



Review Article

Development of clinical practice guidelines for Korean medicine: Towards evidence-based complementary and alternative medicine



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ABSTRACT

Background: Since evidence-based medicine has been pursued in complementary and alternative medicine, the clinical practice guideline (CPG) has become a key factor in providing standardized and validated practices in Korean Medicine (KM). We aimed to review the current status and characteristics of the development, dissemination, and implementation of KM-CPGs.

Methods: We searched KM-CPGs and relevant publication via web-based databases. We organized the searching results focused on the year of publications and the development programs to show which and how KM-CPGs have been development. We also reviewed the manuals for KM-CPG development to introduce concise characteristics of the KM-CPGs published in Korea.

Results: The KM-CPGs have been developed according to manuals and standard templates for developing evidence-based KM-CPGs. First, CPG developers reviews the previously published CPGs for a clinical condition of interest and plans the CPG development. After finalizing the key clinical questions, the evidence is searched, selected, appraised, and analyzed following the internationally standardized methods. The quality of the KM-CPGs is controlled by a tri-step appraisal process. Second, the CPGs were submitted for the appraisal of the KM-CPG Review and Evaluation Committee. The committee evaluates the CPGs according to the AGREE II tool. Finally, the Steering Committee of the KoMIT project reviews the entire process of developing the CPGs and confirms it for public disclosure and dissemination.

Conclusion: Evidence-based KM from research to practice can be achieved with the attention and effort of multidisciplinary entities such as clinicians, practitioners, researchers, and policymakers for the CPGs.

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1. Introduction

Clinical practice guidelines (CPGs) are defined as systematically developed statements that can be used to assess the appropriateness of specific healthcare decisions, services, and outcomes.¹ The CPGs are considered potentially beneficial for patients, healthcare professionals, and healthcare systems because they can improve health outcomes, the quality of clinical decisions, and economic efficiency.² Many researchers, clinicians, and healthcare professionals

have been trying to develop evidence-based CPGs. As of November 2022, more than 2,870 CPGs that were developed or published worldwide were available in the International Guideline Library of the Guidelines International Network (GIN), which is a network of organizations and individuals interested in evidence-based guidelines that was established in 2002.³

Experts on complementary and alternative medicine (CAM) have made an effort to develop and implement CPGs for providing evidence-based and standardized healthcare services to patients, despite many challenges.^{4,5} According to a systematic review, at least 115 CPGs for traditional Chinese medicine had been published by 2015,⁶ while 35 and 17 CPGs released in Japan included recommendations for Kampo medicine and acupuncture therapy, respectively.⁷ It has also been reported that 74 of 604 Western medicine CPGs included CAM therapies in 2015.⁸

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Many evidence-based Korean Medicine (KM)-CPGs have been developed in the Republic of Korea since a CPG for traffic accident injury treatment was published in 2005.⁹ The Association of Korean Medicine (AKOM, the nationally authorized association with licensed KM doctors) and the Society of Korean Medicine (SKOM, an academic research organization of KM with a total of 51 member societies) led the early development of the KM-CPGs, while the Ministry of Health and Welfare in Korea (K-MOHW) has settled down to the national development of the KM-CPGs since 2016.¹⁰

It is very important to share the KM-CPGs with researchers, clinicians, practitioners, and policymakers worldwide to enhance the quality of the CPGs, implement them in practice, and promote evidence-based medical services in CAM. We aimed to review the current status and characteristics of the development, dissemination, and implementation of the KM-CPGs.

2. Methods

This is a narrative review to introduce how KM-CPGs have been developed for years. We searched KM-CPGs via the web-based databases operated by the Korean Institute of Oriental Medicine (KIOM, www.kiom.re.kr/eng) and the National Institute of Korean Medicine Development (NIKOM, nikom.or.kr/engnckm), which have been the leading entities for CPG development in KM. We also searched PubMed and Korean databases (KoreaMed, koreanmed.org; KMBase, kmbase.medic.or.kr; KISS, kiss.kstudy.com; RISS, www.riss.kr; ScienceON, scienceon.kisti.re.kr) and reviewed the publications of history and methodology to develop KM-CPG. We organized the searching results focused on the year of publications and the development programs to show the primary milestones in the history of KM-CPGs development. We also reviewed the manuals for KM-CPG development to introduce concise characteristics of the KM-CPGs published in Korea.^{11,12} Since the project administrators (Seok Hee Chung and Namkwen Kim for the Standard Clinical Practice Guideline Development for Korean Medicine (G-KoM) Project; Minjung Park for the Korean Medicine Innovative Technologies Development (KoMIT) Project) and researchers participated in this review, we tried to provide professional experiences and insight in this review.

