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SYSTEMATIC REVIEW

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# Impacts of National Reimbursement Drug Price Negotiation on drug accessibility, utilization, and cost in China: a systematic review

Zheng Zhu[1], Jiawei Zhang[1], Zhihu Xu[2], Quan Wang[1], Yu Qi[1] and Li Yang[1*]

## Abstract

**Objective** National Reimbursement Drug Price Negotiation (NRDPN) refers to a government-led process of negotiating with pharmaceutical companies to reach reasonable prices for exclusive drugs covered by national reimbursement. Since 2016, the Chinese government has regularly implemented eight rounds of NRDPN. This systematic review aimed to determine the effects of NRDPN on drug price, availability, affordability, utilization, cost, and health outcomes in China in the years 2016–2023.

**Methods** We searched the electronic databases PubMed (which includes MEDLINE), Web of Science, China National Knowledge Infrastructure (CNKI), Wanfang, and VIP for all associated studies published in English or Chinese between January 2016 and December 2023. One of the following outcomes had to be reported: drug price, availability, affordability, utilization, cost, or health outcomes. The study design had to be a randomized or non-randomized trial, an interrupted time series (ITS) analysis, a repeated measures study, or a controlled before-after (CBA) study. Two reviewers independently extracted data and assessed the studies according to Cochrane Effective Practice, Organization of Care (EPOC) guidelines.

**Results** From a total of 2628 studies, we identified 20 studies that met the inclusion criteria (16 interrupted time-series studies and 4 controlled before-after studies). Most of the studies (66%, $n=12$) have some limitations (unclear risk of bias). The published studies indicated the implementation of the NRDPN policy decreased drug prices, ranging from 24 to 72%, which increased the affordability of success-negotiated drugs (refer to those medications that have undergone a successful price negotiation process between pharmaceutical companies and healthcare authorities) and decreased out-of-pocket expenditures. The availability rate increased form 27% to 47%. It has been suggested that the NRDPN was conducive to narrowing disparities in availability and affordability across regions, hospital levels, and types of health insurance. In addition, it was associated with the increased drug expenditure by 61% due to the increased use of successful-negotiated drugs. However, there is insufficient evidence to explore the health outcome changes after the NRDPN policy.

**Conclusion** Evidence to date generally suggests the NRDPN policy is an effective way to decrease drug prices, improve access to innovative medicines, and improve fairness. It provides useful experience and lessons in improving access to innovative medicines for other low-and middle-income countries.

*Correspondence:
Li Yang
lyang@bjmu.edu.cn
Full list of author information is available at the end of the article

**Keywords** China, Drug price negotiation, Availability, Affordability, Drug utilization, Health expenditures

## Introduction

Propelled by revolutionary progress in medical science, an increasing number of innovative medicines (The National Healthcare Security Administration defines innovative drugs as drugs with distinct treatment mechanisms or chemical structures that bring clear benefits to patients) were approved for marketing during the past 2 decades, which address crucial and unmet medical needs for patients and have the potential to improve life expectancy and health outcomes. Nevertheless, due to patent protection and the technology monopoly of innovative drugs, the prices of these innovative medicines are usually unaffordable for patients, as well as posing challenges to healthcare financing systems [1]. The high out-of-pocket (OOP) costs of innovative drugs also resulted in poor adherence to innovative drugs, which further jeopardized the potential benefits of treatment and may lead to an increased risk of emergency room visits and greater healthcare spending [2–4]. For instance, some newly developed immunotherapy drugs can cost tens of thousands of yuan per month, which is far beyond the means of a large portion of patients, especially those from rural areas or with lower incomes. The provision of appropriate innovative medicines in adequate quantities and at reasonable prices is, therefore, one of the most pressing problems facing global policymakers around the world [5]. Globally and nationally, efforts are being made to ensure fair and affordable access to innovative medicines. Many countries implemented price negotiation policies, which effectively lowered prices and increased consumption in Italy, France, the US, and Germany. For example, the American Society of Clinical Oncology (ASCO) has explored cost-cutting proposals like Medicare negotiating anticancer drug prices. The UK has legislated to clarify the patent drug pricing mechanism and incorporated value-based assessment into negotiations. Countries like Canada, South Korea, and Germany have their own systems for drug review, price negotiation, and insurance catalog inclusion. In emerging countries such as Brazil, Mexico, and Thailand, governments are pooling resources to financially protect cancer patients and publicly funding more novel anticancer drugs for better universal health coverage [6].

To improve the availability and affordability of drugs, the Chinese government has formulated a series of policies and strategies over the past decade, such as the zero mark-up drug policy, the centralized procurement program, and tariff exemptions on imported anticancer drugs [6–8]. Despite these efforts, the out-of-pocket (OOP) costs of innovative drugs remained high for patients, since innovative medicines were rarely covered by the National Reimbursement Drug List (NRDL). Incorporating more innovative drugs with outstanding clinical efficacy into NRDL through price negotiation, namely National Reimbursement Drug Price Negotiation (NRDPN) is one of China's recent significant efforts to reduce drug prices and improve access to drugs [6]. Once a drug is on the NRDL after price negotiation, it becomes eligible for reimbursement under the national medical insurance scheme, which substantially reduces the financial burden on patients and promotes its wider use in clinical practice.

Whether one drug is incorporated into the NRDL is determined through a centralized strategic price negotiation. Candidate drugs are assessed comprehensively in terms of safety, efficacy, reference price, comparative value, and clinical need. The negotiated price, payment standards, and detailed reimbursement restrictions (such as indications, treatment duration, the number of doses, etc.) are simultaneously determined in price negotiation. Following the negotiation, provinces are required to update their Provincial Reimbursement Drug Lists (PRDL) to incorporate the negotiated drugs. In practice, most provinces includes all negotiated drugs in PRDL. Public hospitals must purchase these negotiated drugs via the provincial procurement websites based on the negotiated prices. From the perspective of hospital budget management, drugs listed in the NRDL/PRDL offer more predictability. Hospitals can plan their drug procurement budgets better as they have a clearer idea of the reimbursement support [9]. The reimbursement list is determined by the state, while the co-payment ratio depends on the type of medical insurance and the region where one is located. There is disparity in benefits packages between urban and rural residents basic medical insurance scheme (URRMI) and the urban employee medical insurance scheme (UEMI). The reimbursement level in economically developed regions and UEMI tend to be relatively high. Unlisted drugs are fully out-of-pocket.

