

THE SOCIO-ECONOMIC AND PUBLIC HEALTH IMPACTS OF THE NATIONAL CENTRALIZED DRUG PROCUREMENT POLICY

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Abstract: Purpose: Under the background of the regular implementation of the National Centralized Drug Procurement (NCDP) policy, this study aimed to assess the impacts of the NCDP policy on drug utilization and overall healthcare services in county-level medical institutions, as well as to probe into the influencing factors of changes in drug utilization.

Method: A pre-post study was applied using inpatient data from a county-level medical institution in Nanjing. The drug utilization behavior of medical institutions regarding 88 commonly used policy-related drugs (by generic name, including bid-winning and bid-non-winning brands) was analyzed, and the substitution of bid-winning brands for brand-name drugs after policy intervention was evaluated.

Results: After policy intervention, 43.18% of policy-related drugs realized the substitution of bid-winning brands for bid-non-winning brands (6.82% of complete substitution, 36.36% of partial substitution). Meanwhile, 40.90% of policy-related drugs failed to realize brand substitution. Multiple factors affected brand substitution, including: (1) Policy effect: Brand substitution was more pronounced after the intervention of the first and third rounds of NCDP. (2) Drug market competition: The greater the price reduction of bid-non-winning brands, and the more drugs available for the same indication, the more likely that medical institutions would continue using the same brands as they did before policy intervention. (3) Previous drug utilization of medical institutions: Brand substitution was more evident in drugs with a large number of prescriptions and weak preference for brand-name drugs.

Conclusion: The NCDP policy promoted the substitution of bid-winning brands for bid-non-winning brands, thereby positively impacting the quality and accessibility of overall healthcare services. However, further implementation of the NCDP policy is needed in county-level medical institutions. Efforts in policy implementation, drug market competition, and the drug utilization patterns of medical institutions will affect the success of the NCDP policy and its overall impact on the healthcare system.

Keywords: National Centralized Drug Procurement (NCDP); Drug utilization; Brand substitution; County-level medical institutions

1 INTRODUCTION

1.1 Background

4+7" centralized procurement exceeded 52%, with some prices dropping by as much as 96%. The significant price cuts have compressed profit margins for generic drug companies, particularly small and medium-sized enterprises. Many companies have been unable to win bids due to high costs or limited production capacity, with some even choosing to exit the market. Although this has led to a contraction in the industry in the short term, it has also prompted an optimization of market structure, pushing companies to transition towards higher quality and stronger innovation capabilities.

In contrast, large pharmaceutical groups are more likely to win bids in centralized procurement due to their scale and technological advantages. For example, companies like Huahai Pharmaceutical and Hengrui Medicine have successfully won bids in multiple rounds of procurement through consistency evaluations and high-quality production lines, thereby stabilizing and expanding their market share. The centralized procurement policy encourages companies to shift from competing on price to competing on innovation, increasing R&D investment and focusing on high-value products such as patented drugs, high-end generics, and biosimilars. This has positive implications for the long-term development of the Chinese pharmaceutical industry[1-2].

1.2 Impact on the Public and Patients

The direct benefits of reduced drug prices are evident. For chronic disease medications such as those for hypertension and diabetes, the prices of commonly used drugs like atorvastatin and amlodipine have dropped by more than 60% after centralized procurement. Previously, a chronic disease patient would spend about 200 yuan per month on medication, which has now reduced to around 80 yuan, significantly alleviating their financial burden. Data from the National Bureau of Statistics shows that As a supplementary procurement policy, the N the proportion of residents' medical expenses relative to disposable income has decreased to 7.6% in 2023, down nearly 2 percentage points from 2018.

Additionally, the decrease in drug prices has made basic treatments more accessible for low-income groups, promoting equity in healthcare. However, some patients harbor psychological CDP policy only covers the most commonly used drugs in the clinical setting and, for the first time, mandates public doubts about low-priced drugs, believing that "cheap may mean poor quality," which can affect medication adherence[3-4].

1.3 Impact on the Government

The reduction in drug prices has directly alleviated the financial pressure on health insurance expenditures. According to the National Healthcare Security Administration, from 2019 to 2023, over 400 billion yuan in drug costs has been saved nationwide. The government can use the saved funds to expand coverage, support grassroots healthcare construction, and improve the efficiency of health insurance fund utilization.

