General Psychiatry

Protocol for the development of clinical guidelines for the management of chronic primary pain

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INTRODUCTION

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage. In 2018, the World Health Organization (WHO) revised the International Classification of Diseases, 11th Revision (ICD-11) to include chronic pain as an independent disease for the first time (MG30.0).[1] At the same time, the ICD-11 also developed new classifications for chronic pain, including chronic primary pain (CPP), chronic cancer-related pain, chronic post-surgical or post-traumatic pain, chronic secondary musculoskeletal pain, chronic secondary visceral pain, chronic neuropathic pain and chronic secondary headache or orofacial pain.[1] Among these pain variants, the prevalence of CPP is high, and the course of the disease is prolonged, seriously influencing the life and social function of individuals suffering from it.[2] Most of the current pain guidelines address only cancer pain. The National Institute for Health and Clinical Excellence does offer guidelines for chronic pain as a whole, including primary and secondary pain. But the ICD-11 separates primary and secondary chronic pain as independent units,which indicates the necessity of developing different treatment for these two types of chronic pain.Thus, clear clinical practice guidelines for the treatment and management of CPP are lacking. Under the cooperation of the Drug Dependence Group, the psychiatry branch of the Chinese Psychiatrist Association, the pain branch of the Chinese Medical Doctors Association, the mental health branch of the China Narcotics Association and the psychiatry branch of the Shanghai Medical Association, experts from psychiatry, neurology, neurosurgery, pain medicine, anaesthesiology, evidence-based medicine, economics and other disciplines plan to summarise evidence-based recommendations on the treatment and management of CPP and construct clinical management guidelines for clinical decision-making.

Extensive research has emphasised the importance of guideline protocols.[3] Rigorous protocols can ensure an efficient, smooth guideline development process and guarantee the duties and responsibilities of the working group members.[4 5] This protocol aims to provide clear guidance for the development of the CPP guidelines and improve transparency. We summarise here the process of recruiting working group members, the collection and selection of clinical problems, the review of published data, and the formation of recommendations. In addition, we add information regarding the external review, publication, dissemination and implementation of these guidelines.

METHODOLOGY

According to ICD-11, CPP is defined as chronic pain in one or more organs, characterised by significant emotional abnormalities (eg, anxiety, anger/frustration or depressed mood) or dysfunction (eg, impaired daily activities and reduced social involvement).[6] The new guidelines refer to the following references: (1) 'Guiding principles for the formulation/revision of clinical diagnosis and treatment guidelines in China (2022 edition)'[7]; (2) 'Methodology for clinical practice guidelines—writing and presenting guideline recommendations'[4]; (3) 'Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise'[5]; and (4) 'The Reporting Tool for Practice Guideline in Healthcare (RIGHT) statement.'[8] A detailed progression of the guidelines' development is shown in figure 1.

Initiators and participants in the guidelines' development

Development of these guidelines was jointly initiated by :

