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Medical security for rare disease patients in China: Insights from patients with Dravet syndrome

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SUMMARY: The high costs of diagnosing and treating rare diseases impose a substantial financial burden on patients and families, underscoring the need to understand reimbursement experiences and unmet needs to improve medical security. Using Dravet syndrome, a severe and lifelong epileptic encephalopathy, as a representative rare disease, this study conducted an online questionnaire survey completed by 161 respondents, including family members or caregivers of patients with Dravet syndrome. The results revealed that most families had insufficient income to cover treatment costs, with patients' annual treatment expenses generally approaching or even exceeding their families' financial capacity, while 41.67% reported that out-of-pocket payments after reimbursement accounted for more than half of their total treatment expense. Surveyed respondents expressed general satisfaction with various medical security models (over 75%), including basic medical insurance, critical illness insurance, medical assistance, commercial health insurance, and charitable aid. However, challenges remain: the limited funding pool and reimbursement capacity of basic medical insurance, the ongoing development of commercial insurance products (*e.g.*, region-specific Huimin insurance), and the lack of guaranteed scale and sustainability of charitable funding. Thus, further improvements in China's medical security for rare disease are imperative. Key priorities include enhancing policy coherence, improving coordination across security models, and increasing the depth of coverage at all levels to alleviate the financial burden on patients.

Keywords: rare diseases, multi-tiered medical security, Dravet syndrome, policy recommendations, China

1. Introduction

Dravet syndrome, previously known as Severe Myoclonic Epilepsy of Infancy (SMEI), is a drug-resistant developmental and epileptic encephalopathy that begins in infancy and proceeds with accumulating symptom burden that significantly impacts individuals throughout their lifetime (*1,2*). Patients typically experience gradual developmental delay or regression, with most developing varying degrees of intellectual disability, behavioral abnormalities, sleep disorders, and mental health issues by adolescence (*3*). The syndrome carries a high mortality rate of 15–20%, primarily due to sudden unexpected death in epilepsy, prolonged seizures, seizure-related accidents (*e.g.*, drowning), and infections (*4,5*).

China currently lacks large-scale epidemiological data on Dravet syndrome. Existing literature reports its prevalence between 1/40,900 and 1/15,700, estimating approximately 20,000 to 50,000 affected families (*6,7*). Currently, the main therapeutic approaches for Dravet syndrome include antiepileptic drugs, dietary therapies such as a ketogenic diet for children aged 6 years and younger or a modified Atkins diet for adolescents and adults, and neuromodulation techniques like vagus nerve stimulation and deep brain stimulation. Additionally, novel therapies such as serotonergic drugs and gene-modifying therapies are under development (*8,9*). Overall, existing therapies have limited efficacy. While they may reduce seizure severity and frequency, managing non-epileptic episodes remains challenging. Complete cure is currently unattainable, and patients require lifelong medication (*7*). Concurrently, patients often experience developmental delays or intellectual disabilities, necessitating round-the-clock family care. This imposes multidimensional medical demands, high treatment costs, and long-term caregiving challenges on families. These factors severely impact quality of life for patients and their families, causing immense psychological stress and financial burdens (*10*), placing households at significant risk of falling into poverty or relapsing into poverty due to illness (*7*). A systematic review of Dravet syndrome published in 2023 showed that the mean annual direct medical costs for patients were consistently high across studies, ranging from USD 11,048 to USD 77,914 per patient per year (*7*). For these reasons, Dravet syndrome patients urgently require access to new therapies, along with healthcare coverage and supportive systems to ensure treatment accessibility and long-term continuity.

In May 2018, Dravet syndrome was included in China's inaugural Rare Disease Catalog, qualifying for policy support such as accelerated review and medical insurance reimbursement. Related products have since been approved for market release (*11*). Currently, medical coverage for patients with Dravet syndrome in China primarily relies on a multi-tiered medical security system, including basic medical insurance, critical illness insurance, commercial health insurance, medical assistance, and charitable aid. However, despite ongoing policy advancement, systematic evidence at the patient level regarding actual medical burdens and coverage benefits under different insurance systems remains lacking, necessitating practical evaluation.

This study employs a patient-centered approach, selecting Dravet syndrome patients through questionnaire surveys. It examines coverage scope, actual benefits, and unmet needs of patients with Dravet syndrome across multiple insurance models. This study aims to provide empirical support for evaluating the actual effectiveness of China's multi-tiered medical security system for rare diseases, reveal gaps between existing healthcare policies and patient needs, and offer actionable recommendations for refining policies, optimizing healthcare resource allocation, and improving patient quality of life.

2. Respondents and Methods

2.1. Study design

This study employed a cross-sectional design utilizing a self-developed online questionnaire to investigate medical security experiences of patients with Dravet syndrome within China's multi-tiered healthcare protection system. Its design was grounded in the framework of China's multi-tiered medical security system and informed by a review of national policy documents, alongside prior studies on economic burden of rare diseases and health insurance evaluation. Content validity was established through review by a panel of experts specializing in health policy, rare disease management, and health economics. A pilot test was subsequently conducted with 15 caregivers of Dravet syndrome patients (excluded from the main survey) to assess clarity, comprehensibility, and completion time. Utilizing survey data from a national sample of affected individuals and their caregivers, the research examined coverage scope, realized benefits, and unmet needs associated with diverse insurance models, including basic medical insurance, critical illness insurance, medical assistance, commercial health insurance, and charitable aid.

