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Research on Pathways to Improve Innovative Drug Accessibility from the Perspective of Policy Synergy: A Review and Prospect

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Abstract

High-cost innovative medicines is a global priority, prompting China's policy framework to shift from singular price controls toward integrated coordination and value-based approaches. This review examines theoretical mechanisms and empirical evidence regarding policy synergy's impact on drug accessibility. While existing research provides robust theoretical foundations, challenges remain regarding fragmented evaluation systems, limited empirical scope, and inadequate micro-level equity analysis. Future research should advance policy synergy theory, quantitative assessment methodologies, patient-centered equity studies, and dynamic adjustment mechanisms to support evidence-based policy optimization during the 14th Five-Year Plan period.

Keywords

Innovative Drug Accessibility; Policy Coordination; Evaluation Mechanism.

1. Introduction

The accessibility of high-priced innovative medicines to public hospitals is a topic of global concern. In recent years, the Chinese government has introduced multiple initiatives to vigorously promote patient access to innovative drugs. In February 2015, the General Office of the State Council issued the "Guiding Opinions on Improving the Centralized Procurement of Drugs in Public Hospitals" (Guobanfa [2015] No. 7), marking the official commencement of national-level drug price negotiations. Subsequently, the National Reimbursement Drug List (NRDL) negotiation mechanism has gradually become normalized, reducing drug prices through negotiations and improving drug accessibility and affordability. Meanwhile, successive policies such as the "Guiding Opinions on Establishing and Improving the 'Dual-Channel' Management Mechanism for National Reimbursement Negotiated Drugs" (Yibaofa [2021] No. 28) and the "Guiding Opinions of the General Office of the State Council on Establishing and Improving the Outpatient Mutual Aid Security Mechanism for Employee Basic Medical Insurance" (Guobanfa [2021] No. 14) have provided institutional guarantees for hospital admission and benefit coverage to support the continuous promotion and clinical use of innovative drugs. The 15th Five-Year Plan proposes upgrading the focus of innovative drug policy to "systematic coordination and value realization," demonstrating the government's increasing emphasis on collaborative efforts. Innovative drug accessibility is jointly influenced by multiple policy stages including access policies, payment policies, supply policies, and utilization policies. The effectiveness of single policies is often constrained by the "ceiling effect" of other policies, while coordinated implementation may produce stronger promotional or inhibitory effects. Currently, domestic research has provided a rich theoretical foundation for exploring pathways to improve innovative drug accessibility from the perspective of policy synergy; however, challenges remain regarding fragmented evaluation mechanisms, insufficient empirical breadth, and inadequate micro-level equity analysis.

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This paper adopts the perspective of policy synergy, synthesizing domestic and international scholarly research on policy coordination to discuss and reflect on the topic of pathways to improve innovative drug accessibility. It aims to integrate theoretical tools and empirical methods for evaluating policy synergy while identifying theoretical gaps based on domestic and international empirical research progress, thereby providing directions for future research.

2. Definition of Core Concepts

2.1. Drug Accessibility

Drug accessibility is a key concept in the field of public health, referring to the extent to which patients can obtain and use required medicines when needed[1]. The World Health Organization defines drug accessibility through three core dimensions: availability, affordability, and institutional guarantees for accessibility[1,2]. Among these, "availability" focuses on the process from non-existence to research, development, and marketing of drugs, while "accessibility" emphasizes the acquisition of appropriately selected medicines, effective supply systems, economic factors, and patient access to health information[3,4]. Overall, drug accessibility is a multi-dimensional concept. Zhuang Jin approaches the issue from the perspective of the right to health, reconstructing the connotation of drug accessibility as "the public's ability to safely obtain appropriate, high-quality, and culturally suitable medicines at affordable prices, while emphasizing the convenience of accessing rational drug use information"[5]. Gong Shiwei et al., building upon previous research, propose that drug accessibility satisfies five dimensional capabilities of patient medication needs: availability, supply accessibility, utilization accessibility, affordability, and timeliness of medication, forming a relatively complete evaluation indicator framework[2]. The evolution of these definitions reflects a shift in policy focus from simple concerns about "whether medicines exist" and "whether they are affordable" to higher-quality development requirements regarding "whether medicines are appropriate" and "whether services are timely."