The Chinese government has regularly implemented eight rounds of the NRDPN by early 2025. Figure 1 shows the trend in price reduction and quantity of negotiated drugs in China over the years. The prices of the negotiated innovative medicines were reduced by at least 44% on average during the eight rounds of NRDPN. The first round of NRDPN was organized by

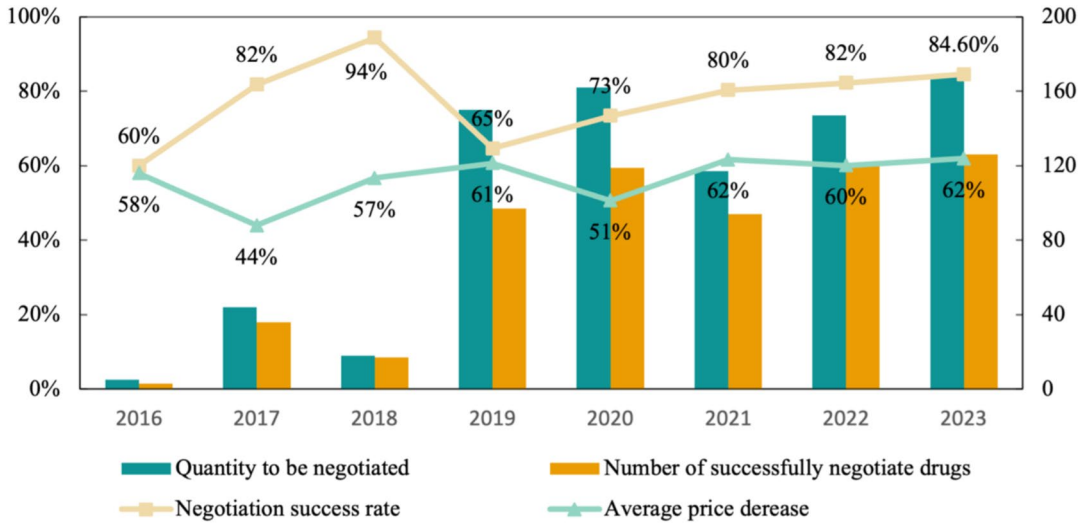


**Fig. 1** The trend of price reduction and quantity of negotiated drugs in China over the years

the former National Health and Family Planning Commission of the People's Republic of China in May 2016 [10], which included three drugs and could be seen as a pilot [11]. In July 2017, the Ministry of Human Resources and Social Security organized the second negotiation and established a framework for following negotiations, especially introducing pharmacoeconomic evaluation as a negotiation tool for the first time [12]. In October 2018, 17 anti-cancer drugs were incorporated in the medical insurance type B reimbursement catalog [13]. In November 2019, the fourth round of NRDPN creatively introduced a competitive negotiation method, that only two drugs with the lowest full-course cost could be allowed to enter the catalog within 2 years, to guide enterprises to fully compete [14, 15]. In December 2020, the fifth round of NRDPN incorporated COVID-19 drugs, in addition to anti-cancer, orphan, and pediatric drugs [16]. The seventh round of NRDPN negotiated upon non-exclusive drugs for the first time.

Nevertheless, entry into the national reimbursement list does not guarantee direct access to individual hospital formularies [17]. It remains challenging to introduce innovative drugs into hospital formulary and routine clinical practice due to the incongruous assessment indicators for public hospitals [18]. Therefore, it is critical to evaluate the actual effects of implementing the NRDPN on the accessibility of innovative drugs. In addition, given that the government has been making tremendous efforts to achieve universal health coverage (UHC) and not to leave anyone behind, it is crucial to generate empirical evidence about whether the NRDPN is conducive to increasing equitable access to medicines and narrowing long-standing treatment gaps across different patient groups.

While various studies have been conducted to analyze the impact and effectiveness of the NRDPN, up to now there is a lack of research in systematically assessing these various contributions. This systematic review synthesized existing evidence and evaluated the effects of NRDPN on various outcomes including drug price, availability, affordability, utilization, cost, and patient health outcomes. Finally, we draw upon our findings and the gaps in evidence to summarize future directions for research and policy.

## Methods

### Literature search

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines were used to identify potential studies and report findings [19]. The systematic literature search was conducted on December 31, 2023 to retrieve all relevant studies using multiple search engines including PubMed, Web of Science, China National Knowledge Infrastructure, Wanfang, and VIP Database. Literature search strategies and methods (i.e., keywords and Medical Subject Headings (MeSH) terms) were shown in Appendix 1. The search articles were further restricted to those including at least one outcome measure related to drug price, availability, affordability, health service utilization, spending, or patient outcomes. In addition, we retrieved the published versions of all candidate articles and reviewed their reference lists to identify additional relevant studies.

### Study selection

Using predefined inclusion and exclusion criteria, two reviewers (ZZ and ZX) independently identified studies with disagreements reviewed and resolved by consensus and consultation with a third reviewer (QW). Abstracts that were duplicates, not conducted in China, or did not evaluate policy relevant to NRDPN were excluded. The studies also needed to have the following characteristics:

a) The study must be original articles published in a peer-reviewed journal.
b) The study design must be randomized trials, non-randomized trials, interrupted time-series studies (including controlled ITS [CITS]), repeated measures study, or controlled before-after (CBA) studies.
c) The study had to include an objective measure from at least one of the following outcome categories. The selection of outcome categories was based on the multifaceted nature of the policy's potential effects. Availability and affordability are key aspects directly affected by price negotiations. Healthcare utilization and costs are important to assess the economic and service utilization implications. Differences in outcomes across various insurance schemes, hospital levels, and areas help to understand the policy's heterogeneous impact.

    i. Availability;
    ii. Affordability;
    iii. Healthcare utilization (as NRDPN may increase uses of negotiated drugs and genetic testing, and office or hospital visits);
    iv. Costs (including total expenditures on drugs specifically and on healthcare generally, fund expenditures, and OOP expenditures);
    v. Health outcomes;
    vi. Differences in these outcomes across different health insurance schemes, different levels of hospitals, and different areas.

