European Journal of Integrative Medicine 8 (2016) 905–915

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim

Research paper

# Preferred Reporting Items for the Development of Evidence-based Clinical Practice Guidelines in Traditional Medicine (PRIDE-CPG-TM): Explanation and elaboration☆

Jiae Choi[a], Tae-Young Choi[a], Ji Hee Jun[a], Ju Ah Lee[b], Myeong Soo Lee[a,*]

[a] Clinical Research Division, Korea Institute of Oriental Medicine, Daejeon 34054, Republic of Korea
[b] KM Fundamental Research Division, Korea Institute of Oriental Medicine, Daejeon 34054, Republic of Korea

ARTICLE INFO

*Article history:*
Received 30 March 2016
Received in revised form 28 July 2016
Accepted 28 July 2016

*Keywords:*
Traditional medicine
Clinical practice guidelines
Reporting items
Evidence based medicine

ABSTRACT

*Introduction:* The development of evidence-based clinical practice guidelines (CPGs) in traditional medicine (TM) is an ongoing challenge as it is unique area. This study describes a unified platform with Preferred Reporting Items for the Development of Evidence-based CPGs in TM (PRIDE-CPG-TM), which has been successfully used by the evidence-based CPGs committee for TM.
*Methods:* Initially we searched the literature and CPG handbooks, collected items from methodology references and drew on experiences gained from Korean medical physicians and methodology experts. A group of experts subsequently edited drafts of the items, identified one or more examples of good reporting for each item, and developed text that explained the rationale and discussed relevant evidence. Face to face meetings were held with experts to finalize the items with the most extensive elaboration.
*Results:* The PRIDE-CPG-TM, in the form of a checklist and description of items with TM approach and TM examples, were designed to improve the reporting of CPG in TM and thereby facilitate their interpretation and replication. The PRIDE-CPG-TM included 5 domains and 40 items. The items pertain to the development methodology (22 items), Overview of diseases and symptoms (6 items), Recommendations (4 items), Implementation and dissemination (5 items) and others (3 items).
*Conclusions:* The completeness of CPG descriptions in TM is very poor. Therefore, a complete description of the recommendations for TM in CPGs is necessary for physicians to implement the recommendations in clinical practice areas. The PRIDE-CPG-TM will provide useful guidance for TM developers in the development of evidence-based CPGs.


## 1. Introduction

The U.S. Institute of Medicine (IOM) defines clinical practice guidelines (CPG) as "statements that include recommendations intended to optimize patient care that are informed by a systematic review (SR) of evidence and an assessment of the benefits and harms of alternative care options" [1] and have become an important vehicle for influencing clinical practice change [2].

CPG development processes vary substantially, and many developed guidelines do not meet the basic quality criteria, which should be precise and rigorous to ensure that the results are reproducible and not vague [3]. Standards for CPG development may help organisations ensure that recommendations are evidence-based and may help users identify high-quality CPGs. As a result of the lack of high quality evidence and understanding of evidence-based medicine (EBM), the scientific validity of traditional medicine (TM) is more challenged than the western

*Abbreviations:* AGREE, Appraisal of Guidelines for Research and Evaluation; AKOM, the Association of Korean Oriental Medicine; COI, conflicts of interest; CPG, clinical practice guideline; EBM, evidence-based medicine; GRADE, Grading of Recommendations Assessment, Development and Evaluation; HIVD, herniated intervertebral disc; IOM, Institute of Medicine; KoMGI, the Korean Medical Guideline Information center; KGC, the Korean Guideline Clearing House; TM, traditional medicine; NICE, National Institute for Health and Clinical Excellence; OASIS, Oriental Medicine Advanced Searching Integrated System; PRIDE-CPG-TM, Preferred Reporting Items for Development of Evidence-based Clinical Practice Guideline in Traditional Medicine; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomized controlled trial; SIGN, Scottish Intercollegiate Guidelines Network SR systematic review; STARIGs, STAndard Reporting Items for clinical practice Guidelines; TM, Traditional Medicine; WHO/WPRO, the World Health Organization Western Pacific Regional Office.

☆ This issue belongs to the Special Issue on Methodological Challenges in Whole Systems Research.

* Corresponding author.
*E-mail addresses:* drmslee@gmail.com, mslee@kiom.re.kr (M.S. Lee).

http://dx.doi.org/10.1016/j.eujim.2016.07.027

medicine field [4]. So, it is difficult to promote the awareness and acceptability of CPG in TM because of the variation in the quality of randomzed clinical trial (RCT)'s quality. This issue is complicated by the fact that recommendations in TM have insufficient evidence to recommend for or against the TM.

