

如何制定中医 临床实践指南

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二零一四年九月五日

- **标准**是为了在一定范围内获得最佳秩序，经协商一致制定并由公认机构批准，共同使用的和重复使用的一种规范性文件。宜以**科学、技术和经验**的**综合成果为基础**
- 标准在提高医疗水平，传播先进技术、节约医疗资源等方面发挥重要作用
- 由于医药卫生领域得特殊性，除一般标准外，医药卫生领域标准还包括**临床实践指南**、临床路径、药典等形式，它们共同构成了医药卫生标准的主体

什么是 临床实践指南？

临床实践指南 Clinic Practice Guideline

针对特定的临床情况，系统制定出的帮助临床医生和病人做出恰当处理的指导性意见

美国医学研究所(Institute of Medicine, IOM). 1990.

根据制定方法CPG大体可分为

✓ 共识的临床实践指南（ **Consensus based clinical practice guidelines** ）

- 经验丰富临床专家----讨论----对具体临床问题达成一致意见-----形成指南

✓ 循证性临床实践指南（ **Evidence -based clinical practice guidelines** ）

- 临床证据（SR, RCT, Cohort study, Case Report）----评价----对具体临床问题形成有据可依的推荐意见----形成指南

✓ **共识临床实践指南**（**Consensus based clinical practice guidelines**）

- 周期短、操作方便、成本较低
- 主观性较强，缺少达成一致性意见应遵循的客观标准容易产生偏倚

✓ **循证临床实践指南**（**Evidence -based clinical practice guidelines**）

- 科学、客观、集合最新研究成果
- 成本较高（时间、人力），现有临床证据不能解决全部问题

- 国际上许多国家陆续开展了系统的指南制定与传播工作
- 成立了专门的临床实践指南制定机构，进行系统的指南制定、传播及推广工作
- 研究规范指南开发的程序与方法
- 美国、英国最多，其次德国、新西兰、加拿大、荷兰



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NGC is a public resource for evidence-based clinical practice guidelines.

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New This Week

December 09, 2013

New Guideline Summaries

- Congress of Neurological Surgeons
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Announcements

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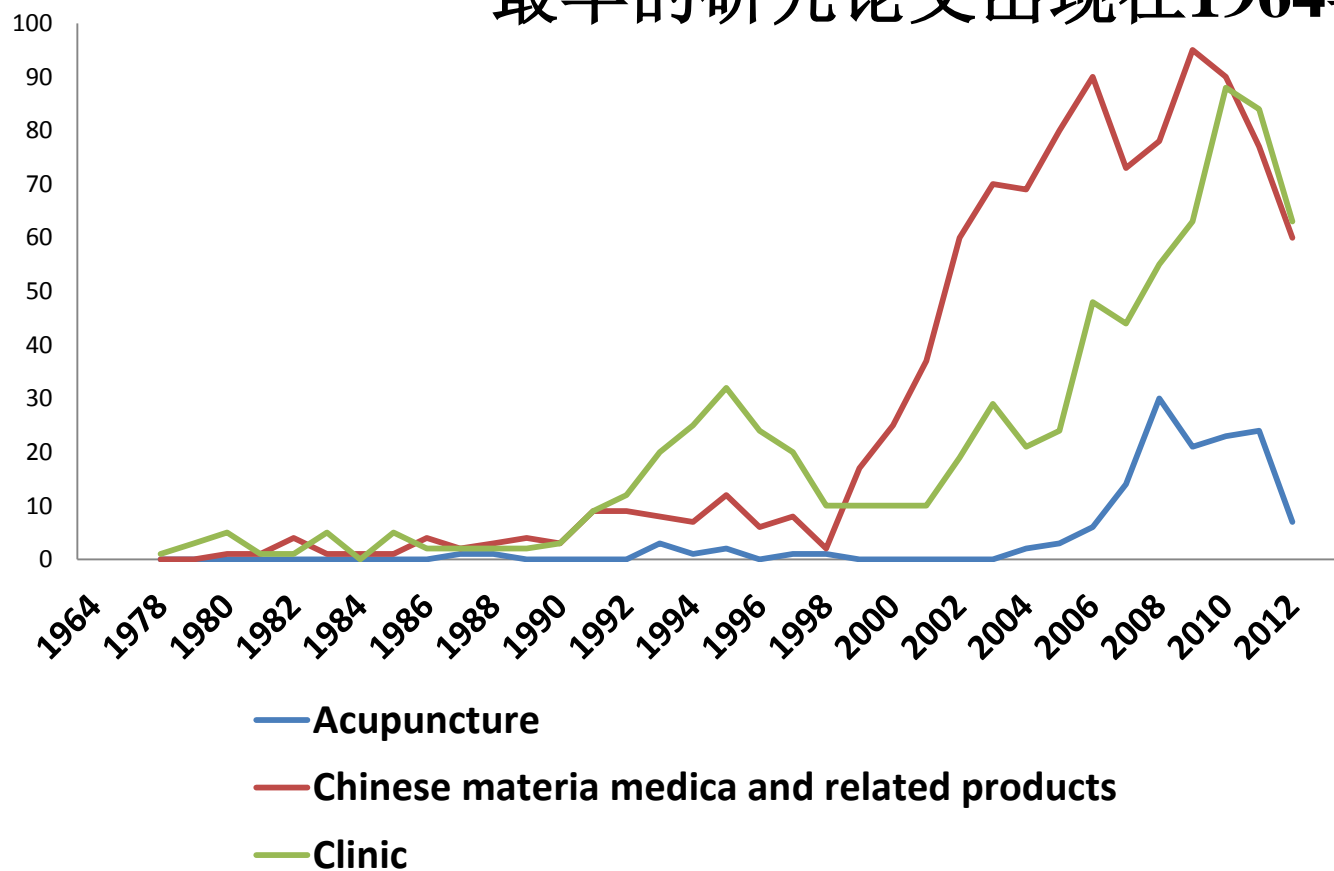
制定临床实践指南 的国际组织和地区举例

中医临床实践指南制定现状

- ✓ 五百余项中医临床实践指南、中医诊疗技术规范（最新统计，中国大陆）
- ✓ 大多数作为行业组织标准
- ✓ 包括内、外、妇、儿、眼、耳鼻喉、肛肠、皮肤、骨伤专科常见病
- ✓ 《中医循证临床实践指南》-----**中医临床实践指南发展的里程碑**