If the title and abstract provided insufficient information to assess the inclusion criteria, a full-text review was conducted.

### Data extraction and quality assessment

Two reviewers (ZZ and XZ) independently extracted data from the included studies. The following information was extracted using a standardized data extraction form.

a) Type of study (randomized trial, ITS, CBA);
b) Rounds of the NRDPN;
c) Study setting;
d) Study diseases;
e) Study drugs;
f) Main outcome measures;
g) The results for the main outcome measures;

The quality assessment tool for quantitative studies suggested by Cochrane Effective Practice, Organization of Care (EPOC) was adopted and used to evaluate all included studies for methodological quality and risk of bias [20]. Two reviewers (ZZ and XZ) independently reviewed each study and assessed the studies as high risks, low risks, or uncertain risks based on the guideline. Any disagreement regarding the quality rating was resolved by proper consultation between the two reviewers.

a) No serious limitations = Low risk of bias = all criteria scored as 'low risk'. Plausible bias is unlikely to seriously alter the results.
b) Some limitations = Unclear risk of bias = one or two criteria scored as 'unclear risk' or 'high risk'. Plausible bias raises some doubt about the results.
c) Serious limitations = High risk of bias = more than two criteria scored as 'unclear' or 'high risk'. Plausible bias seriously weakens confidence in the results.

### Data synthesis

Given the heterogeneity present in the rounds of NRDPN, reported outcomes, study designs, and analytic approaches employed across the identified studies, we conducted a narrative synthesis of available papers. Therefore, the summary of the findings and conclusions is to a great extent qualitative in nature.

## Results

### Description of studies

Through the systematic search, a total of 2916 articles meeting the essential inclusion and exclusion criteria were identified, and 2628 articles remained after removing duplicates. After two independent reviewers reviewed the abstracts using the foregoing methodology, 73 articles met the inclusion criteria for full-text review. Further, a total of 58 articles were excluded, resulting in 20 full articles eventually being included in our systematic review (Fig. 2, Table 1).

#### *Description of the included reviews*

The vast majority of papers were published in or after 2021 (80%, $n=16$). Of the 20 papers included, nearly all used an interrupted time-series design (95%, $n=19$). A

