Introduction to methodology for the development of an integrative medical service model

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\textbf{ABSTRACT}

\textbf{Background:} The purpose of this article was to present a valid and reliable theoretical framework and method for the development of an integrated medical service model for the four major diseases.

\textbf{Methods:} Methodologies for each process were presented based on three theoretical frameworks. The three theories were the double diamond process model, the Donabedian model, and the International Classification of Functioning, Disability, and Health model. Based on this, in the process of problem finding, a literature review, service user questionnaire, and interview methods were applied. For problem definition and solution, expert focus group interview and expert Delphi methods were applied. The subjects of the study were mainly selected from experts for each disease and users of medical services. For literature review, systematic literature review and subject range literature review were conducted, and for analysis, a meta-analysis was carried out. In the case of focus group interview and Delphi, the validity and reliability of domain derivation and sub-items were analyzed by applying the qualitative analysis method.

\textbf{Results:} To develop an integrative medical service model, a theoretical framework and a systematic methodology were needed, and case studies were performed to prove its validity and reliability. This showed that the development of a medical service model needs to follow a scientific procedure.

\textbf{Conclusions:} By introducing methodological approaches and procedures for the development of an integrated medical service model for the four major diseases, the researchers provided basic information on model development.

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1. Introduction

According to the 2021 Implementation Plan for the Comprehensive Plan of National Health Insurance announced in 2020, the South Korean government selected the expansion of health insurance coverage as a national policy agenda, in order to lower the medical expenses of its citizens for the four major diseases (heart disease, brain disease, cancer, and rare and incurable disease).\textsuperscript{1} Although the four major diseases can be cured, there is a risk of
recurrence in stroke or cancer, and continuous rehabilitation and various therapeutic approaches are required. However, the treatment currently being received by patients with four major serious diseases in Korea is mainly Western-style, and only a few hospitals provide Korean and Western medicine collaboration. As a result, this means that the treatment direction is being chosen by doctors, and the importance of trying various therapeutic approaches for patients living with lifelong diseases is overlooked. Accordingly, the government recognized the need for a new concept of medical service support while supporting treatment costs for patients with four major diseases and related research and field investigations. In addition, the need for a holistic intervention for patients and their families, including effective and efficient treatment methods for patients with the four major diseases, has been recognized, specific methods for a holistic intervention or models that can implement have not been reported in Korea.

Only a few studies have reported the need for simple treatment programs or interventions from a social welfare perspective, such as nursing care integrative service. However, because the level and scope of models and programs are diverse, it is limited to provide integrative medical services to patients with four major diseases with one program, and calling this an integrative medical service also has limitations. This means that the concept of integrated medical services in Korea is not yet clear, and individual researchers and medical staff are conceptualizing integrated medical services with their own operational definitions. In particular, the term “integrated medical care”, “medical service”, and “service model” are conceptualized differently for each medical person, and are sometimes not scientific. For example, some think of integrative medicine as medical care that combines cooperative or complementary and alternative medicine, or think that ‘service’ or ‘model’ is simply a program. In addition, in the methodological aspect, there is no valid and reliable methodology that can explain model development in the medical field.

One of the reasons the development of models in the medical service sector in Korea is not being actively pursued may be the lack of a valid and reliable methodology that researchers can apply for medical service model studies. In particular, there are no studies in Korea on the methodology for the development of a IMS model. Only studies in existence are those that were conducted for the design of medical institutions in the service design sector. In addition, there is also a lack of studies that describe and introduce methodologies for collaborative medical models in Korean medicine (KM), which is currently being widely researched.

Accordingly, in this study, we aimed to introduce methodologies that could be applied to the development of an IMS model for holistic treatment of patients with the four major diseases and to provide some processes of development of integrative medical service model for subacute stroke patients that applied such methodologies in the study procedures.

In the case of subacute stroke patients, the mortality rate is lower than that of cancer, but a complete cure is difficult and continuous rehabilitation is required. Therefore, the process of applying the integrated medical service model for subacute stroke patients among the four major diseases will be presented as an example.

