

BACKGROUNDS

- As most innovative drugs are expensive and were not covered by social medical insurance in China, providing universal access to these drugs is a challenge.
- In 2017, China proposed establishing an annual price negotiation mechanism for some patented and expensive drugs.
- Since then, the number of negotiated drugs has increased substantially, drawing significant attention to the resulting improvements in accessibility

OBJECTIVE

- To comprehensively summarize the changes in negotiated drugs regarding quantity, coverage, availability, utilization, price, and expenditure.

METHODS

- We reviewed literatures, government documents, and news reports about negotiated drugs through April 30, 2024.
- For each literature, we recorded basic information (corresponding author, data sources, study design), details about negotiated drugs (negotiated period, disease areas), outcome indicators (availability, affordability), and research findings.
- Following the standardized survey method issued by the World Health Organization and Health Action International (WHO/HAI), we evaluated the access to negotiated drugs. However, due to limitations in its application in China, we supplemented the evaluation indicators on this basis.(Table 1)

RESULTS

- We included 26 literature, of which 17 focused on the National Drug Price Negotiation (NDPN) policy's impact on access to negotiated drugs, while the remaining 9 examined the status of access to negotiated drugs after NDPN.(Table 1)
- From 2017 to 2023, 515 drugs were newly incorporated into National Reimbursement Drug List (NRDL) via seven rounds of negotiation, with average price reductions ranged from 44% to 62% per round. Most negotiated drugs were innovative, including over 70 targeted oncology drugs and over 80 rare disease drugs.(Figure 1)
- Regarding accessibility, all literature mentioned that the NDPN policy significantly increased the availability of innovative drugs. 38.5% (10/26) found uneven availability rate across regions or hospitals .(Table 1)
- Regarding affordability, 57.7% (15/26) reported a significant decrease in expenditure. However, 26.7% (4/15) mentioned that the ratio of out-of-pocket costs for orphan drugs and anticancer drugs to catastrophic health expenditures was still greater than 1 .(Table 1)