3. Development of the KM-CPGs: milestones

Fifteen KM-CPGs were developed between 2005 and 2014, after the development of KM-CPGs for patients injured in a traffic accident in 2005, officially by the Korean Society of Chuna Manual Medicine for Spine and Nerves, a member society of SKOM. The development was mostly led by AKOM or SKOM (including its member societies) based on KM expert consensus.^{9,10} One of the interesting characteristics of the KM-CPGs was that some of them were focused on a specific intervention for a target disease or symptom (e.g., Chuna manual therapy for traffic accident injury, Ephedra for obesity, or acupuncture therapy for knee, neck, or low back pain), which might have been the results that reflected the biggest demand for KM clinical practice.

KIOM, a national institute for research from the basic principles to the clinical applications of oriental medicine established in 1994, started to support the development of KM-CPGs, resulting in the development of a total of seven KM-CPGs (such as for ankle sprain, atopic dermatitis, depression, facial palsy, lumbar herniated intervertebral disk, obesity, and shoulder pain) by 2015.¹³⁻¹⁹ The most important contribution of these CPGs was that KIOM applied evidence-based medicine methodology to evaluate the data and draw recommendations for clinical practice.²⁰

G-KoM Project was initiated in 2016 as an R&D program funded by K-MOHW to provide validated evidence conforming to international standards and standardizing the clinical practices of KM.

By 2022, the project group at NIKOM, a national institute for promoting the KM industry through scientification and standardization, completed the development of 30 newly-developed or updated KM-CPGs in collaboration with SKOM members. The CPGs included six diseases of the musculoskeletal system and connective tissue,²¹⁻²⁶ four mental and behavioral disorders,²⁷⁻³⁰ three injury, poisoning, and certain other consequences of external causes,³¹⁻³³ three diseases of the circulatory system,³⁴⁻³⁶ three diseases of the nervous system,³⁷⁻³⁹ two diseases of the respiratory system,^{40,41} two diseases of the genitourinary system,^{42,43} one disease of the digestive system,⁴⁴ and others.⁴⁵⁻⁵⁰ The key advancement achieved by this project was that the KM-CPGs were standardized and quality-controlled. For this purpose, the project group published a manual for the development of KM-CPGs and comprised an official committee where external peers reviewed and evaluated the KM-CPGs with the Appraisal of Guidelines, Research, and Evaluation (AGREE) II instrument before publishing them.

The K-MOHW launched a new KM R&D program, called KoMIT Project, in 2020. This program is planned to support clinical research on KM, promote evidence-based KM, and enhance the quality of healthcare services with KM in Korea. One of the sub-topics of the KoMIT project is to develop brand new KM-CPGs that are useful in clinical settings and bring the previously developed CPGs up to date with new evidence. The project will make more than 70 *de novo* or updated KM-CPGs by 2029, and some of them, namely, the KM-CPGs for irritable bowel syndrome, gout, tension-type headache, osteoporosis, pediatric growth disorders, and Sasang constitutional symptomatology, have already been published in 2022.⁵¹⁻⁵⁶

All the developed or planned KM-CPGs are listed in Fig. 1.

4. A structured process for achieving standardized and qualified KM-CPGs

The KM-CPGs led by G-KoM or KoMIT projects have been developed following manuals and standard templates for developing evidence-based KM-CPGs.^{11,12} It is stated what and how we should do for planning, developing, evaluating, and disseminating the KM-CPGs in the manuals, which employ Cochrane methods to conduct systematic reviews and meta-analyses and Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) methods to derive evidence-based recommendations for the KM-CPGs.