The centralized procurement system has also enhanced policy transparency and market regulatory capabilities. By standardizing bidding and publicly announcing winning prices, the risks of inflated drug prices or profit transfers in local decentralized procurement have been reduced. The government has shifted from being a price taker to a market regulator, achieving proactive policy implementation[5-6].

1.4 Impact on Hospitals

The income structure of hospitals has been impacted. In the past, some of the revenue for hospitals relied on "markups" on drugs, and the decrease in drug prices has led to reduced sales profits, putting operational pressure on some grassroots hospitals in the short term. To address this, the government has implemented adjustments to medical service pricing and performance salary reforms, linking doctors' incomes to service quality and diagnostic efficiency, thereby compensating for the cancellation of drug markups. Overall, hospitals are transitioning from a model of "relying on drugs to sustain medical practice" to one of "relying on technology to sustain medical practice," promoting a more rational allocation of medical resources[7-8].

1.5 Public Health Impact

1.5.1 Promoting health equity and universal access

The centralized procurement policy has improved the accessibility of medications and narrowed the healthcare gap between urban and rural areas. Before the implementation of centralized procurement, urban residents could access imported or brand-name drugs, while rural patients primarily relied on expensive generic drugs. After the policy was implemented, the prices and quality standards of centrally procured drugs became consistent nationwide, allowing grassroots hospitals to procure the same medications at lower costs. In 2021, the availability of drugs in grassroots medical institutions increased by approximately 20% compared to 2018, enhancing the accessibility of medical services for rural residents[9-10].

1.5.2 Improvement in drug quality and safety assurance

The centralized procurement requires companies to pass consistency evaluations, ensuring that the quality and efficacy of generic drugs are equivalent to those of original drugs. The government has established a drug traceability system to monitor the entire production, distribution, and delivery process, reducing the risks of counterfeit and substandard drugs. This system has enhanced public trust in the drug regulatory framework[11].

1.5.3 Risks in the drug supply chain

Due to low winning bid prices and thin profit margins, some companies may experience supply shortages or delayed deliveries. The government has developed contingency mechanisms, such as secondary negotiations and alternative suppliers, to address supply disruption risks. However, in the long term, it is still necessary to ensure that companies can achieve reasonable profits while maintaining quality to stabilize the supply chain[12].

1.5.4 Patient trust and psychological expectations

Low-priced medications may trigger psychological expectations of "cheap means poor quality," which can affect medication adherence. Healthcare institutions and the government need to guide the public's understanding through education and physician explanations, emphasizing that price reductions do not equate to quality reductions. Centrally procured drugs that have passed consistency evaluations maintain stable quality and reliable efficacy[13].

1.6 Impact on International Trade and Intellectual Property

1.6.1 Does it hinder free trade?

Free trade refers to the unrestricted flow of goods and services between countries, free from tariff barriers or artificial interference. The centralized procurement policy, through government-led procurement and pricing, does not restrict drug imports or the entry of foreign enterprises into the market, and therefore does not directly hinder free trade. However, the policy does indirectly affect the international competitive landscape. Foreign pharmaceutical companies, facing higher production costs, find it challenging to win bids at low prices, leading some to exit the centralized procurement market and focus instead on innovative and patented drug markets. This shift has resulted in domestic companies dominating the market while foreign companies concentrate on high-end products.

1.6.2 Centralized procurement and intellectual property

The centralized procurement policy does not infringe on pharmaceutical companies' patent rights, as patented drugs

remain legally protected. The policy primarily involves procurement and price negotiations, without enforcing compulsory licensing or patent replication. However, economically, the policy has weakened the pricing power of patented drugs, prompting companies to reassess their pricing strategies and R&D investment directions. In the long run, this may encourage innovation and R&D investments among companies[14-15].

