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The Construction of a "Consistency Evaluation" System for Mid-to-High-End Domestic Medical Equipment and Imported Equipment

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Abstract: To break the "import-only" tendency of medical institutions towards medium and high-end domestic medical equipment, this study, based on health technology assessment, value-based healthcare and the full life cycle theory, constructs a consistency evaluation system for medium and high-end domestic and imported medical equipment. Through two rounds of Delphi expert consultation (n=19), the analytic hierarchy process was used to determine the weights of the indicators, and a final evaluation system was formed, which includes four dimensions of economy, technology, clinical adaptability, and full life cycle, as well as 25 secondary indicators. This system innovatively integrates multi-source evaluation theories and establishes a four-dimensional evaluation model covering technological breakthroughs, clinical value, cost control and risk management, providing a scientific decision-making tool for the substitution of domestic medical equipment for imported ones.

Keywords: Domestic medical equipment substitution; Consistency evaluation; Analytic hierarchy process; Delphi method; Full life cycle

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1. Introduction

As the core infrastructure of the national public health system, mid-to-high-end medical equipment represents a critical link in ensuring the autonomous and controllable nature of medical resources. Breakthroughs in technological barriers within fields such as medical imaging diagnostics (e.g., CT, MRI), in vitro diagnostics (e.g., chemiluminescence immunoassay analyzers), and rehabilitation therapy (e.g., rehabilitation robots, laser therapy devices) directly impact the strategic security of the nation's healthcare system. However, medical institutions, as the primary users of mid-to-high-end medical equipment, generally exhibit a tendency to favor imported equipment, which essentially stems from a lack of scientific evaluation criteria regarding the performance and clinical compatibility

of domestically produced equipment. Exploring a scientific, comprehensive, and objective "consistency evaluation" method for comparing mid-to-high-end domestically produced medical equipment with imported counterparts can not only enhance the effectiveness and safety of domestically produced medical equipment, providing medical units with evidence-based grounds for adopting domestically produced equipment, but also reduce expenditure for medical institutions and drive rapid innovation and development in the domestic medical device industry.

The process of studying the consistency between two types of entities, X and Y, involves encoding specific instances x and y of X and Y using the same coding system and then comparing them [1]. In short, the essence of consistency is the manifestation of "non-contradiction" and "self-consistency," which permeates the entire human system of seeking truth, reliability, and system design. In the medical field, "consistency evaluation" research is predominantly applied in the reevaluation of generic drugs, but it is equally applicable to the evaluation of medical equipment. Existing research primarily focuses on comparing the performance of domestically produced and imported equipment, analyzing economic benefits, evaluating user satisfaction, and investigating the current status of equipment allocation. Research methods have gradually evolved from early qualitative descriptions to quantitative analyses, with the introduction of scientific approaches such as the Analytic Hierarchy Process (AHP), Fuzzy Comprehensive Evaluation Method, and Real-World Data Analysis, enhancing the scientific rigor and credibility of research [2,3,4]. Studies by Feng Hanbo et al. indicate that the localization rate of basic hospital equipment, including monitors, infusion pumps, and syringe pumps, has exceeded 85% [5]. Further research by Yang Minmin confirms that for small medical devices such as surgical instruments, infusion pumps, monitors, and electrocardiogram (ECG) machines, domestic brands have fully matured in terms of technology. These devices, characterized by relatively simple functions, high production and sales volumes, assured quality, and superior after-sales service, have gained a competitive edge [6]. According to a survey conducted by Liu Yanning et al. on secondary and tertiary public hospitals in Liaoning Province, domestic ECG machines, digital radiography (DR) systems, and biochemical analyzers even outperform their imported counterparts in terms of return on investment and utilization rates [2]. However, existing research still exhibits significant shortcomings in terms of theoretical systematicness, methodological integration, dynamic perspective, and localization suitability of evaluation indicators, highlighting an urgent need to establish a more scientific and comprehensive integrated evaluation system.