The analytic framework integrated descriptive and comparative methods to evaluate the performance of the multi-tiered medical security system from the perspective, providing empirical evidence to inform policy refinement and resource allocation.

2.2. Questionnaire collection and data analysis

This cross-sectional survey distributed questionnaires online in collaboration with the "CHN Dravet Syndrome Patient Support Group". This patient organization has long provided disease management and information support to patients with Dravet syndrome and their families, and has a relatively stable and representative patient base. Given the nature of Dravet syndrome, all responses were provided by the patient's primary caregiver/family member based on the actual situation to ensure authenticity and accuracy.

Convenience sampling was employed for participant recruitment. Inclusion criteria were as follows: *i*) patients with a confirmed diagnosis of Dravet syndrome established by a qualified medical institution; *ii*) patients or their primary caregivers who were fully informed of the study objectives and voluntarily consented to participate.

Exclusion criteria included: *i*) questionnaires with unclear diagnostic information or missing key data related to disease characteristics or medical costs; *ii*) incomplete questionnaires or those containing evident logical inconsistencies; *iii*) duplicate submissions identified as originating from the same patient.

The questionnaire comprised two sections: basic patient information and issues related to the multi-tiered medical security system for rare diseases, totaling 45 items. The basic information section covered demographic characteristics (age, region, average annual household income), commonly used medications, annual treatment costs, insurance coverage status, *etc.* The security system section addressed economic burden, utilisation of benefits, and reimbursement experiences (including benefit entitlements, reimbursement experiences, and satisfaction levels). Question types included multiple-choice and open-ended fill-in-the-blank items.

The survey was conducted from March 13 to March 24, 2025. Data were processed using SPSS 26.0, with descriptive statistics applied and categorical data were described using frequencies (*n*) and percentages (%). In addition, all costs were assessed in US dollars (USD), using the average RMB/USD exchange rate of 7.1217 in 2024 (*12*).

2.3. Ethical approval

This study, which employed an online questionnaire, received ethical approval from the Ethics Committee of China Pharmaceutical University (Approval no. 2025-09-010). Prior to participation, electronic informed consent was obtained from all participants. They were assured that collected data would be used exclusively for academic purposes, that all provided information would remain strictly confidential, and that their privacy would be protected through anonymization of any personal data. This study also conforms to the provisions of the Declaration of Helsinki.

3. Results

3.1. Basic patient information

A total of 161 online questionnaires were completed by primary caregivers or family members of patients with Dravet syndrome from 27 provinces, including Guangdong, Shandong, Henan, and Jiangsu. The survey results showed that 69.56% (112/161) of the patients were infants or young children aged 0–12 years. Regarding medication use, in addition to valproic acid and clobazam, patients commonly used more than ten other antiepileptic drugs, indicating a high level of treatment complexity.

3.2. Economic disease burden

Patients with Dravet syndrome typically require lifelong treatment, with medication being the primary therapeutic option. The most commonly prescribed drugs include valproic acid, clobazam, and stiripentol (Table 1), though medication choices may vary among patients. The survey showed that 77.36% of respondents reported that the medications required by patients were included in the national reimbursement drug list. However, as detailed in Table 1, 58.49% of respondents indicated that not all medications required by patients were fully covered by insurance.

The survey findings revealed that most patient's families didn't have sufficient income to cover the costs associated with treatment. Among the families, 42.86% (69 families) reported an annual income of less than 7,020.80 USD, while 78.26% had an annual income below 14,041.59 USD. However, 55.28% (89 respondents) reported that patient's annual treatment costs ranged from USD 0 to 7,020.80, and 44.72% indicated annual treatment costs ranged from USD 7,020.80 to 14,041.59. Overall, the treatment expenses borne by many patient families approached or even exceeded their financial affordability (Figure 1).

3.3. Patient insurance coverage and benefits

As detailed in Table 1, enrollment rate for basic medical insurance was 98.14% (158/161), surpassing the national coverage rate of 95% in 2024. In contrast, the uptake of commercial health insurance was 7.45% (12/161), which included "Huimin insurance" (9, 5.59%) and other commercial health insurance (9, 5.59%).

Table 1. Age, geographical distribution, and medication information of the 161 respondents*

Characteristics	Number	Percentage (%)
Age (year)		
0–6	64	39.75
7–12	48	29.81
13–17	12	7.45
18–24	4	2.48
25–40	25	15.53
41–65	7	4.35
> 65	1	0.62
Province		
Guangdong	20	12.42
Shandong	14	8.7
Henan	13	8.07
Jiangsu	12	7.45
Anhui	10	6.21
Sichuan	10	6.21
Others	82	50.94
Commonly Used Medications		
Valproic acid	140	86.96
Clobazam	105	65.22
Topiramate	55	34.16
Stiripentol	41	25.47
Levetiracetam	34	21.12
Clonazepam	22	13.66
Perampanel	16	9.94
Insurance Coverage		
Basic Medical Insurance	159	98.76
Critical Illness Insurance	12	7.45
Huimin Insurance	9	5.59
Other Commercial Insurance (excluding Huimin Insurance)	9	5.59
Medical Assistance	3	1.86
Charitable Aid	3	1.86
Inclusion of Required Medications in Basic Medical Insurance		
None included	36	22.64
Partially included	93	58.49
All required medications included	30	18.87

*All questionnaires were completed by patients' family members or caregivers, who reported patient-related information based on their caregiving experience. Commonly used medications are listed individually only if reported by more than 14 patients (frequency > 14).

