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Strategies to Overcome Challenges in Real-World Value Assessment amid Full DRG Implementation

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Abstract: Against the backdrop of the comprehensive implementation of Diagnosis-Related Groups (DRG), Real-World Value Assessment (RWVA) has become a crucial support for driving healthcare payment system reform and value-oriented decision-making. This paper systematically reviews the evolving trends in international Real-World Evidence (RWE) methodology from 2020 to 2025, analyzing its integration pathways with health economics and the development direction of dynamic value assessment models. Within the context of China's DRG-based payment policy implementation, it explores the application bottlenecks of Real-World Data (RWD) in technology access and price negotiations, proposing optimization strategies from three dimensions: data, methodology, and policy. The study argues that high-quality, interoperable data infrastructure should be constructed, models integrating RWE and health economics should be refined, and a value-oriented payment decision-making system should be established to optimize healthcare resource allocation and enhance the scientific nature of medical insurance payments. By implementing these strategies, the study anticipates the establishment of a closed-loop mechanism linking evidence generation, value assessment, and payment decision-making, thereby improving the transparency, efficiency, and sustainability of China's healthcare payment system. The expected outcome is a more data-driven and outcome-oriented policy framework that aligns real-world clinical performance with medical insurance value recognition.

Keywords: DRG payment; Health economics, Real-world data (RWD); Real-world evidence (RWE)

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1. Introduction

As global healthcare systems transition from "cost control" to "value orientation," the strategic importance of Real-World Evidence (RWE) in drug regulation, medical insurance payment, and clinical decision-making has become increasingly prominent. Since 2020, the United States, the European Union, and the Asia-Pacific region have successively promoted the implementation of RWE policies, providing a new methodological foundation for the entire life-cycle management of pharmaceuticals. In this context, China is comprehensively advancing

DRG payment reform, aiming to standardize medical services and achieve refined allocation of resources through case-based payment. However, the current variable quality of Real-World Data, disconnects between assessment models and payment mechanisms, and unclear policy pathways limit the effective application of RWE in practical decision-making.

Based on the evolution of international methodologies and domestic policy practices, this paper systematically analyzes the current status, challenges, and optimization strategies for Real-World Value Assessment in China, providing references for constructing a value-oriented payment system based on real-world evidence.

2. Current status of real-world value assessment

2.1. International trends in RWE methodology development (2020–2025)

Between 2020 and 2025, RWE has evolved from a supplementary to a decisive component in global regulatory and health technology assessment decisions. Agencies like the US FDA, EMA, and Japan's PMDA have issued guidelines, formally integrating RWE into areas such as post-market evaluation and indication expansion [1]. While this trend is global, regional differences are pronounced. The US FDA adopts a pragmatic, case-by-case approach, granting RWE significant weight. The EMA employs a more standardized model via the DARWIN EU network, prioritizing data harmonization but maintaining RWE as a complement to clinical trials [2].

Japan's PMDA demonstrates greater caution, using RWE primarily for safety and rare-disease assessment. Methodologically, RWE has deepened its integration with health economics, forming a comprehensive framework for "dynamic value assessment." The application of big data, AI, and causal inference has significantly enhanced the scientific rigor and reproducibility of studies. The emergence of patient-centered tools and lifecycle value models has shifted drug assessment towards continuously updated evaluations. Overall, this period has seen systematic advancements in RWE methodology, policy, and technology, laying a solid foundation for a value-oriented healthcare system [3].

2.2. Application progress of domestic real-world data and value assessment in China

Under the "Healthy China 2030" strategy, China is advancing the use of Real-World Data (RWD) for regulation and payment [4]. Agencies like the NMPA and NHSA are promoting multi-center RWD platforms. For instance, Zhejiang Province has integrated data from over 80 hospitals, which has supported evidence generation for 35+ drugs during national reimbursement negotiations [5]. Shenzhen pilots a similar model for DRG payment. RWE is increasingly used to verify real-world drug efficacy and inform pricing. However, applications remain largely exploratory, transitioning from pilots to normalization. The focus is shifting from "data construction" to "value enablement," as China develops a distinctive value assessment framework driven by integrated policy and methodological efforts [6].

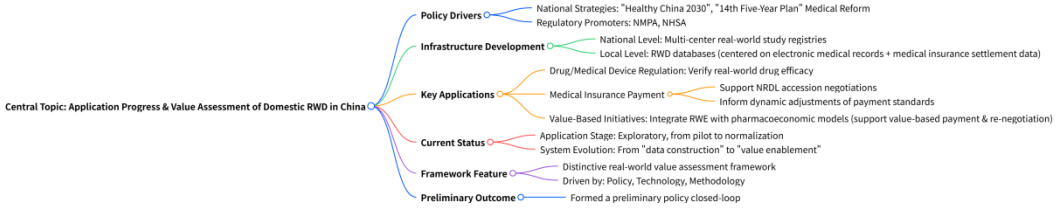

Figure 1. Application progress and value assessment framework of China's domestic RWD.

Figure 1 was sourced and compiled from NMPA and NHSA policy documents (2018–2024), provincial pilot project reports, and peer-reviewed literature [4–6]. The framework illustrates the logical flow from policy and institutional drivers → data infrastructure and technical platforms → application scenarios and value realization. Arrows represent the dynamic feedback loop between data application and policy refinement, indicating how RWD supports iterative improvement in value-based payment decision-making.

