Evidence from systematic reviews on policy approaches to improving access to medicines

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Abstract

The prevailing frameworks on access to medicines advise global procurement as a solution by assuming the presence of medicines on the global market. Yet access to medicines remains challenging, especially in developing countries. This is a global worry because the UN considers limited access to essential medicines as one of the five indicators of securing the right to health. To fill a research gap in health system studies and inform policymaking, we synthesized evidence from systematic reviews of how government policies affect low- and middle-income country (LMIC) medicine access. We chose a rapid review approach to reduce timelines and avoid missing policy "windows of opportunity." To include only studies published after the start of COVID-19, we chose systematic reviews published between 2019 and November 2nd, 2022. This was also in line with recommendations in the literature to look at recent systematic reviews. The themes were grouped using a thematic and textual narrative approach. This review included 32 studies that examined access to medicine from various perspectives. Both supply- and demand-side policies are needed to improve medical access. LMICs cannot afford medicines, and supply never meets demand. LMICs will continue to struggle with pharmaceutical pricing due to their limited bargaining power. The urban bias in health facilities and policy changes reduce medicine availability and use. Leaders must make policy decisions to sustain domestic funds. Policymakers should consider that organizations may act against policy goals. Instead of copying developed nations, LMIC governments must develop multipronged strategies to address their unique challenges.

Introduction

There is a need for more information on how policy options affect drug access in low- and middle-income countries (LMICs).[1] Researchers must evaluate how interventions affect the healthcare system.[2] Grépin[3] supports context-specific research, while others noted a lack of information on how policies affect universal health access.[4] McPake and Hanson[5] show that governments must act through whole-sector policies while Bigdeli *et al.*[6] argue that the main frameworks on access to medicines thinly address how people access medicines. Research on policy and healthcare access should integrate public health and industry because policies do not consider access to medicines.[7] A scoping review of medicine access suggests investigating how universal health access regulations interact with medicine access policies[8] because governance and capital affect medicine availability.[9] We must study how different policy options have shaped medicine access and determine which ones are most effective.[10] Mousavi[11] suggests a broad approach to healthcare that considers how policies affect health outcomes and service delivery. We synthesized evidence from systematic reviews of how government policies affect LMICs' access to medicines. In addition to narrative synthesis, we used realist synthesis to identify policy context.[12]

Existing frameworks for access to medicine have not fully addressed the complex role of medicines in dynamic health systems, as they often focus on specific purposes.[6] Barriers to access are interrelated, occurring simultaneously at various levels of the health system and involving multiple stakeholders, which necessitates a health system view for implementing effective reforms. By adopting a complex adaptive systems lens, the framework proposed by Bigdeli *et al.* identifies linkages, relevant stakeholders, and context for scaling up existing small-scale or fragmented access to medical interventions. This comprehensive view of the complexity of access barriers, enablers, and their interactions stimulates a deeper understanding of access to medicine issues. Applying complex systems thinking in health system strengthening is limited, and documented examples of access to medicine are rare. However, several options for overcoming these challenges and moving the systems thinking agenda forward have been proposed. These options include systematically exploring issues from a health system perspective, fostering more system-wide planning, evaluation, and research, and building a community of practice. Tax reduction policies, policies that cap the maximum price charged to the government, and policies that establish or encourage health technology assessment agencies can improve access to medicines in low- and middle-income countries. By addressing quantification and acquisition errors, therapeutic choices, and other situational factors, policymakers can create a more comprehensive and effective approach to improving access to medicines.

Nevertheless, some people assume that medicines are readily available on international markets therefore global procurement improves access to medicines in LMICs.[13]

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Consequently, health policy debates concentrate on the content of reforms rather than the actors involved in policy reform or local contexts.[14] Although several authors have written on health supply chains and policies,[15-18] there is agreement on a research gap in health system studies to inform policymaking to which declining pharmaceutical sectors act as an impetus for policy research.[19] It is, therefore, critical to review the evidence synthesized on access to drugs to see if it addresses policy interrelationships.

Objective

With this article, we sought to collate evidence from systematic review papers on how policies can affect access to medicines.

Materials and Methods

Though there are various types of reviews, selecting one that addresses pertinent clinical, or policy questions is critical.[20] Koon *et al.*[21] argue that policy interpretations based on a constructivist approach converge on accepting multiple perspectives on societal concerns. This constructivist approach served as the foundation for our rapid review. We intended to find, appraise, and detail findings only from systematic reviews of access to medicines in the context of policies.[22] No study has compiled evidence from systematic reviews of policies affecting access to medicines. By pooling these systematic review papers, we assessed the information available and gaps in the literature on how and which policies influence access to medicines and medical supplies. Due to time constraints, we could not include primary studies and other forms of evidence.[23] We chose a rapid review to shorten timelines and avoid missing a policy "window of opportunity"[24] because Zimbabwe has elections in 2023. There was no need for ethical approval because this was a rapid review.