With regard to insurance benefits, all enrollees in basic medical insurance had access to corresponding benefits. Furthermore, 7.45% (12/161) of respondents received support through critical illness insurance, and 1.86% (3/161) benefited from medical assistance. Despite these reimbursements, a considerable proportion continued to bear a high out-of-pocket share of total medical expenses. Specifically, 41.67% of respondents reported being responsible for over half of their medical costs, highlighting a persistent financial burden (Figure 2).

Recipients of medical assistance included individuals from low-income households, those on the margin of poverty, and patients affected by catastrophic health expenditures. Assistance was delivered in the form of subsidies for basic medical insurance premiums and inpatient treatment costs. Respondents reported a noticeable reduction in their financial burdens after receiving this support.

Among respondents who had purchased commercial health insurance (including Huimin insurance), 75% (9/12) enjoyed the relevant benefits. However, only 33.33% (3/9) of these insured respondents reported a substantial reduction in treatment costs as a result of insurance claims. Furthermore, 22.22% (2/9) indicated they would not renew any commercial health insurance policies in the future, with the exception of Huimin insurance.

Additionally, 1.86% (3/161) of respondents benefited from charitable aid. Support mechanisms included targeted assistance from rare disease foundations (reimbursing out-of-pocket expenses exceeding 421.25 USD with a maximum subsidy of 702.08 USD) and specialized rare disease medical assistance programs.

3.4. Satisfaction and challenges of multi-tiered medical security

Surveyed respondents generally expressed satisfaction or a neutral stance toward the various tiers of medical security, including basic medical insurance, critical illness insurance, medical assistance, commercial health insurance, and charitable aid (Figure 3). Overall, respondents acknowledged the advancements in China's multi-tiered medical security system for rare diseases and the protection it affords, while also underscoring several persistent challenges that require further attention.

Regarding satisfaction with basic medical insurance, 81.13% (129/159) of insured respondents held a positive view. However, they also reported several concerns during reimbursement, including: *i*) limited reimbursement rates, which inadequately alleviated financial burdens (114/159, 71.7%); *ii*) difficulties in reimbursing cross-provincial medical expenses due to discrepancies between local and treatment-site insurance catalogs (67/159, 42.14%); *iii*) stringent eligibility criteria for chronic or critical illness recognition, hindering access to appropriate treatments (65/159, 40.88%); *iv*) high deductibles that impeded reimbursement (59/159, 37.11%); and *v*) low reimbursement caps, leaving

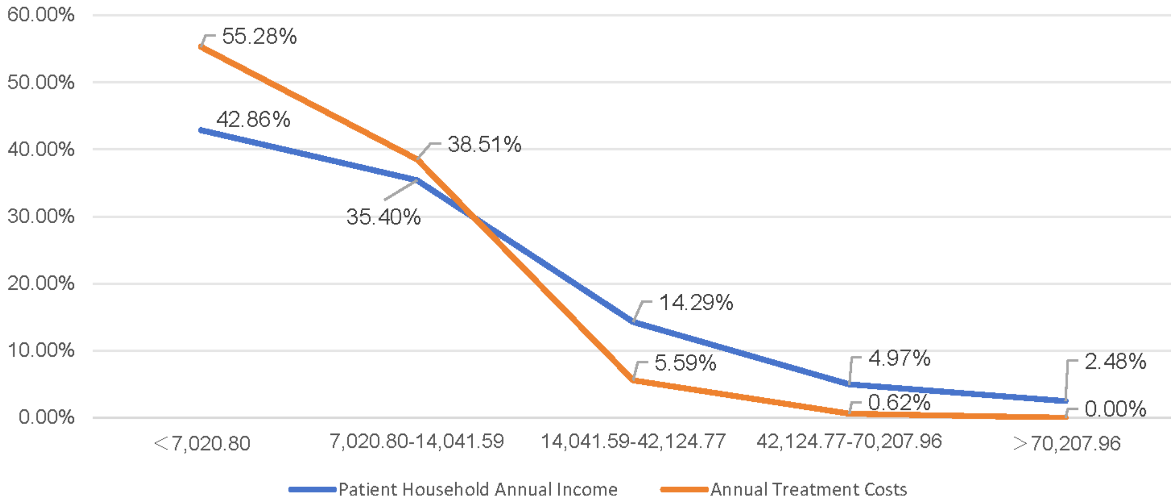

Figure 1. Patient household annual income *vs.* annual treatment costs. Values are presented in US Dollars (USD), converted from Chinese Yuan (RMB) using the average 2024 exchange rate of USD 1 = RMB 7.1217.