In the beginning, researchers need to plan to develop the CPGs after reviewing the previously published ones, if available, for a clinical condition of interest. They can choose to develop it *de novo* or revise it based on the previous version of the CPGs. It is strongly recommended that each development committee includes clinical professionals, methodologists, patients, or primary consumers. The key clinical questions that the committee constituted for a targeted CPG are disclosed to the public in the very early stage, which is a good rudder to reflect what the potential beneficiaries expect. The adequacy of the whole planning process is evaluated by external peer reviewers and amended if necessary.

After finalizing the key clinical questions in the forms of patient, intervention, comparison, and outcome (PICO), the evidences are searched, selected, appraised, and analyzed following the internationally standardized methods for systematic review and meta-analysis. The developers need to follow the Cochrane recommendations for the risk of bias assessments and meta-analysis. Based on those reviews, the committee discusses what to be recommended in the KM-CPGs. The recommendations are drawn after GRADE evaluation process.

The recommendations are addressed using the level of evidence and recommended grades in the KM-CPGs. The level of evidence is defined as how strongly we are confident about the evidence that we have found so far, which is rated at four levels (high, moderate,

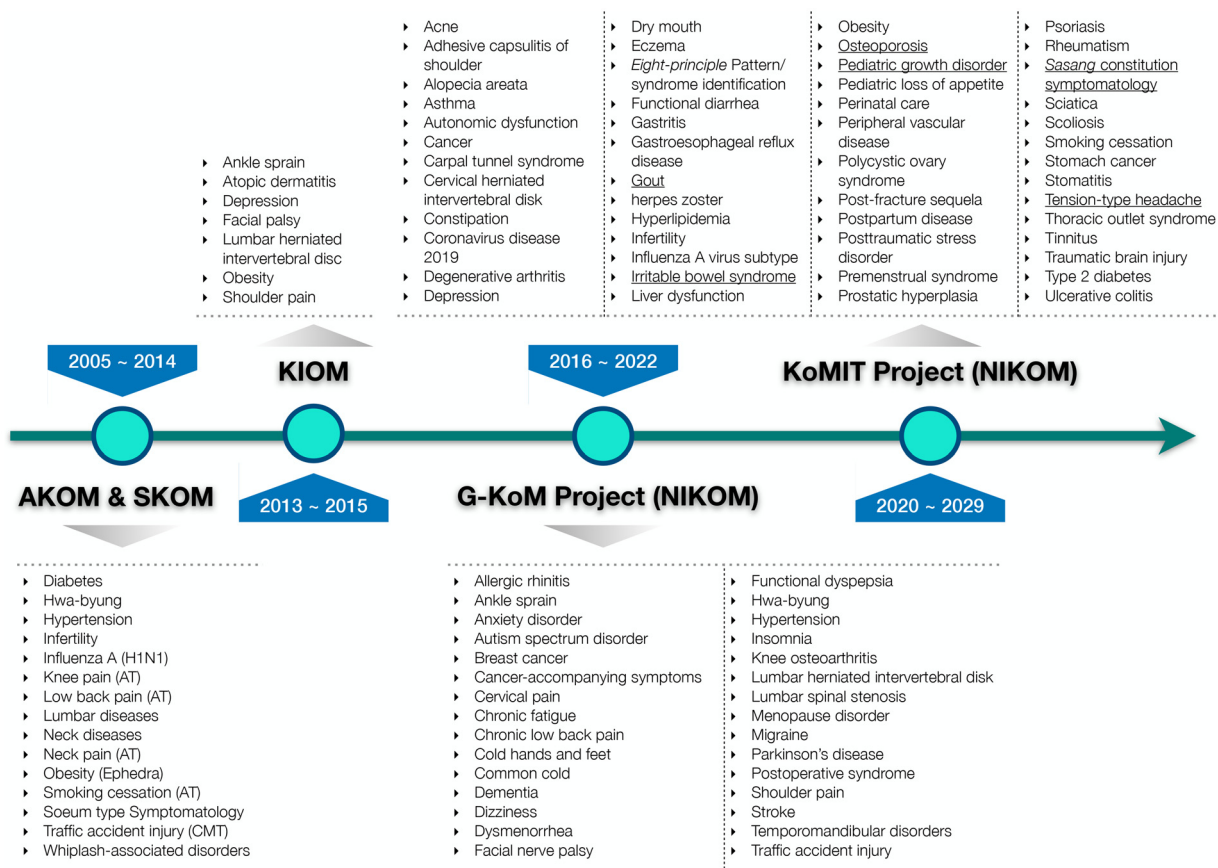


Fig. 1. Milestones of the development of KM-CPGs in Korea.