Therefore, considering the characteristics of medical equipment and associated research costs, as well as incorporating localization features of domestic substitution, it is essential to construct a "consistency evaluation" system for medium-to-large medical equipment from multiple dimensions, including economic efficiency, clinical adaptability, technicality, and full lifecycle management. This system should address four core issues in the process of domestic substitution: cost control, technical benchmarking, clinical implementation, and long-term risk management, providing a scientific and reliable basis for relevant authorities to promote the substitution of imported medical equipment with domestic alternatives.

2. Subjects and Methods

2.1. Establishment of a Project Liaison Team

The Delphi method is a structured approach that involves conducting multiple rounds of anonymous, back-to-back opinion solicitation from experts on the issues to be predicted through written inquiries. Researchers aggregate and provide feedback on the experts' opinions in each round until a consensus is reached among them [7]. The substitution of domestically produced medical equipment involves multidimensional issues such as technology, clinical application, economics, and policy. Experts from different fields may have divergent opinions. The

Delphi method, through its anonymous and multi-round feedback mechanism, systematically converges expert viewpoints, avoids bias from authoritative dominance or groupthink, and ensures the objectivity of indicator selection. To enhance the research progress and the efficiency of Delphi expert consultations, a project liaison team was established, consisting of one professor, one postgraduate student, and three medical equipment engineers. The primary responsibilities of the project liaison team include initially determining the original indicator content and quantity for the "consistency evaluation" of medium-to-large domestically produced medical equipment versus imported equipment, developing expert consultation questionnaires, selecting experts from various fields, coordinating expert consultation activities, and conducting statistical analysis of questionnaire results, ultimately organizing, summarizing, and evaluating the survey outcomes.

2.2. Preliminary Determination of Original Indicator Content and Quantity

By reviewing literature related to medical device evaluations and the implementation policies concerning domestic substitution, the project liaison team, starting from the research objectives of this project and integrating theories such as Health Technology Assessment (HTA) [8], Value-Based Health Care (VBHC) [9], Life Cycle Management (LCM) [10], and Cost-Benefit Analysis (CBA) [11], determined the content and quantity of the original indicators. During the process of constructing a "consistency evaluation" system for medium to large-sized domestic medical devices and imported devices, the team took into account the fundamental needs for medical devices to be affordable, effective, familiar, and durable. Indicators were set up from four aspects: economic efficiency, clinical adaptability, technicality, and life cycle management, resulting in the preliminary formulation of an evaluation system comprising 4 primary indicators and 50 secondary indicators.

2.3. Selection of Consultation Experts

After discussion by the project liaison team, the basic criteria for experts participating in the project consultation were established as follows: ① Their professional fields should cover medical device R&D, hospital equipment management, health policy research, clinical usage experts, medical device maintenance, and medical device procurement; ② They should possess experience in their respective fields and have been actively engaged in relevant positions for at least the past three years; ③ They should hold a deputy senior professional title or above, or a mid-level professional title with a postgraduate degree or higher; ④ They should be interested in scientific research and have sufficient time to fully cooperate with this research work. After unanimous discussion by the liaison team, 19 experts from public hospitals, R&D departments of imported medical device manufacturers, R&D departments of domestic medical device manufacturers, and policy-making institutions were selected as consultation subjects.

2.4. Conduct Delphi Consultation

From February to April 2025, two rounds of expert consultations were conducted through online meetings, with questionnaires distributed via QR codes. In the first round of expert consultation, a five-point rating scale was first employed to define and assign scores for four dimensions: importance, operability, data availability, and familiarity (see **Table 1**). Experts were then asked to make judgments on these four dimensions for each indicator based on their professional backgrounds and work experience. Based on the returned questionnaire results and feedback, revisions were made after comprehensive consideration of the opinions and suggestions to determine the final content of the evaluation indicators. The second round of expert consultation primarily sought opinions on the weights of the revised indicators, utilizing the Analytic Hierarchy Process (AHP) to determine the weights of each primary and secondary indicator.