中医药标准、指南相关研究现状

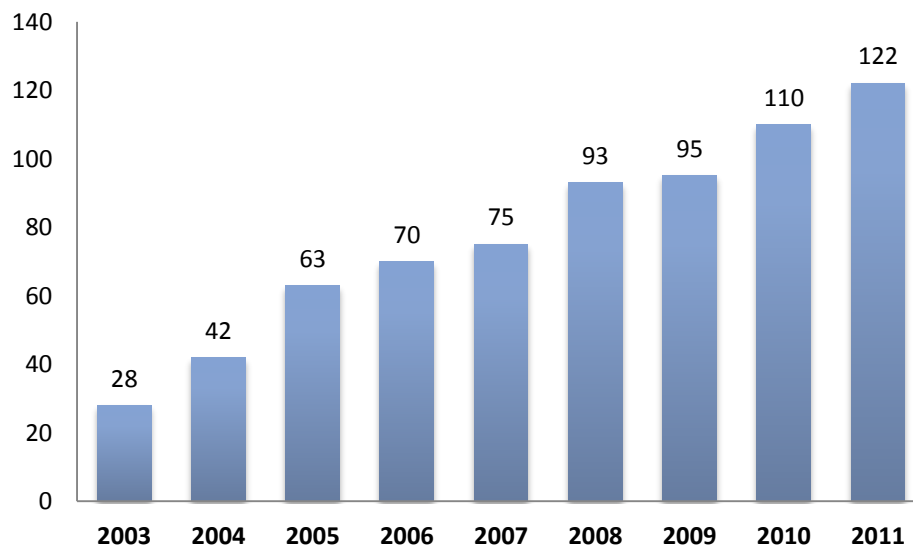
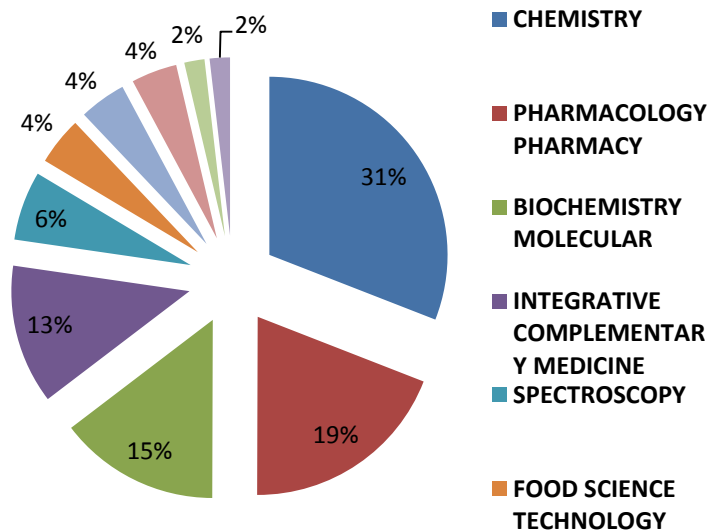
中医药标准、指南研究文章逐年递增，
最早的研究论文出现在1964年



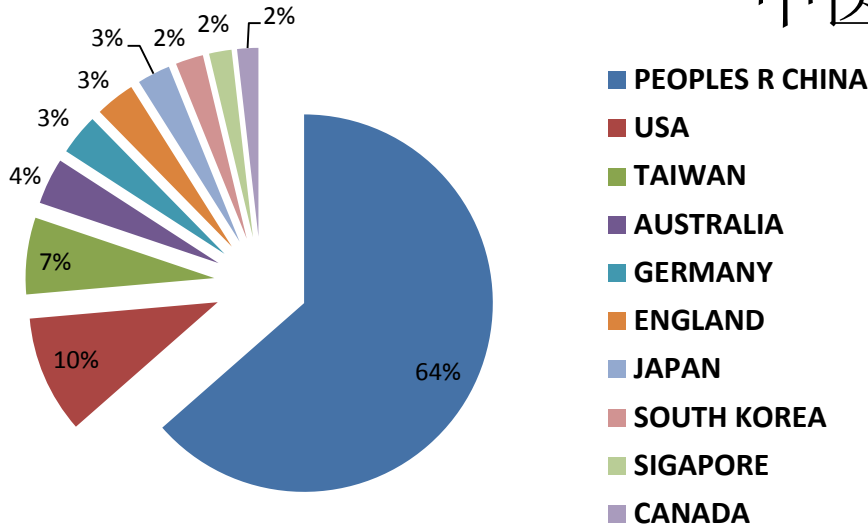
中医药标准、指南研究越来越国际化

SCI数据库中检索到的中医药标准、指南相关的研究论文逐年递增，研究领域不断拓宽

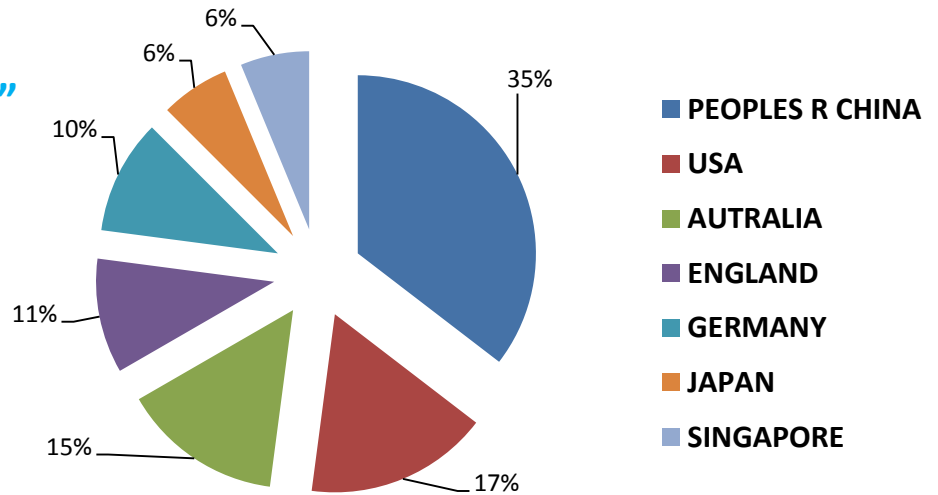
“Standard/guideline and Traditional Chinese medicine”



越来越多的国家和地区参与到中医药标准、指南研究当中



“Standard and Traditional Chinese medicine”