2.2. Policy Synergy

Early research defined policy synergy as "a process pursuing consistency, coherence, comprehensiveness, and harmonious and compatible results"[6], emphasizing the mutual matching and coordination among policy elements. As research has deepened, policy synergy studies have moved beyond technical-level coordination issues to encompass complex processes involving institutional arrangements, power allocation, and value choices. It can also be viewed as a state of consistency achieved between policy priorities and resource allocation for development goals, aiming to create an orderly and coordinated state within the same policy and across different policies, increasing coordination to form policy synergy and promote the realization of policy objectives[7]. It represents the design of mutually coordinated policy measures by policy actors when formulating policies to achieve policy goals[8]. This synergistic effect may be either positive or negative[9].

3. Theoretical Research on Policy Synergy and Drug Accessibility

Drug accessibility results from the interaction of multiple factors including availability, affordability, and institutional guarantees[2]. Availability is the foundational dimension of drug accessibility, referring to the "on-the-shelf" presence of medicines at delivery points[10]. From the supply side, national drug expenditure, price levels, supply chain efficiency, procurement, and regulatory policies are key variables determining availability[10,11]. From the demand side, disease burden, drug utilization levels, and medical culture shape the structure and scale of drug demand[10]. Affordability is the economic dimension of drug accessibility, reflecting the

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cost burden patients bear to obtain required medicines, primarily determined by drug prices and insurance coverage[12].

Within this complex system, the institutional and policy environment constitutes the structural guarantee for drug accessibility, determining whether availability and affordability can translate into real patient access. Through institutional arrangements affecting the behavioral incentives of various stakeholders, policies can directly intervene in drug prices, supply, and reimbursement levels. Specifically, National Reimbursement Drug List negotiations act directly on drug "availability" and "affordability" through a "volume-for-price" mechanism, incorporating clinically valuable but expensive innovative drugs into the insurance catalog and substantially reducing patient out-of-pocket expenses[4]. The centralized volume-based procurement (CVP) policy reshapes drug circulation and procurement through "procurement and usage integration with volume-price linkage," reducing "inflated" drug prices, saving insurance funds, and ensuring the "supply accessibility" of selected drugs through guaranteed usage and timely payment[13]. Empirical research also demonstrates that policy implementation significantly reduces drug prices, improves drug availability rates and utilization volumes, and positively impacts population health performance[14].

In reality, the introduction and implementation of various policies always proceed simultaneously. On one hand, single policy effects can directly improve accessibility in specific dimensions; on the other hand, an optimal policy portfolio should pursue "coherence" among policy objectives and "consistency" among policy instruments[15]. When payment policies, drug regulatory policies, and healthcare service policies form a synergistic pattern with consistent objectives and complementary instruments, drug accessibility can be systematically improved[16]. Conversely, fragmentation, objective conflicts, or incentive misalignment among policies may lead to offsetting effects or even unexpected negative consequences.

Therefore, policy effects and integration degree are deep institutional factors influencing drug accessibility, involving multiple government departments including healthcare insurance, health administration, drug regulation, and pricing, as well as multiple stages of drug production, circulation, and utilization, requiring cross-departmental and cross-level policy synergy[15]. Differences in policy synergy across three dimensions-issue concentration, interest concentration, and policy targeting-directly affect the realization of policy effects[17]. In the pharmaceutical policy domain, when relevant policies lack effective synergy, policy objective conflicts or instrument mutual exclusion may occur, thereby weakening improvement effects.