3. Challenges in real-world value assessment

3.1. Data-level issues: Insufficient quality, interoperability, and traceability

Although the infrastructure for RWD in China has begun to take shape, significant challenges persist regarding data quality, interoperability, and traceability, which constitute major bottlenecks undermining the scientific rigor of real-world value assessment [7]. Substantial variations in data collection standards, coding systems, and documentation practices among different healthcare institutions result in high data heterogeneity, complicating multi-source integration and cross-validation [8]. Healthcare information systems are not fully interconnected; limited integration exists between electronic medical records, insurance claims data, and drug utilization data, leading to widespread issues such as missing key variables and data fragmentation [9].

3.2 Methodological-level issues: Disconnect between assessment models and payment mechanisms

A significant methodological gap exists between real-world value assessment models and DRG payment systems [10]. Traditional pharmacoeconomic models, often based on static trial data, fail to capture real-world cost and effectiveness variations. While RWE is increasingly used, its integration into economic models lacks standardization [11]. Furthermore, most models assess single technologies, misaligning with DRG payment logic that focuses on overall cost control for a patient group. This disconnect is compounded by payers' limited use of RWE, preventing assessment results from translating into payment incentives [12].

4. Optimization strategies for real-world value assessment

In summary, the challenges identified across data, methodological, and policy dimensions highlight the structural gaps that hinder the effective application of Real-World Value Assessment under the DRG-based payment system. Specifically, the issues of insufficient data quality and interoperability underscore the need to prioritize the construction of a high-quality, standardized RWD infrastructure.

4.1. Building high-quality, interoperable RWD infrastructure

Building a high-quality, interoperable RWD infrastructure is fundamental [13]. This requires establishing national, unified standards to integrate multi-dimensional data, from electronic records and insurance claims to patient-reported outcomes, into a standardized framework. Accelerating interoperability between hospital, insurance, and research systems is crucial for secure, multi-source data sharing [14]. A full lifecycle quality control and traceability mechanism must ensure data authenticity and consistency. Leveraging technologies like blockchain can enhance security and provenance management, balancing accessibility with privacy. This robust data ecosystem forms the essential backbone for generating reliable real-world evidence and supporting value-based decisions for payment, reimbursement, and drug assessment [15].

Table 1. Action plan for building a high-quality, interoperable RWD infrastructure

Initiative/action	Description/key components	Primary stakeholders	Expected outcome/quantitative target
Establish national data standards	Develop and mandate unified standards for data collection, formatting, and coding (e.g., diagnoses, procedures, PROs)	NMPA, NHSA, standardization administration	≥ 90% of tertiary hospitals to adopt standardized medical coding systems by 2027; inter-institutional data consistency improved by 40%.
Promote system interoperability	Facilitate semantic and technical interoperability between HIS, regional health platforms, and national insurance databases	NHSA, healthcare institutions, IT vendors	By 2026, achieve ≥ 80% data exchange compatibility among core systems; reduce manual data transfer time by 50%.
Implement data governance & QC framework	Establish full-lifecycle quality control and traceability mechanisms with regular audits	Data custodians, regulatory bodies	Annual data audit compliance rate ≥ 95%; reproducibility of RWE studies improved by 30%.
Leverage advanced technologies	Pilot blockchain for auditability and privacy-preserving computation (e.g., federated learning) for secure analysis	Researchers, tech providers, regulators	Launch ≥ 5 national-level pilots; data breach incidents reduced to < 0.1% annually.
Develop a centralized metadata catalog	Create a national catalog documenting RWD sources, access protocols, and quality metrics	Researchers, NHSA	Comprehensive metadata coverage across ≥ 70% of public medical institutions by 2027; improve RWD discoverability and reuse efficiency by 50%.

4.2. Refining dynamic assessment models integrating RWE and health economics

Refining dynamic models that integrate RWE with health economics is essential for multi-dimensional value assessment. The focus should be on adopting a "Life-cycle Value Assessment" approach, extending drug evaluation from pre-market to post-market phases for continuous value re-assessment. Methodologically, dynamic cost-effectiveness models should be developed, centered on real-world outcomes like effectiveness and adherence. Advanced techniques are crucial: causal inference methods (e.g., PSM, DID) mitigate confounding bias, while machine learning algorithms (e.g., Random Forest) model complex, non-linear interactions and enable continuous parameter updates as new data arrives. These methods are selected for their robustness with high-dimensional data. Simultaneously, establishing model validation and re-calibration mechanisms ensures external validity across diseases and payment systems.

5. Conclusion

Real-World Value Assessment (RWVA) is pivotal for shifting China's healthcare system from volume-based to quality-driven care. While international methodological advances and domestic DRG reform are promoting evidence-based decision-making, progress is hindered by uneven data quality, model inflexibility, and policy misalignment. Future priorities must be building a high-quality data infrastructure, creating dynamic models that integrate RWE with health economics, and fostering institutional innovation. This will establish an integrated "evidence-assessment-payment" cycle to optimize resource allocation. This study's limitations include its focus on national/provincial data, potentially underrepresenting primary care, and its exploratory conclusions on policy linkage, which require validation through longitudinal, multi-center studies incorporating broader data sources.

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