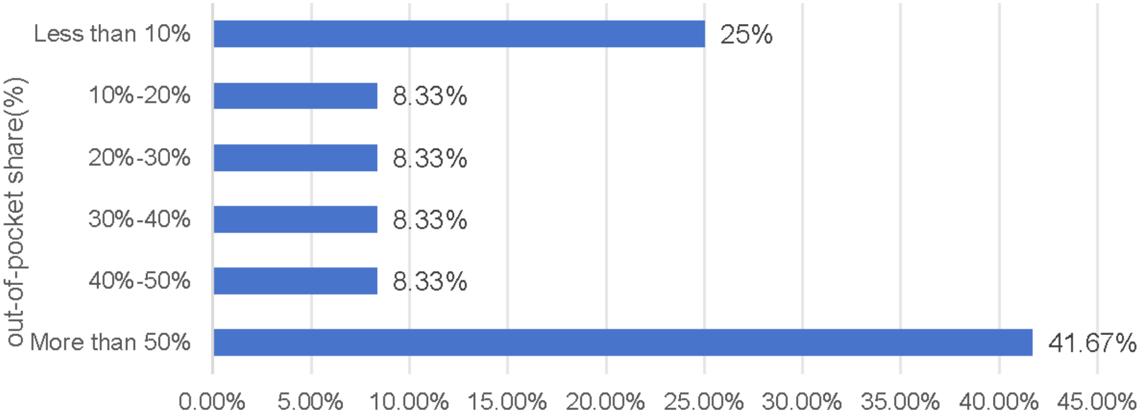

Figure 2. Patient's out-of-pocket share after basic medical insurance and critical illness insurance reimbursement.

substantial out-of-pocket expenses (53/159, 33.33%) (Figure 4).

For critical illness insurance, 91.67% (11/12) of insured respondents expressed satisfaction. Nevertheless, they highlighted several issues: *i*) high deductibles (8/12, 66.67%); *ii*) limited reimbursement rates providing insufficient financial relief (6/12, 50%); *iii*) low reimbursement caps (3/12, 25%); *iv*) financial pressure from prepaying cross-provincial medical expenses (3/12, 25%); and *v*) the need for better integration with basic medical insurance (5/12, 41.67%) (Figure 5).

All respondents receiving medical assistance were generally satisfied with the benefits but noted specific challenges, such as: *i*) cumbersome qualification verification procedures requiring multiple certifications across regions and institutions, and *ii*) high deductibles and low reimbursement rates that limited the overall reduction of financial burden (Figure 6).

As a supplementary layer to basic medical insurance, commercial health insurance was viewed positively by 77.78% (7/9) of insured respondents. Huimin insurance emerged as a commonly used plan among rare disease respondents. However, 77.78% (7/9) cited issues such as limited coverage and high deductibles or reimbursement thresholds (Figure 7). For other commercial health insurance products (excluding Huimin insurance),

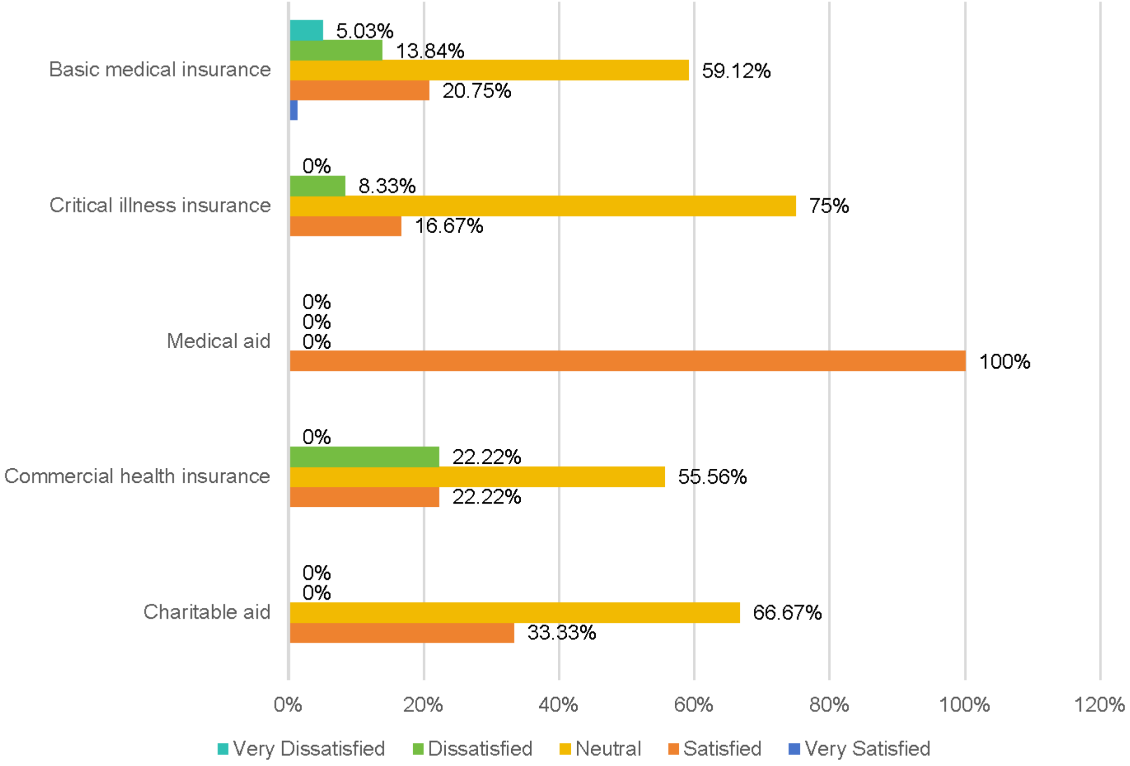

Figure 3. Patient satisfaction with the multi-tiered medical security system for rare diseases.