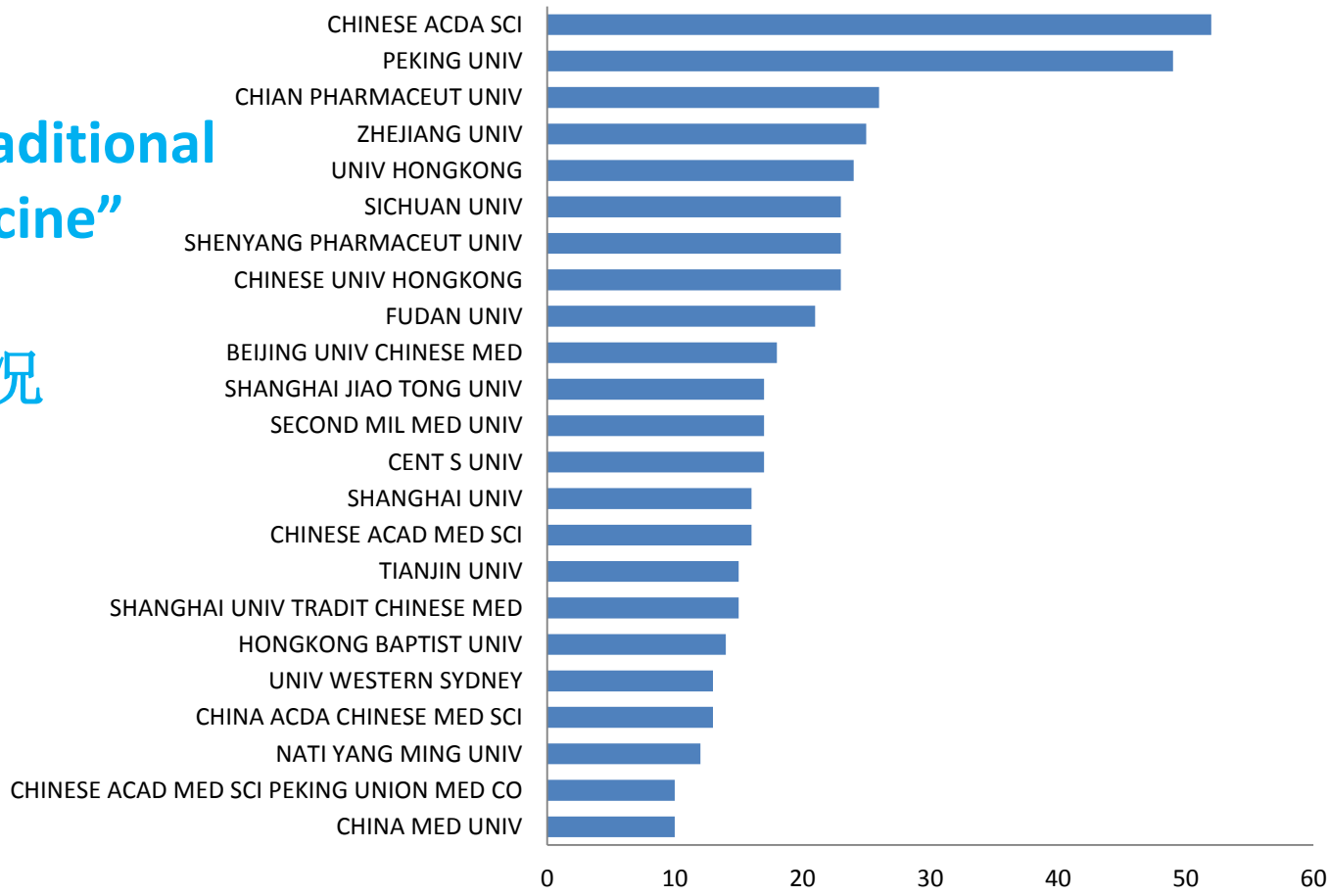


“CPG and Traditional Chinese medicine”

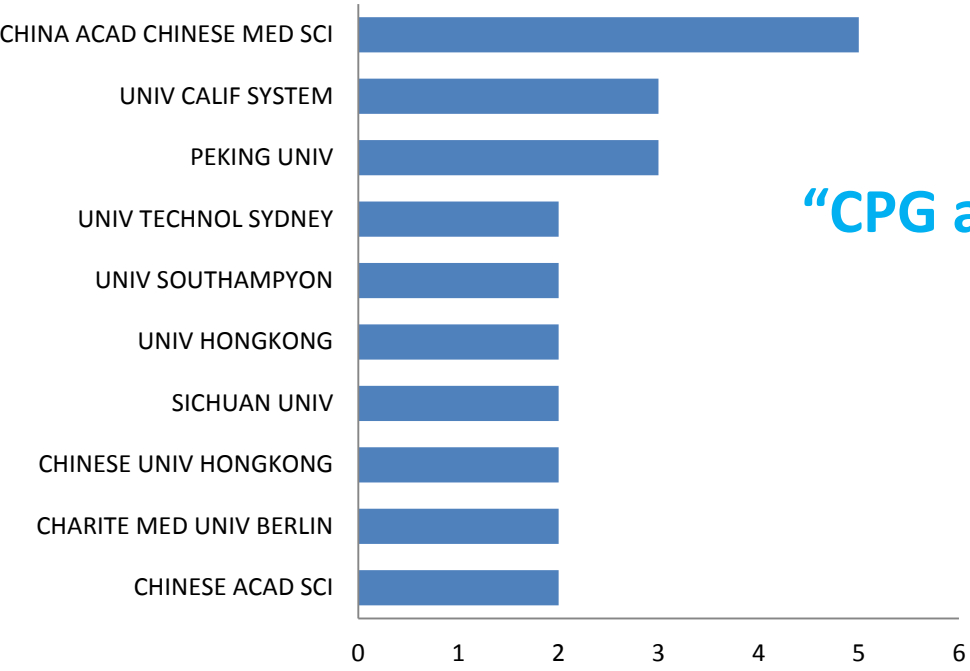
越来越多的研究机构和研究者参与到中医药标准、指南研究当中

“Standard and Traditional Chinese medicine”

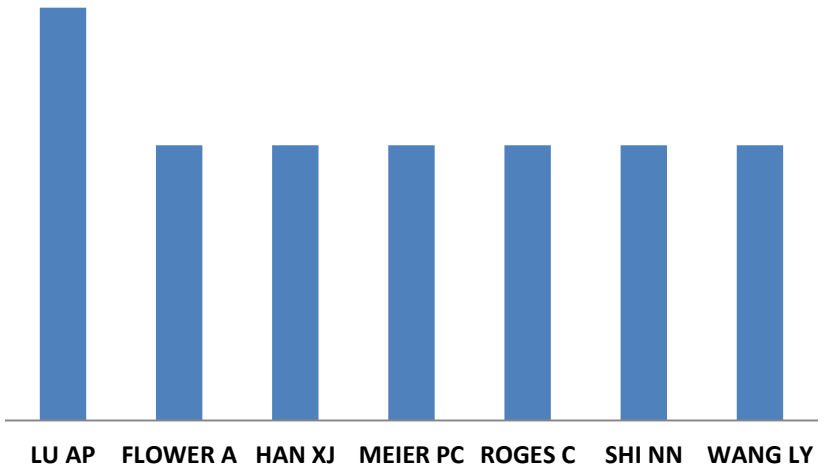
研究机构情况



“CPG and Traditional Chinese medicine”



研究机构



研究者

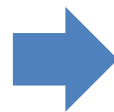
中医药临床实践指南发展存在的问题

- 以专家共识的指南为主，缺少客观性、公正性的中医临床实践指南
- 作为独具特色的传统医学，没有可供直接参考借鉴的的指南制定方法

制定中医临床实践指南的方法

中医临床实践指南的制定方法

循证医学方法
专家共识法
中医标准数据挖掘技术
.....



关键共性技术



指南 标准 共识



- 总结中医指南编制的共性技术
- 建立指南的指南

- 基于专家共识的中医指南

 - 中医内科常见病诊疗指南（132个病种）

- 基于临床证据的中医指南

 - 中医循证临床实践指南（28个病种+5病种针灸指南）



• 基于共识-证据的中医指南

➤ Expert consensus on the treatment of rheumatoid arthritis with Chinese patent medicines (Journal of Alternative and Complementary Medicine 2013 Feb;19(2):111-8)

➤ Expert consensus on the treatment hypertension with Chinese patent Medicine (*Evidence based complementary and alternative medicine* 2013 Apr)

Display Settings: Abstract

Send to:

[Evid Based Complement Alternat Med. 2013;2013:510146. doi: 10.1155/2013/510146. Epub 2013 Apr 3.](#)

Expert consensus on the treatment of hypertension with chinese patent medicines.

Wang LY, Chan KW, Yuwen Y, Shi NN, Han XJ, Lu A

Institute of Basic Research in Clinical Medicine, China Academy of Chinese Medical Sciences, Beijing 100700, China.

