

"4+7" city drug volume-based purchasing and using pilot program in China and its impact

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Summary

In order to deepen the health system reform and improve the mechanism for the formation of drug prices, in January 2019, the General Office of the State Council of the People's Republic of China issued the "National centralized drug purchasing and using pilot program", selected 11 cities in mainland China to carry out "4+7" city drug volume based purchasing pilot work. This paper introduces the specific implementation plan, organizational structure and drug selection process of China's "4+7" city drug volume-based purchasing pilot work, and expounds the initial effects, existing problems and policy development after the implementation of the policy. After the implementation of the policy, the prices of 25 selected drugs were significantly lower, compared with the minimum purchase price of the same drugs in 11 pilot cities in 2017, the average drop was 52%. After the pilot scope was extended to the nation, compared with the minimum purchase price of the Union in 2018, the proposed price of the 25 drugs have an average price drop of 59%, compared with the selected price of the "4+7" pilot cities, the average price drop was 25%, and the price of drugs dropped further. By the end of August 2019, the implementation progress of 25 selected drugs in the "4+7" city drug volume-based purchasing was better than expected, the burden of patients' drug expenses was reduced, and the pilot work was beginning to bear fruit. The long-term influence and effect of the "4+7" city drug volume-based purchasing and policy implementation after the expansion needs to be further observed.

Keywords: Volume-based purchasing, centralized drug purchasing, pilot program

In recent years, China's total investment in health expenditures has basically increased linearly, increasing at a faster growth rate year by year (1). From 2008 to 2017, China's total health expenditures rose from 1453.54 billion yuan to 5259.83 billion yuan. The average annual compound growth rate is 13.51% (2). According to comparable prices, compared with 2016, China's total health expenditure in 2017 increased by 9.03%, higher than the GDP growth rate (6.86%) (3).

The total drug expenditure in China is also showing a growing trend. The drug expenditure for outpatients, hospitalizations and retail sales is increasing year by year. The proportion of drug expenditure to total health expenditure is still high (3), higher than the international level, and high drug price is one of the important reasons. At present, many problems still exist in the field of drug circulation in China, such as the obvious distortion of interests in the drug circulation, complicated circulation of drugs, disordered order, imperfect drug purchasing mechanisms, and the degree of marketization is not high and so on (4), all of which contribute to the high price of drugs. The burden of medicines for patients is heavier, and the problem of "expensive medical treatment" still exists.

In order to deepen the health system reform and

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improve the mechanism for the formation of drug prices, in January 2019, the General Office of the State Council of the People's Republic of China issued the "National centralized drug purchasing and using pilot program" (hereinafter referred to as the "Program"), selected 11 cities (include 4 municipalities: Beijing, Tianjin, Shanghai, and Chongqing; 7 key cities: Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu, and Xi'an) in mainland China to carry out "4+7" city drug volume-based purchasing pilot work (5). The so-called drug volume-based purchasing refers to clarify the purchase volume when the purchaser conducts bidding or negotiation in the drug centralized purchasing process, and the drug supply enterprise bids or negotiates through the centralized purchasing platform for the specific quantity, and finally determines the purchase price (6). The significance is to determine the contractual relationship between price and volume. The higher the dosage, the lower the price (7), to achieve "volume-price linkage", "volume-for-price", and "price-based volume".

The basic idea of the "Program" is that the national level formulates basic policies, scope and requirements, and organizes 11 pilot cities to form a purchasing alliance. The public medical institutions in the alliance area are the main purchasing entities, and estimate the total purchase amount according to 60-70% of the total annual drug use of all public medical institutions in the league, and conduct a cross-regional alliance mechanism for drug volume-based purchasing. The pilot work is mainly carried out by the pilot working group and the joint purchasing office. The Shanghai Pharmaceutical Centralized Bidding and Purchasing Management Office undertakes the daily work of the Joint Purchasing Office and is responsible for the specific implementation. The organizational framework for its work is shown in Figure 1.

The drug volume-based purchasing in "4+7" city

are selected from the varieties with large sales volume in the fields of cardiovascular, anti-tumor, antibiotics, and psychology. The drug needs to be the original drug, the generic drug, which passes the evaluation of the consistency of quality and efficacy by the State Drug Administration, or the corresponding reference preparation (8). The drugs of volume-based purchasing will be declared by the enterprise first, and the selected varieties will be determined after pre-selection and quasi-selection. The process is shown in Figure 2. Adopting respective bidding purchasing, bargaining purchasing and negotiation purchasing methods according to the number of production enterprises of each pre-selected drug, a total of 25 drugs were selected, of which 22 (88%) were generic drugs, and 3 (12%) were original drugs. Only one company is selected for each variety, and the purchasing cycle is 12 months (9). If the agreed purchase amount is completed ahead of the purchasing cycle, the excess will still be purchased at the selected price until the purchase cycle expires.

