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Global Disparities and Equity in Financing New Therapies: Analyzing Access, Affordability, and Investment Trends Across High-Income and Low-and-Middle-Income Countries

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Abstract

The financing of new therapies remains a critical factor influencing global health equity. This review examines disparities in investment, access, and affordability of innovative therapies across high-income and low- and middle-income countries (LMICs). We explore current financing mechanisms, including public funding, private investment, and philanthropic contributions, and analyze how these vary geographically and economically. Challenges such as high development costs, regulatory barriers, and intellectual property issues disproportionately affect LMICs. Future strategies including innovative financing models, regulatory harmonization, and global partnerships are discussed to promote equitable access. The review underscores the need for multi-stakeholder collaboration to create sustainable pathways for financing precision medicine and advanced therapies worldwide.

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1. Introduction

The rapid advancement of biomedical research has led to the development of innovative therapies that have the potential to transform patient outcomes worldwide. However, despite these breakthroughs, significant disparities persist in the financing, access, and affordability of new therapies across different regions, particularly between high-income countries (HICs) and low- and middle-income countries (LMICs) (Mackey *et al.*, 2020) ^[18]. These global inequities are driven by a complex interplay of economic, regulatory, and infrastructural factors that influence how new medical technologies are developed, funded, and distributed. While HICs benefit from robust healthcare financing systems supported by public funds, private investment, and advanced insurance mechanisms, LMICs often face challenges such as limited healthcare budgets, weak infrastructure, and inadequate investment in biotechnology sectors (Wirtz *et al.*, 2017) ^[36].

The financing models that underpin therapeutic innovation play a crucial role in shaping both the availability and affordability of new treatments. Public funding agencies, venture capital, pharmaceutical companies, and philanthropic organizations contribute to the development pipeline, yet the distribution of these resources is often uneven, exacerbating disparities in healthcare outcomes (Liu *et al.*, 2019) ^[17]. Moreover, intellectual property regimes and pricing strategies frequently limit access in resource-constrained settings, where the cost of cutting-edge therapies can be prohibitively high (Wirtz *et al.*, 2017; Babar *et al.*, 2020) ^[37, 1]. These challenges highlight the ethical imperative for global health stakeholders to address equity in financing mechanisms to ensure that innovations benefit populations irrespective of geographic or economic status.

Addressing disparities in financing and access is critical not only for ethical reasons but also to achieve global health goals, including universal health coverage and the Sustainable Development Goals (SDGs) (United Nations, 2015) ^[35]. A comprehensive understanding of the current financing landscape and investment trends in both HICs and LMICs is essential to identify barriers and opportunities for more equitable allocation of resources. This review aims to analyze global disparities in financing new therapies, focusing on access and affordability challenges, investment patterns, and policy frameworks.

By synthesizing evidence from recent research and case studies, this paper seeks to inform stakeholders on strategies to promote equitable financing and improve health outcomes globally.

2. Healthcare financing in high-income vs. low- and middle-income countries

Healthcare financing systems vary widely between high-income countries (HICs) and low- and middle-income countries (LMICs), reflecting differences in economic capacity, health infrastructure, and policy priorities. In HICs, healthcare is predominantly funded through a combination of public expenditure, private insurance, and out-of-pocket payments, with substantial government investment directed toward the research, development, and acquisition of new therapies (OECD, 2022) ^[26]. For instance, countries like the United States and members of the European Union allocate significant resources through national health services, research grants, and reimbursement schemes that support early access to innovative treatments (Garau *et al.*, 2021) ^[9]. This robust financing environment encourages public-private partnerships and facilitates venture capital investments, accelerating the development and commercialization of cutting-edge therapies (DiMasi *et al.*, 2020) ^[6].

Conversely, LMICs often face constrained public budgets and rely more heavily on out-of-pocket payments and donor funding to finance healthcare (Geldsetzer *et al.*, 2018) ^[10].

Public investment in biomedical innovation is limited, resulting in slower adoption and availability of novel therapies (McMahon *et al.*, 2020) ^[19]. International aid organizations, such as the Global Fund and Gavi, play a critical role in bridging financing gaps by providing grants and subsidies aimed at expanding access to essential medicines and vaccines (Moon *et al.*, 2019) ^[20]. Despite these efforts, fragmented health financing systems and weak regulatory frameworks challenge the equitable distribution of new therapies within LMICs (Glassman *et al.*, 2020) ^[11]. Additionally, local biotech ecosystems in many LMICs remain underdeveloped, limiting opportunities for domestic innovation and investment (Kebede *et al.*, 2021) ^[15].

