



Development of Quality Management Systems for Clinical Practice Guidelines in Korea

Heui-Sug Jo,^{1,2} Dong Ik Kim,³
Sung-Goo Chang,^{2,4} Ein-Soon Shin,^{2,5}
and Moo-Kyung Oh⁶

¹Department of Health Management and Policy, Kangwon National University, School of Medicine, Chuncheon; ²The Executive Committee for Clinical Practice Guideline, The Korean Academy of Medical Sciences, Seoul; ³Department of Radiology, Yonsei University Sevrance Hospital, Yonsei University College of Medicine, Seoul; ⁴Department of Urology, Kyung Hee University Medical Center, School of Medicine Kyung-Hee University, Seoul; ⁵Research Agency for Clinical Practice Guidelines, KAMS Research Center, The Korean Academy of Medical Sciences, Seoul; ⁶Department of Preventive Medicine, Kangwon National University Hospital, Chuncheon, Korea

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Address for Correspondence:

Moo-Kyung Oh, MD

Department of Preventive Medicine, Kangwon National University Hospital, 156 Baengnyeong-ro, Chuncheon 24289, Korea
Tel: +82.33-258-9031, Fax: +82.33-258-9294
E-mail: somanghana@gmail.com

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This study introduces the Clinical practice guidelines (CPGs) appraisal system by the Korean Academy of Medical Sciences (KAMS). Quality management policies for CPGs vary among different countries, which have their own cultures and health care systems. However, supporting developers in guideline development and appraisals using standardized tools are common practices. KAMS, an organization representing the various medical societies of Korea, has been striving to establish a quality management system for CPGs, and has established a CPGs quality management system that reflects the characteristics of the Korean healthcare environment and the needs of its users. KAMS created a foundation for the development of CPGs, set up an independent appraisal organization, enacted regulations related to the appraisals, and trained appraisers. These efforts could enhance the ability of each individual medical society to develop CPGs, to increase the quality of the CPGs, and to ultimately improve the quality of the information available to decision-makers.

Keywords: Clinical Practice Guideline; Health Policy; Quality Control; Health Care Quality; Korea, Korean Academy of Medical Sciences

INTRODUCTION

Clinical practice guidelines (CPGs) are used to improve the quality of care by providing scientific information that can inform decision-makers (1). In terms of several notable characteristics, quality management policies vary among different countries (2), which have their own cultures and health care systems; CPGs management methods also vary accordingly.

In Korea, over 100 CPGs have been developed in the past decade, with more than 70 CPGs currently in development (3). Furthermore, Korean-specific appraisal tools have also been introduced (4). However, the development of these CPGs is disparate, and development competency remains insufficient (5,6). Unfortunately, there have been no discussions on the governance of CPGs at the early stages; as a result, CPG quality management policies are minimal and differ according to the organizations developing the CPGs.

In the case of the Korean government, the majority of their focus has been on financial support, but this has not been based on a long-term, detailed plan. Furthermore, different departments within the government support different developers. Guidelines have been developed by only a few research groups or academics working individually (7), such that an interdisciplinary approach is lacking. Moreover, support is not provided after development, and appraisals or implementation strategies are not taken into consideration. As a result, low-quality CPGs and significant variations in their quality represent a serious problem (5,6).

To address this situation, the Korean Academy of Medical Sciences (KAMS), an organization representing medical science in Korea, has been striving to establish quality control systems and is working in collaboration with the government to create policies that ensure the quality of CPGs. CPG development is now a priority; the situation has reached a point in Korea whereby systematic CPG quality management policies can

now be established.

To identify future directions in CPG quality management policies in Korea, this study describes the CPG quality management systems used in Western countries, and introduces the appraisal system of the KAMS, an organization that provides the main policies that provide CPG quality control in Korea.

CPGs QUALITY CONTROL SYSTEMS IN KOREA AND OTHER COUNTRIES

Countries that have actively introduced CPGs have established unique systems that enable the organization and step-by-step management of the development, distribution, evaluation of CPGs as well as the implementation phases for quality control (2,8). Furthermore, they manage the whole process in accordance with the cooperation of both public and private organizations; cooperation with the public and private sectors is achieved at a higher administrative level. For such collaborative development of CPGs to address national diseases, building consensus for various forms of cooperation between countries have been achieved concerning the legal status of CPGs (Table 1).