Abstract

Objectives. This study was aimed to determine the therapeutic principle and identify Chinese Patent Medicine (CPM) with corresponding indications for hypertension treatment. **Methods.** Three rounds of Delphi survey were mailed among 40 cardiovascular integrative medicine specialists. Items with agreement of more than 80% respondents were included in the consensus. **Results.** According to majority of the panelists, CPM is suitable for most hypertensive patients and should be used according to traditional Chinese medicine pattern classification. CPM could be used alone for grade 1 hypertension and could be used in combination with Western biomedicine (WM) for both grade 2 and grade 3 hypertension. It is recommended that less than two CPMs are used simultaneously. For the treatment of grade 2 and 3 hypertension, CPM and WM should be taken separately. Recommended CPMs included Tianma Gouteng granule, Qiju Dihuang capsule, Jinkui Shenqi pill, Yinxingye tablet, Niu Huang Jiangya pill and Banxia Tianma pill. The indications of 4 CPMs were specified with symptoms related to TCM pattern classification by the experts. **Conclusions.** An expert consensus on CPM application was formed for the treatment of hypertension in the form of integrative medicine. A flow of IM hypertension management was proposed based on the results of the survey.

[J Altern Complement Med. 2013 Feb;19\(2\):111-4. doi: 10.1089/acm.2011.0370. Epub 2012 Aug 8.](#)

Expert consensus on the treatment of rheumatoid arthritis with Chinese patent medicines.

Zhao J, Zhao D, Jiao M, Gao M, Liu L

Institute of Basic Research in Clinical Medicine, China Academy of Traditional Chinese Medicine, Dongchamen, Beijing, China.

Abstract

BACKGROUND: Chinese patent medicines (CPMs) are widely used for the treatment of rheumatoid arthritis (RA) in China and especially by Western biomedical doctors who are not well trained in TCM. Thus, it is important to create a guideline or an expert consensus so that the CPMs are used correctly.

METHODS: The Delphi technique was used to generate the expert consensus. Twenty-eight (28) integrative medicine rheumatologists joined the consensus. A questionnaire regarding the general therapeutic principles, the categories, and the indications for the specific CPMs used for RA treatment was drafted for this study.

RESULTS: More than 80% of the experts agreed on the following therapeutic principles: CPM could be used to treat all patients with RA (82.10%), CPM should be used under the guidance of Traditional Chinese Medicine (TCM) (100%), and CPM could be used for active RA treatment in combination with Western medicine (WM) (85.71%), but could be used alone (92.86%) for the treatment of inactive RA. In addition, CPM and WM should be taken separately (82.14%), although the CPM could reduce the side-effects of the WMs if used in combination with CPM (96.43%). For the treatment of active RA, the CPMs were recommended by more than 50% of the experts included the Leigongting Duogan tablets (85.7%), Zhongxing Dingtongling tablets (64.3%), and Simiao pills (53.6%). Alternatively, for the treatment of inactive RA, Duzuo Jisheng mixture (71.4%), Yishen Juanshi pills (53.6%), and Wangbu electrolyte (50.0%) were recommended. Total paeonin glucoside capsules were recommended for the active (50.0%) and inactive RA (64.3%) treatment. The indications of each CPM were specified according to the symptoms related to the TCM pattern classification.

CONCLUSIONS: This expert consensus regarding the treatment of RA with various CPMs was formed to aid WM doctors in the correct use of CPMs.

香港中医临床实践指南现状

- 已经启动制定工作

- 第一批选择三个常见疾病

不寐_{失眠} 中风_{脑梗塞} 胃脘痛/ 胃痞/ 胃脘_{慢性胃炎}

- 香港医院管理局资助

香港浸会大学承担研究工作

研究方法

临床证据、数据支持、专家共识

已有中医指南质量评价



筛选高质量指南内容

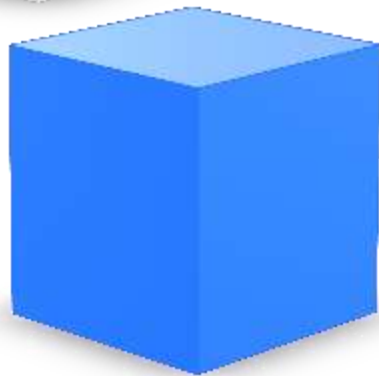
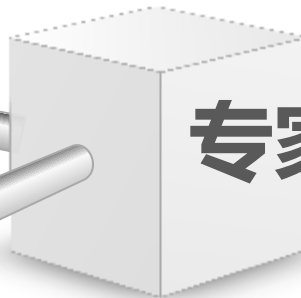