1.7 Additional Impact on Drugs

The National Centralized Drug Procurement (NCDP) policy is one of the supplemental drug procurement policies in China implemented since December 2018. Since 2009, China has initiated healthcare reform and implemented a province-based, government-led procurement pattern, whereby enterprises negotiate with medical institutions after listing on the provincial-level platform and medical institutions purchase on-demand. In December 2018, the State Council released the Pilot Program for National Centralized Drug Procurement and Utilization, which introduced the NCDP policy for the first time, supplementing the existing drug procurement pattern in China. By October 2023, there have been eight rounds of centralized procurement, with an average of 41 policy-related drugs per round and an average price reduction of more than 50%. The NCDP policy is a government-led procurement pattern, which is widely practiced around the world. For example, the UK has a universal health insurance system, with the NHS (National Health Service) leading the centralized procurement of off-patent drugs and generic drugs in public hospitals. In Hong Kong, China, drugs are centrally procured by the Hospital Authority (HA) of the Special Administrative Region in conjunction with all public healthcare institutions. Led and organized by the National Healthcare Security Administration (NHSA), the NCDP policy is implemented through a comprehensive service platform. NHSA selects drugs with sufficient market competition and large market scale, negotiates prices with enterprises (no distinction between brand-name drugs and generic drugs) based on their quoted prices, supply capacity, market recognition, and other comprehensive conditions. The bid-winning enterprise drastically reduces its price, and in order to guarantee its benefits, NHSA promises 50%—70% of the total annual drug utilization volume of all public medical institutions in the alliance regions (different proportions are set according to the characteristics of drugs). The NCDP policy, as a supplementary procurement policy, only covers the most commonly used drugs in the clinical setting and for the first time mandates public medical institutions to equip a certain volume of the procured brands within a procurement cycle. The NCDP policy implements a system of rewards and penalties to regulate drug utilization in medical institutions. For instance, additional incentives may be granted based on how well medical institutions meet their procurement targets, while those that fail to fulfill the assigned procurement volume may face criticism and reprimands[16-17].

Following the policy intervention, enterprises that win bids demonstrate two key characteristics. Firstly, the prices of the winning brands experience a significant decline. For example, Wuhan Da'an Pharmaceutical Co., Ltd., the winning bidder for Flurbiprofen Ester Injection, saw a 64.46% reduction in DDDc (from 61.77 to 21.95, $P < 0.000$), which is markedly lower than the prices of non-winning bidders (21.95 vs. 62.25, $P < 0.000$). This clearly indicates that winning bidders benefit from a substantial pricing advantage.

Secondly, winning enterprises capture 50%-70% of the market share for policy-related drugs in the subsequent procurement cycle. Additionally, these policy-related drugs gain direct access to medical institutions, allowing winning enterprises to dominate the market in comparison to non-winning bidders after the policy intervention.

However, to maintain the autonomy of medical institutions in drug procurement and to address supply risks, non-winning enterprises will still retain a portion of the market. Medical institutions are permitted to procure drugs from non-winning bidders as long as they meet the assigned procurement volume for the winning brands.

As a specialized drug procurement policy, the NCDP has influenced changes in drug utilization within medical institutions in three main ways. First, the NCDP policy has encouraged the substitution of generic drugs for brand-name drugs, with most doctors and pharmacists in China supporting this approach based on their professional judgment. This has led to a notable increase in the use of generic drugs over brand-name options[18-21].

Second, the policy has facilitated the substitution of winning brands for non-winning brands, resulting in a significant rise in the utilization rate of winning brands in medical institutions and consequently lowering the average medication costs. Lastly, the NCDP policy has led to an increase in the overall utilization volume of winning brands as shown in table 1.

Table 1 Inpatient Drug Utilization Information

Round of NCDP	Time of Implementation	Number of Varieties	Research Cycle
1st	23rd December 2019	25	23rd June 2019-23rd June 2020
2nd	27th April 2020	32	27th October 2019-27th October 2020
3rd	1st November 2020	55	1st May 2020-1st May 2021
4th	27th April 2021	45	27th October 2020-27th October 2021
5th	1st November 2021	62	1st May 2021-31st December 2021a

*The last round is only included one month after implementation due to data limitations

2 DATA AND METHODS

2.1 Data

2.1.1 Target varieties

As of the time this study was conducted, eight rounds of the National Centralized Drug Procurement (NCDP) policy have been implemented in China. However, the sixth round focused solely on insulin, which involves complex drug substitution. Additionally, the seventh and eighth rounds were carried out in Jiangsu in November 2022 and August 2023, respectively, within a short timeframe. Therefore, this study only includes drugs from the first to fifth rounds of the NCDP.