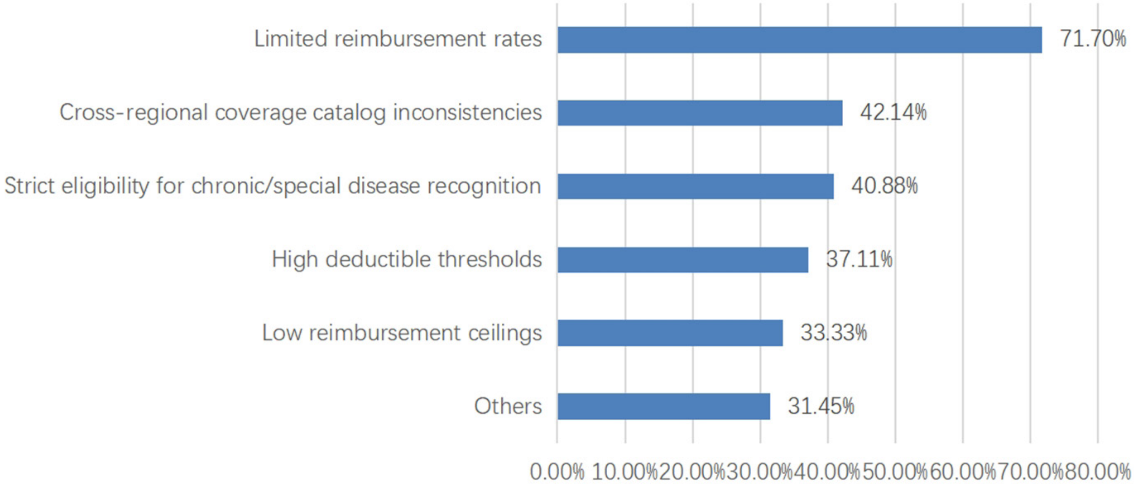

Figure 4. Challenges and issues faced by patients in reimbursement and services under basic medical insurance.

55.56% (5/9) reported exclusions related to pre-existing conditions, while 44.44% (4/9) highlighted high out-of-pocket costs, elevated deductibles, and expensive premiums — all contributing to additional financial strain on families (Figure 8).

Charitable aid is a form of support provided through foundation grants, medication assistance, and medical aid. Respondents who have received such benefits have expressed satisfaction with them.

Furthermore, in relation to the overall multi-tiered medical security system for rare diseases, 80.75% (130/161) of respondents emphasized the need to

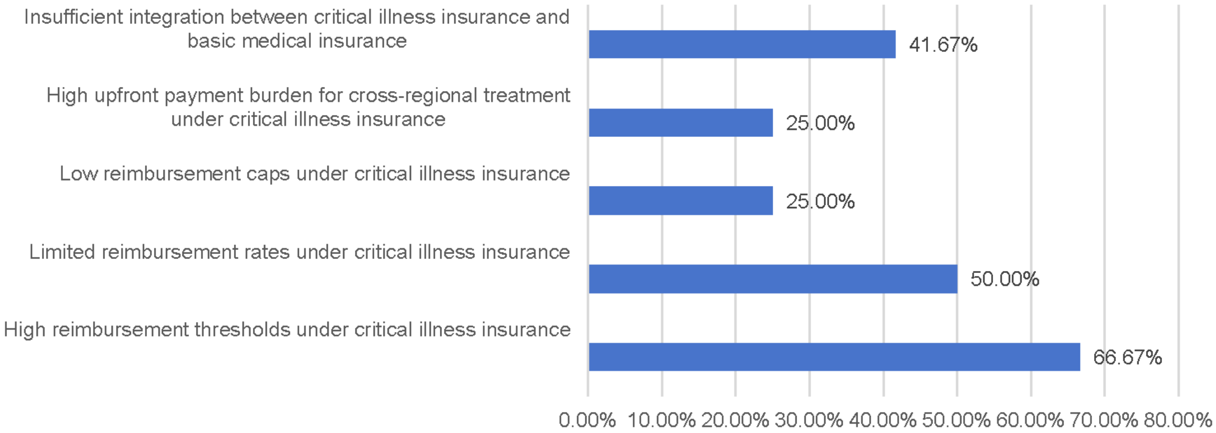

Figure 5. Challenges and issues faced by patients in reimbursement and services under critical illness insurance.

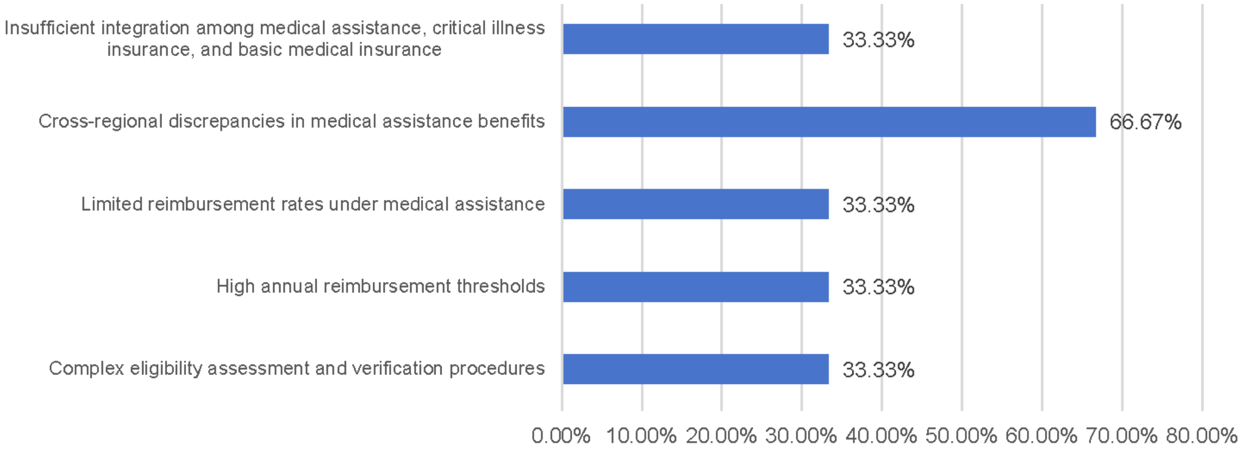

Figure 6. Challenges and issues faced by patients in reimbursement and services under medical assistance.