香港适用性评价



- 地域特点
- 诊疗环境
- 法律法规

专家共识



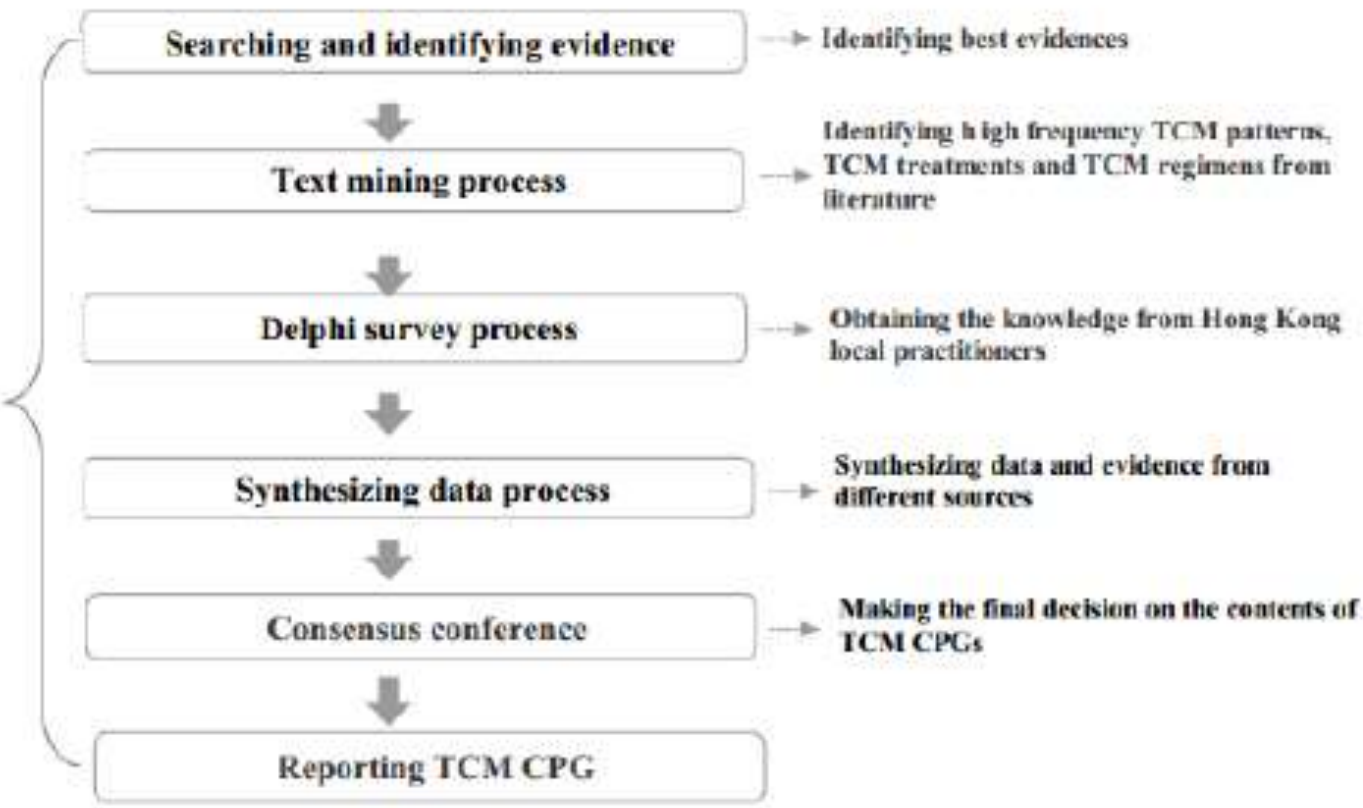
形成中医指南

Phase 1: Preparation

Establishment of steering committee and panel



Phase 2: Development



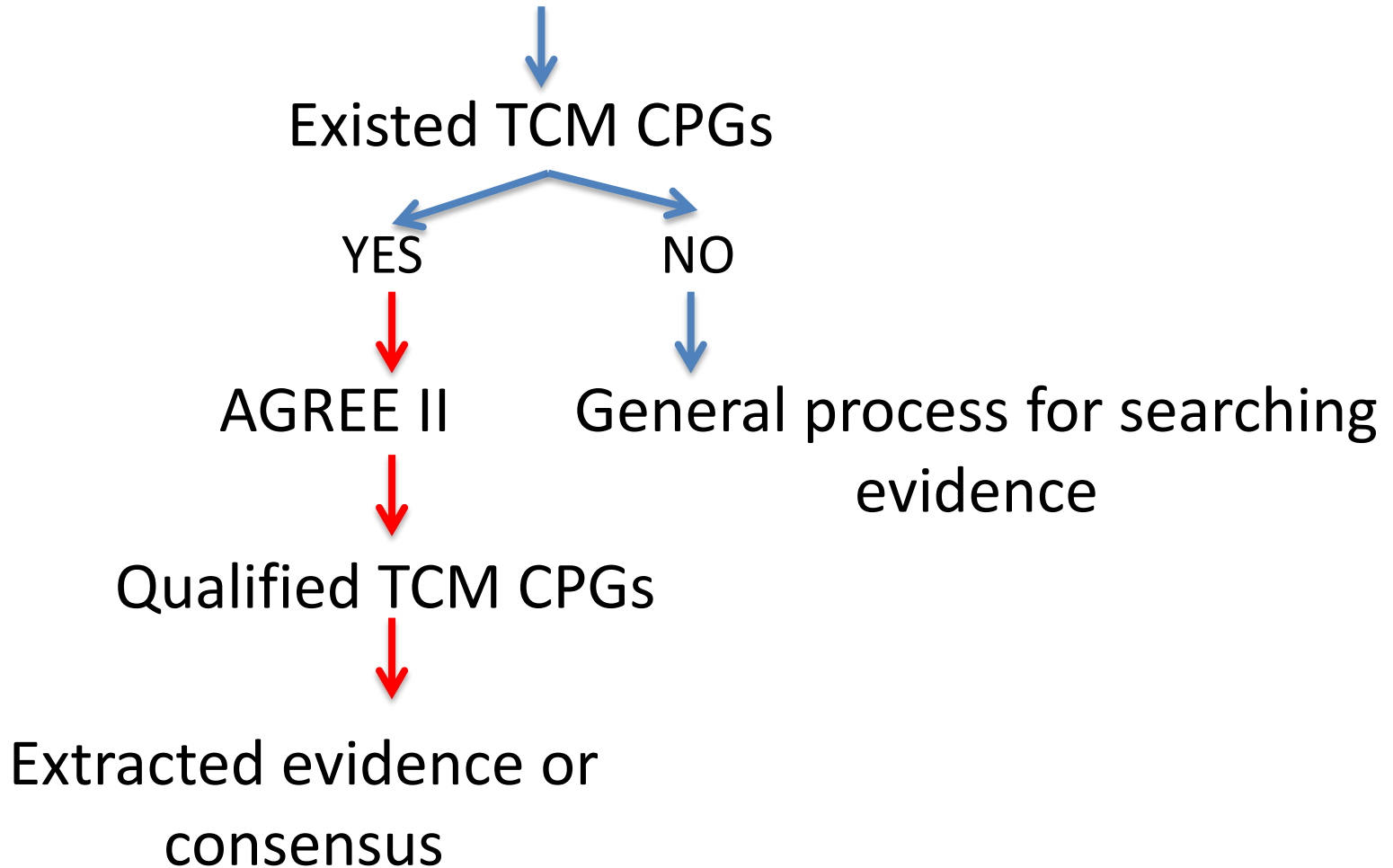
Phase 3: Finalization

Publication, Dissemination, Implementation and Updating



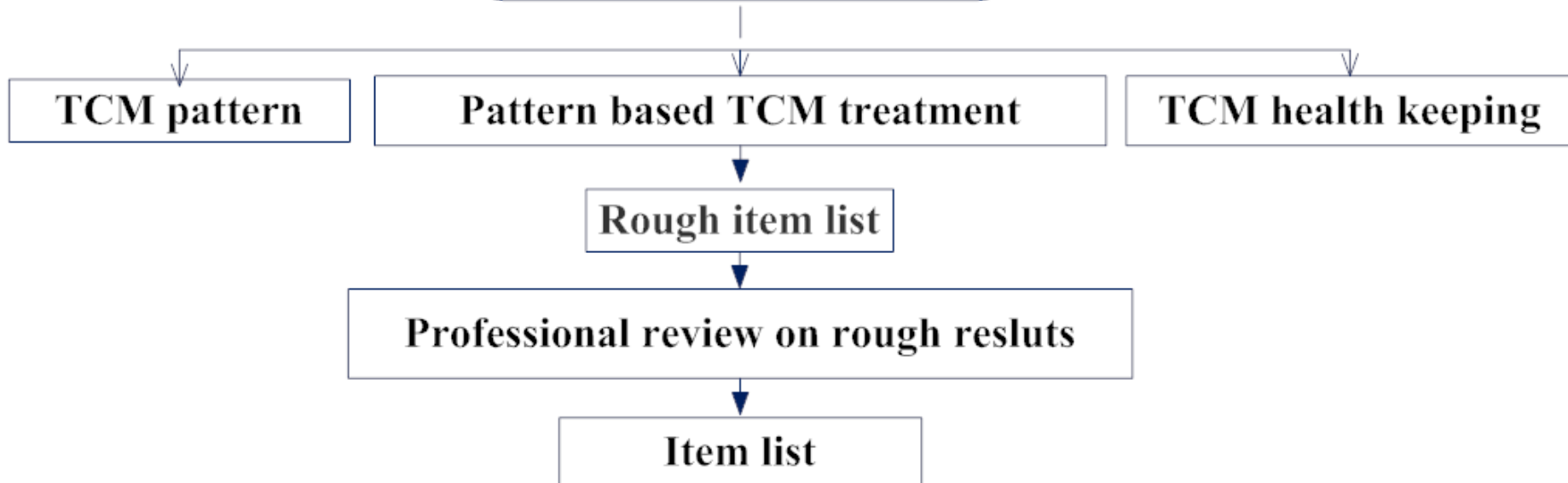
Step 1

Searching and identifying for evidence



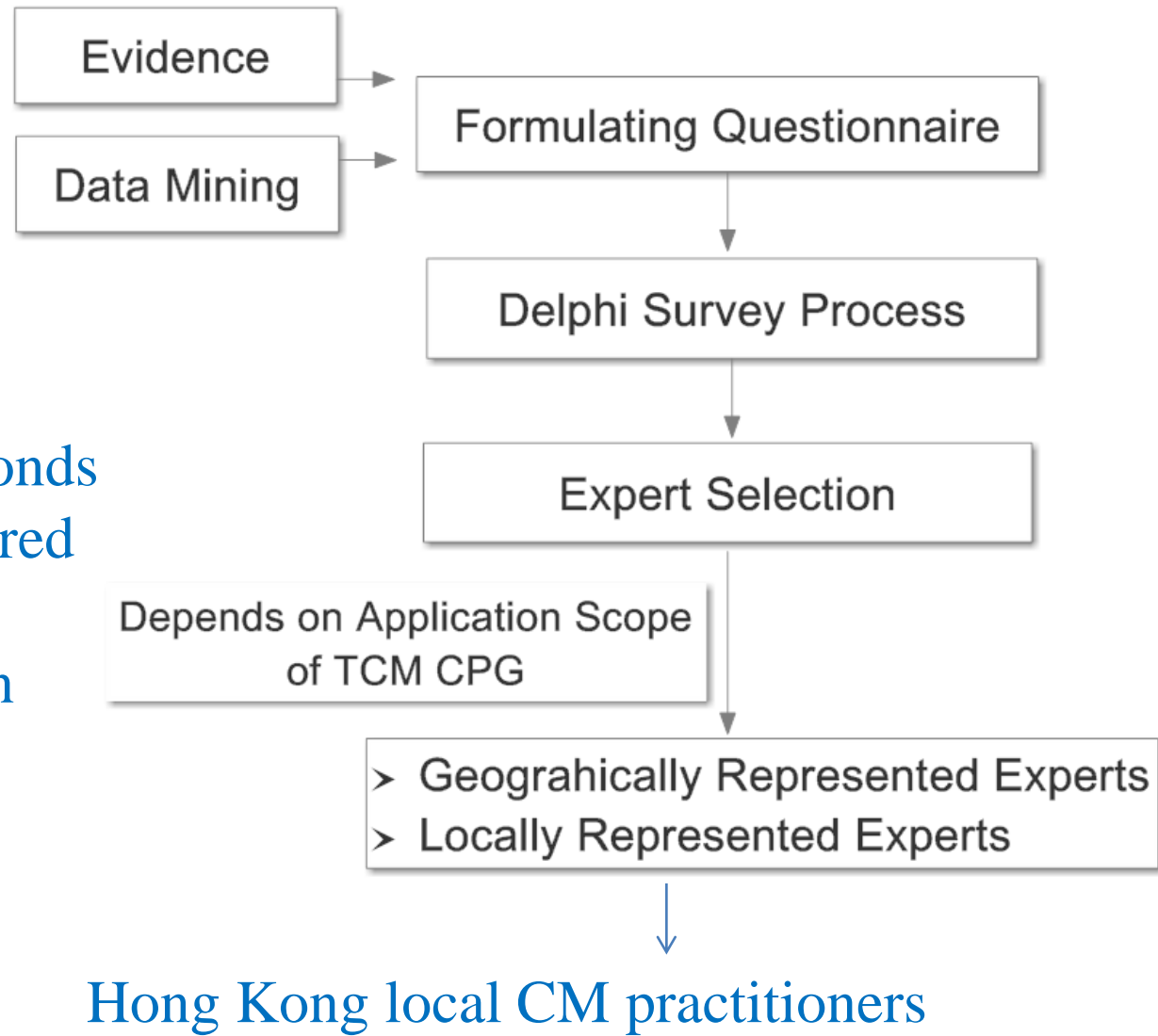
Step 2

Runing data mining process