Figure note: The underlined CPGs led by the KoMIT project have been published, while the others are being developed or planned for *de novo* or updated development by 2029. AKOM, The Association of Korean Medicine; AT, acupuncture therapy; CMT, Chuna manual therapy; CPG, clinical practice guideline; G-KoM, Standard Clinical Practice Guideline Development for Korean Medicine project; KIoM, Korean Institute of Oriental Medicine; KM, Korean Medicine; KoMIT, Korean Medicine Innovative Technologies Development Project; NIKoM, National Institute of Korean Medicine Development; SKoM, The Society of Korean Medicine

low, and very low) based on the design, quality, quantity, and consistency of the clinical research selected for the recommendation. The recommended grade is defined as the strength of the recommendation, meaning how strongly we are certain that the benefits are greater or lesser than the harms from the recommended interventions. The strengths of the recommendations of the KM-CPGs are classified into five levels: A, B, C, D, and inconclusive. These levels are based on the benefits and harms, level of evidence, use in clinical settings, economic evaluation, and preferences and values.¹¹ The detailed interpretations of each level of evidence and grade of recommendation are summarized in Table 1.

The endeavors have also reduced the discrepancies between evidence and practice and enhanced the validity of the evidence-based KM-CPGs. The G-KoM and KoMIT projects organized a panel with KM doctors of primary care and made all groups involved in the development of the KM-CPGs include one or more members of the panel. These groups should involve KM doctors in primary care from the beginning of the development of the CPGs. Additionally, the key clinical questions formulated by the committees should be open to the public before searching for relevant evidence, which can help the CPGs reflect consumers' needs for KM healthcare services. Meanwhile, the National Agency for the KoMIT project reinforced the process of external peer reviews of the KM-CPGs under development. The key clinical questions formulated according to the principles of patient, intervention, comparison, and outcome, and the draft or revised version of the KM-CPG statements, should go through an advisory review process several times.

The quality of the KM-CPGs is controlled by a tri-step appraisal process. After being reviewed and amended, the CPGs should ob-

Table 1 Level of evidence and grade of recommendation in KM-CPGs.

Category	Interpretation
Level of evidence	
High	Very confident; the true effect lies close to the estimate of the effect.
Moderate	Moderately confident; the true effect is likely to be close to the estimate of the effect, but it is possible to be substantially different.
Low	Limited confidence; the true effect may differ substantially from the estimate of the effect.
Very low	Very little confidence; the true effect is likely to differ substantially from the estimate of effect.
Grade of recommendation	
A	Strongly recommended in almost the entire clinical practice.
B	Should be considered in the majority of clinical practices.
C	May be considered in some of the clinical practices.
D	Not recommended in the majority of clinical practices.
Inconclusive	A recommendation is not made because of a lack of consensus.

CPG, clinical practice guideline; KM, Korean Medicine.

tain the approval of one or more academic members of SKoM, which makes the CPGs an official publication of the societies. Second, the CPGs were submitted for the appraisal of the KM-CPG Review and Evaluation Committee, which was modulated by the national agency of the KoMIT project. The committee evaluated the CPGs according to the AGREE II tool and presented a decision to accept them with minor or major revisions or reject them. Finally,