Among quality control agencies, the relevant public organizations include the National Institute for Health and Care Excellence (NICE) in the UK, the National Health and Medical Research Council (NHMRC) in Australia, and the Agency for Healthcare Research and Quality (AHRQ) in the US. These bodies are responsible for policies on healthcare quality management, which include CPGs (9,10). The private sector for CPG quality control is represented by the following organizations: the Canadian Medical Association (CMA), the Association of the Scientific Medical Societies in Germany (AWMF), and the

German Agency for Quality in Medicine (AZQ). In Canada, the CMA has led CPG quality management activities, including development strategies and the application and implementation of guidelines (11). The AWMF is responsible for the development of CPGs and for the provision of professional training, whereas the AZQ focuses on quality assurance activities such as effective implementation and CPG quality management programs (12). However, public and private cooperation is prevalent in the development of CPGs for high-burden chronic diseases and in quality control in Germany (13). In Korea, KAMS has carried out activities concerned with CPG quality control in Korea. To achieve this, KAMS has established a CPG committee that supports the development and dissemination of CPGs. In particular, KAMS has studied the scientific methodology underlying the development of CPGs, including Korean-specific appraisal tools, scoring guides, etc. Moreover, it has enhanced the capabilities of developers by educating them on the development of CPGs. With respect to the government, the level of cooperation has increased to include CPG topic selection rather than just merely initial financial support.

In the majority of countries, appraisals have commonly been done using standardized tools to improve the quality of the development process. However, CPG accreditation processes vary among countries. Both the US and Canada require checklists to develop CPGs, in addition to periodic updates after guideline registration (14-16). Germany also considers each criterion separately during the development and registration of CPGs, and assigns a rating based on the degree of development. In contrast, the UK has a management process involving strict regulatory and certification procedures. To accredit CPGs, Accreditation Advisory Committee meetings are held, with CPGs certi-

Table 1. Main body and activities of CPGs quality control in Korea and other countries

Process		Korea	UK (England)	USA	Australia	Canada	Germany
Quality control	Main body	· KAMS	· NICE	· AHRQ	· NHMRC	· CMA	· AZQ/AWMF
Development	Main body	· Professionals	· Professionals · Central	· Professionals	· Professionals · Central · Regional	· Professionals · Central · Regional	· Professionals · Central · Regional
	Activities	· Research & development	· Topic selection · Scientific advice · Research & development	· Research & development	· Research & development	· Research & development	· Research & development · National topic selection
Accreditation or Appraisal	Main body	· KAMS	· NICE (Accreditation advisory committee)	· AHRQ	· NHMRC's council	· CMA	· AZQ
	Activities	· Appraisal	· Appraisal & accreditation · External opinion & public consultation	· NGC Standard · Appraisal · Public consultation	· NHMRC Standard · Appraisal · Public consultation	· CMA standards · Appraisal · Public consultation	· Appraisal · Public participation
Dissemination & Implementation	Main Body	· KAMS	· NICE	· AHRQ	· NHMRC	· CMA	· AWMF
	Activities	· Clearinghouse (KOMGI) · Education	· Clearinghouse (NICE)	· Clearinghouse (NGC)	· Clearinghouse (NHMRC)	· Clearinghouse (CMA infobase)	· Clearinghouse (AWMF)

KAMS, Korean Academy of Medical Sciences; NICE, National Institute for Health and Care Excellence; AHRQ, Agency for Healthcare Research and Quality; NHMRC, National Health and Medical Research Council; CMA, Canadian Medical Association; AZQ, German Agency for Quality in Medicine; AWMF, Association of the Scientific Medical Societies in Germany; KoMGI, Korean Medical Guideline Information center; NGC, National Guideline Clearinghouse.

fied in accordance with regular evaluation procedures. NICE introduces all CPGs that are registered on the National Health Service, but the Accreditation Advisory Committee introduces only those guidelines that have obtained final accreditation (17). Australia also has a CPG accreditation process, which involves eight recommendations with respect to the legal implications of guidelines pertaining to early breast cancer (18). In accordance with the CPG development process suggested by the NHMRC, these recommendations were then included at an institutional level (19).

When it comes to the dissemination of CPGs, almost all countries operate on-line databases for the distribution of CPGs. Clearing houses in the US and Canada verify the requirements for CPGs upon guideline registration, and play a key role in evaluating their quality. In Korea, the Korean Medical Guideline Information center (KOMGI) – a CPG portal – also plays an important role in dissemination and quality assessment (20).

However, strategies and activities concerning the implementation of CPGs are insufficient with respect to the active development and dissemination of CPGs. Countries have attempted to improve their level of CPG use, but establishing effective strategies is difficult because influential factors and health environments vary among countries (21). The proportion of CPGs implemented in Korea reportedly remains at 30%-50% (22).