Framework

We refined our inclusion criteria using Munn *et al.*'s population, the phenomenon of interest, and the context (PICo) framework.[20] For the population, we concentrated on people living in low- to middle-income countries. We were interested in health, industrial, economic, and other policies that affect access to medicines. We chose systematic reviews published between 2019 and November 2nd, 2022, to include only studies published after the start of COVID-19. We did not concentrate on a specific outcome statement or comparator because this was a text review.[20]

Search strategy

We used the search criteria below and modified them to fit the search database by removing Boolean operators as needed. In line with the literature,[25] only one reviewer (CK) conducted the searches and screened the documents for inclusion. The other reviewer (AQ) helped develop the search criteria and conducted preliminary investigations to validate them. We created a review protocol and registered it on PROSPERO as CRD42022370376. Furthermore, in the second search, we left any reference to policy in the search criteria to widen the pool of articles from which to choose. Relying on a seminal paper,[26] we adapted principles from qualitative research and strived for heterogeneity in the studies.

Search criterion

Medicines are accessible if they are available, affordable, and acceptable, and people can obtain them.[27] We also disaggregated "access to medicines" into its components using the three frameworks.[6]

WHO-MSH 2000: availability, accessibility, affordability, or acceptability of (medicines or drugs) and "systematic review."

WHO (2004c): "rational use or affordable price or sustainable financing or reliable health and supply systems" (of medicines or drugs) AND systematic review

Frost & Reich (2010): (availability, affordability, or adoption) of medicines AND systematic review.

Using the above definition of access to medicines, we came up with the following search criteria: the initial criteria (First search) were "policy" AND "access to medicines" AND "systematic review" OR "policing" AND "access to medicines" AND "systematic reviews" OR "access to drugs" AND "policy" AND "systematic review" OR "access to medicines" AND "policy" AND "systematic review" OR "policy" AND "access to drugs" AND "systematic review". We removed reference to policy for the second search to broaden the search results.

Databases

We used Harzing's Publish or Perish (Windows GUI Edition) 8.5.4149.8315 software to search on CrossRef, Scopus, PubMed, OpenAlex, Semantic Scholar, and Google Scholar. We set all searches to a maximum of 1000 results.

Manual searching

The review aimed for an interpretive explanation;[27] therefore, we followed up on some references to explore thematic leads. We searched the literature for studies on the suggested policy recommendations.

Eligibility criteria

We focused on systematic reviews of articles published in English between 2019 and 2022 on policies and access to medicines in LMICs. Because of the perceived impact of COVID-19, we chose 2019 as the cutoff date. Furthermore, we had to cover a period that started only three years ago following Dobbins'[28] recommendation to synthesize using evidence within three years of publication, and we did it in the context of low-income countries. We excluded articles that did not meet these criteria. We also excluded reviews that did not evaluate the quality of primary studies published before 2019 or focused on countries other than LMICs.

Data extraction

We extracted the names of the authors, article information (full citation, year of the study objective), key findings, and recommendations that have policy implications. We searched articles for the consequences of the policies discussed,[29] how these policies could affect access to medicines, and the context for policy implementation.

Data synthesis

We undertook a narrative synthesis[30-32] and used a thematic approach to group data into themes and a textual narrative approach to provide details of the characteristics, context, and similarities of the studies included in the review.[33] We described the policies discussed concerning access to health, highlighted gaps in the literature, and commented on the breadth of the evidence; therefore, a textual narrative synthesis was more appropriate.[33]

Results

This review included 32 studies as shown on the PRISMA flow chart below (Figure 1).

The search yielded various studies on access to medicine, which focused on different aspects such as trade treaties, financing, public access, specific condition-specific medicines, anti-infectives, vaccine access, maternal and child health, noncommunicable disease medicines, sexual and reproductive health, post-abortion care, and pediatric access to medicines (Figure 2). The studies were clustered into four categories: availability, usage, cost and affordability, and accessibility. Access to medicine is a fundamental component of the full realization of the right to health, and it is intrinsically linked with the principles of equality and non-discrimination, transparency, participation, and accountability.