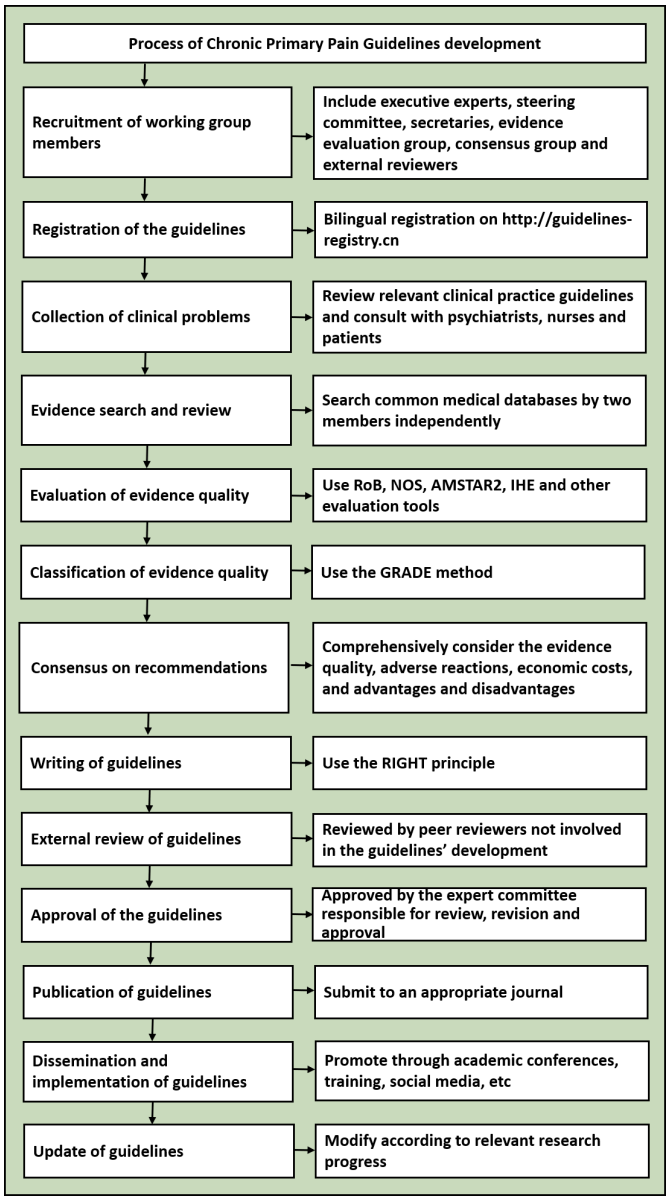

Figure 1 The protocol progression for the development of the clinical guidelines for the management of chronic primary pain. AMSTAR2, Measurement Tool to Assess Systematic Reviews 2; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; IHE, Institute of Health Economics; NOS, Newcastle-Ottawa Scale; RIGHT, Reporting Tool for Practice Guideline in Healthcare; RoB, risk of bias.

-The drug dependence group of the Chinese Psychiatrist Association;
-The pain branch of the Chinese Medical Doctors Association;
-The mental health branch of the China Narcotics Association;
-The psychiatry branch of the Shanghai Medical Association;
-Shanghai Mental Health Center;
-Renji Hospital Affiliated to Shanghai Jiao Tong University School of Medicine;
-Shanghai Jiao Tong University School of Medicine;
-Ningbo University of Nottingham;
-School of Basic Medicine of Lanzhou University;
-The Second Xiangya Hospital of Central South University;
-The Sixth Hospital of Peking University;
-The National Institute on Drug Dependence Affiliated to Peking University;
-Zhongda Hospital Affiliated to Southeast University;
-Renmin Hospital of Wuhan University;
-The Affiliated Brain Hospital of Guangzhou Medical University;
-Hangzhou Seventh People's Hospital, West China Hospital Sichuan University;
-Wuhan Mental Health Center;
-China–Japan Friendship Hospital;
-The Second Affiliated Hospital of Xinxiang Medical College;
-Shanghai Fourth People's Hospital;
-Shanghai Sixth People's Hospital;
-Huadong Hospital Affiliated to Fudan University ;
-Zhongshan Hospital, Fudan University Shanghai Cancer Hospital;
-Other units participated in the guideline development.

Working groups

The creation of the working groups has referred to previous practice guidelines and has been adjusted according to the needs of these current guidelines.[9] Six working groups have been formed: executive experts, steering committee, secretary group, evidence evaluation group, consensus group and external review group. The specific duties and responsibilities of each group are shown in table 1.

Registration of the guidelines

These guidelines have been registered in the International Practice Guideline Registry Platform (http://guideline-registry.cn).

Management of conflicts of interest

Before participating in the development of the guidelines, all the working group members are required to declare any potential conflicts of interest. The secretary group will collate the declaration of conflicts of interest, which will then be reviewed and judged by executive experts. If there is no conflict of interest, group members can participate in the entire process of the guideline development. If a group member has any conflicts of interest, they will be discussed by executive experts to determine the individual's degree of participation.

Scope of the guidelines

These guidelines cover the clinical issues related to symptom assessment and the pharmacological and non-pharmacological management of CPP. The users of these guidelines will include clinicians, nurses, psychotherapists and rehabilitation therapists in psychiatry, neurology, neurosurgery, pain medicine and anaesthesiology at all levels of medical institutions. The target population for