2. Methods

This study intends to introduce methodological design for model development. Accordingly, the methodology introduces three theoretical frameworks introduced for the development of this model. The three are (1) Double Diamond Design Process Model, (2) Donabedian Model (1988) and (3) ICF Model. First, according to the double diamond design process, it went through four procedural steps: discovery, definition, development and delivery. The study method for each step is shown in Fig. 1. Second, the Donabedian model is the most commonly used model in terms of quality evaluation of medical services, and its components include structure, process, and results. Structure is a resource related to the physical (facility, equipment), human and organizational (composition of medical staff and the type of organization) of the environment related to the provision of services. A process is a series of activities that are actually performed in the service provision process. Outcome is an outcome generated by the provided medical service, and it was made by evaluating the patient’s health status and satisfaction with medical use. Using this, the flow chart of this study model was prepared. This is shown in Fig. 2. Third, the ICF model for the development of treatment manuals is explained. The ICF model is a conceptual framework proposed by the World Health Organization (WHO) to describe health conditions and health-related conditions.

Through the ICF model, the patient’s condition is classified into impairment, activity limitation, and participation restriction. Most of patients with Four major disease have activity limitations that require continuous rehabilitation, and biological, psychological, and social models are needed because they have to live with them or preventing recurrence.

In this regard, by applying the ICF model, it is intended to explain this as a medical approach in terms of physical function and structure, and to provide integrative medical services including complementary and alternative and various medical services in terms of activities and social participation. So, the service design process and the content, methods, and procedures of performing the service are modeled by conducting (1) literature (including systematic, scoping, integrative) review, (2) survey of service consumers and providers, (3) expert focus group interview (FGI), and (4) expert Delphi. After that, model implementation will be made through a case study in the future. The specifics are as follows.

2.1. Problem discover phase

2.1.1. Literature (including systematic, scoping, integrative) search

The status of IMS for patients with the four major diseases in Korea and abroad was identified through a literature search using the following procedure: First, one disease was selected from the four major diseases. Second, the IMS status for each disease (therapeutic intervention, various intervention methods, nursing care services, medical welfare services, etc.) was analyzed. Here, treatment methods and programs were searched for a medical perspective, while factors related to the overall quality of life of patients were searched for a social perspective. Articles were searched using the following search engines: National Assembly Library, RISS, PubMed, EMBASE, Cochrane Central Register of Controlled Trials, and CINAHL. Next, a systematic review was performed if the PICOS (participants [persons], intervention, controls [comparators], outcome[s], and study design) criteria were satisfied. A scoping review was used if the PICOS criteria for each disease could not be satisfied. The biggest differences between the two methodologies are clarity of the PICOS criteria and the presence/absence of quality assessment, such as risk of bias assessment. Therefore, researchers must choose the methodology by checking these conditions when performing a literature search. Moreover, simultaneous meta-analysis is recommended when quantitative values are provided, and analysis of a statistically significant effect size is necessary. Table 1 shows examples of literature search for the development of the IMS model for the four major diseases presented in the study results.
2.1.2. Survey and interviews with consumers and stakeholders

Interviews were conducted with the IMS consumer group and service provider (expert) group to identify the implications and analyze the problems of current medical services.

Participants: Surveys and interviews were conducted with the participants divided into two groups. The first group was the consumer group, consisting of patients and guardians who had experienced each disease. The second group consisted of providers of services for each disease, in and out of hospital settings, such as medical/healthcare and nursing care.

Survey and interview processes: The survey consisted of importance/satisfaction items for use in importance/performance analysis.28 Interviews were conducted when necessary. For the interviews with stakeholders, the theme was to identify the current status of IMS provision for each disease.

Analytical procedure: Importance/performance analysis was performed using SPSS 23.0. Through this, the importance and satisfaction as perceived by service consumers and providers were extracted, and the efficiency of allocation of resources was explored.

2.2. Problem define and solution develop phases

Subsequent to discovering the problems through literature search and interviews, expert FGI and expert Delphi were performed for the development of a new model.
Table 1
A comprehensive example of literature search results.

| Disease                                      | Service perspective | Key words                                                                 | Literature search methodology      | Results                                                                 |
|----------------------------------------------|---------------------|---------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------|
| Stroke                                       | Rehabilitation      | Variables related to rehabilitation motivation: psychological intervention (depression, self-efficacy, self-determination), environmental factors (social and family support) | Scoping review, meta-analysis      | Among the factors affecting rehabilitation, support has the greatest effect |
| Cognitive impairment after stroke            | Treatment method    | Western and Oriental Therapeutic Intervention -Acupuncture, drugs, chuna, etc. | Systematic review, meta-analysis   | Various treatment method manuals included                               |
| Cancer (breast cancer)                       | Post-surgery care   | Distress-related factors: a psychosocial approach                          | Systematic review, meta-analysis   | Exploring factors for reducing distress                                 |
| Rare incurable disease (sarcoma)             | Treatment method    | Various exercise interventions Circuit, resistance, aerobic, compound exercise | Systematic review, network analysis | Exploring effective rehabilitation treatment methods for sarcoma       |
| Rare incurable disease (fibromyalgia)        | Treatment method    | Current therapeutic intervention methods                                   | Scoping review                     | Exploring intervention methods through Case studies theorem             |
| Rare incurable disease (rheumatoid arthritis) | Treatment method    | Current therapeutic intervention methods                                   | Systematic review, meta-analysis   | Comprehensive cooperative manual for rheumatoid arthritis               |