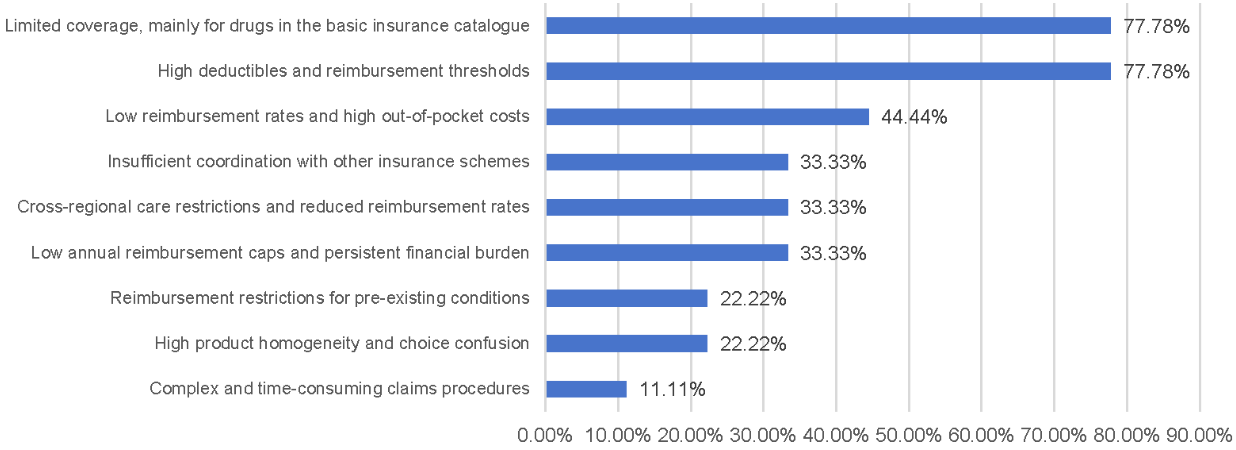

Figure 7. Challenges and issues faced by patients in reimbursement and services under Huimin insurance.

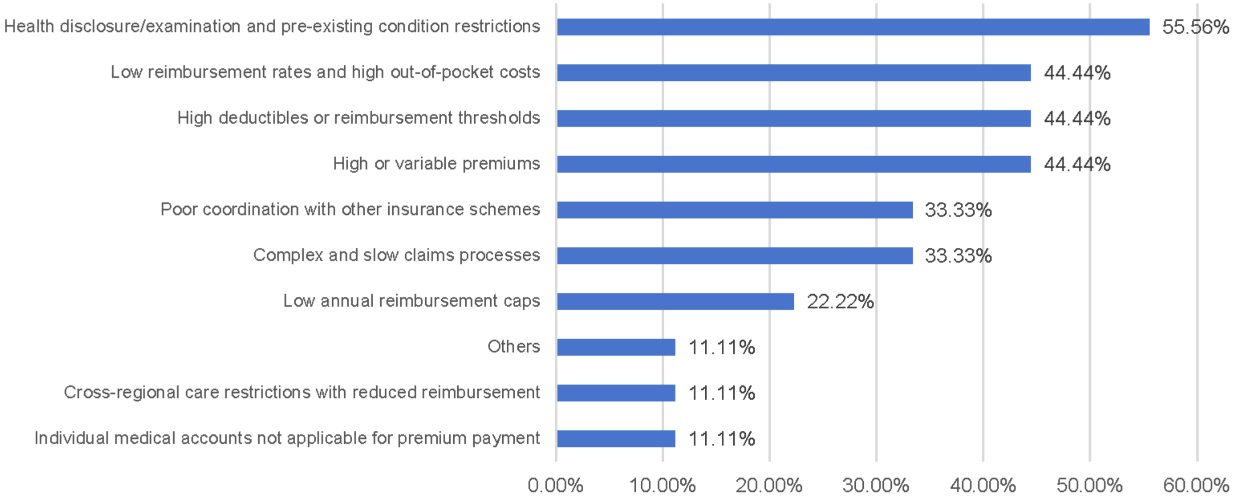

Figure 8. Challenges and issues faced by patients in reimbursement and services under other commercial health insurance (excluding Huimin insurance).