4. Empirical Research on Policy Synergy and Drug Accessibility

Reviewing relevant research reveals that CVP and NRDL negotiations can form positive synergistic effects with other policies, positively impacting overall drug accessibility. Scholars including Tan Qingli, Niu Ben, and Lu Mengqing have employed policy interpretation methods, descriptive statistical methods, and policy evaluation methods to reveal the synergistic mechanisms between these two policies from different perspectives[13][17-19]. Research findings indicate that the two policies form a cascading price reduction effect through "volume-for-price": innovative drugs first enter the catalog through initial NRDL price reductions, then undergo secondary price reductions through CVP after patent expiration, ultimately achieving the dual objectives of NRDL expansion and continuous drug price decline[13]. Duan & Yang employed a regression discontinuity design, using 2019 CVP and NRDL as policy breakpoints, finding that the policy combination improved resident health performance by 3.4%, with mechanisms manifested as reduced drug expenditure, incentivized pharmaceutical R&D, and optimized drug import-export structures[14]. Wang Huan et al. examined the synergy between the essential medicines system and CVP policy, finding that selected essential medicines achieved price reductions and supply guarantees under the dual policy support; however, CVP

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also indirectly crowded out the allocation and utilization space for essential medicines in aspects such as drug production and catalog overlap[20]. Barwickemployed a structural model to evaluate China's NRDL negotiation reform, finding that the "negotiation plus expansion" policy combination reduced innovative drug retail prices by 48%, patient out-of-pocket expenses by 80%, and increased utilization volume by 350%[21].

Existing empirical research still contains gaps and controversies. First, methodologically, studies predominantly rely on qualitative descriptions and case analyses, lacking a standardized set of indicators and methods capable of quantitatively evaluating the synergy degree of pharmaceutical policy portfolios, making cross-regional and cross-temporal comparative research difficult to conduct[22]. Second, regarding the impact of synergy, whether "strong synergy" necessarily leads to better accessibility outcomes or whether pitfalls exist remains insufficiently supported by empirical evidence[15]. Meanwhile, significant differences exist in drug availability rates across different negotiation batches, with longer-implemented varieties showing higher availability rates, suggesting that the realization of policy synergy effects may involve "time lags" rather than occurring instantaneously[4]. Furthermore, whether policy synergy, while improving macro-level efficiency in drug accessibility, exacerbates micro-level inequalities-such as substantial differences in drug allocation rates across regions and hospital levels-represents an urgent research topic requiring attention.

5. Implications and Prospects

In summary, the perspective of policy synergy provides a new analytical framework for understanding innovative drug accessibility issues. Existing domestic research has provided a rich foundation for exploring pathways to improve innovative drug accessibility from the policy synergy perspective, while also exposing critical gaps including incomplete theoretical systems, fragmented evaluation mechanisms, and insufficient empirical breadth. Future research should commit to constructing an integrated analytical model combining policy synergy theory with the multi-dimensional framework of drug accessibility.

At the theoretical level, there is a need to construct a pharmaceutical policy synergy theory model within the Chinese context, combining the "tri-medical linkage" (healthcare, medical insurance, and pharmaceutical) reform practice to clarify the subjects, objects, mechanisms, and effects of synergy, revealing transmission pathways and effect boundaries. At the methodological level, causal inference methods suitable for high-dimensional policy portfolio evaluation should be developed to achieve quantitative measurement and effect decomposition of policy portfolio synergy degrees. At the empirical level, micro-level empirical research based on patient-level data should be conducted, focusing on distributional differences of policy effects across urban-rural, regional, and income groups, revealing whether policy synergy exacerbates micro-level inequalities while improving macro-level efficiency. Finally, real-time monitoring and dynamic adjustment mechanisms for policy synergy should be established, exploring the construction of monitoring indicator systems for policy synergy to provide evidence-based support for dynamic policy adjustment, promoting the transformation of innovative drug policy from "each performing its own duties" to "coordinated implementation," and facilitating the optimization and implementation of innovative drug policy during the 15th Five-Year Plan period.

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