During the defined research period, the target medical institution utilized 103 policy-related drugs, representing 47.48% of the drugs involved in the five rounds of NCDP, making the sample highly representative. However, among the 103 policy-related drugs, 15 had fewer than 20 prescription records. Such a small data volume may lead to extreme values, so these drugs were excluded from the analysis. Consequently, a total of 88 drugs were included for analysis of brand substitution.

2.1.2 Research cycle

This research utilized inpatient data from a county-level medical institution in Nanjing, covering the period from January 1, 2019, to December 31, 2021. The interval between two rounds of NCDP is approximately six months. Moreover, the therapeutic areas of policy-related drugs may overlap between rounds. To avoid interruptions between rounds, the research cycle for this study was set at 12 months for each round, consisting of six months before and six months after policy implementation (see Table 1 for inpatient drug utilization information).

2.1.3 Target data

Given that this study was conducted during the COVID-19 pandemic, some medical institutions closed their outpatient services, while inpatient services were affected to a lesser extent. Therefore, outpatient data was excluded to maintain data integrity. Additionally, there is a possibility that outpatient patients opted not to purchase drugs from the hospital pharmacy, potentially substituting bid-winning drugs for brand-name drugs. Thus, only inpatient data was used for analysis to ensure that the results accurately reflect real-world conditions.

After desensitizing patients' personal information and removing incomplete or abnormal records (where volume or amount ≤ 0), a total of 2,190,677 medication records from 76,284 patients were retained, including 167,116 records of policy-related drugs (see Table 2 for inpatient drug utilization information).

2.2 Methods

The National Centralized Drug Procurement (NCDP) policy has played a significant role in reducing drug prices, alleviating the burden on medical insurance, improving drug quality, and promoting public health equity. From a socio-economic perspective, the policy has optimized the industry structure and encouraged innovation and transformation among enterprises. From a public health standpoint, it has enhanced the accessibility of medications, strengthened regulation, and promoted health equity. However, the implementation of the policy has also brought challenges, such as the exit of small and medium-sized pharmaceutical companies, supply chain risks, and public psychological concerns. While the policy is legally and reasonably sound in terms of international trade and intellectual property, it has altered the distribution of market power. Overall, the NCDP policy is a beneficial institutional innovation that serves the public and the country, bringing positive impacts on society and public health.

Drug utilization analysis Through detailed analysis of 167,116 medication data of 88 commonly-used policy-related drugs, this study summarized the patterns of brand substitution after policy intervention: 43.18% varieties have achieved brand substitution, including high-intensity substitution (complete substitution) and middle-intensity substitution (partial substitution); 40.90% varieties have not achieved brand substitution; 15.91% have achieved alternation of varieties (Table 3 Summary of the substitution of policy related drugs). Situation 1: brand substitution High-intensity substitution High-intensity substitution (complete substitution) referred to the partial or complete utilization of bid-non-winning brands before policy intervention, and complete utilization of bid winning brands after policy intervention. 6 (6/88, 6.81%)

Based on the medication data of 88 policy-related drugs commonly used in medical institutions, this study analyzed the substitution of bid-winning brands for bid-non-winning brands.

3 RESULT

Statistical analysis Index This study focused on the change in price and volume of policy-related drugs after policy intervention. Drug price was evaluated by Defined Daily Dose Cost (DDDC). DDDc takes DDD as the unit of measurement to reflect the average daily medication cost. The larger the DDDc, the higher the price as shown in table 2.

Table 2 Inpatient drug utilization information

Data Type	Information Details
Basic information	Item name,item code,dosage form,brand,specification,license number
Drug utilization information	Unit price,drug utilization volume,drug utilization expenses

$$DDDC = \frac{\textcircled{1} \text{Unit price}}{\textcircled{2} \text{Package size}} \times \frac{\textcircled{4} \text{DDD}}{\textcircled{3} \text{Unit strength}}$$

(1)

①Unit price: sales price of the target drug per pack-age size.