Table 1. Definitions and Scoring Rules for the Four Dimensions

Dimension	Description	Scoring Rules
Importance	The criticality of this indicator for evaluating domestic substitution of imported equipment.	Very Important (5), Fairly Important (4), Moderately Important (3), Slightly Important (2), Not Important (1)
Operability	The feasibility and cost of measuring this indicator in practical application.	Extremely High (5), High (4), Moderate (3), Low (2), Very Low (1)
Data Availability	The difficulty level in obtaining the data required for this indicator.	Very Easy (5), Fairly Easy (4), Moderate (3), Fairly Difficult (2), Very Difficult (1)
Familiarity	The expert's degree of familiarity with this indicator.	Very Familiar (5), Fairly Familiar (4), Moderately Familiar (3), Slightly Familiar (2), Unfamiliar (1)

2.5. Data Processing and Statistical Methods

Data were organized and summarized using Excel spreadsheets, and then analyzed using Python software to assess the scoring results provided by each expert. Firstly, the liaison team conducted a quantitative assessment of the experts' qualifications based on their professional backgrounds, calculating data dispersion and information utility values to obtain a weighted average score for expert qualifications. The weight coefficients of each expert were then adjusted using the entropy weight method. Next, the original data from the 19 experts were integrated to construct a matrix, and weighted scores for importance, operability, and data availability were calculated for each indicator. A comprehensive screening threshold was applied, and the correlation coefficients of the indicators were calculated. Similar indicators were merged, and the final evaluation indicators were determined. Finally, the Analytic Hierarchy Process was used to construct a judgment matrix and calculate the consistency ratio (CR < 1), while the entropy weight method was employed to calculate information entropy and utility values, thereby determining the final weights of the evaluation indicators. In summary, the final evaluation system was established.

3. Results Analysis

3.1. Introduction to Basic Information of Experts

The liaison group selected a total of 19 experts to participate in this study, including 3 experts in the research and development of domestically produced medical equipment, 3 in the research and development of imported medical equipment, 4 in hospital equipment management, 2 in health policy research, 4 clinical users, 2 medical equipment maintenance personnel, and 1 medical equipment purchaser. Experts with a professional title of associate senior level or above accounted for 78.95%, and all experts had work experience of 10 years or more (see **Table 2**).

Table 2. Summary of Basic Information of Experts

Category	Characteristic	Number of Experts	Percentage
Gender	Male	13	68.42%
	Female	6	31.58%
Age	30-45 years	15	78.95%
	>45 years	4	21.05%
Education Level	Bachelor's Degree	5	26.32%
	Master's Degree or above	14	73.68%

Table 1 (Continued)

Category	Characteristic	Number of Experts	Percentage
Years of Experience	10-15 years	10	52.63%
	>15 years	9	47.37%
Professional Title	Intermediate Title	4	21.05%
	Deputy Senior Title or above	15	78.95%

3.2. Expert Enthusiasm

The enthusiasm coefficient of experts is represented by the response rate of the questionnaire[12]. In the first round of expert consultation, a total of 21 experts were invited to participate in the questionnaire survey, and 19 valid questionnaires were collected, resulting in an expert enthusiasm coefficient of 90.47%. In the second round of expert consultation, a total of 19 experts were invited, and 19 valid questionnaires were collected, resulting in an expert enthusiasm coefficient of 100%. During the two rounds of expert consultation, in addition to providing professional scores, the experts also proposed a total of more than 30 suggestions and comments, indicating that the participating experts were highly interested in and concerned about this research topic.