2.2.1. Expert FGI

Participants: In accordance with the report by Patton,28 purposeful sampling and snowball sampling were performed. Purposeful sampling was applied for the selection of IMS experts, based on previous studies related to IMS. In addition, snowball sampling was performed by explaining the objective of the study to experts in each field and receiving recommendations from other experts who were interested in IMS and had actual experience in medical service with the theme of shared care or integrative medicine.

To select members from each field for the IMS model, professional occupational groups considered by experts from administrative and legal, education and counseling, welfare, medicine (KM and Western medicine [WM]), health sector, and complementary and alternative medicine (CAM) fields were selected. The sample size for each group was set to 3–5 persons based on the optimal number of participants for FGI reported in studies by Carlsen et al.30 and McLafferty31; thus, a total of 30–60 participants in two focus groups with 18–30 experts from six fields were selected.

Procedures: FGI and in-depth one-on-one interviews for the development of an IMS model for stroke patients were conducted with experts representing each field. Through this, data for establishing an IMS model for stroke patients were collected and organized.

Participants of the FGI were experts from fields related to the development of an IMS model for stroke patients, consisting of medical/health experts (KM/WM, CAM, etc.), legal, administrative, social welfare, education, and counseling experts.

Analytical methods: The analytical methods for the FGI were as follows.

Qualitative data analysis was performed based on preliminary expert FGIs and in-depth interviews. Qualitative data were categorized by theory, and tentative concepts were constructed. Specifically, systematic coding was performed, where open, axial, and selective coding were used to identify and dimensionalize the subcategories, domains, and attributes of the IMS model for stroke patients. Subsequently, a paradigm model was used to implement a conditional matrix diagram that identifies the social, economic, and medical environmental conditions that make up the medical service model, and the outcome model was used for analysis.

2.2.2. Expert Delphi for validity testing

Problems in the current medical services were explored through a literature search and expert FGI. Consensus by expert Delphi was performed on domains derived as essential domains in the IMS model for patients with the four major diseases. Domains were explored by each disease and a consensus on the domains was reached through emails from experts of each disease, after which construct and content validity analyses were performed. The questionnaire was constructed online and sent via text messaging and email. The sampling and specific procedures were as follows:

Participants: The total number of participants was 45–100, from nine IMS expert groups (KM/WM, nursing care, CAM, welfare, administrative, legal, and counseling) for expert Delphi. The detailed sampling method and sample size were as follows: In accordance with the report by Patton,29 purposeful sampling and snowball sampling were performed. Specifically, purposeful sampling was applied for the selection of IMS experts, based on previous studies related to IMS. In addition, snowball sampling was performed by explaining the objective of the study to experts in each field and receiving recommendations from other experts who were interested in IMS and had actual experience in medical service with the theme of shared care or integrative medicine.

To select members from each field for the IMS model for rehabilitation of subacute stroke patients, professional occupational groups considered by experts from administrative and legal, education and counseling, welfare, medicine (KM/WM), health sector, and CAM fields were selected. The sample size for each group was set to 5 or more per domain, but no more than a total of 100, as suggested by Dalkey N and Helmer.32

First Delphi: Domains derived by reviewing studies from the perspective of an IMS model for stroke patients and questionnaires derived through expert FGI for increasing field suitability were distributed to experts for factor (construct) validity and expert assessment. Subsequently, opinions about the assessment were accepted, and additional opinions about IMS domains and items were enquired. Based on this, the model domain construct was revised by increasing the suitability of items and systematic aspects of the domain construct. Specifically, the research team performed factorial validity testing according to the importance and necessity of the first Delphi to identify the domain priority, whereby improvement was made through the classification of deleted and revised domains.

Second Delphi: The second Delphi involved an expert review of domains and items that were revised through the first Delphi. Moreover, content validity and field suitability were reviewed, and a consensus was reached.

To determine the suitability of each domain and item, the constructed questionnaire was distributed online to the expert panel for review of content validity.

