Introduction

Korea is a representative country where traditional Korean medicine (KM), coexists within the healthcare system [1]. This dual system of healthcare facilitates the promotion and modernization of KM theories and technologies through an integrative and collaborative approach. The Korean government has developed a comprehensive five-year plan for KM development known as the “Act on promotion of Korean medicine and pharmaceuticals.” This plan aims to support research and development (R&D), establish an industrial foundation between KM and the Korean government, and improve the quality of KM products like herbal medicines. Accordingly, national funds across various ministries are allocated to support the R&D of KM.

Since the Korea Institute of Oriental Medicine was established in 1994 and the Ministry of Health and Welfare (MoHW) in Korea initiated the research for KM development in 1997, the amount of national funds for KM has increased significantly. As of 2021, approximately 131.8 billion KRW (110 million USD) across various ministries, was invested in KM R&D (Table 1) [2]. The Korean Medicine Innovation Technology (KoMIT) development project, funded by MoHW since 2020, is the most representative and largest-scale project in the clinical research field of KM currently. A total budget of 157.6 billion KRW (131 million USD) has been allocated to be invested in the project between 2020 and 2029. This editorial provides an overall framework of the KoMIT development project to appreciate the endeavors required to build clinical evidence on KM (Figure 1).

1. Development and dissemination of KM clinical practice guidelines

The development of clinical practice guidelines (CPGs) for KM began in 2005. The Grading of Recommendations, Assessment, Development, and Evaluations methodology [3] used to develop and validate KM CPGs was first initiated by the Korea Institute of Oriental Medicine in 2015. This led to the launch of a new MoHW-funded project for KM CPG development in 2016 called the Korean Medicine Clinical Practice Guidelines Development Project. Following CPG development for 30 different conditions/diseases over 5 years, in 2020, the KoMIT development project started. It included the R&D subcategory to continue to develop new CPGs and update predeveloped CPGs. As of the end of May 2024, there have been KM CPGs published for 45 conditions/diseases which apply globally standardized methodologies (including the Cochrane methods of systematic review and meta-analysis, the Grading of Recommendations, Assessment, Development, and Evaluations approach for clinical recommendations, and the Appraisal of Guidelines for Research and Evaluation II [4], assessments for independent and external peer-review of CPGs) [5]. The KM CPGs have contributed not only to evidence-based practice but also to the standardization of Korean medicine treatments. The guidelines recommend which evidence-based treatment should be chosen as the first line of treatment for a particular condition/disease, how long the treatment should last, and which indicators should be used to evaluate efficacy and safety. This has contributed to the standardization of the treatment process.

The development of CPGs in Korea has two distinct characteristics (Figure 2). Firstly, the strategy for dissemination
and utilization was considered simultaneously during the development phase. Flyers for patients’ understanding and schematized clinical pathways were provided with CPGs to the clinical process. Continuing medical education programs with developed CPG content for KM doctors have commenced. Clinical performance examination based on CPGs was also implemented for KM undergraduate students. Secondly, the development of CPGs has provided a foundation for new projects and often serves as a stepping stone for evidence-based decision-making. For example, a pilot project to embrace herbal medicine within the national health insurance system has been initiated recently for limited conditions/diseases, which were selected based on the level of recommendations included in the developed CPGs and the use of statistics from KM clinics. In addition, the KM community care program for the elderly and disabled incorporated KM CPG-based content. Furthermore, a new R&D project to construct and exploit real-world big data for KM is in progress with standardized KM terminology, clinical pathways, and patient assessment tools derived from KM CPGs.

2. Evidence generation through clinical research

The KoMIT development project supports clinical research to generate evidence in the field of KM. Many KM technologies used to treat patients such as pharmacopuncture, thread embedding therapy, or acupotomy, still lack rigorous scientific evidence despite being widely used in the clinical setting. Verifying evidence for actual treatments used in clinical practice through national support is very significant. The ultimate aim of funding clinical research into these technologies is to facilitate coverage for these treatments in the national health insurance system based on the validated evidence. Expanding the scope of insurance-covered items in KM