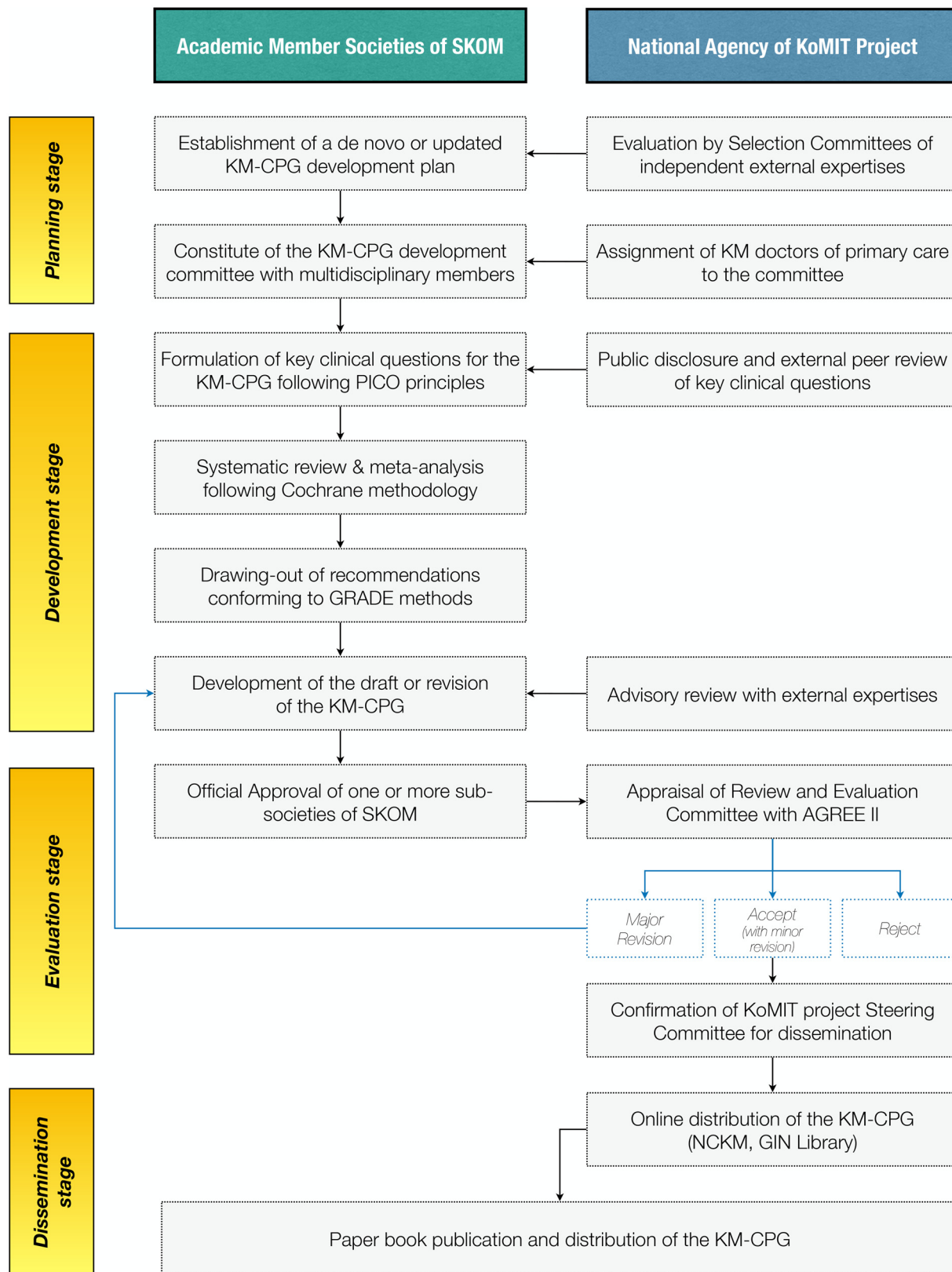


Fig. 2. Overall process of planning, developing, evaluating, and disseminating KM-CPGs in Korea. AGREE, Appraisal of Guidelines, Research, and Evaluation; AKOM, The Association of Korean Medicine; CPG, clinical practice guideline; GIN, Guidelines International Network; GRADE, Grading of Recommendation, Assessment, Development, and Evaluation; KoMIT, Korean Medicine Innovative Technologies Development Project; NCKM, National Clearinghouse for Korean Medicine; PICO, patient, intervention, comparison, and outcome; SKOM, The Society of Korean Medicine.