Discussion

We discussed the findings under components of access to medicines: availability, usage (rational), cost and affordability, accessibility, and acceptability to gain a better understanding of these challenges.

Availability

The are several causes for the unavailability of medicines. LMICs never have enough medicine[34-39] while legal and moral concerns prevent prescribers and dispensers from dispensing certain drugs.[40,41] The inequitable distribution of pharmacies and other health institutions[39] limits medicine availability by favoring towns and underserving the poor. Hospital subsidies also perpetuate inequality.[42] Patients may not fully understand the services available. For example, palliative care[39] and indiscriminate antimicrobial use may be unfamiliar to the public[43] so Abu-Odah *et al.* recommend educating the public about services available and rational medicine use.[44] For human capacity, reviewers recommend empowering health workers through training and well-framed treatment guidelines.[44] This empowerment entails strengthening and updating treatment guidelines.[36-7] Kibirige *et al.* recommended incorporating complementary medicine in national health policies and changing policies and laws that restrict or discourage drug access.[37]

Factors within the health system interact in complex ways to affect availability and affordability.[38] Consequently, addressing access to medicines requires harmonizing multisectoral policies to improve the chances of sustainability.[45,36] These policies can promote innovations and local manufacturing to improve resilience and self-reliance. In some cases, ensuring availability is an urgent concern[41] therefore international bodies should institutionalize policies that ensure equity in the global pharmaceutical market.[46] Sekalala *et al.* recommend reparative justice, not through charity but through redistribution, expanding manufacturing capacity in the global south.[47] By working together, governments, international organizations, and the private sector can create a more equitable environment for access to medicines ensuring that all individuals have the opportunity to receive the healthcare they need.

Usage

The literature needs more evidence on how medicines are used,[48] or how policy changes affect access to medicines.[49] Concerns about sustainability in the absence of funding partner support hamper the adoption of new products.[43] There have been reports of irrational medicine use attributed to either client demand for antibacterial medications or business interests pushing for profit.[46,50,51] To address these issues, LMIC governments can implement policies that promote the rational use of medicines, such as establishing guidelines for the appropriate use of antibacterials and providing education to both healthcare professionals and the public.[52] However, tight antibacterial dispensing regulations must be balanced with access to medicines for people in rural areas who may have difficulty obtaining prescriptions.[50] Some scholars call for incentives that enhance the desired behavior and retard the unwanted behavior of health practitioners.[50] Therefore, it is necessary to generate robust evidence on the effect of policies on patient and provider behavior and government choices.[53]

The urban bias in the distribution of health facilities also influences medicine usage.[54] However, program-specific aid can improve geographical coverage and increase usage.[43] Also, inadequate distribution of available medicines decreases their use.[46] Low usage of some products occurs when providers are afraid of restrictive policies, despite guidelines outlining their indications.[54] Incorporating traditional medicines into health policies and insurance plans will increase and document their use.[34] Though out-of-pocket expenditure for medicines was offset in some way by other payments for medical services, zero-markup policies resulted in increased medicine use.[53] Adane *et al.* called for cooperation between traditional and conventional medicine practitioners.[48] Some researchers advise incorporating traditional medicine into the referral and health insurance schemes.[34] Aslam et al. suggested integrating health strategies.[43] Similarly, Izugbara *et al.* recommended pooling services such as nutritional care, gender violence, and post-abortion care.[54] Equity is also a topical issue in universal health coverage discussions. Scholars propose covering marginalized communities through outreach programs.[43]

Another option is training and using traditional medicine practitioners as community health workers because people already consult traditional medicine practitioners. By implementing policies that ensure a qualified workforce, governments can