Table 1 Composition and responsibility of the working groups

Working groups	Composition	Duties and responsibilities
Executive experts	1-2 executive clinical experts and 1-2 executive experts on guideline methodology	1. The executive clinical experts are the overall directors of the guidelines and are responsible for their content. 2. The executive experts on guideline methodology are responsible for the top-level design, quality control of the entire process and the methodology of the guidelines. 3. The executive experts will manage conflicts of interest for members of the working groups.
Steering committee	10–20 experts, including senior clinical experts, guideline methodology experts and other personnel	1. Set up the working groups. 2. Approve the development of the guidelines' protocol. 3. Guide and identify the applicable population, topics and scope of the guidelines. 4. Guide and supervise the methodology and procedures for the development of the guidelines. 5. Guide and supervise the evidence search, evaluate and form evidence summaries. 6. Review and revise the full text of the guidelines and external review opinions. 7. Approve the publication of guidelines.
Secretary group	3-5 members, including clinicians and guideline methodology experts	1. Draft the guidelines' protocol and complete the guidelines' registration. 2. Investigate and survey the clinical problems. 3. Organise meetings during the development of guidelines. 4. Coordinate the external review of the guidelines. 5. Document the entire process of guideline development. 6. Coordinate all other related issues. 7. Draft the guidelines' manuscript. 8. Submit the guidelines.
Evidence evaluation group	5–10 people with experience in evidence-based medicine and evidence review	1. Complete the evidence search, selection and classification. 2. Draft a summary of the evidence and create a decision table based on the recommendations. 3. Assist the secretary group during the development of guidelines.
Consensus group	10–30 multidisciplinary experts, including clinicians, psychotherapists, nurses and economists	1. Vote to reach a consensus on the recommendations. 2. Evaluate the comprehensibility of the recommendations. 3. Finalise the full text of the guidelines.
External review group	3-5 peer experts who did not directly participate in the development of these guidelines	1. Review the final guidelines to ensure their scientific rigor, clarity and fairness. 2. Report revised opinions and suggestions to the secretary group.

the CPP guidelines is people who are affected by CPP (age ≥16 years) .

Collection of clinical problems

According to our plan, we will collect clinical questions through the following two methods: (1) literature review: existing guidelines or literature on CPP will be reviewed to analyse relevant clinical issues and their recommendations to form a list of questions, and (2) clinician consultation: a questionnaire will be used to collect a list of possible clinician concerns in psychiatry, neurology, neurosurgery, pain medicine, anaesthesiology and other disciplines.

After summarising the list of clinical problems, experts in psychiatry, neurology, neurosurgery, pain medicine, anaesthesiology and other fields will be invited to conduct two to three rounds of the Delphi method to reach a consensus.

First, the importance of the proposed clinical questions will be scored by the expert group. A 5-point scale is scored by this measure: "Is this question necessary for forming recommendations in the guidelines?';

1 to 5 points, respectively, indicate 'extra unnecessary', 'unnecessary', 'neutral', 'necessary' and 'extra necessary'. Experts can also add other clinical questions. According to the score of each item in the first round, clinical questions with an average score less than 3 or a coefficient of variation greater than 30% will be deleted, and newly collected items will be added. In the following rounds, the questionnaire will be designed according to the results of the previous round, and the items with an average score greater than or equal to 3 and a coefficient of variation less than 15% will be included in the guidelines.

Data search and selection

The guidelines will deconstruct the final questions according to the principles of population, intervention, comparison and outcome and formulate corresponding search strategies. The same search strategies will be used by all members of the evidence evaluation group under the guidance of the steering committee. The searches concentrating on clinical practice guidelines, expert consensus, systematic reviews and meta-analyses, randomised controlled trials (RCTs), cohort studies, case-control studies, case series, and case reports will utilise Chinese databases–China National Knowledge Infrastructure, Wanfang Database, Chongqing VIP and Chinese Biomedical Literature Database, and English databases–MEDLINE (via PubMed), Web of Science, Embase and Cochrane Library. Searches focusing on clinical practice guidelines and expert consensus will search guideline publishing platforms or databases, including the WHO, Guideline International Network, the National Institute for Health and Care Excellence, the Scottish Intercollegiate Guideline Network, the Chinese Medical Ace Base, the Canadian Medical Association Clinical Practice Guidelines InfoBase, the Australian Clinical Practice Guideline, the New Zealand Guideline Group, and the Medical Information Network Distribution Service and Emergency Care Research Institute.[10] Evidence-based medicine reviews will be searched, such as Dyna Med, UpToDate and BMJ Best Practice.[11] Finally, a supplementary search on Baidu Academic, Google Academic and the official websites of authoritative organisations/institutions will be also conducted. The search time is limited from the establishment of these databases to the present.