<table>
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<th>2014 (USD)</th>
<th>2015 (USD)</th>
<th>2016 (USD)</th>
<th>2017 (USD)</th>
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ICT = information and communications technology; USD = United States dollar; SMEs = small and medium-sized enterprises.
requires evidence of safety, efficacy, and cost-effectiveness. The KoMIT development project supports not only explanatory clinical trials (which quantify the biological effect of a treatment in a well-controlled environment to identify the direct effect of the treatment and typically have a high level of evidence) but also pragmatic clinical trials (PCTs) which assess the effects in the real-world setting with unrestricted patient inclusion, thus exploring effectiveness in the actual medical environments [6]. Due to the nature of KM, the treatment strategy for the same condition/disease can vary depending on the patient. For instance, in an explanatory trial focusing on acupuncture, all patients would have a predefined regimen in the protocol. In PCTs, acupoints can be selected patient-by-patient, based on various factors like the pattern identification, and the location of symptoms. The techniques for chuna, one of the representative treatments in KM, are often chosen
based on individual body variations and symptoms in real-world settings [7, 8]. Similarly, the pharmacopuncture solution and acupoints can vary based on individual patient characteristics [9-11]. In reflecting on these clinical peculiarities of KM, PCTs can show a large variance in individual treatment effects and broader confidence intervals compared with explanatory trials (Figure 3).

3. Research for real-world evidence in KM

Research with KM real-world data (RWD) can be divided into retrospective studies that utilize already established electronic medical records or the national health insurance claims database, and prospective studies that build RWD through condition/disease-based registries. Since various treatments, such as acupuncture, cupping, moxibustion, and electroacupuncture in KM are supported by national health insurance, analysis of the health insurance claims dataset can provide evidence of the current state as well as the effectiveness or safety of KM medical services. Even though expanding insurance coverage for KM has been implemented (for example, Chuna has been newly covered for limited musculoskeletal conditions/diseases since 2019), there are still many non-covered KM services (e.g., herbal medicine, pharmacopuncture), presenting challenges for RWD research. For this reason, the need to build RWD through condition/disease-based registries has been raised.

Considering most KM practices are conducted in primary care clinics, where clinical trials are not feasible following the relevant regulations in Korea, supporting and funding the RWD research of the KoMIT development project is very encouraging. The KoMIT development project operates an official website, National Clearinghouse for Korean Medicine, where databases originated from disease-based registries are built. The registries have started with specific conditions/diseases for the spine, postpartum period, post-cancer surgery symptoms, shoulder pain, psychiatry, stroke, and obesity. For data transparency, the KoMIT development project is trying to ensure data quality, and provides a standardized guideline for data coding and electronic case report forms. While registry enrollment is ongoing, more extensive research of real-world evidence is expected in the future.

4. Research on interaction of herbal-conventional drugs

Since the integrative and collaborative healthcare system, there are a lot of patients who administer herbal and conventional drugs simultaneously in Korea. Spontaneously, clinical questions arise about the safety of taking those multiple medications together. The KoMIT development project started to support research on the pharmacokinetics/pharmacodynamics and safety for the interactions between herbal and conventional drugs to give evidence-based answers. Starting from drugs for diabetes, cardiovascular diseases, stroke, acute respiratory infections, depression, and dementia, more research will be funded within years for herbal-conventional drugs interaction. This part will lead to the development of co-administration clinical guidelines. And the KoMIT development project plan to provide the research results via the Drug Utilization Review system, which monitors prescription data in real-time as medications are being dispensed in hospitals and clinics, allowing for safe medication use in Korea’s dual medical system, and potentially offering a basis for using combination drugs globally.

5. Integrating tradition with modernity: transforming KM with evidence-based R&D

There are many KM R&D projects in Korea so this...
article focused primarily on research conducted in clinical settings under the KoMIT development projects, although this presents a limitation. In addition, since the KoMIT development project began in 2020, the projected period of 2020-2030 is incomplete making it difficult to report significant results. Thus, the introduction has been focused more on the direction of the projects rather than their outcomes.

The World Health Organization reported there are not many countries where traditional medicine is included in the health insurance system or is supported by the government [12]. While in many countries national R&D support for traditional medicine is not widespread, Korea has actively supported KM R&D. In addition, KM R&D projects align with internationally standardized methodologies in healthcare areas whilst preserving the characteristics of KM.

Following rapid technological advancements brought about by the trends of the Fourth Industrial Revolution, KM R&D projects strive to secure big data for Korean medicine in the future. It is hoped that the KoMIT development project will achieve its targeted outcomes to build clinical evidence on KM and build a strong foundation for integrated medicine.

**Author Contributions**

Conceptualization: JY and MP. Methodology: JY and MP. Writing original draft: YJL and SS. Writing - review and editing: YJL, SS, JY, and MP.

**Conflicts of Interest**

The authors have no conflicts of interest to declare.

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**Ethical Statement**

This article did not include any personal information therefore, no ethics approval was needed.

**Data Availability**

There is no usable data in this article.

**References**