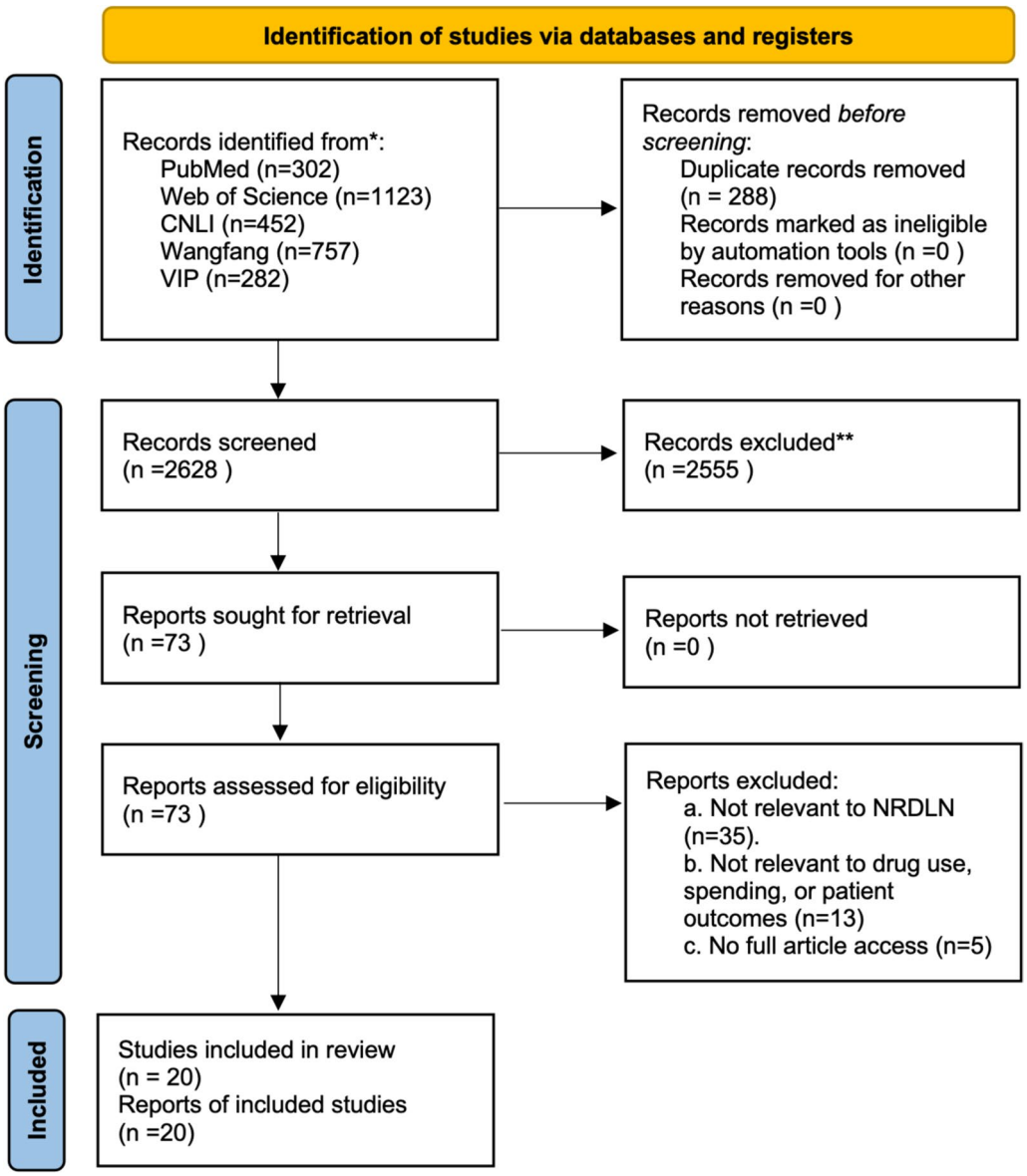


**Fig. 2** Systematic literature review flow chart

single study used a propensity score-matching design (Appendix 3). Most papers (80%, $n=16$) did not include and define a control group, as the NRDPN policy was universally implemented in China. In terms of outcome measures, a wide variety of the effects of the NRDPN were reported across the studies, including drug price ($n=8$), availability ($n=5$), utilization ($n=17$), affordability ($n=3$), and costs ($n=16$). However, we found no studies examining the impact of the NRDPN on health outcomes probably due to the lack of data and the complexity of measuring health outcomes. Appendix 1 summarizes the results of evidence of these studies included in our systematic review.

#### *Risk of bias in included studies*

The risk of bias graphs and the summary assessments of included studies are also shown in Fig. 3 and Appendix 2. Overall, we assessed most of the studies (70%, $n=14$) as having some limitations (unclear risk of bias) mainly because of uncertainties about the risk that the intervention was not independent of other policy changes, such as COVID-19, the national volume-based drug procurement policy, and health insurance payment reform.

**Table 1** Summary of findings of included studies in China

| Author | Rounds | Study disease | Study drugs | Setting | Study design | Outcomes | Key findings |
|---|---|---|---|---|---|---|---|
| Zhang et al., 2021 [21] | 2017 | - | 15 anticancer drugs | 789 public hospitals from 30 provinces | CITS | DDDc; DDDs; expenditure | The DDDc of price-negotiated medications decreased by 48.9%. The DDDS increased by 143.0%. The hospital medication spending decreased by 6.9% |
| Sun et al., 2022 [11] | 2017 | - | rituximab, trastuzumab, and recombinant human endostatin (RHE), | 11 provinces | CITS | Monthly; average expenditure; DDDS; Availability | The monthly expenditures of rituximab increased by 6.0% The volume and availability of rituximab increased by 949.6 DDDs and 1.56%, respectively. The availability of trastuzumab increased by 5.14% immediately |
| Li et al., 2021[22, 23] | 2016 | lung cancer | gefitinib, icotinib | Fuzhou city | ITS | The monthly number of patients adopting gefitinib and icotinib; OOP expenditure share | The monthly number of patients using gefitinib and icotinib increased by 26. The OOP expenditure share patients covered by UEMI and URRMI were higher than patients with government-funded supplementary |
| Fang et al., 2021 [24] | 2017 | - | 15 innovative anti-cancer medicines | Nanjing city | ITS | DDDc; DDDs; Availability; Affordability of patients | The DDDc reduced 34%~65%. The DDDs of most drugs increased. The availability rate increased form 27.44% to 47.33%. The affordability of patients improved |
| Diao et al., 2021 [25] | 2017 | breast cancer | trastuzumab | A tertiary public hospital in Fujian province | ITS | The monthly proportion of patients adopting study medicines; Determinants of patient's medication choice | The monthly proportion of patients adopting study medicines increased by 18.3%. The gaps of the proportions of patients adopting study medicines between the urban and rural areas, and among the patients enrolled in different health insurance programs diminished. The critical determinants of patient's medication choice were patient's health insurance benefits packages |
| C. Huang et al., 2021 [26] | 2016 | lung cancer | icotinib and gefitinib | 594 tertiary hospitals from 29 provinces | ITS | DDDc; DDDs; expenditure | The DDDC of icotinib and gefitinib decreased by 50.08% and 53.89%.The volume increased 4.87 thousand DDDs and 6.89 thousand DDDs. The monthly purchasing spending decreased rapidly by US$0.51 million and US$0.82 million |

**Table 1** (continued)

| Author | Rounds | Study disease | Study drugs | Setting | Study design | Outcomes | Key findings |
|---|---|---|---|---|---|---|---|
| Zhu et al., 2022 [6] | 2017 | - | 18 anticancer drugs | 31 provinces (nationwide) | ITS | Accessibility; DDDc; | The overall availability increased by 30%;The average DDDc dropped by 23.88%.Drug availability experienced a larger instant and slope increase in Western Medicines and in secondary hospitals |
| Liu et al., 2022 [18] | 2016; 2018 | Lung Cancer | gefitinib, bevacizumab and recombinant human endostatin | Nanjing city | ITS | DDDs; DDDc; Availability; Affordability | The DDDs of the three drugs increased significantly. The trend of DDDc showed a significant decrease. The mean availability of these drugs increased form 30% to 60.33%. The financial burden is higher for the rural patients compared with the urban patients, although the gap is narrowing |
| Mao et al., 2021 [27] | 2019 | - | 70 negotiated drugs | Hubei Provinces | ITS | Expenditure; DDDs; DDDc | The expenditure increases by 61.48%.The DDDs increased by 4.85 times. The DDDc decreased 72.38% |
| Feng et al., 2020 [51] | 2018 | Hepatitis C | - | Tianjin and Chengdu city | ITS | Total healthcare expense; Medicine expense; other expense | In Tianjin, the total, drug and other expense dropped significantly. In Chengdu, the total expense and drug expense increased significantly |
| Chen et al., 2018 [28] | 2017 | All patients | - | A Tertiary Oncology Institution in Beijing | ITS | The number of outpatients; Average expense; Auxiliary drug share; Drug expense share; OOP share | The number of outpatients rose by 20. The average expense for outpatient and inpatient dropped by 33.44 CNY and 468.75 CNY respectively. The auxiliary drug share, drug expense share, and OOP share decreased |
| Li et al., 2021[22, 23] | 2017 | HER 2 positive breast cancer | trastuzumab, lapatinib | Fuzhou city | ITS | The number of patients adopting study medicines; OOP expenditure share | The number of patients adopting study medicines increased 24. The OOP expenditure share of patients enrolled in URRMI were higher than patients with government budget funded supplementary |