Procedures: An online questionnaire was distributed for the second time to experts from each field who were interested in developing an IMS model for stroke patients and voluntarily consented to participate in the study.
**3. Results**

In this section, partial results of cases of the four major diseases being developed by applying the methodologies of the development of the IMS model are presented as examples.

#### 3.1. Literature search and stakeholder survey results

##### 3.1.1. Stroke

When stroke was divided into acute and sub-acute phases, long-term rehabilitation treatment programs and sociopsychological interventions were needed for the development of a holistic IMS model.

Existing studies indicate that the motivation for rehabilitation in stroke patients is highly associated with depression. However, scoping review and meta-analysis results showed that social support, especially support from medical staff and family, significantly increased the motivation for rehabilitation. The next highest factor was self-efficacy. These findings showed that social support should be provided in psychological intervention for stroke patients, more so for depression, which has been reported to be important in clinical settings. In addition, the results also indicated the need for programs that can enhance self-efficacy. Furthermore, the results also showed that social support plays an important role in the IMS model domain for the enhancement of rehabilitation of stroke patients. The findings also showed that exercise programs accounted for most of the rehabilitation therapy for stroke patients.

The results showed that acupuncture or KM treatment was administered more actively than drug therapy. These findings indicate that KM interventions needed for stroke patients should be more diverse.

##### 3.1.2. Cancer

With respect to cancer, the number of patients with breast cancer is increasing, while the age of cancer patients is decreasing. Analysis of studies related to patients with breast cancer indicated that postoperative reconstruction and psychological intervention were more important to these patients than surgery itself. The findings confirmed the need for an intervention program focusing on stress management for postoperative care of patients with breast cancer.

##### 3.1.3. Rare incurable diseases (Sarcopenia and fibromyalgia)

In contrast, rare and incurable diseases still lack clinical evidence or valid criteria for diagnosis and treatment. Therefore, clarity regarding diagnosis and prognosis is important. Interestingly, most of the study reports in Korea on fibromyalgia reported on KM interventions. For sarcopenia, combined exercise was predominantly used, but single exercise was more effective (Supplement 2).

#### 3.2. Results of expert FGI

The following is a part of the qualitative data from the IMS model FGI related to rehabilitation motivation of subacute stroke
patients in the development of the IMS model for patients with the four major diseases (Supplement 3). Subacute stroke patients require continued rehabilitation, but because there are no easy methods once they are discharged from the hospital, the experts presented the following opinions:

Based on the methodology mentioned above, domains were developed through qualitative analysis, and the items suitable for the domains were categorized to derive the results for the subsequent expert Delphi. An example of the results of the domains derived through the IMS model expert FGI for the rehabilitation of subacute stroke patients is shown in Table 3. A total of 34 items in seven domains were derived. The categorization of treatment program manuals was divided and drafted in the medical staff domain.

**Other results**

Some case studies with the application of such methodologies are presented as results. In addition, a rough draft of the flow chart for conducting the IMS model development study was drafted according to this methodology. Accordingly, the flow chart for “IMS model for rehabilitation of subacute stroke patients,” which was implemented with the application of this methodology, is shown in Fig. 2.

A unique aspect of the results presented above is that the need for management of computerized DB for medical service provision is shown as a flow chart. It also showed the need for online availability of patient experience assessment. In other words, the results provided by the flow chart have the advantage of specifying and showing the domains or components that are needed in the development of future models.

### 4. Discussion

The objective of this study was to introduce methodologies for the development of an IMS model for four major diseases. Accordingly, a methodology was presented for each phase based on the service development model as evidence, while studies currently being conducted according to the methodology are presented as examples.

The contents included the following aspects. First, the double diamond design process, which is the most popular and efficient
theory for service design development, and the Donabedian model, which explains the medical service process, were introduced and procedures using these were presented. This was based on the study by Yang et al.,\textsuperscript{12,3} on medical service design research trends, in which the majority of the studies used the double diamond design process model. In other words, as reported by Lee and Lee,\textsuperscript{36} the majority of medical service designs set the theoretical framework by selecting either the double diamond design process or the Donabedian model.

Next, the World Health Organization ICF model was introduced for the development of content for the IMS model. Regardless of whether it is in Korea or abroad, the perspective on disabilities and rehabilitation now includes social aspects, instead of only the medical aspect of attempting therapeutic intervention. Accordingly, organizing and providing only treatment methods in the development of an IMS model does not bear the meaning of “integrative” and “holistic treatment.” Therefore, the four major diseases, which require long-term treatment and rehabilitation, have high medical costs, and have various treatment methods available, should no longer be interpreted as personal problems, but rather, as interactions between individuals and the environment. As shown in the study by Stucki G, et al.,\textsuperscript{33} the IMS model requires support and intervention from various domains, including treatment manuals. This is consistent with the values ascribed by the ICF model and is also in consensus with the report by Bae, Jang, and Baik,\textsuperscript{37} which stated that community-based rehabilitation services are essential.