- ②Package size: the minimum quantity of measurement units included in the package unit.
 ③Unit strength: the content of active ingredients in the minimum unit of measurement of the target drug.
 ④DDD: Defined Daily Dose, that is, the average daily maintenance dose for adults, determined according to the Guidelines for ATC Classification and DDD Assignment 2021 issued by WHO and the package insert.

Take Acarbose (the second round) for example. Its DDDc of 2.46 is calculated based on the unit price of 36.9 CNY/box, the package size of 30 tablets/box, the unit strength of 0.25ug, and the DDD of 0.5ug. Drug volume was evaluated by Defined Daily Dose (DDDs). DDDs takes DDD as the unit of measurement to reflect days of application. The larger the DDDs, the larger the volume.

$$DDDs = \frac{\textcircled{5} \text{Drug volume}}{\textcircled{4} \text{DDD}} \quad (2)$$

Take Acarbose (the second round) for example. The DDDs of 30 is calculated by the DDD of 0.5ug and the drug volume of 0.25ug*30 tablets/box*2 boxes. Analytical method For one thing, the data of this study is not linearly distributed, and it is difficult to choose the control group because NCDP is a nationwide policy. So ITS or DID analysis is not suitable. Eventually, through pre-post study, interrupted by the time of NCDP implementation, this study applied the descriptive statistics to analyze the change in target indexes, and applied rank-sum test or unpaired t test for statistics test. For another, after grouping the results through descriptive statistics, this study applied rank-Sum test of categorical variables and one-way Anova of continuous variables to launch the between-group test of influencing factors (see Influencing factors of drug utilization change section) so that whether the difference between situations was large could be investigated. This study used Microsoft Excel 2019 to establish data base and used the statistical data analysis software Stata 16.0 to complete the analysis. $p < 0.05$ was considered statistically significant.

4 CONCLUSION AND DISCUSSION

This study uses a range of methods to address the portfolio selection problem. First, the optimal portfolio is screened through the non-dominated sorting genetic algorithm NSGA-II, which is more effective in solving multi-objective optimization problems. Subsequently, in order to simulate the uncertainty of the stock market, this study uses Monte Carlo simulation based on the geometric Brownian motion model to generate the return curve of the portfolio. Finally, the sampling method is improved through MCMC to obtain stationary distribution samples so that the distribution converges more effectively [16-18].

The experimental results of this paper also effectively demonstrate the effectiveness of NSGA-II in multi-objective optimization, the flexibility of Monte Carlo simulation, and the superiority of the MCMC method in sampling methods. There may be some limitations to the methodology of this study, and the reliability of the model needs to be further tested. Nonetheless, the method we use is highly general and can effectively solve asset allocation problems in financial markets as shown in table 3 and table 4.

Table 3 Summary of the Substitution of Policy-Related Drugs

No.	Brand	Substitution	Intensity	Situation	Explanation	Proportion	
1	Yes	High	Complete substitution		Bid-non-winning brands were only or partially used before policy intervention, while only bid-winning brands were used after policy intervention	6.82%	43.18%
2		Middle	Partial substitution		Utilization volume of bid-winning brands increased after policy intervention, progressively substituting for bid-non-winning brands	36.36%	
3	No		No substitution		① Bid-winning brands were used both before and after policy intervention, brand selection did not change while dddc and ddds changed; ② DDC of bid-non-winning brands decreased after policy intervention; medical institutions did not raise the proportion of bid-winning brands	40.90%	40.90%
4	Alternation of varieties			Policy-related drugs came into use after policy intervention	Policy-related drugs were not used before policy intervention and came into use after policy intervention	9.09%	15.91%
5				Policy-related drugs no	Policy-related drugs were no longer used after policy intervention	6.82%	

