

# Application Practice of Comprehensive Clinical Evaluation of Drugs in Hospital New Drug Selection

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**Abstract:** Objective: To explore the construction of a new model for hospital new drug selection, providing reference for optimizing the drug formulary of medical institutions. Methods: Conducted the practice of hospital new drug selection management based on comprehensive clinical evaluation of drugs. Results: After the implementation of the scientific management new model for hospital new drug selection in our hospital, drug selection was oriented towards clinical diagnosis and treatment needs and patient medication safety, resulting in a significant increase in clinical satisfaction. Conclusion: This model contributes to optimizing the drug catalog of medical institutions and enhancing the level of rational drug use. It fully demonstrates the professional value of pharmacists in pharmaceutical management and rational drug use in medical institutions.

**Keywords:** Drug Comprehensive Evaluation; Hospital New Drug Selection; Pharmaceutical Management; Pharmacists

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## 1. Introduction

Clinical comprehensive evaluation of drugs is the fundamental work to promote the clinical value of drugs, consolidate and improve the essential medicine system, and is a specific requirement for the sound pharmaceutical supply guarantee system<sup>[1]</sup>. In recent years, the role of clinical comprehensive evaluation of drugs in healthcare decision-making has become increasingly prominent. Drug selection is one of the important tasks in pharmaceutical management of medical institutions. Medical institutions should optimize their drug formularies in a timely manner based on the principles of safe, effective, and economical medication, as well as the treatment characteristics of the institution[2,3]. The continuous development and marketing of innovative drugs provide more choices for clinical drug therapy, but also bring greater challenges to the drug selection work of medical institutions. The National Health Commission and various professional academic organizations have successively issued several guidelines on drug clinical comprehensive evaluation<sup>[4]</sup>, which play an important role in providing technical guidance for the selection and elimination of drugs in medical institutions<sup>[5]</sup>. Our hospital has established a medical institution drug selection method based on comprehensive clinical evaluation of drugs, aiming to strengthen pharmaceutical management in healthcare facilities and promote the implementation and application of drug clinical comprehensive evaluation.

## 2. Comprehensive evaluation methodology and content

A scientific and standardized qualitative and quantitative evidence integration analysis and comprehensive judgment are conducted from six dimensions: safety, effectiveness, economy, innovation, suitability, and accessibility, proposing policy recommendations for the supply and standardized use of essential drugs in disease prevention and treatment at different decision-making levels[6,7].

### 2.1 Safety

Comparing the safety of drugs in the same category refers to the difference in safety between the drug under investigation and the control drug with the same indications, focusing on the comparison of adverse reaction incidence and/or severity. Real-world studies and literature evaluations are emphasized, focusing on comparing the incidence rates of serious adverse events.

### 2.2 Effectiveness

The latest and authoritative domestic and foreign diagnosis and treatment guidelines or expert consensus recommendations are used to select endpoint indicators (such as survival rate, cure rate, control rate, and mortality rate) that reflect the true effects of drugs and consider the comparability of different regimens. When obtaining endpoint indicators is difficult, appropriate alternative indicators (such as laboratory

measurements, changes in clinical symptoms or signs, etc.) may be used based on evaluation objectives, relevant disease diagnosis and treatment guidelines, literature evidence, etc.

### **2.3 Economy**

Economic evaluation should be based on real-world scenario simulations and consider using basic data from the Chinese population obtained from real clinical diagnosis and treatment pathways. Real-world data can be used to obtain information such as medical expenses, drug costs, duration of medication, and health outcomes. When real-world data are insufficient to support all the information needed for economic evaluation, or when conducting rapid comprehensive drug evaluation, literature review methods, expert consultation methods, or reliable data information from credible websites (such as government or corporate announcements, open network databases, etc.) may be used to obtain necessary parameters for analysis.

### **2.4 Innovation**

Whether a drug can meet health needs that other clinical drugs cannot, such as improving different outcome indicators, including its use for rare diseases, refractory diseases, diseases in special populations, or emerging infectious diseases. The technical characteristics of the drug should have significant technical advantages over other similar substitute drugs (such as stability of formulations, bioavailability, pharmacokinetic properties, efficacy, dosage form, taste, route of administration, dosage, split packaging, and storage conditions).

### **2.5 Accessibility**

This includes storage conditions and shelf life, whether light protection is required, and whether temperature requirements are specified. For biologics, it also includes storage and transportation conditions. It also includes factors related to compliance such as administration route, dosing frequency, and timing of administration. All information should be based on the latest version of drug instructions approved by China's drug regulatory authority.

### **2.6 Availability**

Assessments of availability, affordability, and sustainability are conducted based on information such as drug dosage form, specifications, manufacturer, and price. It also includes the basic medical insurance attributes of drugs, medical insurance classification, and limited payment scope, as well as whether they belong to "negotiated drugs within the agreement period" and "drugs for centralized volume procurement".

## **3. Drug selection workflow**

This method mainly recommends a design around the common methods and links of drug selection in the drug selection workflow of medical institutions.

### **3.1 Determination of candidate drugs**

Clinical departments of medical institutions propose drug selection needs based on their own clinical diagnosis and treatment needs and intentions. The pharmacy department conducts formal reviews of the proposed drug varieties and preliminarily determines the candidate drugs based on the institution's management system; based on the drug instructions, treatment guidelines, clinical department opinions, and the current situation of routine procurement drug varieties in the institution or domestically marketed drugs, appropriate reference drugs for each candidate drug are determined.

### **3.2 Drug comprehensive evaluation information form**

The pharmacy department prepares a drug comprehensive evaluation information form for each candidate drug and its reference drugs

according to the requirements of the “comprehensive evaluation information framework”.

### 3.3 Determination of selected drug varieties

The pharmaceutical management and clinical therapeutics committee (group) of the medical institution tentatively selects the candidate drug varieties based on the results of the formal review, comprehensive evaluation information form, and clinical department requirements, and convenes a meeting to vote on the candidate drugs for final selection of the selected drug varieties.

## 4. Conclusion

Our institution closely follows national policies, actively explores innovative pharmacy service models, adopts target management approaches, and draws on evidence-based pharmacy and comprehensive drug clinical evaluation methods. We have explored a new scientific management model for drug selection, constructed a medical institution drug selection method based on comprehensive drug clinical evaluation. This method is guided by clinical diagnosis and treatment needs and patient drug safety, significantly increasing clinical satisfaction. It provides a reference for promoting the strengthening of pharmaceutical management in medical institutions, promoting rational drug use, and advancing the development and application of comprehensive drug clinical evaluation work.

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