Evaluation of evidence quality

Evidence quality evaluation tools will be consistent with the type of evidence. For example, the Cochrane risk of bias (RoB) tool will be used in RCTs[12]; the Newcastle-Ottawa Scale will be used in observational studies[13]; and the assessment of multiple systematic reviews 2 (AMSTAR 2) scale will be used for systematic reviews.[14] Meanwhile, case reports will be evaluated by quality appraisal tool for case series studies using a modified Delphi technique developed by the Canadian Institute of Health Economics.[15] Evidence quality will be evaluated by two members independently at the same time, and the disputes will be resolved by consulting a third researcher.

Evidence may be obtained from two principal sources: scientific evidence and opinion-based evidence. There will be two categories of scientific evidence: category 1, RCTs reporting comparative findings between clinical interventions for specified outcomes, and category 2, observational studies or RCTs without pertinent comparison groups that may permit the inference of beneficial or harmful relations among clinical interventions and clinical outcomes. Opinion-based evidence will include expert opinion, survey data, internet-based comments, letters, editorials, and so on.

Grading of evidence quality

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool will be used to grade the evidence quality of quantitative systematic reviews.[16] Evidence-based RCTs will be considered high quality and evidence-based observational studies will be considered low quality. However, these initial quality grades can be adjusted. Five factors may reduce the quality of evidence: RoB, inconsistency, indirectness, imprecision and publication bias. Three factors may increase the quality of evidence: effect size, dose–response and all possible remaining confounders. According to the aforementioned factors, the quality of evidence will be classified into four levels: high, medium, low and extra low.

Formation of a consensus on recommendations

After grading the evidence quality, the members of the evidence evaluation group will organise all the evidence for each clinical problem, clearly present the type of research and the quality of evidence, and form a detailed summary of the evidence, combined with the values and preferences of people who are affected by CPP, economic costs and the balance of advantages and disadvantages to form the preliminary recommendations and corresponding evidence. The consensus group members will reach a consensus on recommendations after two to three rounds of the Delphi method. Each recommendation will be classified according to the Delphi survey level of consensus. If the consensus level is greater than or equal to 70%, a consensus will be reached on this recommendation. If the consensus level is less than 70%, the recommendation will be deleted or revised by the steering committee. If the consensus level on the revised recommendation is greater than or equal to 70%, the recommendation can be written into the guidelines, and the corresponding recommendation classification is marked.

Writing and external review of the guidelines

The secretary group will write the first draft of the guidelines in strict accordance with the format of RIGHT.[8] The draft will then be submitted to the experts of the external review group for review and feedback. The secretary and the evidence evaluation groups will revise the first draft based on the opinions of external experts.

Publication of the guidelines

The steering committee shall review and polish the final draft of the guideline. The entire revision process will be documented by the secretary group. After approving the final draft of the guidelines, the secretary group will submit the manuscript for publication in an appropriate journal.

Dissemination and implementation of the guidelines

After the publication of the guidelines, each working group will continue the dissemination and promotion of the guidelines: (1) introduce and disseminate the guidelines at relevant domestic and international academic conferences; (2) organise nationwide training for clinicians, nurses, psychological therapists and rehabilitation therapists in neurology, neurosurgery, pain medicine and anaesthesiology; (3) write articles related to these guidelines for journal publications; (4) simplify guidelines in a format suitable for newspapers and manuals; and (5) publicise the guidelines on major medical websites and popular science platforms in China.

Update of the guideline

To ensure the applicability and advancement of these guidelines, they will be updated according to the latest evidence. The update process will refer to the corresponding update methods and procedures.

SUMMARY

The clinical guidelines for the management of CPP are being jointly developed by experts from psychiatry, neurology, neurosurgery, pain medicine, anaesthesiology and other disciplines. Evidence-based medicine research is being conducted in strict accordance with the 'Guiding principles for the formulation/revision of clinical diagnosis and treatment guideline in China (2022 edition)',[7] 'Methodology for clinical practice guideline—writing and presenting guideline recommendations',[4] the RIGHT statement[8] and the GRADE method.[16] These guidelines will further standardise the clinical management of people with CPP and will guide the development of clinical work.

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