Effect analysis of a novel pharmacy service model on promoting precision management of nationally negotiated drug

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Abstract: The national negotiation policy has been implemented, with the number of negotiated drugs increasing annually and forming a normalized promotion mode. Faced with the urgent requirements of national policy promotion, hospital discipline development, and improvement of patient medical quality, the precision management of nationally negotiated drugs has become a key issue for medical institutions. Our hospital established a cost control group for nationally negotiated drugs and innovatively set up an independent "Temporary Procurement Drug Catalog for Nationally Negotiated Drugs" outside our hospital's basic drug catalog. We implemented a multidimensional precision management of nationally negotiated drugs, including drug selection, clinical application management, and monitoring and evaluation of drug usage. This study analyzes the effects of this novel pharmacy service model on the control of nationally negotiated drugs. Data on nationally negotiated drugs in a tertiary hospital from March 2021 to March 2023 were collected. The changes in relevant indicators such as hospital's nationally negotiated drug allocation and accessibility, drug utilization, and clinical usage were compared before and after the implementation of the novel pharmacy service model. The results show that after the implementation of the novel pharmacy service model, the hospital's nationally negotiated drug allocation, accessibility, procurement amount, prescription rationality rate, and clinical satisfaction rate all increased compared to before the implementation. The proportion of nationally negotiated drug expenses (total drug expenses) was <15%, controlled within a reasonable range. This novel pharmacy service model, starting from the actual clinical needs of our hospital, not only optimizes the entry and usage process of nationally negotiated drugs but also improves its supervision and evaluation system. It actively promotes the implementation of national negotiation policies while strengthening their rational use, gaining clinical recognition, and playing a positive role in the precision management of nationally negotiated drugs.

Keywords: Pharmacy service model; Nationally negotiated drugs; Precision management; Effect analysis

1. Introduction

As of March 2023, the new national negotiation policy has been implemented, with the number of negotiated drugs increasing annually and forming a normalized advancement pattern. The new policy introduces the rules for national negotiation bidding, once again innovating the system. The innovative mechanism of national negotiation drugs, characterized by precise efficacy, provides an effective for improving clinical diagnosis and treatment. Faced with the urgent requirements of national policy promotion, hospital discipline development, and the enhancement of patient medical quality, the management of nationally negotiated drugs has become a key issue for medical institutions. The value-oriented medical approach under medical insurance and the new national negotiation policy has also promoted the exploration of new pharmaceutical service models. Our hospital has established a control team for nationally negotiated drugs and innovatively created an independent "Temporary Procurement Drug List for Nationally Negotiated Drugs" outside our hospital's basic drug catalog. This aims to achieve precise management of nationally negotiated drugs management, and supervision and evaluation of drug usage. This study analyzes the effectiveness of this new pharmaceutical service model in the control of nationally negotiated drugs.

2. Data and Methods

2.1 Study subjects

This study includes nationally negotiated drugs in our hospital from March 2021 to March 2023, and relevant data in the hospital are analyzed.

2.2 Study content

Comparative analysis is conducted on the control of nationally negotiated drugs by our hospital's cost control team before (March 2021 to March 2022) and after (April 2022 to March 2023) the control period. This includes the allocation and accessibility of nationally negotiated drugs, drug utilization, and clinical usage situations.

2.3 Our hospital's measures for controlling nationally negotiated drugs

Our hospital has established a cost control team for nationally negotiated drugs and created an independent "Temporary Procurement Drug List for Nationally Negotiated Drugs" outside our hospital's basic drug catalog. Tailoring to the actual needs of diseases in our hospital, we conduct a comprehensive evaluation of the effectiveness, necessity, economy, and safety of nationally negotiated drugs, screening the temporary catalog. We actively carry out policy and clinical drug-related training, participate in discussions to formulate rational drug use plans for major diseases, establish clinical monitoring and abnormal warning mechanisms for the use of nationally negotiated drugs, and take corresponding control measures for varieties with abnormal growth in usage, high proportions of unreasonable use, and frequent severe adverse reactions. We formulate clinical application norms for nationally negotiated drugs, conduct prescription reviews, strengthen their rational use, and dynamically adjust the catalog or procurement methods based on monitoring results. We effectively utilize the national negotiation bidding mechanism and the national negotiation "dual-channel" policy to expand the economical use of effective drugs, improve the external usage process of nationally negotiated drugs, and strengthen medication risk management, among other initiatives.

2.4 Research indicators

(1) Provision and accessibility of nationally negotiated drugs

The number of nationally negotiated drugs provisioned = The number of nationally negotiated drugs included in our hospital's "Temporary Procurement Drug Catalog for Nationally Negotiated Drugs."

Accessibility of nationally negotiated drugs = (Nationally negotiated drugs provisioned in our hospital / Total number of drugs in the National Medical Insurance Negotiation) $\times 100\%^{[1]}$

(2) Drug utilization

Purchase amount: The total amount spent on the procurement of nationally negotiated drugs during the specified period (excluding the purchase amount for a large quantity of nationally negotiated drugs used in the treatment of the COVID-19 pandemic, such as the purchase amount for the combination of Nirmatrelvir/Ritonavir tablets and Azvudine tablets).