3.3. Determination of Expert Weights and Indicator System

Construct an expert weight matrix (see Formula 1), where each row represents an expert, each column represents an indicator, and each cell contains the expert's ratings for the importance (1-5 points), operability (1-5 points), and data availability (1-5 points) of the indicator. Based on the qualifications and the weights (W_k) adjusted by the Delphi method, calculate weighted scores for each indicator after expert ratings, including weighted importance $S_j^{importance} = \sum_{n=1}^{19} W_k * s_{jn}^{importance}$, weighted operability $S_j^{operation} = \sum_{n=1}^{19} W_k * s_{jn}^{operation}$, and weighted data availability $S_j^{data} = \sum_{n=1}^{19} W_k * s_{jn}^{data}$, to ensure objective and authentic results. After completing the first round of expert consultations, calculate the final contribution scores for each expert. The contribution score is calculated as follows: (importance × 0.4 + operability × 0.3 + data availability × 0.2 + familiarity × 0.1) × expert weight. Use the threshold value method to screen indicators [4], and combine expert opinions to add or delete indicators. Indicators with a contribution score ≥ 4.3 are ultimately included, resulting in an indicator system consisting of 4 primary indicators and 25 secondary indicators, as shown in **Table 3**.

$$X = \begin{bmatrix} X_{11} & X_{12} & \cdots & X_{1j} \\ X_{21} & X_{22} & \cdots & X_{2j} \\ \cdots & \cdots & \cdots & \\ X_{i1} & X_{i2} & \cdots & X_{ij} \end{bmatrix}$$

Formula 1. Expert Weight Matrix

Table 3. Consistency Evaluation Indicator System for High-end Domestically Produced Medical Equipment and Imported Products

Primary Dimension	Secondary Dimension	Secondary Indicator Code	Secondary Indicator Name	Expert Consensus Score (Average)
A. Economic Dimension	A1 Initial Investment Cost	A1-1	Equipment Purchase Price (Tax-Inclusive)	4.60
	A2 Operation & Maintenance Cost	A2-1	Annual Preventive Maintenance (PM) Cost	4.82
	A3 Consumables & Compatibility	A3-1	Unit Price of Dedicated Consumables (vs. Imported Counterpart)	4.48
	A4 Asset Efficiency	A4-1	Daily Revenue Contribution Rate per Unit	4.30
B. Technical Dimension	B1 Core Performance	B1-1	Key Parameter Compliance Rate (vs. Imported Benchmark), e.g., Imaging Resolution, Detection Sensitivity/Specificity, Response Speed	4.88
		B1-2	Equipment Uptime Rate (≥95% Standard)	4.43
	B2 System Reliability	B2-1	Mean Time Between Failures (MTBF)	4.78
		B2-4	Comprehensive Incidence of Faults and Adverse Events	4.50
	B3 Technical Upgradability	B3-2	Hardware Module Expansion Compatibility	4.63
	B4 Localization Adaptation	B4-1	Completeness of Chinese User Interface	4.72
		B4-2	Regional Service Network Coverage (2-Hour Response Radius)	4.32
	B5 Safety	B5-1	Radiation Leakage / Bio-contamination Protection Level	4.92
		B5-2	Data Encryption & Transmission Compliance	4.68
		B5-3	Automatic Blocking Response Speed for Misoperation	4.40
	B6 User Support	B6-1	24/7 Remote Technical Support Connection Rate	4.58
C. Clinical Adaptability Dimension	C1 Diagnostic/Therapeutic Efficacy	C1-1	Improvement in Diagnostic Concordance Rate (vs. Gold Standard)	4.70
	C2 Departmental Operation	C2-1	Average Daily Number of Patients Treated per Device	4.55
	C3 Clinical Experience	C3-1	User Interface Friendliness (Clinician Evaluation)	4.80
		C3-4	Physician Satisfaction (Ease of Operation)	4.38
D. Full Life Cycle Dimension	D1 Procurement & Installation	D1-1	Equipment Delivery Lead Time (Contract Signing to Acceptance, days)	4.65
	D2 Operational Cost	D2-1	Annual Maintenance Cost Ratio (Maintenance Cost / Total Equipment Cost, %)	4.75
		D2-2	Spare Parts Supply Timeliness Rate (%)	4.35
	D3 Clinical Use	D3-3	Time per Examination	4.45
	D4 Repair & Response	D4-1	Average Repair Response Time	4.85
	D5 Decommissioning & Replacement	D5-2	Technology Obsolescence Cycle	4.52