Step 3

- 1st round: formed questionnaires; 33-34 responds pre disease; synthesis of data
- 2nd round: 21-23 responds pre disease; HK Registered Chinese Medicine practitioners Association
- Rounds depends on consensus



Step 4

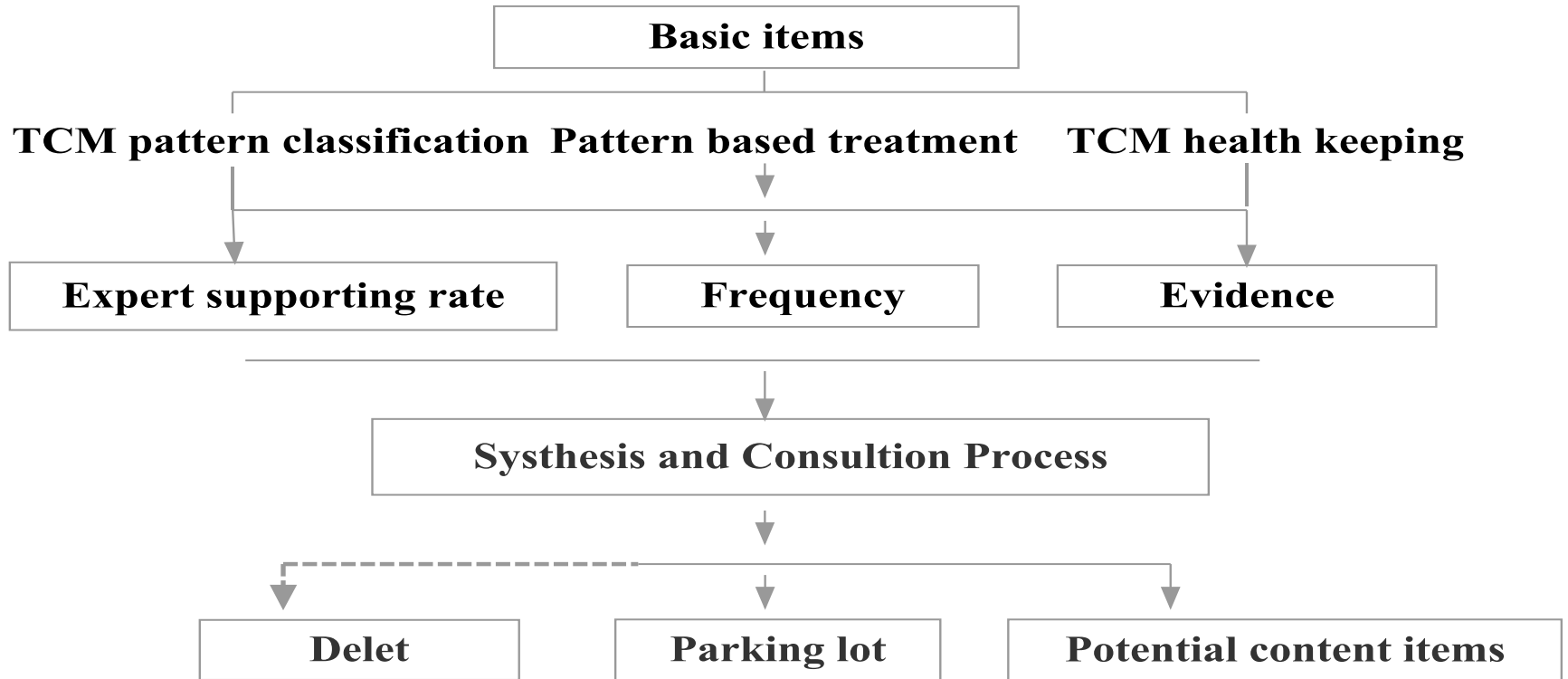


Table 2 Matrix Table for Synthesizing Data of TCM Pattern

Pattern items from DM	Pattern 1	Pattern2	Pattern3	Pattern N
Frequency in Research Literature					
Supported by level of evidence					