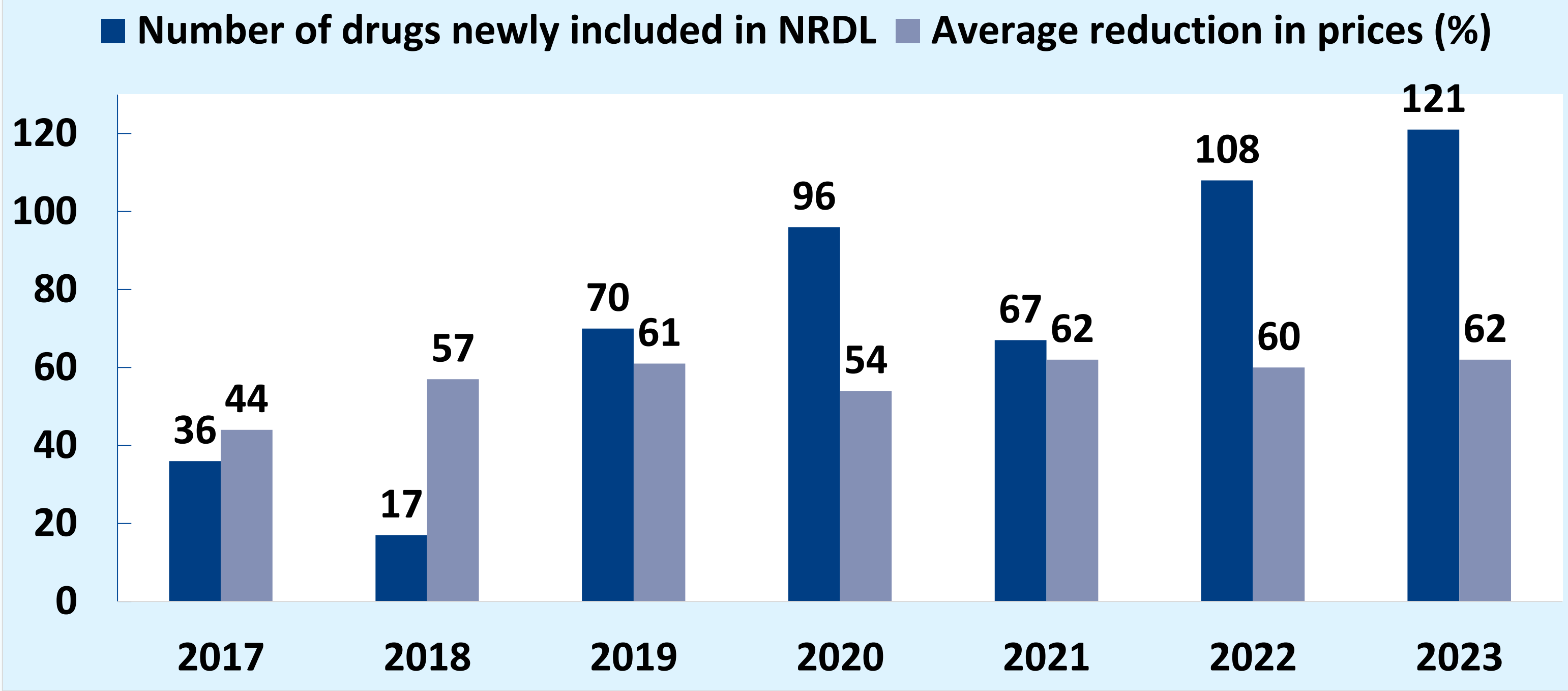


Figure 1. Number of successfully negotiated drugs and average price reductions, China, 2017-2023

Literature	Study design	Accessibility				
		Availability			Affordability	
		Availability rate	DDDs	Utilization rate	DDDc	OOP
Fang 2020	Pre-post		↑		↓	
Wu 2023	Cross-sectional	↑ Uneven	↑		↓	
Chen 2023	Cross-sectional	↑ Uneven	↑			
Li 2023	Cross-sectional	↑ Uneven				
Qiu 2022	Cross-sectional	↑				
Shen 2022	Pre-post		↑		↓	
Cao 2022	Cross-sectional			↑		
Chen 2020	Cross-sectional	↑ Uneven				
Liu 2023	Single-group ITS		↑		↓	
Cao 2022	Single-group ITS			↑		
Yue 2023	Single-group ITS		↑			
Ren 2023	Pre-post		↑			↓ OOP ratio>1
Li 2021	Single-group ITS			↑		
Jiang 2021	Cross-sectional	↑ Uneven				↓ OOP ratio>1
Li 2023	Cross-sectional	↑ Uneven	↑		↓	
Fang 2021	Single-group ITS	↑ Uneven	↑			↓ OOP ratio>1
Cai 2022	Multiple-group ITS	↑ Uneven	↑		↓	↓ OOP ratio>1
Wu 2022	Cross-sectional		↑		↓	
Shang 2023	Single-group ITS			↑		
Huang 2021	Single-group ITS		↑		↓	
Zhang 2021	Multiple-group ITS		↑		↓	
Yang 2023	Single-group ITS			↑		↓
Zhu 2022	Single-group ITS	↑ Uneven			↓	
Sun 2022	Multiple-group ITS	↑ Uneven	↑			
Diao 2021	Single-group ITS			↑		
Liu 2023	Single-group ITS			↑		

Notes: Availability rate=(Number of hospitals that procured the drug/ Number of hospitals) × 100%; DDDs(Defined Daily Doses)=Total quantity procured/DDD(Defined Daily Dose); Utilization rate=(Number of drug users/Total population) ×100%; DDDc(Defined Daily Dose Cost)=Total quantity procured/DDDs; OOP ratio=Out-of-pocket cost/CHE(Catastrophic health expenditure) ;*CHE was defined as the proportion of households whose annual healthcare expenditure exceeded 40% of non-food expenditure.

CONCLUSIONS

- The NDPN policy effectively improved the accessibility and affordability of innovative drugs in China.
- However, access to negotiated drugs needs further improvement.
- Additional efforts are required in payment, supply guarantee, and health insurance treatment policies related to negotiated drugs.