The direct implementation impact of the "Program" is to achieve a significant reduction in drug prices. Compared with the minimum purchase price of the same drug in 11 pilot cities in 2017, the average price drop of 25 proposed selected drugs was 52%, with a maximum drop of 96%. Among them, the price reduction of imported original drug gefitinib and fusinopril were respectively 76% and 68%, and price reduction of domestic original drug flurbiprofen ester injection was 44%. The effect of "volume-for-price" has been revealed. The sharp drop in drug prices has driven the price linkage of non-selected drugs, further amplifying the price reduction effect, reducing the burden of medication for patients, and effectively alleviating the problem of expensive medical treatment. The "4+7" pilot city's joint volume-based purchasing model clarifies the price of drugs and

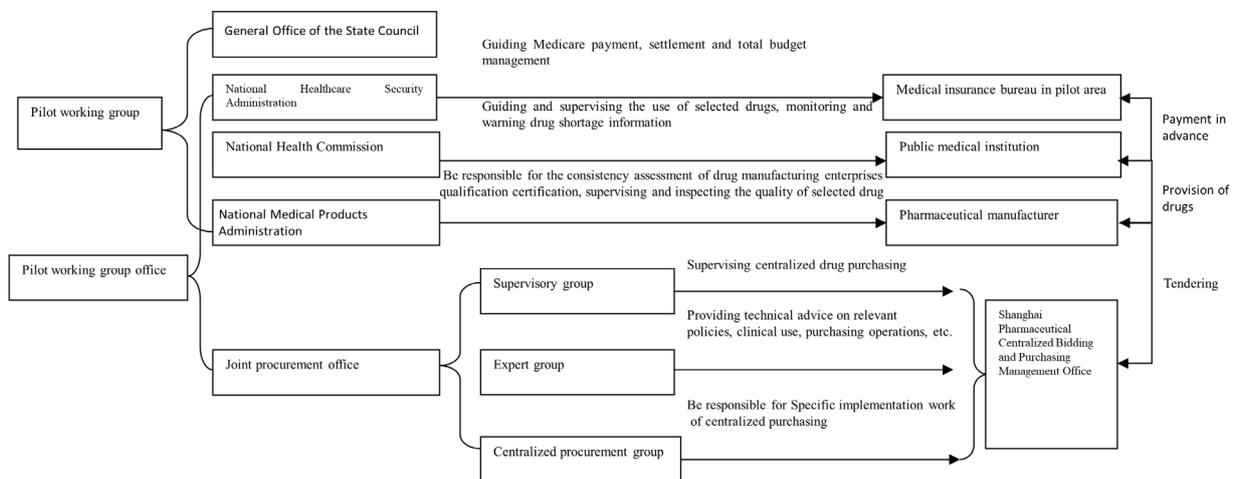


Figure 1. Organizational framework of "4+7" city drug volume-based purchasing and using pilot program.