Academic-industry collaborations have emerged as an important mechanism to foster innovation and knowledge transfer across income settings. Collaborative programs between universities, pharmaceutical companies, and governments help build capacity in LMICs while facilitating access to promising therapies (Tait *et al.*, 2021) ^[34]. However, significant disparities remain in the scale and sustainability of such initiatives, often dependent on external funding cycles and political will (Peprah *et al.*, 2022) ^[27]. Addressing these gaps requires strategic alignment of financing models tailored to the unique challenges of LMICs, ensuring that investments not only drive innovation but also promote affordability and access for underserved populations.

Table 1

Aspect	High-Income Countries (HICs)	Low- and Middle-Income Countries (LMICs)
Healthcare Financing Sources	Public expenditure, private insurance, out-of-pocket	Mostly out-of-pocket, donor funding, limited public expenditure
Public Investment in Innovation	Significant government funding for R&D and new therapies	Limited public investment, reliance on international aid
Role of Donor Organizations	Limited or indirect	Critical role (e.g., Global Fund, Gavi)
Access to New Therapies	Generally faster adoption and reimbursement mechanisms	Slower adoption, fragmented access
Private Sector Involvement	Strong venture capital and public-private partnerships	Underdeveloped biotech sector, limited domestic private investment
Academic-Industry Collaborations	Common, well-funded	Emerging but often reliant on external funding
Regulatory and Policy Framework	Robust and supportive	Often weak and fragmented
Challenges	High costs, regulatory hurdles	Financing gaps, affordability, infrastructure limitations

3. Discussion

3.1 Global disparities in access and affordability of new therapies

Access to innovative therapies varies significantly between high-income countries (HICs) and low- and middle-income countries (LMICs), creating profound global health disparities. Research indicates that while HICs benefit from faster adoption and wider availability of novel treatments due to robust healthcare infrastructure and reimbursement systems, LMICs face substantial barriers that limit patient access to these lifesaving interventions (Wirtz *et al.*, 2017) ^[36]. High costs of new therapies, combined with limited public health budgets and out-of-pocket payment reliance in LMICs, often render these treatments unaffordable for large portions of the population (Moon *et al.*, 2019) ^[24]. Intellectual property regimes, particularly stringent patent protections under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, restrict the production and

distribution of affordable generic alternatives in many LMICs, further exacerbating access challenges (Correa, 2016) ^[4]. Tiered pricing models, which propose differential pricing based on country income levels, have been suggested as potential solutions but face implementation difficulties due to concerns about parallel trade and fairness (Danzon & Towse, 2019) ^[5]. Moreover, international donor programs and global health initiatives, such as those led by the Global Fund and Gavi, play crucial roles in bridging some gaps by subsidizing access to essential medicines and vaccines in LMICs (Yamey, 2019) ^[40]. Despite these efforts, disparities remain stark in key therapeutic areas like oncology, HIV/AIDS, and rare diseases, where advanced diagnostics and personalized therapies are often unavailable or unaffordable outside wealthier nations (Saxena *et al.*, 2020) ^[31]. Addressing these inequities requires coordinated policy responses that balance incentivizing innovation with mechanisms to enhance affordability and equitable

distribution globally (Moon *et al.*, 2020) ^[21].

3.2 Investment trends and strategies to address global equity

Investment in new therapies demonstrates stark contrasts between high-income countries (HICs) and low- and middle-income countries (LMICs), reflecting broader economic disparities that influence access to healthcare innovations. According to Suh *et al.* (2020) ^[33], the majority of venture capital and private equity funding for biotechnology and pharmaceutical development is concentrated in North America and Europe, leaving LMICs with comparatively limited direct investment. This geographic imbalance hinders the development and commercialization of therapies tailored to the unique epidemiological profiles and healthcare infrastructures of LMICs (Kesselheim & Avorn, 2018) ^[16]. To address these gaps, innovative funding mechanisms have emerged, including impact investing and public-private partnerships (PPPs), which aim to blend financial returns with social impact objectives (Rangan *et al.*, 2020) ^[29]. International organizations such as the Global Fund, Gavi, and the World Bank play pivotal roles by channeling philanthropic and concessional financing to support healthcare innovation and access in resource-limited settings (Yamey, 2019) ^[40]. Advanced financing models like advance market commitments (AMCs) incentivize pharmaceutical companies to develop and supply vaccines and therapies for neglected diseases by guaranteeing future purchase agreements (Bärnighausen & Bloom, 2019) ^[2]. Additionally, pooled procurement strategies enable LMICs to aggregate demand, reduce prices, and improve bargaining power with manufacturers (Wirtz *et al.*, 2017) ^[36]. Case studies, such as the Affordable Medicines Facility–malaria (AMFm), highlight successes and challenges of these approaches, demonstrating the potential to increase equitable access while maintaining innovation incentives (Yeung *et al.*, 2017) ^[43]. However, sustainable progress requires strengthening local research capacity and regulatory frameworks to better integrate global investment flows with country-specific health priorities (Moon *et al.*, 2020) ^[21]. Ultimately, a multipronged approach combining targeted financing, capacity building, and global collaboration is essential to bridge the investment divide and promote health equity worldwide.

