

Study Protocol for Transparent Reporting Appraisal in National Health Insurance Claims-based Evidence in Korean Medicine (TRACE-KM)

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 February 2026 and was last updated on 25 February 2026.

INTRODUCTION

Study aim To assess the completeness of reporting of Korean Medicine studies utilizing National Health Insurance claims data in the Republic of Korea from 2012 to 2025.

Background In the Global traditional medicine strategy 2025-2034, the World Health Organization (WHO) proposed the necessity to investigate research approaches appropriate for the characteristics of Traditional, Complementary and Integrative medicine (TCIM), involving the use of real-world data (RWD). RWD indicates routinely collected healthcare data, not for the purpose of conducting research. The sources of RWD span clinical documentation including electronic medical records (EMR) and registries, administrative data

including insurance claims data and vital statistics, and data from digital health devices. Previous study suggested that as the study designs move from traditional randomized controlled trials (RCTs) towards externally controlled trials and observational studies, the reliance of RWD increases.

In the Republic of Korea, national health insurance (NHI) claims data occupy the main position of the nationwide RWD. Two government agencies, the National Health Insurance Service (NHIS) and the Health Insurance Review and Assessment Service (HIRA), provide representative sample cohorts (approximately 2–3% of the population) and customized datasets covering the entire population for academic and scientific purposes.

A previous report has demonstrated a significant increase over the past decade in publications

leveraging NHI claims data for outcome research and analyses of healthcare utilizations in Korean medicine (KM). Transparency in the RWD study process facilitates rigorous evaluation of methodological quality and evidence applicability and supports research reproducibility. However, to our knowledge, the reporting quality of KM studies using NHI claims data has not been systematically evaluated. Therefore, this study aims to assess the completeness of reporting of NHI claims data-based research in KM as a foundational study to support the establishment of an RWD-based TCIM research support system.

METHODS

Search strategy Two international databases including PubMed/MEDLINE and EMBASE, and four Korean publication databases including ScienceON, Research Information Sharing Service (RISS), Oriental Medicine Advanced Searching Integrated System (OASIS) and Korean Medical Database (KMBASE) will be systematically searched in January 2026. The following search terms, including relevant Medical Subject Headings (MeSH) terms, will be combined by Boolean operators: 'National Health Programs', 'health insurance claims data', 'Korea', 'traditional Korean medicine', 'acupuncture', 'moxibustion', 'chuna', 'herbal medicine', and additional terms related to KM practices reimbursed by the NHI service.

Eligibility criteria This study will include all studies utilizing Korean NHI claims data that are related to KM, regardless of population, disease, exposure, or analysis method. Publications from 2012 to 2025 will be eligible for assessment, as the HIRA initiated the provision of NHI databases to researchers in 2012. Studies using both representative sample cohorts and complete (customized) datasets will be included. Studies involving linkage between NHI claims data and other databases will be eligible for inclusion. Eligible study types will include outcome research, hypothesis evaluating treatment effectiveness (HETE) studies, healthcare utilization pattern analyses, and studies predicting factors associated with KM use.

Full-text articles published in either Korean or English will be included, given that access to NHI claims data for academic and scientific research is restricted to researchers based in Korea under the Personal Information Protection Act, which strictly regulates the cross-border provision of personal data.

Studies using only registry or EMR datasets established by individual hospitals and

communities, panel survey data, or private automobile insurance datasets without linkage to NHI data will be excluded.

Data extraction Descriptive information, including authors, title, publication year, language, journal name, impact factor, and funding source, will be extracted. Study characteristics will include study design, study objectives, data type and provider, study population, KM practices of interest, and analysis method. Disease and procedure codes used to define study population, exposure, interventions, outcomes, confounders, and effect modifiers will be collected from the included studies. Information required to assess the completeness of reporting will also be extracted. All extracted data will be entered into a pre-designed electronic spreadsheet.

Outcome definitions The assessment tool for evaluating completeness of reporting was selected through two rounds of consultation with nine external experts, resulting in the adoption of The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement. The primary outcome of this study is the completeness of reporting, assessed using the RECORD checklist. For each included study, individual RECORD items will be evaluated as binary variables (reported vs. not reported). Completeness of reporting will be operationally defined as a continuous variable, calculated as the proportion of reported items relative to the total number of applicable RECORD items for each study. Items judged as not applicable to studies using Korean NHI claims data through expert consultation will be excluded from the denominator when calculating completeness scores. To identify highly and poorly reported items, the reporting proportion for each item will also be calculated.

Strategy of data synthesis / Statistical analysis

In the descriptive analysis, absolute numbers and relative proportions for categorical variables and means and 95% confidence intervals for continuous variables will be presented. If continuous variables do not satisfy the assumption of normality, medians and interquartile ranges will be reported. The primary analysis will summarize the overall completeness of reporting across all included studies.

Included studies will be classified according to study design and type of database used. Differences in study characteristics and reporting completeness between groups will be assessed using: Chi-squared tests or Fisher's exact tests for categorical variables; independent t-tests or Mann-Whitney U tests for continuous variables

with two groups; or one-way analysis of variance or Kruskal–Wallis tests when comparing more than two groups.

To identify factors associated with reporting quality, regression analyses will be conducted with the completeness of reporting as the dependent variable.

Country(ies) involved The Republic of Korea.

Keywords Reporting quality; Transparency; Real-world data; National Health Insurance claims data; Korean medicine; Traditional, Complementary, and Integrative Medicine.

Dissemination plans The results of study will be disseminated through submission as part of the terms of reference of the WHO Collaborating Centre for Traditional Medicine and publication in a peer-reviewed journal.

Contributions of each author

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