Conditions	Korean Medicine treatments							Korean Medicine treatments along with conventional therapies							Other interventions (with or without conventional therapies)		
	HM	AT	PT	MT	CT	TET	CMT	EX	HM	AT	PT	MT	CT	TET		CMT	EX
Allergic rhinitis	O ⁽¹⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Intranasal phototherapy
Ankle sprain	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	RICE, Cold therapy, TENS, Taping
Anxiety disorder	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Qigong, Meditation, Behavioral/cognitive/relaxation therapy, Biofeedback
Autism spectrum disorder	○	O ⁽³⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Manual/music/art/dance therapy, Qigong
Breast cancer	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Cancer-accompanying symptoms	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Meditation
Cervical pain	○	O ⁽⁴⁾	○	○	○	○	○	O ⁽⁷⁾	○	O ⁽⁴⁾	○	○	○	○	○	○	
Chronic fatigue	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Qigong, Music therapy
Chronic low back pain	○	O ⁽⁵⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Cold hands and feet	○	O ⁽⁶⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Lifestyle modification
Common cold	○	O ⁽⁶⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Bloodletting therapy
Dementia	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Cognitive/remembrance therapy, Meditation, Caregiver education
Dizziness	○	○	○	○	○	○	○	○	○	O ⁽⁴⁾	○	○	○	○	○	○	Manual/traction/cognitive behavior therapy, Cervical muscle relaxation
Dysmenorrhea	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Manual therapy, TENS
Facial nerve palsy	○	O ⁽⁵⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Enema
Functional dyspepsia	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Qigong, Meditation
Gout	○	O ⁽⁴⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Bloodletting therapy
Hwa-byung	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Relaxation/counseling/education/manual therapy, Qigong, Meditation
Hypertension	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Qigong, Device induced breathing exercise
Insomnia	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Meditation, Aromatherapy, Neurofeedback, Qigong, Music/relaxation therapy
Irritable bowel syndrome	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Knee osteoarthritis	○	O ⁽⁴⁾	○	○	○	○	○	○	○	O ⁽⁴⁾	○	○	○	○	○	○	Physical/bloodletting therapy
Lumbar herniated intervertebral disk	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Lumbar spinal stenosis	○	O ⁽⁴⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Menopause disorder	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Migraine	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Bloodletting therapy
Osteoporosis	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Parkinson's disease	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Qigong
Pediatric growth disorder	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Muscle-tendon release manual therapy, Lifestyle modification
Postoperative syndrome	O ⁽¹⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Physical therapy
Sasang constitution symptomatology	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Diet therapy, Psychotherapy
Shoulder pain	O ⁽¹⁾	O ⁽⁴⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Physical/manual therapy
Stroke	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Temporomandibular disorders	○	O ⁽⁵⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Physical therapy
Tension-type headache	○	O ⁽⁵⁾	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Cognitive/physical therapy, Relaxation
Traffic accident injury	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	Physical/bloodletting therapy, Psychotherapy

Fig. 3. Interventions recommended in KM-CPGs.

Figure note. AT primarily includes various types of acupuncture therapies such as manual, electrical, ear, fire or warm needling. (1) External application of herbal medication is included; (2) Steaming and washing treatment using Herbal medication is included; (3) Acupressure is included; (4) Acupotomy is included; (5) Laser acupuncture is included; (6) Acupoint application is included; (7) Daoyin exercise therapy is included. AT, acupuncture therapy; CMT, Chuna manual therapy; CT, cupping therapy; EX, exercise therapy; HM, herbal medications; MT, moxibustion therapy; PT, pharmacopuncture therapy; RICE, rest, ice, compression, elevation; TENS, transcutaneous electrical nerve stimulation; TET, thread embedding therapy

the Steering Committee of the KoMIT project reviews the entire process of developing the CPGs and confirms it for public disclosure and dissemination. Only the finalized CPGs accepted by the Review and Evaluation Committee for the KM-CPGs will be reviewed and confirmed by the Steering Committee.¹¹

The structured process for the development of KM-CPGs is depicted in Fig. 2.