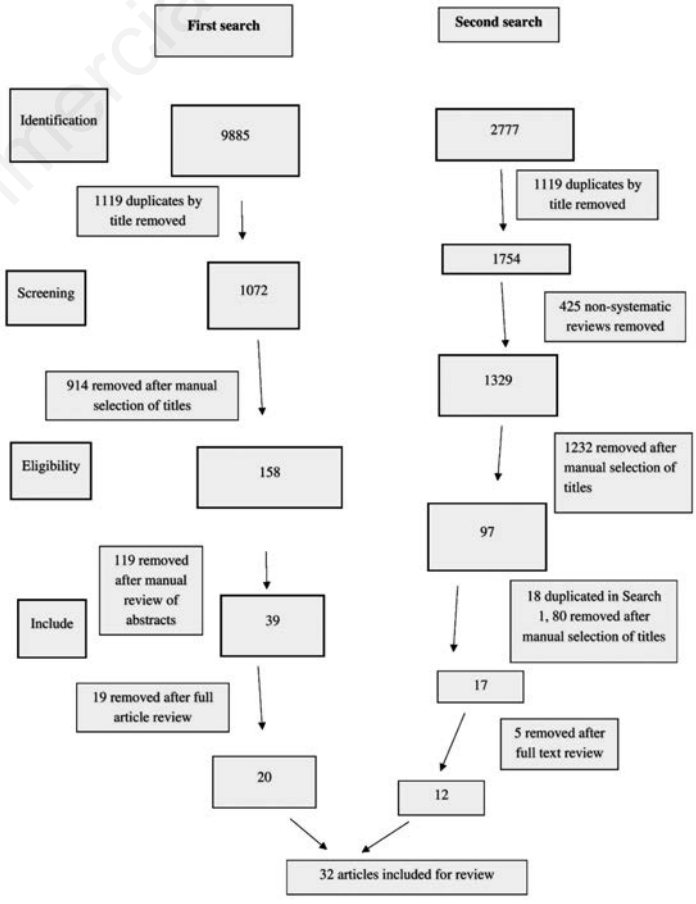

Figure 1. PRISMA Flowchart of the screening of systematic review articles.

improve the appropriate selection, prescription, and use of medicines, reducing the risk of medication errors, adverse drug reactions, and antimicrobial resistance. Furthermore, well-trained healthcare providers are more likely to adhere to clinical guidelines and promote patient-centered care, ultimately improving patient outcomes and overall healthcare system performance.[55-56]

Cost and affordability

People in LMICs, in general, cannot afford medicines.[41,42,46,57,58] The costs of accessing health products are generally higher in the private sector than in the public sector.[38,57] For example, women who seek sexual and reproductive healthcare face financial hardship.[57] This expenditure can lead to financial catastrophe.[58] These high prices arise because of insufficient price controls, public insurance schemes, limited generic manufacturing in LMICs, and the lack of co-financing arrangements.[37] Innovator products are generally more expensive than their generic counterparts[59] and studies show that the TRIPS Agreement increased drug prices.[49] Intellectual property provisions can reduce medicine's affordability.[38] To improve cost and affordability, LMIC governments should consider implementing policies such as tax reduction, price control, and support for generic manufacturing. For example, some countries have reduced or eliminated taxes on essential medicines, leading to lower retail prices and improved access for patients.[60] Policies setting the maximum price charged to the government for medicines can also play a crucial role in controlling costs and ensuring affordability.[61] Pricing will continue to be an issue for LMICs due to their low bargaining power in the international pharmaceutical market.[46] As a result, scholars have called for policies to resolve pricing concerns.[39,54,59,62]

Policy decisions require political will from leaders and assured domestic funds for sustainability.[63] Policymakers should remember that organizations may respond in ways that contradict policy objectives; hospitals responded to the zero-markup policy for essential drugs by raising non-drug costs to maintain their revenue.[53] Subsidies given to hospitals marginalize those who use primary healthcare facilities.[64] While using health service usage as a proxy, the distribution of total healthcare benefits favors the wealthy over the disadvantaged.[65] As a result, socioeconomic disparities can persist or be exacerbated by well-intended policies. Overall, health insurance programs reduced the likelihood of financial disasters, though vulnerable people faced high out-of-pocket expenses.[42] Health insurance schemes to decrease out-of-pocket expenditure can solve this.[37,38] In addition, LMIC governments should consider implementing compulsory insurance policies to improve equity in access to medicines, as low coverage by public insurance limits access due to costs.[39] Another important policy approach involves establishing or encouraging health technology assessment (HTA) agencies. The use of HTA agencies in LMICs can improve access to cost-effective and high-quality medicines, while also promoting the rational use of healthcare resources.[66-67]

Instead of copying developed nations, LMIC governments should develop multipronged strategies to address their unique challenges, such as promoting local production of medicines, fostering regional cooperation for joint procurement, and advocating for fairer international trade agreements.[45] At the same time, mechanisms that permit people to compare prices before buying can be beneficial.[39] Governments are also encouraged to implement economic policies that improve the public's capacity to pay.[59] This raises several policy implications.

Nudge behavior

Governments should equip and encourage people to use primary health centers[57] and incentivize generic prescribing.[39] Rules and regulations are not enough, as people and organizations can circumvent them. The policy should be consistent throughout the government, and government communication must be unambiguous[57] to promote the desired behavior.