KOREAN CPG QUALITY CONTROL: THE KAMS SYSTEM

Establishment of a quality management organization

In Korea, KAMS, the main quality management body, has been

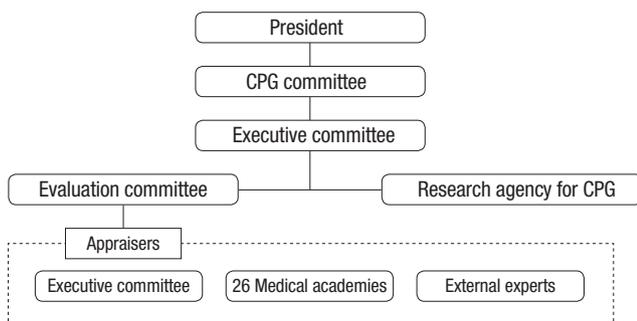


Fig. 1. Quality management organizations of CPGs by KAMS.

Table 2. Establishment activities for quality management system of CPGs by KAMS

Date	Goals	Activities
2011.12	Establishment of quality appraisal system	Research for quality appraisal model in Korea
2012.6		Development of Korean specific appraisal tools
2012.6-11	Collect opinions from interest	Information session for presidents of 26 representative societies
2013.4	Institutionalization	Announce the plan for the development of quality appraisal system
		Enact policies for appraisal
2013.5-8	Operate quality appraisal	Manpower training for quality appraisal
2013.9-		Quality appraisal

engaged in efforts to contribute to the development of evidence based medicine (EBM). Since 2006, KAMS has implemented new offices dedicated to CPGs, and has also operated both CPG and Executive committees. The CPG committee, composed of individuals drawn from 26 specialized academy societies, promotes dissemination activities (through networks that exist between societies) and development projects (by cooperating with societies). The Executive Committee facilitates these practices by developing CPG-related systems and methodologies and by promoting direct training pertaining to guideline quality management. These activities have led to the development of management quality policies and a quality appraisal system, which have in turn enabled higher-quality CPGs (Fig. 1).

Establishment of the quality appraisal system

CPG quality appraisal involves the assessment of development processes rather than guideline contents, so that the most-reliable information and recommendations are provided to guideline users (23). In Korea, the demands are higher for the appraisal and quality control of CPGs led by expert groups. Through several studies done on policies aimed at developing quality evaluation tools and on building a quality management system, KAMS developed a quality appraisal model reflecting the characteristics of the Korean health care system, and then collected opinions from other societies through two public hearings. As a result, in April 2013, regulations for CPG appraisal were established in accordance with the principles of independence, transparency, objectiveness and timeliness. Furthermore, procedures and methods related to quality appraisal were organized such that the Executive Committee and a research agency independently evaluate the CPGs (Table 2).

Manpower training for quality appraisal

To appraise CPGs, an Evaluative committee was established consisting of the Executive Committee members, clinical specialists recommended by the various societies, and external experts. Appraisers were able to provide professional-quality evaluations and CPG appraisal following completion of the KAMS education program. To date, 58 appraisers have been trained and participated in these quality appraisal activities.