3.4. Determination of Indicator Weights

After finalizing the indicator system, conduct a second round of expert consultations. First, experts are required to conduct pairwise comparisons of the relative importance of the four dimensions and pairwise comparisons of the secondary indicators within the same indicator layer (according to the 1-9 scale definition table). Calculate the

weights of indicators at all levels in combination with expert weights; then perform normalization and calculate the consistency ratio (if CR < 0.1, the test is passed; otherwise, rescoring is required), to obtain the final weights of the secondary indicators (see **Table 4**).

Table 4. Results of Indicator Weights

Comprehensive weight of first-level indicator (economic dimension)			
First-level indicator	**Comprehensive weight**	**Consistency Check (Average CR)**	**Kendall's W**
A. Economy	0.165	0.072	0.83
B. Technicality	0.341	0.068	0.79
C. Clinical adaptability	0.238	0.081	0.76
D. Full life cycle	0.256	0.085	0.72
Comprehensive weight of secondary indicators (economic dimension)			
Secondary indicators	**Comprehensive weight**	**Consistency Check (Average CR)**	**Kendall's W**
Purchase price of bare equipment	0.402	0.048	0.86
Annual PM expenses	0.263	0.051	0.81
Unit price of special consumables procurement	0.187	0.063	0.78
contribution rate of daily average diagnosis and treatment revenue per unit	0.148	0.074	0.71
Comprehensive weight of secondary indicators (technical dimension)			
Secondary indicators	**Comprehensive weight**	**Consistency Check (Average CR)**	**Kendall's W**
The key parameter compliance rate	0.218	0.055	0.84
Operating rate	0.132	0.062	0.8
MTBF	0.095	0.058	0.77
Failure incidence rate	0.072	0.067	0.74
Hardware expandability	0.063	0.07	0.72
Chinese interface	0.058	0.069	0.69
Maintenance network coverage rate	0.105	0.061	0.76
Protection grade	0.042	0.075	0.66
Data encryption	0.053	0.073	0.68
Misoperation blocking	0.047	0.071	0.65
Remote support	0.065	0.064	0.7
Comprehensive weight of secondary indicators (dimension of clinical adaptability)			
Secondary indicators	**Comprehensive weight**	**Consistency Check (Average CR)**	**Kendall's W**
Improvement in diagnostic accuracy rate	0.418	0.049	0.85
Average daily number of patients treated	0.227	0.057	0.79
User-friendliness of the operation interface	0.198	0.063	0.75
Doctor satisfaction	0.157	0.072	0.7
Comprehensive weight of secondary indicators (full life cycle dimension)			
Secondary indicators	**Comprehensive weight**	**Consistency Check (Average CR)**	**Kendall's W**
Delivery cycle	0.285	0.052	0.83
Maintenance cost proportion	0.208	0.061	0.78
Timeliness rate of spare parts supply	0.182	0.065	0.75
Time for a single inspection	0.125	0.074	0.69
Maintenance response time	0.105	0.071	0.67
Technology obsolescence cycle	0.095	0.076	0.64

4. Discussion

4.1. Method Selection

Both the Delphi method and the Analytic Hierarchy Process (AHP) are commonly used structured methods, each with its own advantages in structuring (see **Table 5**). In the initial stage, the Delphi method was employed to gather expert opinions and establish an evaluation index system. Subsequently, AHP was utilized to calculate the weights of each indicator. The key factor for the success of Delphi method predictions lies in the selection of experts [7]. The number of experts should be determined based on the complexity of the subject matter, with a general recommendation of 15 to 50 participants for consultations [13]. After rigorous screening by the liaison team, 19 experts were selected for this study, covering the fields of domestic medical equipment R&D, imported medical equipment R&D, hospital equipment management, health policy research, clinical use, medical equipment maintenance, and medical equipment procurement. These experts were spread across four provinces and cities in China, with 78.95% holding associate senior or higher professional titles and an average work experience of 15.95 years, reflecting their representativeness in their respective academic and professional domains. Meanwhile, the experts actively participated in the questionnaire survey and provided numerous valuable insights. The entire consultation process took nearly a month, with over 90% of the questionnaires returned being valid, further ensuring the quality of the research findings.