Defined Daily Dose (DDD) per drug = (Drug procurement quantity \times Specification \times Conversion factor) / DDD / Number of days

Defined Daily Dose cost (DDDC) = Total drug procurement amount / DDDs / Number of days.

Where DDD represents the defined daily dose for each drug, determined according to the "Anatomical-Therapeutic-Chemical Classification Index and Defined Daily Dose Regulations for Drugs 2022" or the drug instructions. DDDC represents the treatment cost required for a patient to use a particular drug per day.

(3) Clinical usage of nationally negotiated drugs

Clinical usage includes the analysis of the rationality rate of prescriptions and clinical satisfaction during the specified period.

3. Research Results

(1) Allocation and accessibility of nationally negotiated drugs: After the control of the cost control team for nationally negotiated drugs, the number of nationally negotiated drug allocations increased by 127.27%, and accessibility rose by 16.62%, as shown in Table 1.

 Table 1: Comparison of Allocation and Accessibility of Nationally Negotiated Drugs before and After the Control of the Cost Control Team

Group	Allocation	Accessibility
Before Control	44	37.61%
After Control	100	43.86%
Growth Rate	127.27%	16.62%

(2) Drug utilization. The total purchase amount of nationally negotiated drugs has significantly increased compared to the pre-control period, as shown in Table 2. The Defined Daily Doses (DDDs) for each nationally negotiated drug have shown varying degrees of growth, with an average growth rate of 31.86%. The overall trend for DDDc for each nationally negotiated drug is a decrease, with an average reduction of 11.26% after the implementation of controls.

 Table 2: Comparison of Drug Procurement Amount and Proportion Before and After the Control of the Cost Control Team for Nationally Negotiated Drugs

Group	Procurement Amount (CNY)	Drug Cost Proportion
Before Control	91189172.58	12.17%
After Control	129290563.70	13.99%
Growth Rate	41.78%	14.95%
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(3) Clinical usage of nationally negotiated drugs: The prescription review qualification rate for nationally negotiated drugs increased by 5.72%, and clinical satisfaction increased by 19.15%, as shown in Table 3.

 Table 3: Comparison of Prescription Qualification Rate and Clinical Satisfaction of Nationally

 Negotiated Drugs Before and After the Control of the Cost Control Team

Group	Prescription Qualification Rate (%)	Clinical Satisfaction (%)
Before Control	91.24%	7.94%
After Control	96.47%	94.78%
Growth Rate	5.72%	19.15%

4. Discussion

4.1 Challenges and importance of nationally negotiated drug control

The national negotiation of drug prices is a crucial aspect of healthcare policy, presenting challenges and highlighting its significance in the healthcare system. The implementation of policies related to the negotiation of drug prices at a national level faces several complexities. One of the major challenges is aligning the interests of various stakeholders, including pharmaceutical companies, healthcare providers, and patients. Negotiating fair and sustainable prices while ensuring accessibility to essential medications poses a delicate balancing act. The involvement of multiple parties with diverse interests requires careful consideration and strategic planning. Additionally, the rapid introduction of innovative drugs into the market poses a challenge in keeping up with the negotiation and inclusion of these drugs in the national drug formulary. The dynamics of drug development and approval require an adaptive and efficient negotiation process to accommodate new therapeutic options. Furthermore, the impact of national drug price negotiation on hospital budgets and overall healthcare expenditure necessitates thorough financial management and planning. Healthcare institutions need to navigate the financial implications of negotiated drug prices, considering factors such as reimbursement structures and budgetary constraints. The importance of national drug price negotiation lies in its potential to enhance the affordability and accessibility of essential medications. By negotiating favorable prices, healthcare systems can ensure the availability of crucial drugs to a wider population, contributing to improved public health outcomes. Additionally, effective negotiation strategies can lead to cost savings, enabling healthcare institutions to allocate resources efficiently. In conclusion, while the national negotiation of drug prices presents challenges, its importance cannot be overstated. It serves as a critical mechanism to control healthcare costs, improve drug accessibility, and

ultimately contribute to the overall efficiency and effectiveness of the healthcare system. Successful navigation of these challenges requires collaborative efforts and strategic planning among policymakers, healthcare providers, and pharmaceutical stakeholders.