**Table 1** (continued)

| Author | Rounds | Study disease | Study drugs | Setting | Study design | Outcomes | Key findings |
|---|---|---|---|---|---|---|---|
| Liu et al., 2020 [52] | 2018 | lung cancer | 5 anticancer drugs | A tertiary hospital in Shanghai city | ITS | Drug costs | The average drug cost decreased by 28,200 CNY in outpatient and emergency departments; The average drug cost decreased by 16,700 CNY in inpatient department |
| Cao et al., 2020 [35] | 2018 | lung cancer | 5 anticancer drugs | A tertiary hospital in Shanghai city | ITS | The number of patients adopting study medicines; The proportion of genetic test | The number of patients adopting study medicines increased; The proportion of genetic test increased from 9.93% to 19.42% |
| Diao et al., 2022 [29] | 2017 | breast cancer | trastuzumab | Fujian province | PSM | Medical expenditure; OOP expenditure share; The proportion of patients who adopted trastuzumab | The medical expenditure decreased by US$18,661.02. The OOP expenditure share decreased by 24%. The proportion of patients who adopted trastuzumab increased from 29.9% to 61.8%. Patients enrolled in URRHI benefit less form the policy |
| Cai et al., 2022 [30] | 2018 | - | 17 anticancer medicines | 31 provinces (nationwide) | CITS | Availability; DDDs; DDDc; Affordability | The availability increase by 25.22%.The utilization of the medicines increased by 11.44 DDDs. The DDDc decreased by US$109.09. The affordability ratio decreased from 17.35 to 1.99 |
| Liu et al., 2022[18, 31] | 2017 | - | Six types of anti-HER2 drugs | Nanjing | ITS | DDDs; DDDc | The DDDs anti-HER2 drugs increased. The DDDc decreased |
| Ding et al., 2022 [32] | 2017 | cancer | - | four cities in Shandong province | ITS | The outpatient and inpatient care visits per capita; The proportion of OOP expenditure; The proportion of medication costs; | The outpatient care visits per capita significantly decreased. The proportion of OOP expenditure in outpatient medical costs decreased. The proportion of OOP expenditure in inpatient medical costs increased. The proportion of medication costs in outpatient medical costs rose by 0.28%.The proportion of medication costs in inpatient medical costs decreased 0.2% |

**Table 1** (continued)

| Author | Rounds | Study disease | Study drugs | Setting | Study design | Outcomes | Key findings |
|---|---|---|---|---|---|---|---|
| Liu et al., 2023 [33] | 2021 | - | lenvatinib | Nanjing city | ITS | The utilization of lenvatinib; The total hospitalization expenses | The NHIC policy has significantly increased the utilization of lenvatinib. The total hospitalization expenses increased |
| Yang et al., 2023 [34] | 2017 | cancer | targeted anticancer medicines | 31 provinces (nationwide) | ITS | Price-negotiated TAMs use, Direct medical costs | The government price negotiation and reimbursement policy improved patient access to targeted anticancer medicines and narrowed disparities among insurance schemes. TAMs users' daily medical costs increased |

*DDDs* Defined daily doses, *DDDc* Defined daily drug cost, *OOP* Out of pocket, *ITS* Interrupted time series, *CITS* Controlled interrupted time series, *PSM* Propensity score-matching

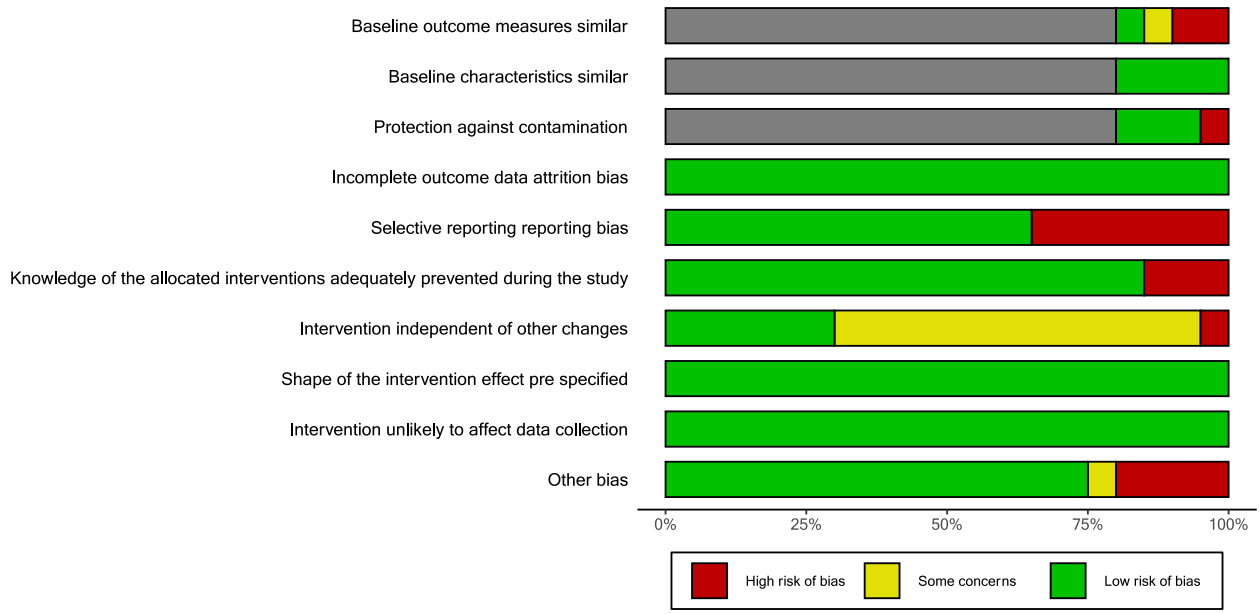


**Fig. 3** Methodological quality graph: review authors' judgments about each methodological quality item presented as percentages across all included studies

## Effects of NRDPN

The evidence from the 20 studies that examined the association between the implementation of NRDPN and drug price, availability, affordability, utilization, and cost is summarized in Appendix 1.