Table 5. Comparison of Advantages between Delphi and Analytic Hierarchy Process Methods

Dimension	Delphi Method	Analytic Hierarchy Process (AHP)
Core Objective	Convergence of Group Consensus	Multi-Criteria Weight Calculation
Input Form	Expert Qualitative Opinions (can incorporate quantitative ratings)	Quantitative Paired Comparisons (e.g., 1-9 Scale)
Process Focus	Multi-Round Iteration and Feedback	Matrix Construction and Mathematical Computation
Primary Output	Qualitative Group Consensus or Quantitative Statistical Indicators (e.g., Kendall's W, mean scores)	Weight Values and Ranking Across Hierarchical Levels
Common Structured Features	Standardized, Repeatable, and Transparent Process	Standardized, Repeatable, and Transparent Process

4.2. Interpretation of Results

After two rounds of expert consultations, the experts provided relatively consistent opinions on the first-tier indicators across four dimensions: economic viability, technical feasibility, clinical adaptability, and whole lifecycle management. Among these, technical feasibility had the highest weight (0.341), followed by whole lifecycle management (0.256), clinical adaptability (0.238), and economic viability (0.165). The ranking of these indicator weights also reveals that, under the policy trend of replacing imported medical equipment with mid-to-high-end domestically produced alternatives, technological breakthroughs serve as the core driving force for domestic substitution. The "key parameter compliance rate" stands out with a significantly higher weight (21.8%), aligning closely with the policy emphasis on the "autonomous control of critical components" strategy. Whole lifecycle management determines the sustainability of substitution, with the "technological obsolescence cycle" emerging as the most closely watched indicator. Medical institutions are concerned about the long-term cost risks associated with lagging equipment iteration speeds. Domestic manufacturers can establish ongoing technological upgrade mechanisms (such as modular design) and a spare parts supply system to break the vicious cycle of

"technological lock-in—high-priced maintenance" associated with imported equipment. Clinical adaptability reshapes medical value standards, with the "improvement in diagnostic accuracy rate" carrying a weight of 41.8%, far exceeding other indicators, reflecting experts' ultimate pursuit of diagnostic precision. The paradox of economic viability weights reveals policy guidance; although the economic viability dimension has the lowest weight (16.5%), the "equipment base price" carries a high weight of 40.2%, creating a structural contradiction. This means that while policies do not encourage price wars, actual procurement by medical institutions remains constrained by budget considerations. Currently, the substitution process is in a technologically intensive phase guided by policies, focusing on overcoming technological hurdles and addressing "bottleneck" issues. Over the next 3-5 years, it will transition into an ecosystem-building phase, establishing local supply chains and forming differentiated advantages.

5. Summary

Based on Health Technology Assessment (HTA), Value-Based Healthcare (VBHC), and Life Cycle Management (LCM) theories, this study employs the classic Delphi method and Analytic Hierarchy Process (AHP) to construct an index system capable of objectively and systematically evaluating the substitution of imported medical equipment with mid-to-high-end domestic alternatives. However, the Delphi method is also prone to interference from subjective factors [14], potentially introducing risks of systematic bias. Subsequent empirical research will be conducted based on the consistency evaluation system for substituting imported medical equipment with mid-to-high-end domestic alternatives. This will involve selecting imaging equipment, in vitro diagnostic equipment, and therapeutic equipment to assess the scientific rigor of the selection process within the consistency evaluation system, thereby enhancing the robustness of the conclusions drawn from the Delphi method.

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