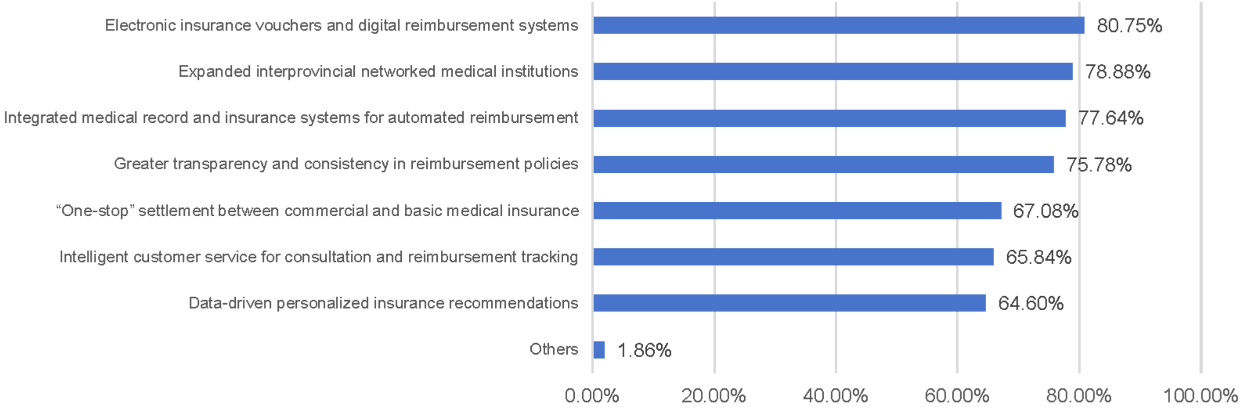

Figure 9. Patients' perceptions of areas for improvement in multi-tiered medical security systems (reimbursement convenience, information sharing, *etc.*).

improve reimbursement convenience and called for accelerating the rollout of electronic medical insurance systems. In addition, 78.88% (127/161) suggested enhancing the convenience and accuracy of cross-regional insurance settlement to alleviate difficulties associated with seeking medical care outside their home regions. Moreover, 77.64% (125/161) considered the interoperability of medical insurance information essential (Figure 9).

4. Discussion

The findings of this study indicate that although China has initially established a multi-tiered medical security system for rare diseases, respondents still report a significant lack of satisfaction with the reimbursement experience and an insufficient sense of financial relief. This result, to some extent, corroborates conclusions drawn by domestic and international scholars, who think the medical security system for rare diseases is universally plagued by insufficient coverage and uneven accessibility. This study, however, diverges from research that highlights institutional progress. Its main contribution lies in elucidating the disparity between the designed system and patients' reimbursement experiences, a disparity that manifests most significantly in limited coverage and high out-of-pocket expenditures. The finding reveals that proliferation of different models (*e.g.*, basic insurance, commercial insurance) has not been fully translated into effective protection for patients.

However, this study has several limitations. First, this research employed a cross-sectional design and convenience sampling through an online survey distributed *via* a patient support group, which may limit the generalizability of the findings. The sample, though national in scope, may not fully represent all patients with Dravet syndrome in China, particularly those without access to online patient communities or with varying socioeconomic backgrounds. Additionally, the study focuses solely on Dravet syndrome, and while informative, the results may not be fully transferable to other rare diseases with different treatment patterns and cost structures. Future research could further conduct cross-regional and cross-disease comparative studies to uncover the heterogeneity in the fairness and accessibility of security among different rare disease populations.

The following sections will provide an in-depth analysis based on survey data, covering four aspects: basic medical insurance, critical illness insurance, medical assistance, commercial insurance.

4.1. Three shortcomings of basic medical insurance: limited coverage, regional imbalances, and high out-of-pocket burden

Although China's basic medical insurance coverage has reached 98.76%, patients with Dravet syndrome continue to experience a disproportionate economic burden. The core challenge lies not in insurance enrollment but in the depth of coverage and the alignment of existing schemes with the long-term, high-cost nature of Dravet syndrome treatment. Coverage of high-cost orphan drugs within the national reimbursement drug list remains limited (*13*) and substantial regional variation in outpatient policies for chronic and special diseases further increases uncertainty in long-term medication management and cross-regional healthcare utilization. Moreover, low reimbursement rates, high deductibles, and strict reimbursement caps mean that a considerable proportion of patients must still bear substantial out-of-pocket costs even within the insurance framework, pushing some families toward sustained financial strain at or beyond their economic capacity (*13*).

4.2. Critical illness insurance: high deductibles and low reimbursement rates undermine its supplementary role

In theory, critical illness insurance is designed to complement basic medical insurance by alleviating catastrophic health expenditures. However, for patients with Dravet syndrome, its supplementary role remains largely unrealized. The extremely low participation rate suggests limited accessibility, while high deductibles substantially weaken its protective capacity, particularly for families facing long-term and continuous medication needs. Although many regions have adopted tiered reimbursement mechanisms, the reimbursement gradients remain insufficient to meaningfully offset costs during high-expenditure phases. More importantly, the persistence of high out-of-pocket payments even after dual reimbursement highlights structural misalignment between critical illness insurance and basic medical insurance, resulting in fragmented protection rather than cumulative risk pooling.

4.3. Medical assistance: inadequate safety-net coverage for rare disease patients

Medical assistance is intended to serve as the last line of defense within China's healthcare security system. However, its actual protective effect for patients with rare diseases is constrained by both systemic design and implementation barriers. Strict eligibility thresholds based on household income and assets exclude the majority of families affected by Dravet syndrome, many of whom, while not meeting conventional poverty criteria, endure prolonged financial pressure from high and continuous medical expenses. In addition, medical assistance is limited in both coverage and funding amount, typically only reimbursing a portion of costs specified under basic medical insurance policies (*14*). For patients with Dravet syndrome who rely on high-cost, long-term medication, the risk-mitigation effect is very limited, making it difficult to establish an effective economic safety net. Therefore, within the multi-tiered medical security system for rare diseases, the role of medical assistance remains largely supplementary and constrained, highlighting an urgent need for institutional optimization in terms of coverage, funding standards, and application accessibility.