### *Price*

A total of 8 studies reported the defined daily dose cost (DDDc) to express price, and the magnitude of changes in DDDc largely reflected the direct effect of the intervention. All studies reported decreases in DDDc, ranging from 24 to 72%, which is consistent with price reduction reported by the government [6, 18, 21, 24, 26, 27, 30, 31].

### *Availability*

A total of 5 studies evaluated the impact of NRDPN policy on the availability of success-negotiated drugs [6, 11, 18, 24, 30]. The availability of each drug was usually documented as the percent availability of surveyed medicines in a facility on the day of data collection. As expected, all included studies reported the NRDPN policy was associated with increased availability of insure-approved drugs. Regardless of the drug category, hospital level, and region, a greater number of hospitals were able to provide insure-approved drugs after NRDPN policies [6]. However, a nationwide study reported that the availability of insure-approved drugs in 2019 is only 30%, even with the implementation of the policy [6].

### *Utilization*

The review identified 15 studies that assessed the impact of NRDPN on innovative drug use. Eight of these studies reported defined daily doses (DDDs) and consistently revealed that the implementation of the NRDPN significantly increased the utilization of the vast majority of negotiated medicines. However, a study conducted in Nanjing city found no obvious upward trend in the DDDs of trastuzumab, erlotinib, and everolimus, which may be associated with the limitation of indications by the insurance program [24]. In addition, the epidemic characteristics of diseases may affect the utilization of drugs. For example, the medicine treated for lung cancer, breast cancer, and gastric adenocarcinoma significantly increased, mainly due to the high incidence in China [24].

Five studies consistently reported the number of patients who adopted successful-negotiated drugs significantly increased after the NRDPN policy [22, 23, 33–35]. Similarly, two published studies indicated the proportion of patients who adopted successful-negotiated drugs for treatment increased owing to the price reduction of these drugs [25, 29]. In addition, [35] Cao et al. report the utilization of genetic tests increased from 10 to 19%. One study conducted in a tertiary oncology institution in Beijing found the number of daily outpatient visits increased by 20.04 per month, and the proportion of outpatient auxiliary drug use had a long-term decline trend of 0.61% [28]. On the contrary, one study conducted in Shandong province demonstrated that the outpatient care visits per

capita and the inpatient care visits per capita decreased after the intervention. They conjecture the NRDPN policy might decrease the unnecessary outpatient care utilization of cancer patients [32].

#### *Affordability*

The three published studies used the WHO/Health Action International (WHO/HAI) Project on Availability methodology to estimate the affordability of the drug, considering the number of working days (daily wages) of the lowest paid unskilled government employee that enable him/her to purchase the course of standard treatment for common conditions with specific medicines [18, 24, 30]. The affordability of success-negotiated drugs increased after the implementation of the NRDPN policy, and the gap between rural patients and urban patients is narrowing. However, the financial burden is higher for rural patients compared relative to urban patients [18, 24].

#### *Cost*

Reporting of cost outcomes varied significantly across studies (Appendix 3). Some studies reported costs separately for patients and insurers, some separately reported drug and nondrug expenditures, and others reported only changes in drug expenditures or total expenditures or some combination of these variables.

Five studies compared changes in total healthcare expenditures. A quasi-experimental study showed an association between the health insurance coverage of novel breast cancer drugs and the reductions in healthcare expenditure by US$18661.02 [29]. Chen et al. [28] found that the average expenditure per visit decreased by 33.44 CNY in the outpatient department, and decreased by 468.75 CNY in the inpatient department. However, one study reported a decrease in total healthcare expenditures in Tianjin city, but an increase in Chengdu City, which might be attributed to the disparity of the health insurance payment methods. Two studies found the total hospitalization expenses increased [33, 34].

Six studies compared changes in OOP costs and healthcare insurance expenditures. The share of patient OOP expenditure was significantly decreased generally, and the proportion of healthcare insurance funds correspondingly increased. Surprisingly, Ding et al. found that the proportion of OOP expenditure in inpatient medical costs increased [32]. Furthermore, several studies showed significant differences between different patient groups. A quasi-experimental study found that rural patients had a 12% higher OOP share than urban patients [29]. Studies in other provinces reported similar results that the financial burden of rural residents was much more serious than that of urban residents [23, 24]. The patients enrolled in urban and rural resident health insurance schemes had a 16% higher OOP share than patients enrolled in urban employee medical insurance schemes (UEMI), and the non-local patients had a 6% higher OOP share than local patient [29].

Five studies compared changes in drug expenditures. Two nationwide studies using procurement data reported a decreased monthly average expenditure on negotiated drugs [21, 26]. Sun et al. [11] reported a significant increase in monthly average expenditure on rituximab and trastuzumab, but no detectable difference in recombinant human endostatin (RHE). One study using individual-level data found that drug expenditure per visit declined both in the outpatient and inpatient sector. However, another study found that drug expenditure increased by 61% after the fourth round of NRDPN, likely resulting from the increase in drug use [27].

## Discussions

Incorporating drugs into NRDL through price negotiation with manufacturers is a major innovation in China's reimbursement drugs list adjustment in recent years. As a great payer in the health system, the government sufficiently leveraged its bargaining power to exert downward pressure on the prices of innovative medicines. We reviewed the evidence regarding the impact of NRDPN on drug price, availability, utilization, affordability, and spending. In general, findings from these studies revealed that the NRDPN is associated with a price reduction, accessibility improvement, and patient financial burden alleviation. Furthermore, the previous studies demonstrated that the NRDPN policy was conducive to narrowing disparities in availability and affordability across regions, hospital levels, and types of health insurance schemes, which substantially improved the equity in drug accessibility. Drug price negotiation policies have exerted diverse impacts in other countries. In terms of procurement and supply, after innovative drugs were incorporated into reimbursement lists in countries like South Korea and Mexico, the procurement volume in the pharmaceutical market increased. It also had a positive effect on the availability of negotiated anticancer drugs in some regions, albeit with potential drug shortages as an unintended consequence [36–39]. Regarding drug prices, in middle-income countries, the establishment of negotiating commissions led to price reductions and better market access; in developed countries like Germany, price negotiations brought about a 24.5% decrease in negotiated prices relative to launch prices [38, 40]. However, in the US, contrary to expectations, the prices of anticancer drugs went up after the launch of negotiation policies [41].