longer used
after policy
intervention

Table 4 Drugs of Complete Substitution

No.	Round	Generic Name	Brand	DDDe			DDDs		
				Before	After	Rate of Change	Before	After	Rate of Change
1	First	Tenofovir disoproxil fumarate tablets	Bid-winning	0.47	-97.15%***		45.00	3.25%***	
			Bid-non-winning	16.33		43.58			
2	First	Montelukast sodium tablets	Bid-winning	3.79	-32.27%***		11.19	13.22%	
			Bid-non-winning	5.60		9.88			
3	Third	Montelukast sodium oral granules	Bid-winning	1.60	-76.45%***		13.17	-2.41%	
			Bid-non-winning	6.78		13.50			
4	Third	Ticagrelor tablets	Bid-winning	3.71	1.02	-82.10%***	28.00	41.08	34.14%**
			Bid-non-winning	8.45		70.00			
5	Fifth	Docetaxel injection	Bid-winning	92.67	6.45	-91.96%***	18.74	17.51	-16.04%***
			Bid-non-winning	79.22		21.03			
6	Fifth	Potassium chloride	Bid-winning	2.35	2.03	-4.18%***	7.17	7.91	10.91%***
		sustained-release tablets	Bid-non-winning	1.36		7.03			

Standard errors in parentheses

** p <0.05 *** p <0.01

Policy-related drugs achieved complete substitution (see Table 4 for drugs with complete substitution). Among the six drugs that underwent complete substitution, the Defined Daily Doses (DDDs) of three bid-winning brands (3 out of 6, or 50%) saw a significant increase. Notably, ticagrelor tablets for cardiovascular conditions exhibited the highest growth rate in DDDs, which was 34.14% when comparing the average values from the six months before and after the policy intervention.

It is important to highlight that after the complete substitution, the DDDs for docetaxel injection experienced a significant decline, while there was no notable change in the DDDs for montelukast sodium oral granules. Two factors contributed to this outcome, as revealed by on-site interviews at the medical institution: firstly, the efficacy became inconsistent following the brand substitution, prompting doctors to switch to alternative options like docetaxel injection; secondly, the reciprocal substitution among policy-related drugs resulted in a reduction of DDDs for the bid-winning brands. For instance, montelukast sodium oral granules from the third round had their tablets and chewable tablets procured in the first and third rounds, respectively. In the six months following the policy intervention, the DDDs for these two forms increased by 13.22% and 24.39%, respectively, thereby impacting the utilization of montelukast sodium oral granules.

Middle-intensity substitution, or partial substitution, refers to the scenario where the utilization volume of bid-winning brands increased following the policy intervention, gradually replacing bid-non-winning brands. In the analyzed data, 32 drugs (32 out of 88, or 36.36%) achieved partial substitution, which was the predominant trend (see Table 5 for drugs with partial substitution).

Among the 32 drugs that underwent partial substitution, 27 bid-winning brands (27 out of 32, or 84.37%) were not utilized prior to the policy intervention. Following the intervention, medical institutions began to incorporate these brands into their practices. Additionally, the bid-winning brands of five drugs (5 out of 32, or 18.75%) were rarely used before the policy intervention, but their utilization volumes significantly increased afterward, gradually capturing market share from the bid-non-winning brands.

This study examines the impact of the National Centralized Drug Procurement (NCDP) policy on the substitution patterns of policy-related drugs in a medical institution in Nanjing. The research focuses on 88 commonly used drugs from the first to fifth rounds of the NCDP, analyzing how bid-winning brands replaced bid-non-winning brands following the policy's implementation.

The findings reveal that among the drugs analyzed, six achieved complete substitution, with three of these showing a significant increase in Defined Daily Doses (DDDs). Notably, ticagrelor tablets for cardiovascular conditions had the highest growth rate. However, the study also highlights challenges, such as a significant decrease in DDDs for docetaxel injection and no notable change for montelukast sodium oral granules, attributed to concerns over efficacy and the dynamics of drug substitution.

Additionally, the research identifies a middle-intensity substitution trend, where 32 drugs experienced partial substitution. Most of these bid-winning brands were not utilized before the policy intervention, indicating a shift in prescribing practices. The study underscores the NCDP's role in optimizing drug accessibility and promoting cost-effective healthcare while also noting the challenges faced by smaller pharmaceutical companies and potential impacts on drug efficacy.

Overall, the NCDP policy demonstrates a significant influence on drug utilization patterns, contributing to the broader

goals of reducing drug costs, enhancing quality, and promoting public health equity.

COMPETING INTERESTS

The authors have no relevant financial or non-financial interests to disclose.

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