4.4. Commercial health insurance: challenges in balancing market incentives and public good for rare diseases

Commercial health insurance has the potential to supplement gaps in the public insurance system, particularly in financing innovative therapies for rare diseases. However, for patients with Dravet syndrome, its practical impact remains constrained by market-driven incentive mechanisms. Risk-selection practices, such as exclusion of pre-existing conditions, high deductibles, limited reimbursement ceilings, and restrictions on policy renewal, substantially reduce both accessibility and financial protection. Although inclusive products, such as public-benefit insurance schemes, have modestly expanded coverage, their depth of protection remains limited and out-of-pocket costs remain relatively high, constraining their overall effectiveness. This structural tension between profitability and social protection highlights the inherent difficulty of relying solely on market-based mechanisms to address long-term, high-cost medical needs of individuals with Dravet syndrome (*15*).

5. Suggestions

5.1. Enhancing policy coherence in China's multi-tiered medical security system for Dravet syndrome

China's multi-tiered medical security system for Dravet syndrome faces dual challenges in policy coherence and regional equity (*13*). There is an urgent need to strengthen institutional coordination, establish a nationally integrated multi-tiered security network, and gradually narrow regional gaps to improve system-wide integrity and equity.

In the short term, the government can refine implementation of the medical insurance benefits list by allowing greater flexibility in local policy execution while maintaining centralized coordination. For provinces that have already established specialized local coverage schemes for Dravet syndrome, a transitional period of three to five years could be granted to ensure a smooth integration into a nationally unified policy and prevent interruptions in patient coverage (*16*). This approach would maintain continuity of care for patients while enabling gradual alignment with nationwide standards.

In the long term, the government can strengthen legislative safeguards for Dravet syndrome and establish a dedicated national fund for this condition. Resource allocation can be dynamically adjusted based on patient numbers and regional fiscal capacity, with priority given to Dravet syndrome cases that remain unaffordable at the local level. In addition, the government can introduce appropriate payment and intergovernmental transfer incentives to support economically disadvantaged regions.

5.2. Enhancing coordination in China's multi-tiered medical security system for Dravet syndrome

China's medical insurance system for Dravet syndrome continues to face coordination challenges, which significantly affect patients' diagnostic pathways, treatment continuity, and medication management. To address these challenges, policy efforts should prioritize strengthening cross-departmental coordination and promoting synergies across all levels of the healthcare security system, thereby establishing a more sustainable, accessible, and predictable framework for drug coverage.

A centralized platform should be established to systematically collect patient experiences, clinical data, and input from multiple stakeholders, including government agencies, healthcare providers, insurers, pharmaceutical companies, and patient organizations. Such a platform would facilitate evidence-based decision-making, support long-term planning, enhance stakeholder awareness, guide development of unified national guidelines, and foster multi-stakeholder consensus in the governance of Dravet syndrome.

5.3. Building an equitable and sustainable multi-tiered medical insurance system for Dravet syndrome

To address the three main shortcomings of basic medical insurance, which is limited catalog coverage, regional disparities, and high out-of-pocket burdens, it is essential to strengthen national-level coordination and reinforce its central role in systematically optimizing the rare disease security system. The supplemental function of critical illness insurance should be enhanced by optimizing deductibles and reimbursement structures and strengthening linkages with basic insurance to reduce patients' financial burden. Medical assistance, as a safety net, requires broader eligibility criteria and expanded coverage to secure its foundational role (*17*).

A better balance between market orientation and social function of commercial health insurance should be pursued through stronger government guidance and oversight, encouraging inclusion of high-cost drugs and reasonable off-catalog expenses. At the same time, improving data interoperability and mutual recognition between basic and commercial insurance would support actuarial soundness and "one-stop" settlement, thereby enhancing product inclusivity and service efficiency (*18*).

Finally, to foster sustainable development of charitable aid and social mutual assistance, functional boundaries should be clarified and collaborative mechanisms established for targeted and shared responsibility. Expanding stable funding channels, optimizing the policy environment, and channeling social resources toward high-leverage, systematic supports can help shift away from fragmented aid toward integrated assistance (*19*), strengthening the role of charitable medical aid within the multi-tiered security system.

6. Conclusion

This study reveals a critical gap within China's multi-tiered medical security system for rare diseases, as experienced by patients with Dravet syndrome. Despite high enrollment in basic medical insurance, the financial burden remains severe due to limited reimbursement depth, regional disparities, and high out-of-pocket costs. Critical illness insurance, medical assistance, and commercial health insurance each exhibit structural limitations, such as high deductibles, restrictive eligibility, and inadequate coverage, that collectively fail to provide sufficient, coordinated protection.

These findings underscore the need to shift from expanding coverage models to deepening protection and enhancing policy coherence. Strengthening national coordination, optimizing reimbursement mechanisms, and better integrating all security tiers are essential to alleviate the financial burden on rare disease families and ensure sustainable, equitable healthcare access.

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Conflict of Interest: The authors have no conflicts of interest to disclose.

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