program of China* (No.2019YFC1712200).

Reference

[1] GB/T 40972—2021, *Specification of formulation and evaluation for the clinical practice guideline of acupuncture and moxibustion*

[2] ISO/IEC Directives, Part 2, 2018, *Principles and rules for the structure and drafting of ISO and IEC documents*

[3] *WHO Handbook for Guideline Development (2015)*

[4] *Technical Procedure for the 2nd term of the Acupuncture Standardization Committee of World Federation of Acupuncture Societies*

[5] *AMSTAR 2: A critical appraisal tool for systematic reviews that include randomized or non-randomized studies of healthcare interventions, or both*

Website: https://www.bmj.com/content/358/bmj.j4008.long

[6] *Appraisal of Guidelines for Research and Evaluation II (AGREE II)*

Website: http://www.agreetrust.org/

http://www.agreetrust.org/resource-centre/agree-ii-translations/

[7] *RIGHT for Acupuncture: An Extension of the RIGHT Statement for Clinical Practice Guidelines on Acupuncture (RIGHT for Acupuncture)*

Website: http://www.right-statement.org/extensions/12