Table 3 Matrix Table for Synthesizing Data of TCM Treatment-Formula

N	TCM Pattern	Formula from DM	Supported by level of evidence	Support by local practitioner	Frequency in Research Literature	Synthesis
1		Formula 1				Select/Reject

Table 4 Matrix Table for Synthesizing Data of TCM Treatment-Acupuncture

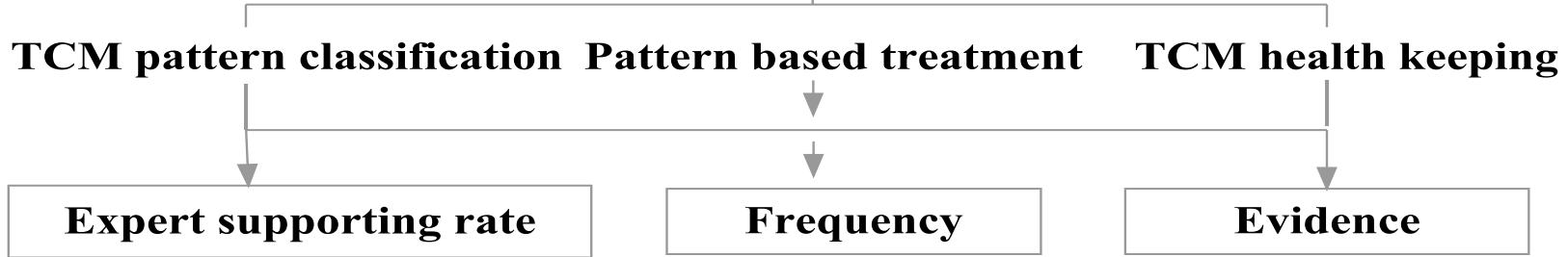
Pattern items from DM	Acupoint 1	Acupoint 2	Acupoint 3	Acupoint N
Frequency in Research Literature					

Table 5 Matrix Table for Synthesizing Data of TCM Health Keeping

Supp	Pattern items from DM	Item 1	Item 2	Item 3	Item N
Supp	Frequency in Research Literature					
	Supported by level of evidence					
	Supported by local practitioner					
	Synthesis	Select/Reject

Step 4

Basic items



Systhesis and Consultion Process



Experts Consensus Conference: Final Decision

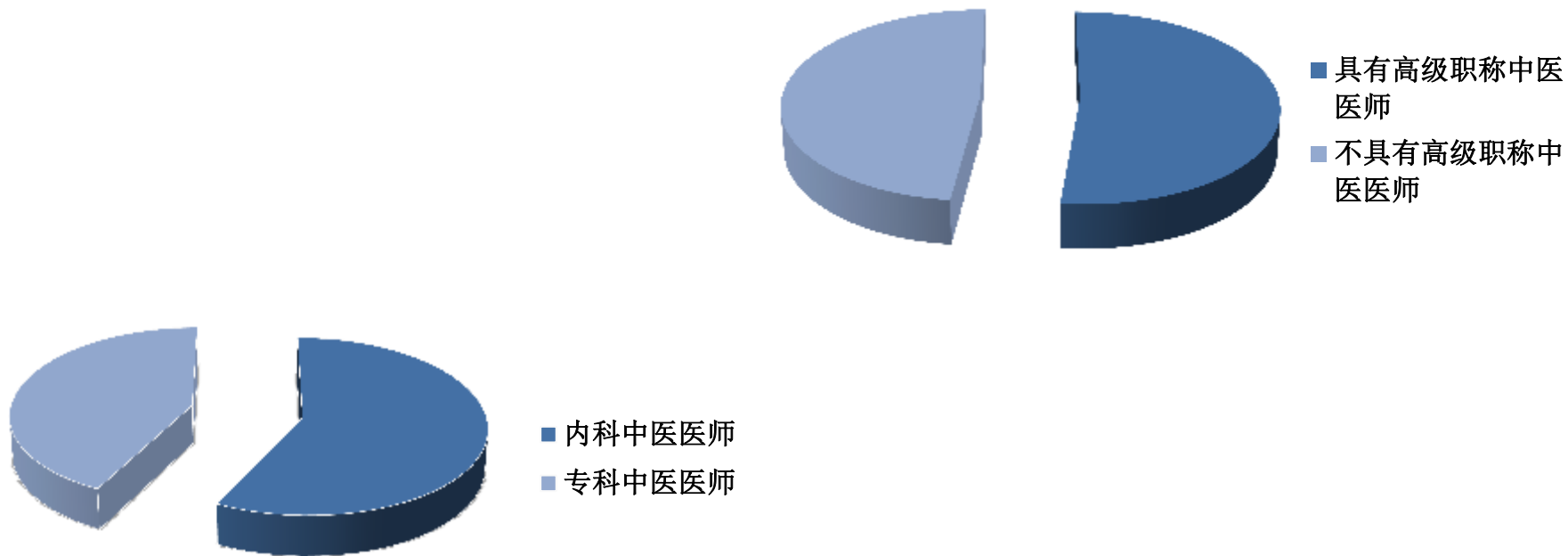
中医临床实践指南评价及修订

- 国家中医药管理局批准成立了第一批中医药标准研究推广基地（试点）建设单位42家
- 妇科、儿科、眼科、耳鼻喉科、肛肠科、肿瘤科、皮肤科9个学科
- 353个中医临床诊疗指南
- 4495一线中医师参与