The NRDPN policy has been acknowledged as an effective policy to increase the availability of insure-approved drugs. A greater number of hospitals were able to provide innovative drugs after the NRDPN policy, thus improving access to quality-assured medicines for patients [6, 24]. However, entry into the national reimbursement list does not guarantee direct access to individual hospital formularies. The availability of most medicines in public hospitals is still low, which might be associated with insufficient procurement incentives for public hospitals. Under the case of total pre-payment of health insurance, once the medical insurance costs of the hospital exceed the budget, the hospital needs to pay the excess cost, particularly for the public health sector with insufficient funds. Second, the use of innovative drugs significantly increased the average expenditures of hospitalization, drug expenditures share, and other incongruous assessment indicators for public hospitals set by the the National Health Commission, which also weakens policy effects [6, 24, 27, 42, 43]. The studies conducted in India and Pakistan also showed that public hospitals experienced medicine shortages or medicine unavailability more frequently compared to private hospital pharmacies and retail pharmacies [44, 45]. In April 2021, NHSA introduced the Dual Channel policy that patients can purchase drugs in both designated medical institutions and designated retail pharmacies, and be simultaneously reimbursed by health insurance [46].

Furthermore, the previous studies demonstrated that the NRDPN policy has great potential to decrease disparities in availability across regions and hospital levels, improving the equity in drug accessibility [6]. The growth of availability in secondary hospitals was greater than in tertiary hospitals, and that in Western China was greater than in Eastern China. Of note, the co-payment ratio depends on the type of medical insurance and the region where one is located, the discrepancies in drug availability remained, even though they have narrowed [47]. Generally, the drug availability in tertiary hospitals and Eastern China was higher than in secondary hospitals and in Northeastern China throughout the study period, respectively [6].

The evidence suggested that NRDPN was an effective policy in increasing the utilization of the vast majority of negotiated drugs. The proportion of patients who adopted negotiated drugs for treatment considerably increased accordingly [29]. Furthermore, the gaps in the proportions of patients adopting negotiated medicines between the urban and rural areas, and among the patients enrolled in different health insurance programs also diminished [25]. However, the monthly utilization trend of several drugs decreased significantly after NRDPN [24, 47]. The decrease may be associated with the limitation of indications by the insurance program. For example, only eight treatment courses of rituximab are covered by medical insurance [24]. Another possible reason might be the requirement for genetic testing before initiating the negotiated medication. If the cost of genetic testing for negotiated innovative drugs is added, the overall cost of the treatment will be equal to or even higher than that of alternative drugs not requiring genetic testing [47]. The indication limitation and gene testing might divert some patients from taking negotiated innovative drugs to alternative drugs. Therefore, on the one hand, health insurance programmes should consider reducing reimbursement restrictions and expanding the payment scope under the premise that health insurance funds are safe and sustainable [28]. Moreover, one study shows that the proportion of adjuvant medication decreased in both outpatient and inpatient departments, which suggested the rational use of medications was continuously ensured and optimized. However, overprescribing innovative drugs has been observed in Chengdu city. The utilization of Afatinib and Osimertinib for non-small cell lung cancer exceeded the warning line in 2019 and 2020, which not only lead to the irrational use of anticancer drugs but also put pressure on healthcare budgets [48]. The increasing utilization that originated from unmet medical needs should be promoted while those from inappropriate prescriptions should be prohibited [11].

The existing evidence in either China or many other countries showed that higher OOP costs and poor health insurance benefits packages were associated with poor treatment adherence, decreased quality of life, increased mortality, as well as impoverishing households [2, 23]. There is evidence that the NRDPN policy substantially reduced patient financial burden in general, thus reducing financial barriers to access. The role of patients' affordability in determining the patient's medication choice weakened to an extent after the implementation of NRDPN. More patients could afford and purchase innovative medicines, which can effectively improve the quality and length of life [24]. However, although the prices of the newly covered medicines were reduced by at least 44% on average during the eight rounds of NRDPN in China, there are still some patients who have financial difficulties in adopting these drugs for treatment and struggle to afford the out-of-pocket payment charges, especially for low-income populations in rural areas, as the initial market prices of these drugs were very high and the Patient Assistance Programs (PAP) was canceled after the implementation of NRDPN [24, 26]. There are still quite a large number of patients with the insurance-covered indication who did not choose negotiated drugs for treatment or cease the treatment due to the poor affordability, even though strong evidence supported

that these drugs have outstanding clinical effects compared with the other existing therapies [29, 49]. Patient affordability might still be an obstacle to the adoption of successful-negotiated medicines and the completion of a full course of treatment. Other supplementary measures such as catastrophic medical insurance and additional medical assistance should be established to provide extra financial protection and prevent catastrophic healthcare expenditures for groups of greater social vulnerability and financial deprotection in health [26].

While the NRDPN policy addressed persistent treatment gaps between rural and urban patients to an extent, the considerable disparities between urban and rural areas remained even after NRDPN, which were still the major factors contributing to the inequity. Multiple studies have shown that the financial burden of rural and non-local medical patients was much more serious than that of urban and local patients, respectively [18, 22, 29]. These differences were driven by Per capita disposable income and OOP expenditure. The health insurance benefits packages with disparate reimbursement ratios is a key determinant in OOP expenditure. The rural patients enrolling in urban and rural resident medical insurance schemes (URRMI) and non-local patients were entitled to relatively poor health insurance benefit packages and low reimbursement ratios under the situation that all diagnoses and treatments complied with the national guideline [29]. Additionally, the inconsistency of the reimbursement policies across different areas and the complicated reimbursement procedures further contributed to the insufficient benefit from the NRDPN policy [25].