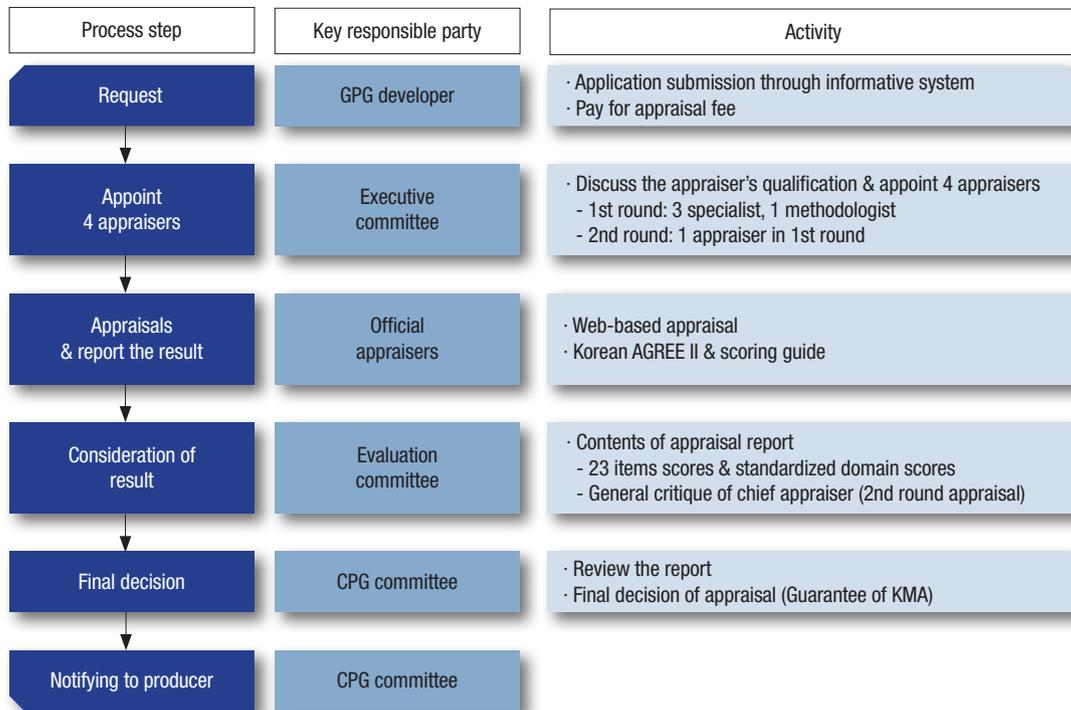


Fig. 2. CPGs appraisal process by KAMS.

Quality appraisal process

The quality appraisal of CPGs starts with requests from guideline developers to KAMS. Following registration of a formal request of a developer, the Executive Committee appoints four KAMS appraisers with professional interests relevant to the guideline in question. These appraisers are forwarded the appraisal request and information on the guideline, and evaluate the CPG using the Korean AGREE II Scoring Guide document, which improves the reliability of the AGREE II tool (4,24). Appraisers evaluate the CPG for 2 weeks, and submit the results of their appraisal, including their opinions on whether the guideline should be used, to the Executive Committee. The Executive Committee then determines whether KAMS recommends use of the CPG, based on the results of the appraisals, and informs the developers of their final decision. If there is no objection from the guideline developers, the decision of the Committee is finalized, and remains in effect for 5 yr. If there is an objection from the developer, the Executive Committee appoints four new appraisers, who re-appraise the CPG, in terms of whether it should be used, before making a final decision. The whole process from the request of a developer to the appraisal by the appointed appraisers and final notification of the appraisal results is conducted using the on-line portal KoMGI (Fig. 2).

CONCLUSION

The goals of CPG quality management are to improve the quality of the development process, to provide fair and reliable eval-

uation recommendations, and to ensure evidence-based decision-making during patient care and management.

US and Europe share common features in their quality management policies on CPGs with which to appraise the development process by using standardized tools and disseminating qualified CPGs through clearinghouses. Besides, to ensure professionalism and objectivity, and to manage quality on a continuous basis, appraisal by an independent organization of experts is guaranteed (25).

Following the introduction of EBM, the requirement for specialized agencies to support the development of CPGs, and to evaluate developed guidelines, has increased in Korea. KAMS, as a professional body representing the medical community, carries influence regarding the development and management of CPGs; it has established foundations for the assessment of CPGs, including the development of Korean-specific quality appraisal tools. KAMS has also set up an independent appraisal organization (the Executive Committee), established regulations related to appraisals, and improved the evaluation system for CPG quality (which is appropriate to the Korean health care environment). The Executive Committee appraises CPGs and gives accreditation only to those with high quality, which motivates the various societies to manage quality continuously. KAMS has trained staff to conduct appraisals in accordance with the participation of medical academies, to which it assigns appraisals, thereby enhancing the ability of each society to develop CPGs and increasing the quality of CPGs.

KAMS has established a CPG quality management system

that reflects the characteristics of the Korean healthcare environment and the needs of its users. In particular, CPG quality appraisals assess their independence and the scientific methodologies used during the development process, and provide users with the most reliable guidelines and recommendations. This could improve the quality of information available to decision-makers and thus ultimately enhance EBM in practice.

DISCLOSURE

The authors have no conflicts of interest regarding the material presented here.

AUTHOR CONTRIBUTION

Design of the study: Jo HS, Oh MK. Data collection and analysis: Shin ES. Writing manuscript: Jo HS, Oh MK. Revision: Kim DI, Chang SG. Approval of final version of this manuscript: all authors.

ORCID

Heui-Sug Jo <http://orcid.org/0000-0003-0245-3583>
 Dong-Ik Kim <http://orcid.org/0000-0001-7527-3829>
 Sung-Goo Chang <http://orcid.org/0000-0003-0733-7266>
 Ein-Soon Shin <http://orcid.org/0000-0002-5086-6086>
 Moo-Kyung Oh <http://orcid.org/0000-0002-2011-5708>

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