5. Recommended major interventions included in the published KM-CPGs

It is very important to provide practitioners with necessary evidence-based recommendations for the KM interventions commonly used in primary cares, since most of those interventions are not newly developed but have been used for a long time in Korea. The 36 CPGs led by G-KoM and KoMIT projects recommended those KM treatments comprehensively, including herbal medication, acupuncture therapy, pharmacopuncture therapy, moxibustion therapy, cupping therapy, thread embedding therapy, Chuna manual therapy, or various types of exercise therapies. Most of the developed CPGs recommended administration of herbal medications (34 of 36 CPGs), followed by acupuncture therapy (33 of 36), moxibustion therapy (24 of 36), and pharmacopuncture therapy (22 of

36). The CPGs recommended that those KM interventions should or can be applied to patients solely or combined with other KM treatments or conventional therapies of western medicine. The interventions included in each KM-CPGs structured are summarized in Fig. 3.

6. Dissemination and implementation of the KM-CPGs: from research to practice

The CPGs accredited by the Steering Committee were published for dissemination and implementation. The website of the National Clearinghouse for Korean Medicine (NCKM) is a web portal that shares various results and outcomes from national R&D projects for KM. The NCKM has built a database for the KM-CPGs and provides structured and summarized information about the KM-CPGs in Korean and English, such as a rationale for development, a target disease with a relevant International Classification of Diseases code, a responsible member society of SKOM, recommendations with their levels of evidence and grades, and a release date for each CPG with an electronic portable document format (.pdf) file.⁵⁷ Clinicians, practitioners, researchers, and healthcare consumers can access the database and download the CPG files with introductory brochures anytime for free. Recently, the national agency for the

KoMIT project became a member of the GIN and started to register the developed KM-CPGs in its library to disseminate them internationally.³

It is still the biggest challenge to implement the KM-CPGs in practical use, even though approximately 51 to 91% of KM doctors recognize the publications of the CPGs.^{58–60} NCKM is providing an algorithmic framework of clinical decisions illustrated from CPG recommendations on the NCKM website to help KM doctors of primary care understand and adopt each CPG more easily. Another effort to implement the KM-CPGs is to use the CPGs to deliver a standard clinical pathway for a specific disease or symptom. Clinical pathways are a set of sequential components used in clinical practice to reduce variation, improve the quality of care, and maximize the outcomes for specific groups of patients.⁶¹ The national agency for the KoMIT project is also trying to train licensed KM doctors and undergraduate students with refresher training programs, which are legally compulsory for KM doctors, and clinical performance examinations, an objective-structured examination to assess the clinical performance of students majoring in KM.⁶²

7. Conclusion

It is important to provide a reliable and validated healthcare service that can be approached more closely by qualified CPGs. Since evidence-based medicine has become widespread in CAM, the importance of CPGs has grown more than ever. This study reviewed a series of efforts in the field of KM to standardize clinical practice based on evidence and improve the quality of medical services through CPGs. It is meaningful that the K-MOHW started nationally funded R&D programs to support the development, dissemination, and implementation of the KM-CPGs in 2016. The evidence-based methodology of the Cochrane network, the GRADE statements, and the AGREE tool have become the norm for developing and validating the KM-CPGs. The dissemination and implementation of the CPGs are as critical as the development of qualified KM-CPGs to achieve evidence-based KM practices. Attention, effort, and multidisciplinary entities, such as clinicians, practitioners, researchers, and policymakers, should be made in the future to accomplish this.

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Ethical statement

No ethical approval was required as this study did not involve human participants or laboratory animals.

Data availability

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

Conflict of interests

The authors declare that they have no conflicts of interest.

CRedit authorship contribution statement

Seungwon Shin: Conceptualization, Methodology, Writing – original draft. **Wonkyung Moon:** Writing – review & editing. **Suran Kim:** Writing – review & editing. **Seok Hee Chung:**

Project administration. **Jongwoo Kim:** Writing – review & editing. **Namkwen Kim:** Project administration. **Yoon Jae Lee:** Writing – review & editing. **Minjung Park:** Conceptualization, Writing – review & editing, Project administration, Funding acquisition.

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