Although the NRDPN was demonstrated to be conducive to promoting the accessibility of innovative drugs, as well as narrowing regional and hospital-level disparities, there are still barriers to access to negotiated drugs, including unavailability of the medicine at the facilities due to the uncoordinated supportive policies, limited coverage of health insurance, and unequal access to drugs across insurance schemes and regional variations. Unilateral policy implementation without a common policy framework did not fundamentally remove these barriers [50]. Policymakers should pay attention to the synergy among different policies, thus developing a more collaborative policy combination to coordinate with the NRDPN policy. Success in the implementation of NRDPN will also require much more integrated action across all levels of government and with non-governmental actors to support multisectoral and multistakeholder work. Considering the disparity in benefits packages between urban and rural residents basic medical insurance scheme (URRMI) and the urban employee medical insurance scheme (UEMI), vulnerable populations enrolled in URRMI are very likely to encounter financial distress under such a system [23]. Therefore, it is urgent to optimize the current financing mechanism of the health insurance system and strengthen the health insurance benefits packages of patients enrolled in URRMI to maximize the welfare of NRDPN and enable patients to benefit from NRDPN more equally and thoroughly. The action to tackle the insurance structures perpetuating these inequalities may have a greater effect. Policymakers should also consider expanding the coverage of health insurance to incorporate genetic tests, medical examinations, and adjuvant chemotherapy in it and increase investment in the health system.

In the complex landscape of the pharmaceutical industry, the issue of drug pricing has far-reaching implications. Although the price reduction of innovative drugs undeniably presents a glimmer of hope for patients, potentially improving their quality of life and survival rates. However, it's a double-edged sword. The very act of slashing prices might inadvertently set off a chain reaction. Pharmaceutical companies, which rely heavily on revenue streams to fuel their continuous research and development efforts, could find themselves strapped for cash. When the profit margins shrink due to price cuts, the funds available for them to pour into the painstaking and costly process of R&D take a hit. This, in turn, has the potential to slow down the discovery and development of new drugs. In the long run, it might mean that future patients could face a dearth of novel treatment options, ultimately lowering access to the next generation of life-changing pharmaceuticals and leaving them in a precarious position where medical advancements stall.

In addition to summarizing the evidence, our review identified several important limitations in the existing literature that have implications for future research and policy.

a) Firstly, policy recommendations still require methodologically rigorous study designs. The existing studies lack the contemporaneous control group except for a few studies. There is a critical need for more quasi-experimental research studies including the contemporaneous control group to evaluate outcomes before and after the NRDPN, given the rapid changes in available treatments and the introduction of generic substitutes.
b) Secondly, this review highlighted the need for more comprehensive and representative data to fully assess interventions. The evidence remains mainly limited to public facilities and a small number of drug classes, especially anti-cancer drugs. Only three studies investigated the impact of NRDPN policy based

on procurement data from a nationally representative sample of hospitals. None of the studies included data from private hospitals or retail pharmacies, which may result in selection bias to a certain extent [18].

c) Thirdly, research examining broader health outcomes is unavailable. After the NRDPN policy, more patients can purchase innovative medicines, which may effectively improve the quality and length of life. Therefore, there is a critical need to further evaluate whether the NRDPN may cause patients to forego, delay, or decrease adherence to innovative drugs and whether that results in better health outcomes. There is also a notable lack of evidence of medium-and long-term policy effects. More patient focus may be important to consider in future research in the measurement of outcomes.

d) Finally, our quality assessment revealed that fewer studies in our review considered the potentially relevant confounding factors and the interactive effect of other policies on outcomes, such as market approval of novel medicines and volume-based procurement policy, which could lead to biased effect estimates. For instance, each year one or more anti-lung cancer drugs were approved, covered by health insurance, or selected in the volume-based procurement list, which substantially adds complexity to the evaluation of the NRDPN policy. Understanding the interactive effect of all these policies on outcomes is crucial for policymakers to formulate effective strategies and design optimum drug policy.

The limitations of this review are as follows. Firstly, although multiple databases (PubMed, Web of Science, CNKI, Wanfang, and VIP) were used, there may be other relevant sources that were not included, potentially missing some studies. Secondly, the search terms used might not have captured all possible relevant studies. Some relevant research could have been published with different terminologies that were not accounted for in the search strategy. Thirdly, limiting the review to specific study designs may have excluded other valuable research that could provide different perspectives on the impact of NRDPN. Focusing on particular outcome measures related to drug price, availability, affordability, utilization, cost, and patient outcomes might have overlooked other important aspects or indirect effects of the NRDPN policy. Finally, there could be a publication bias as only studies published in peer-reviewed journals were included. Unpublished studies or those with negative results might not have been considered, which could affect the overall conclusions.

## Conclusion

Evidence to date generally indicates the implementation of NRDPN policy contributes to increasing and improving the accessibility of innovative medicines, as well as narrowing disparities across the region, hospital level, and type of health insurance. It is also associated with a price reduction and patient financial burden alleviation. These results suggest that NRDPN may be an effective policy strategy to promote universal access to innovative medicines for China and other countries. The government should conduct further price negotiations for more medicines with clinical benefits. However, there are still challenges to benefiting patients sufficiently and equally. The long-standing disparities across insurance schemes and regional variations remained even after NRDPN, which were still the major factors contributing to the inequity. Policymakers should develop a more collaborative policy combination to coordinate with the NRDPN policy, as well as improve financial protection and equal opportunities in access to medicine.

## Supplementary Information

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Supplementary Material 1.

**Authors' contributions**
Li Yang: Conceptualization, Writing-Review & Editing. Zheng Zhu: Methodology, Formal analysis, Writing-Original Draft. Jiawei Zhang: Writing-Original Draft, Writing-Review & Editing. Zhihu Xu: Data Curation. Quan Wang: Writing-Review & Editing. Yu Qi: Writing-Review & Editing.

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**Data availability**
No datasets were generated or analysed during the current study.

## Declarations

**Ethics approval and consent to participate**
Not applicable.

**Competing interests**
The authors declare no competing interests.

**Author details**
[1]Department of Health Policy and Management, School of Public Health, Peking University, Beijing 100191, China. [2]Climate, Air Quality Research Unit, School of Public Health and Preventive Medicine, Monash University, Melbourne, VIC 3004, Australia.

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## Publisher's Note