- 2012年度中医诊疗指南评价项目
- 2013年度公共卫生专项资金中医临床诊疗指南应用评价项目

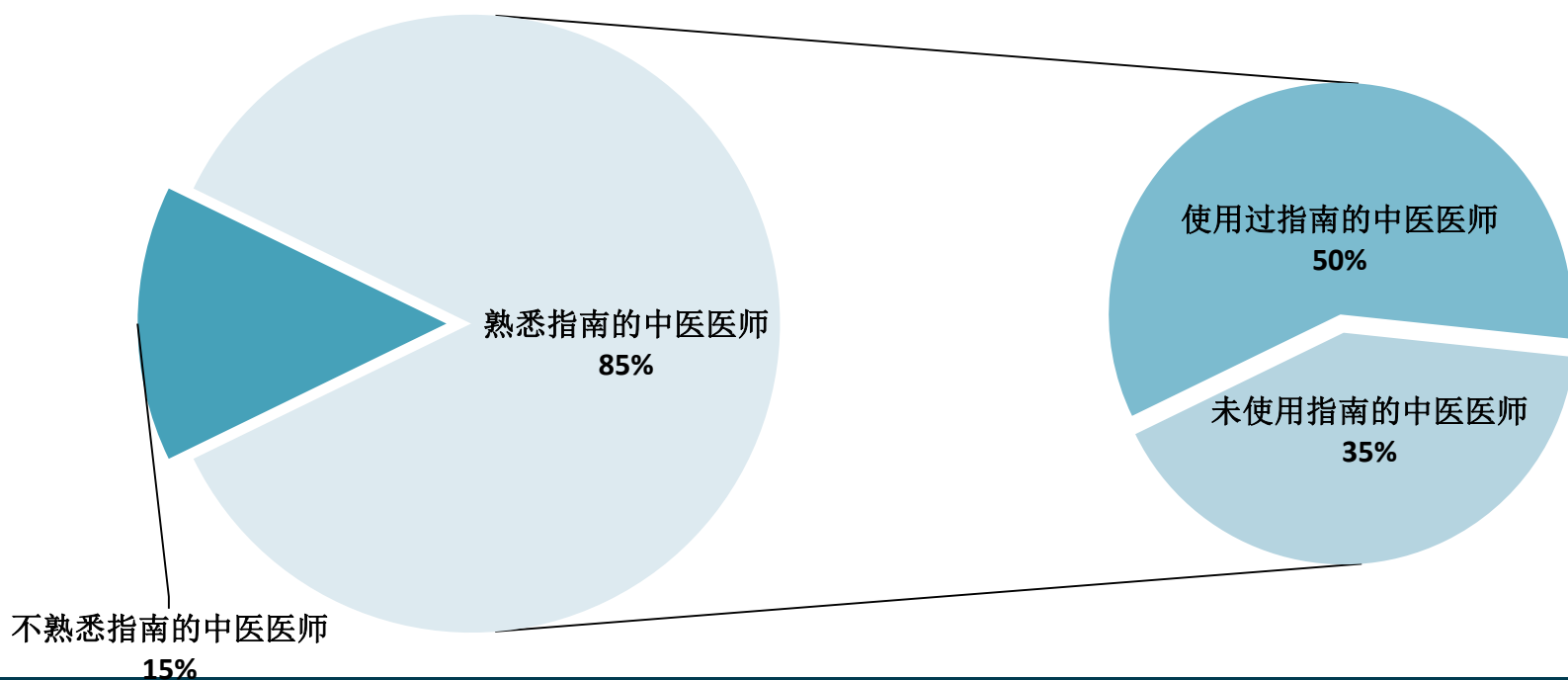


4495名中医医师基本情况

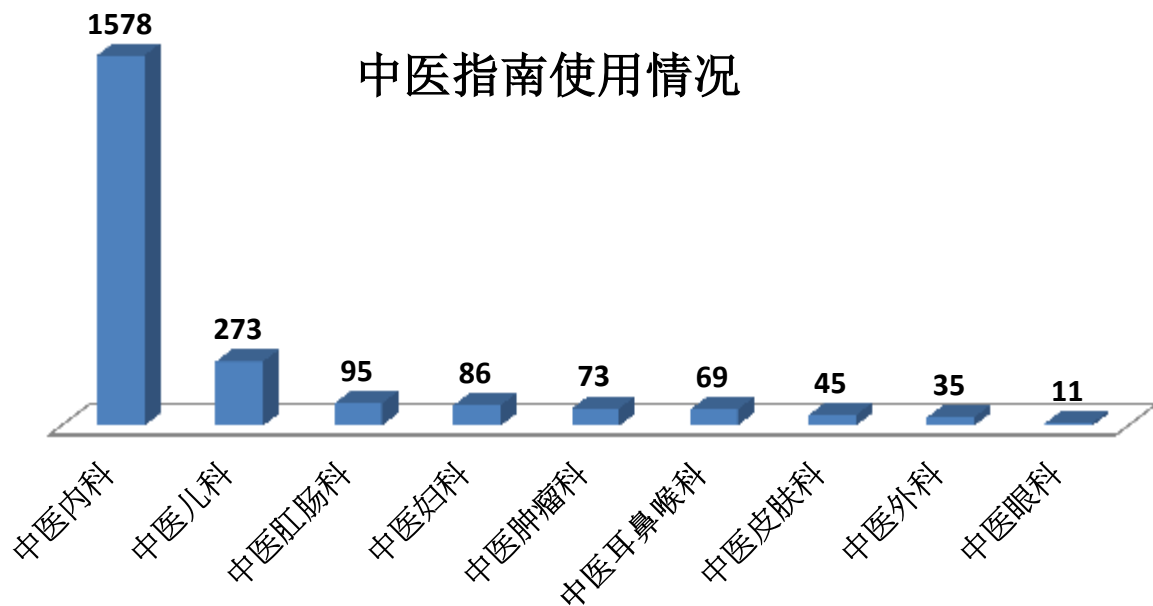


4495名中医医师使用中医临床实践指南的情况调查

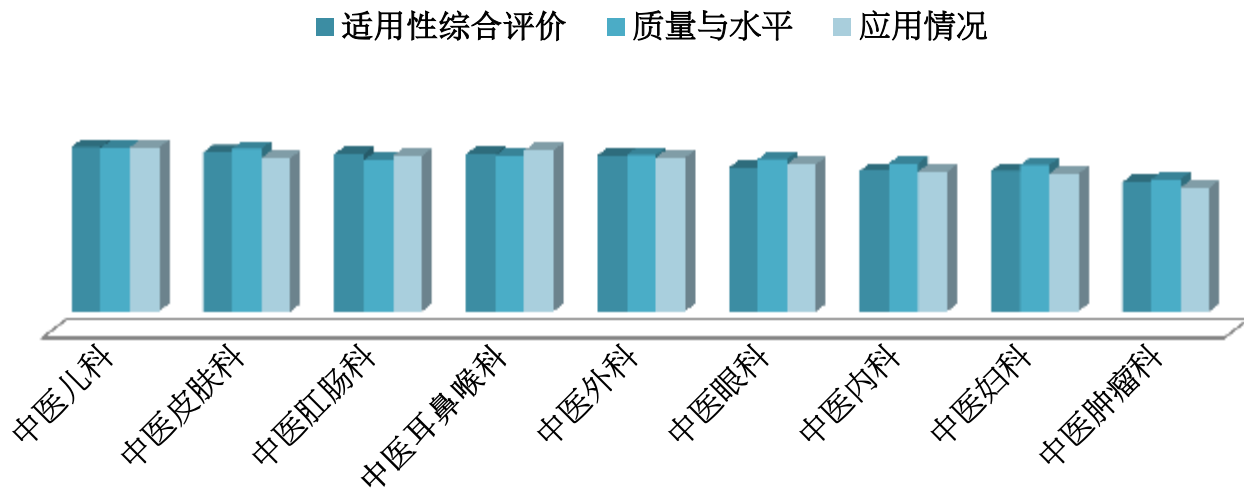
- 对于中医诊疗指南的综合评分为68.90%
- 整体评价指南质量水平，得分为71.32%
- 对于中医诊疗指南的综合评分为68.90%



中医指南使用情况



中医指南总体质量水平



- 中医指南质量和使用情况尚佳
- 但有些学科不够成熟，循证证据少，专家少，中医指南学科间发展不平衡，需要加强
- 中医指南的应用与评价对指南的修订和完善有重要指导作用