The negotiation of national medical insurance drug prices is an important aspect of deepening the reform of the medical and health system. Centered around patients and guided by clinical needs, the successful implementation of nationally negotiated drugs is a systematic and strategic task that requires collaboration across relevant departments, combining policy and system construction with practical implementation^[2]. To promote the implementation of nationally negotiated drugs, hospitals need to ensure that they "should be allocated and fully allocated." However, the performance assessment standards of tertiary hospitals at the national level have imposed restrictions on the growth rate of average/individual drug costs for medical institutions. The introduction of nationally negotiated drugs will inevitably impact drug expenses, increase the cost of drug storage for medical institutions, affect the implementation of medical insurance payment methods, make budget management difficult, and increase the difficulty of managing the proportion of essential drugs^[3]. All these factors may affect the enthusiasm of medical institutions to quickly adopt nationally negotiated drugs. Moreover, the continuous emergence of innovative drugs, driven by scientific and industry progress, enhances the diagnostic and treatment capabilities of hospitals and meets patient needs. However, after some innovative drugs are introduced to the market, they quickly enter medical insurance programs. These drugs may lack clinical usage experience, and the negotiation of some national drugs also faces competition from similar drugs. The hospital's drug access mechanism cannot adapt to the rapid update of medical insurance drugs, further increasing the operational burden on hospitals^[4]. Selecting a nationally negotiated drug catalog that suits the actual needs of the hospital and managing it within a reasonable and controllable range is a current challenge for medical institutions. Therefore, it is urgent to establish a standardized management model for nationally negotiated drugs, including systematic management such as catalog screening, usage monitoring, and application standardization.

4.2 Necessity of pharmaceutical service transformation under the national negotiation policy

Hospital pharmacy is an essential component of the hospital's medical work, playing a crucial role in ensuring rational drug use, controlling medical insurance costs, and improving medical quality. With the continuous deepening of healthcare reform, including the implementation of the national negotiation policy, new opportunities and challenges have emerged for the development of hospital pharmacy departments. The role of pharmacy in the high-quality development of hospitals has undergone significant changes. Exploring the transformation path of pharmaceutical services in medical institutions under the new medical reform situation has become a key issue in the current development of hospital pharmacy^[5].

Pharmacy departments need to closely follow the hospital's high-quality development strategy. Combining policies such as the national performance evaluation of public hospitals, nationally negotiated drugs, and medical insurance payment reforms, they must intelligently fulfill high-quality development tasks to enhance the level of rational drug use and medical quality. Multiple aspects, including the pharmaceutical management system, drug evaluation system, pharmaceutical service models, pharmacy workforce, and pharmaceutical informatization construction, urgently require transformation. Under the new national negotiation policy, pharmaceutical services first need to comply with policies to ensure the full implementation of relevant policy requirements. Secondly, by leveraging various pharmaceutical means, they can effectively carry out pharmaceutical management work from the perspective of the hospital, addressing various aspects of nationally negotiated drug management. Rational drug use is the core of pharmaceutical services^[6] and a key factor for the successful transformation of pharmaceutical services. Therefore, pharmacists should continuously strengthen their professional competence and service capabilities, playing a role and demonstrating their advantages^[7].

4.3 Exploration of the role of the new pharmaceutical service model

In our hospital, pharmacists use payment reforms as a means to participate comprehensively in the management of nationally negotiated drugs before, during, and after the process. We have established a national negotiation drug cost control team to conduct drug evaluations beforehand, formulate drug selection catalogs, and innovatively create an independent "Temporary Purchasing Drug Catalog for Nationally Negotiated Drugs" outside our hospital's basic drug catalog. This approach allows for more flexible adjustments to the catalog based on updates to the national negotiated drug catalog and policies.

Moreover, it considers our hospital's actual needs, screening out nationally negotiated drug catalogs that genuinely meet clinical demands and are necessary, ensuring a rigorous selection process for new drugs.

During the process, pharmacists actively participate in clinical drug use. They contribute to discussions on formulating rational drug use plans for major diseases, providing professional guidance on rational drug use, conducting targeted training and assessments for doctors in pharmacology, and educating and counseling patients on medication use to promote rational drug use. Afterward, they analyze medication usage, construct a monitoring mechanism for nationally negotiated drug use, and, from the perspective of diseases, analyze drugs that exceed the budget under cost control. This involves problem analysis, plan adjustments, drug cost control, and strengthening prescription reviews to identify areas for improvement.

In addition, attention is given to clinical applications and safety data monitoring domestically and internationally. A mechanism is established to eliminate high-risk drugs, optimizing drug use structures. This pharmaceutical service model involves the precise management of nationally negotiated drugs in multiple dimensions, including drug selection, clinical application management, drug use monitoring, and evaluation. It has achieved positive results, with a significant increase in the availability and accessibility of nationally negotiated drugs. The Defined Daily Doses (DDDs) of these drugs have shown varying degrees of growth, while the overall DDDc has declined. The cost of nationally negotiated drugs accounts for less than 15%, within a reasonable and controllable range. Meanwhile, the rationality of clinical drug use has increased, and high levels of clinical satisfaction have been achieved.

5. Conclusion

While medical institutions are promoting the implementation of national drug negotiation policies, it is essential to exercise control over their usage. Therefore, fine management of nationally negotiated drugs is indispensable. Our hospital's new pharmaceutical service model, in addition to ensuring the selection and availability of nationally negotiated drugs, has improved its evaluation methods and management regulations. It has also enhanced the level of clinical rational drug use, gaining recognition in clinical practice. This model has actively promoted the refined management of nationally negotiated drugs. We believe that through continuous exploration and practical efforts, pharmacy professionals can grasp the new opportunities under healthcare reform and national drug negotiation policies. By applying their professional knowledge and skills, they can provide high-quality, valuable, and meaningful pharmaceutical services for patients and the general public.

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