Third, methods applied to conduct actual studies based on theoretical frameworks may be divided largely into four types – two methods from the problem discover phase and two methods from the solution develop phase. In the problem discovery phase, literature search, service consumer and provider survey, and interviews were applied, while methods for defining and resolving the problems included expert FGI and expert Delphi. This was the same methodology that Kim and Kim\textsuperscript{39} presented in their study on the measurement of efficiency and effectiveness of regional healthcare systems.

In particular, the literature search method was similar to the methodological approach suggested by Kim.\textsuperscript{39} In other words, there were two methods: systematic review when the search criteria were clear and scoping review for searching the overall theme when the criteria were unclear. Moreover, a simultaneous meta-analysis may be performed when checking quantitative statistics. Moreover, obtaining data through expert FGI is a method that can produce more in-depth results than qualitative studies, since expert Delphi is a method for scientifically developing valid and reliable models by building consensus among medical service users in Korea. This was the same methodology used in the study by Kim and Kim\textsuperscript{40} and is a method generally used when attempting studies on medical services from experts’ point of view.\textsuperscript{41}

Cases studies were conducted for completing the development of the model developed using this method. This could identify areas for improvement from the perspective of medical service users (consumers and providers) before finalizing the development, while applying this to the assessment could demonstrate its validity.

This study had some limitations. First, as a study that introduced methodologies needed for the development of an IMS model, it did not present sample cases with various diseases. Thus, this methodology should be applied to develop an IMS model for each disease and propose a case study applying the model. Second, this study provided methodologies for searching each content with a theoretical background with respect to the service design model and medical service process. However, researchers have suggested the introduction of methodologies for the development of new models that are applicable in various fields of medical service. Lastly, although IMS model development methodologies were introduced through this study, we also identified the existence of diseases that need KM service models. Therefore, the development and introduction of KM research methodologies and research education theories for scientific and holistic treatment are suggested.

Despite these limitations, this study has several strengths. First, by introducing methodological approaches and procedures for the development of an IMS model for the four major diseases, the study provided basic information to researchers on model development. It is significant that the study clearly demonstrated methodological evidence for a holistic approach, which overcomes the limitations of simple treatment programs. Second, by introducing methodologies for the development of a medical service model, the study demonstrates to researchers who will develop models in the future that such models must be developed with scientific procedures and evidence. In other words, model development must follow scientific procedures, and researchers arbitrarily carrying out development on their own could compromise the validity and reliability of the model. Third, the study also has the significance of questioning whether it is scientific to arbitrarily define and conduct research instead of following methodological procedures to define “integrative” in “integrative medical service.” Finally, we believe that our study will help to develop scientifically valid and reliable medical service models in future, which could ultimately enhance the health and quality of life of the general public.

In conclusion, this study established a framework for the development of a Korean version of the IMS model in CAM within the dual healthcare system with KM and WM.

In addition, the concept of integrative medical service is operationally defined as providing a holistic psychosocial intervention that improves the quality of life of patients and enables them to participate socially while based on medical care rather than a simple therapeutic approach.

We hope that registry studies based on this and development of clinical pathway and clinical practice guideline link to clinical trials will follow.

Supplement
Supplement 1. Network meta-analysis results for rehabilitation exercise program for sarcopenia patients
Supplement 2. The protocol Examples of focus Group Interview related to rehabilitation motivation of subacute stroke patients
Supplementary 3. The definition and formular of L_CVI/Ave and S_CVI/UA

Conflict of interest
Myeong Soo Lee is the editor of this journal but his status had no bearing on the editorial process or decision. The authors have no other conflict of interest to declare.

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CRediT authorship contribution statement
Moon Joo Cheong: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization, Software, Data curation. Myeung Su Lee: Validation, Investigation, Writing – review & editing, Software, Data curation. Min Cheol Joo: Software, Data curation. Sang-Yeol Lee: Software, Data curation. Jung-Han Lee: Investigation, Software, Data curation. Jong-Min Yun: Investigation, Software, Data curation. Yeonseok Kang: Investigation, Software, Data curation.
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Ethical statement

Not applicable for this study.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.imjr.2022.100840.

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