In East-Asian countries, 80% of the population depends on TM for primary health care, and 70–80% of the population in many developed countries has used some form of alternative or complementary medicine (CAM) [5]. Therefore, the development and application of CPGs using an evidence-based approach have been the agenda and have rapidly developed worldwide. South Korea has maintained a dual healthcare delivery system that incorporates both traditional Korean and Western medicine. The development of CPGs was initiated approximately 15 years ago and resulted in an increased interest in the development of CPGs in healthcare [6]. TM in Korea remains in the beginning stage of development. Currently, only 17 CPGs are available regarding TM and the reporting of the CPGs is very unclear. Thus, many CPGs in TM are developed based on consensus based CPGs.

There are many formal reporting guidelines to improve the quality of scientific publications by promoting transparent and accurate reporting and enabling readers to better understand the design, conduct, analysis and findings of the research via the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network [7]. Additionally, international TM researchers have developed a set of recommendations for improving the reporting of interventions in parallel group trials of acupuncture [8] and herbal medicine [9].

The Korean medical world has previously developed the STAndard Reporting Items for clinical Guidelines (STARIGs) [10] and translated the Appraisal of Guideline Research & Evaluation II (AGREE 2.0) for the Korean model of CPGs development [11], education and dissemination to advance the standard of CPGs. There are insufficient examples or toolkits; however, several tools or handbooks for guidelines exist. In addition, the guidance regarding TM for guideline development is lacking for embodying the characteristics of TM and understanding of TM interventions requires a detailed description of the interventions and diagnosis. Because of the unique features of TM interventions, reporting guideline is needed.

There are some existing international guidance for CPG like GRADE, IOM standard, GIN standards, Guideline 2.0 and WHO standards. To the best of our knowledge, no study has developed reporting guidelines for CPGs of TM based on EBM; however, CPG development is rapidly researched in the TM or CAM community. With the existence of references to guideline methodology, the key rationale for having an extra CPG reporting guideline is to cover areas unique to TM which are not covered by these references. Therefore, we aimed to develop proper and important reporting guidelines with key considerations for CPGs in TM. The main motivation for the development of the PRIDE-CPG-TM is to facilitate the development and publication of high quality CPGs for TM.

## 2. Methods

### 2.1. Development process

We developed PRIDE-CPG-TM in 3 phases that included: pre-meeting item generation, face to face consensus meeting, and then a draft report circulated to invited experts to ensure that it accurately represented decisions made during development process.The project of PRIDE-CPG-TM for CPG in TM led by collaboration of researchers, methodologists, CPG developers, funders and had many face to face meeting to conclude the final items. Specially, methodologist led the identified items that facilitate SR.

Five experts who were experienced SRs were contacted to help in the development of the CPG and to extract the items and examples. The development of PRIDE-CPG-TM was based on two concepts. The first concept included a comprehensive search for published guidance or checklists for the reporting of CPGs using an evidence-based approach and extracted the methodological items; the second concept addressed how and to what extent TM issues comprised pattern identification, individualized intervention and the experiences of clinical experts regarding the effective ways to develop and implement the reporting guidelines for CPG. We addressed TM issues not covered by the existing international guidance. The PRIDE-CPG-TM development process is shown in Fig. 1.

### 2.2. Literature search

We systematically searched the literature and guideline handbooks or checklists and collected information on the methods and reporting of the included CPGs from inception to March 2014. PubMed was searched as an international database to retrieve references. Moreover, other sources were browsed, including International specific public databases for CPGs, the National Guideline Clearinghouse (NGC), the Guideline International Network (GIN), including the following Korean Guideline clearinghouse (KGC), and the Korean Medical Guideline Information Centre (KoMGi). We selected and reviewed handbooks regarding the methodology of developing the evidence-based CPG and extracted the examples from domestic and international CPGs.

### 2.3. Item and example extraction

From each included handbook or guideline, a content analysis was conducted to identify domains, and items of PRIDE-CPG-TM which we needed to be modified were nominated, referring to included handbooks or guidelines and then items were grouped into these domains based on the questions or items from checklists/frameworks (unit of analysis). The included examples in this guideline were extracted from original reports of CPGs. Our research team attempted to understand developers in the TM field were excerpts from the CPGs associated with TM.

### 2.4. Draft reporting guidelines

A group of experts edited drafts of the items, identified one or more examples of good reporting for each item, and developed text that explained the rationale and discussed the relevant evidence with TM.

### 2.5. Composition and content rationale

PRIDE-CPG-TM was composed of 5 domains, including development methodology, Overview of diseases/symptoms, Recommendation, implementation and dissemination and others; 40 items were included for examination according to the description order that may be listed in CPGs development.

The specific contents of the items are composed with explanations and examples to facilitate the developer's understanding. PRIDE-CPG-TM is a development guide that may be applied in the De Novo process, which is a method of developing CPGs through the steps of analysis, composition and summarisation, following the assessment of the quality of the evidence selected, according to the methodology of SR, when CPGs have not been previously developed for a key question.