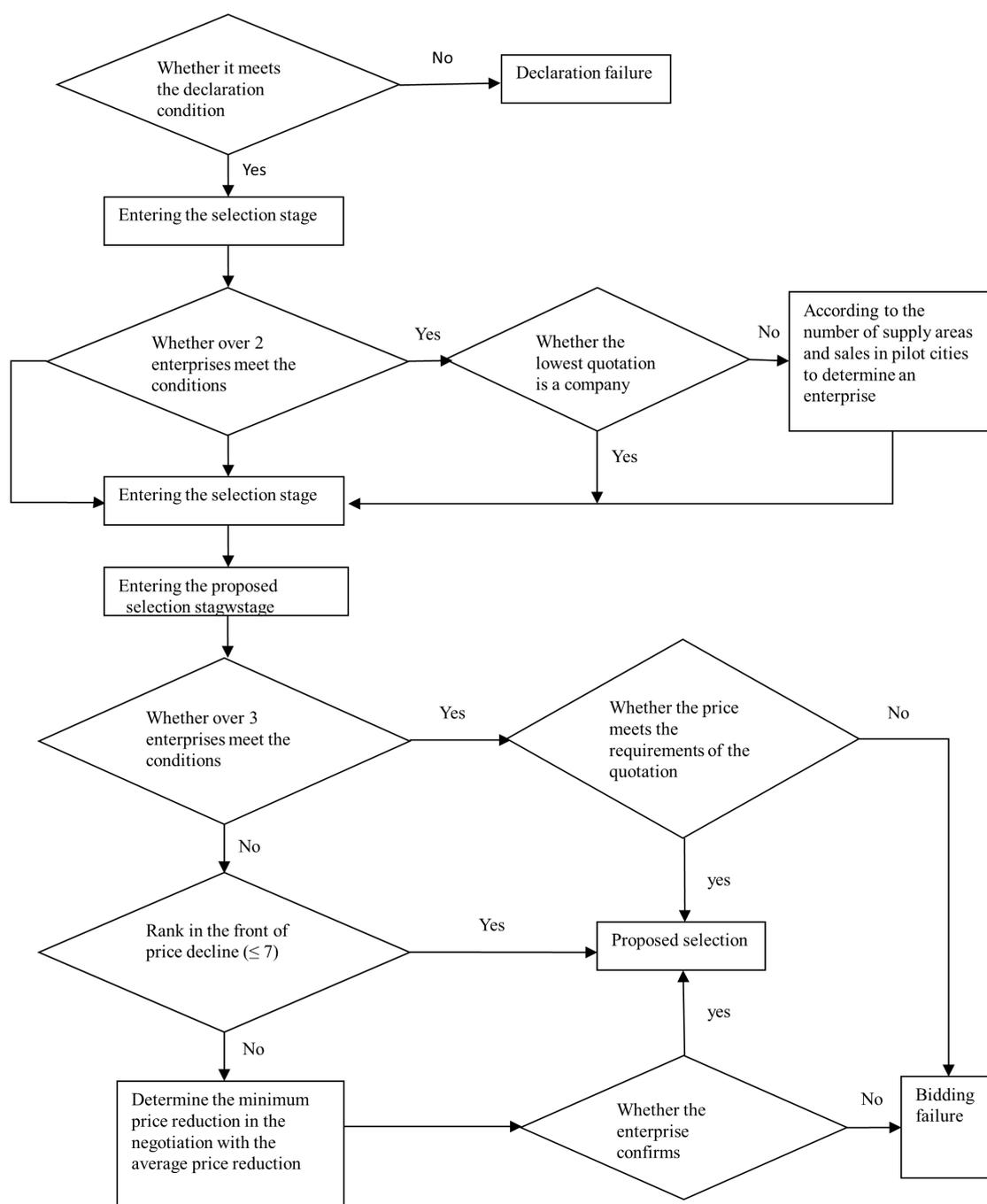


Figure 2. Selection flow chart of "4+7" city drug volume-based purchasing.

specific purchase quantity. The agreement changes the drug circulation model, cuts off the interest chain of drug circulation (10), regulates distribution behavior and purchasing behavior, and also simultaneously reduces the sales and transaction cost of the company (11). In addition, the reduction of drug prices also contributes to the achievement of the control fee index in hospital management. At the same time, the "volume-price linkage" has positive significance for the ethos construction of medical personnel. The medical insurance department also needs to realize change through volume-based purchasing and use limited

resources on a more valuable level.

There are also some potential risks and disputes in the implementation of the "Program": In terms of drug supply security, the selected drugs take the form of a "single source" supply method. It is not only easy to frustrate the enthusiasm of the unsuccessful enterprise to improve the quality and consistency of efficacy in the early stage of the trial. There is also the risk of supply shortages (7). In the clinical use of drugs, in order to implement the use of selected drugs, the use of non-selected drugs is limited, and to a certain extent, it also limits the doctor's prescription rights and

patients' drug choice. Upon drug quality, there is still a lack of authoritative data such as adverse reaction reports and defect reports related to the quality of the selected drugs. Clinicians and patients have doubts about the quality of the selected drugs at a low price. Due to the drug prices in the pilot areas, which are significantly lower than those in other areas, this forms a "price depression effect". Non-pilot patients go to the pilot areas to see doctors and buy drugs themselves, which interferes with the medical circulation order and increases the burden on patients.

In September 2019, in order to expand the "4+7" city drug volume-based purchasing pilot reform effect, based on the valuable experience accumulated in the previous pilot work, under the guidance of the China National Healthcare Security Administration and other departments, 25 provinces in mainland China and the Xinjiang Production and Construction Corps formed a new cross-regional purchasing alliance to purchase twenty five "4+7" pilot drugs, except for the "4+7" pilot city, Fujian Province, and Hebei Province that have previously been followed up. All 25 varieties were purchased successfully in this alliance purchase, 45 enterprises and 60 products are to be selected. Compared with the lowest purchase price in 2018 in the alliance area, the average decline of selected prices is 59%. Compared with the selected price of the "4+7" pilot city, the average decline is 25% (12). The expansion of the national drug centralized purchasing pilot not only promoted the policy nationwide, but also joined the military medical institutions participating in the pilot expansion of the regional scope and medical insurance designated social medical institutions, medical insurance designated retail pharmacies volunteering to participate in the pilot expansion of the regional scope. It also solved the problem of large price gap of pilot drugs in the "4+7" pilot city and other related regions, and also made the reform results benefit more people (13). In addition, the expansion has improved and adjusted the selection rules on the number of enterprises and the quotation level based on previous pilot experience, many enterprises can be allowed to win the bid. The bid price of different enterprises can be different to guide the enterprises to compete in an orderly manner. The increase in the number of selected enterprises also avoids the risk of supply shortage and monopoly of the exclusive winning bid, and guarantees the long-term stable implementation of the national drug centralized bidding purchasing policy (14).

The 25 drugs selected by "4+7" volume-based purchasing were fully implemented on April 1, 2019. As of the end of August, the purchase quantity of 25 selected drugs in the "4+7" area was 1.7 billion tablets. The progress of total purchase quantity exceeded expectations, and the purchase quantity of selected drugs accounted for 78% in the same generic name drugs (15). The pilot work achieved initial results. In

September 2019, China expanded the scope of pilot and the price of 25 drugs was decreased further. Nine central departments such as China National Healthcare Security Administration issued a document to guide the development of related work (13). In the next step, all localities and departments will focus on the implementation of the selected results, to ensure that patients gain high quality and low price for selected varieties before the end of the year and effectively reduce the drug burden of patients (12).

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