3.3 Challenges and barriers to equitable financing and access

Despite ongoing efforts to enhance global health equity, multiple challenges continue to impede equitable financing and access to new therapies across low- and middle-income countries (LMICs) compared to high-income countries (HICs). Economic constraints remain a primary barrier, as LMICs often face limited healthcare budgets and competing priorities, which restrict their ability to invest in cutting-edge therapies or provide adequate reimbursement mechanisms (Farmer *et al.*, 2018) ^[8]. Intellectual property rights and patent protections, while intended to incentivize innovation, can restrict generic production and maintain high prices, thus limiting affordability and availability in resource-constrained settings (Reich *et al.*, 2016) ^[30]. Regulatory fragmentation further complicates the process, with varying approval requirements and limited harmonization delaying the introduction of novel treatments in many countries (Kaplan *et al.*, 2019) ^[13]. Additionally, inadequate healthcare

infrastructure and delivery systems in LMICs reduce the capacity to effectively implement and distribute advanced therapies, exacerbating disparities (Wirtz *et al.*, 2017) ^[36]. Ethical considerations also arise regarding pricing strategies and prioritization of limited resources, raising concerns about fairness in access and the potential for exacerbating health inequities (Persad *et al.*, 2019) ^[28]. Addressing these multifaceted challenges requires coordinated international collaboration, policy reforms to balance innovation incentives with accessibility, and investments in local capacity building to ensure sustainable and equitable healthcare outcomes (Moon *et al.*, 2020; Yamey, 2019) ^[21, 40].

4. Future strategies and policy recommendations

Addressing the entrenched disparities in financing and access to new therapies requires a multifaceted and collaborative approach. Innovative financing mechanisms have shown promise in bridging resource gaps for LMICs. For example, tiered pricing strategies, where pharmaceutical companies adjust prices based on a country's income level, can improve affordability without undermining incentives for innovation (Moon *et al.*, 2019) ^[25]. Pooled procurement and advance market commitments also enable LMICs to negotiate better prices through collective bargaining power and guaranteed markets, respectively, reducing financial risk and encouraging manufacturer participation (Brenzel *et al.*, 2017) ^[3]. Strengthening regulatory harmonization and capacity across countries is vital to streamline approval processes and reduce delays; initiatives such as the African Medicines Regulatory Harmonization (AMRH) exemplify effective regional collaboration that enhances access while maintaining safety standards (Sims *et al.*, 2020) ^[32]. Moreover, public-private partnerships and global collaborations can leverage diverse expertise and funding sources, facilitating technology transfer and infrastructure development necessary for sustainable health systems (Kaye *et al.*, 2020) ^[20]. The use of real-world evidence and adaptive licensing pathways holds potential to expedite access by allowing earlier introduction of therapies with ongoing data collection, balancing timely availability and safety oversight (Eichler *et al.*, 2018) ^[7]. Additionally, promoting policies that encourage local manufacturing and technology transfer can reduce dependency on imports and lower costs, building long-term capacity within LMICs (Kaplan & Laing, 2018) ^[12]. Ethical frameworks underpinning these strategies are essential to ensure fair pricing and equitable distribution, fostering trust and global solidarity in health innovation (Persad *et al.*, 2019) ^[28]. Collectively, these future-oriented strategies can catalyze more equitable financing and access to advanced therapies worldwide.

5. Conclusion

Global disparities in financing new therapies present profound challenges to equitable access, affordability, and health outcomes. This review highlights that while high-income countries benefit from robust investment landscapes, low- and middle-income countries (LMICs) often face significant barriers including limited funding, regulatory complexities, and infrastructure constraints. Bridging these gaps requires innovative financing models, enhanced regulatory harmonization, and strengthened global partnerships. Ethical frameworks and policies promoting local capacity building and fair pricing are critical to ensure sustainable access. Ultimately, addressing these disparities is

not only a matter of social justice but also essential for global health security. Coordinated efforts among policymakers, investors, healthcare providers, and international organizations will be pivotal in financing a future where advanced therapies are accessible to all, regardless of geography or income.

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