Local solutions for local contexts

Governments in LMICs must seek and develop multisectoral strategies to address their specific challenges rather than copying solutions from developed countries.[45] One

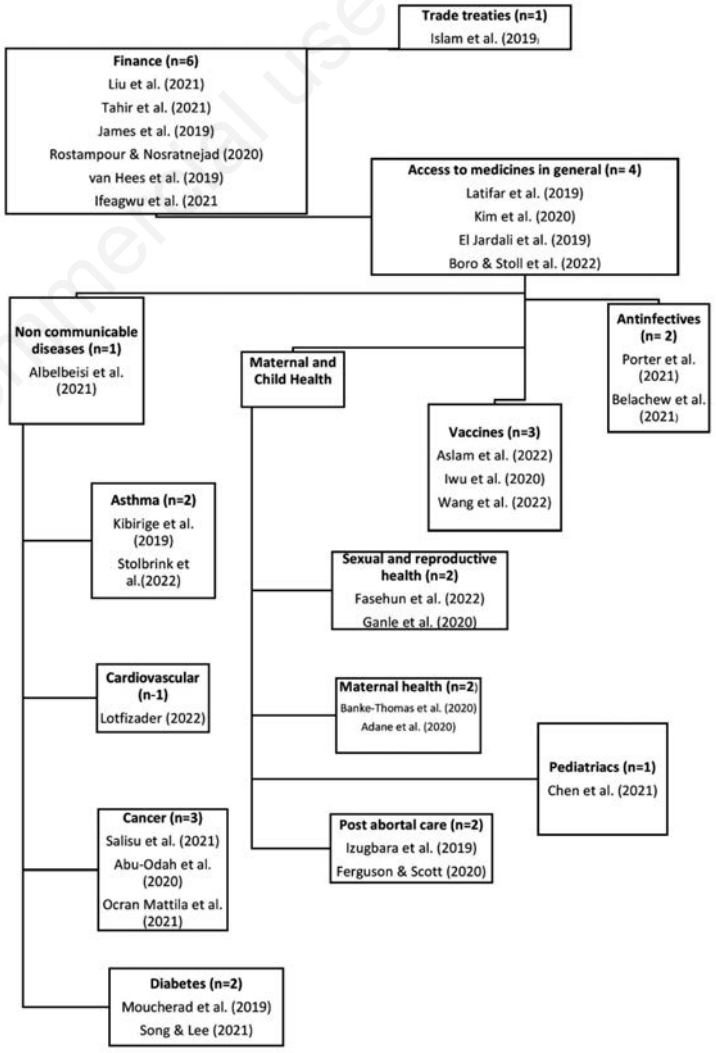

Figure 2. Focus of the studies included.

option is to incentivize the manufacture of products locally while registering them preferentially.[37] Despite this call for self-reliance, increasing access to medicines requires multisectoral approaches[41] and global cooperation.[58] International bodies, too, must promote equity in the international pharmaceutical markets.[46]

Review of legislation and policies

There is a need for policies specifically addressing medicine costs, the capacity of people to pay, and the retail prices for medicines, for example, China implemented a "zero markup" drug policy.[53] Insurance and prices based on the capacity to pay increase equity.[39,64] Guidelines must be updated to reflect contextual evidence on safety, effectiveness, and acceptability.[37 35]

Accessibility

Lockdown policies that restricted movement reduced access to medicines during the peak of the COVID-19 pandemic.[46] Poor healthcare facilities, a shortage of health workers, and limited equipment reduce physical access to medicines.[68] Transportation issues and a lack of knowledge about available services[69] also hinder access to medicines. Some academics have proposed changes to intellectual property laws to improve access to medicines, though several factors can mitigate the impact.[49] The distribution and availability of service providers are skewed toward urban facilities. This, combined with transportation costs, limits access for people outside cities.[54] For oncology medicines, medicine stockouts and the lack of updated guidelines were identified as barriers to access.[39] In a separate study, medicine stockouts, and high prices all reduced access to medicines.[70] Subsidies and tax policies that consider one's ability to pay to improve equity in access to medicines.[64]

LMIC governments should consider implementing policies that foster greater equity in healthcare facility distribution, such as investing in rural healthcare infrastructure and incentivizing health workers to serve in underserved areas, encouraging the use of telemedicine or mobile clinics to reach remote populations, as well as subsidize transportation costs for patients in need. Addressing both demand-side factors and supply-side factors improved access during emergencies.[71]

Here are some recommendations to improve accessibility: i) increase coverage for specific treatments; ii) engage key stakeholders and actors; iii) integrate services and interdisciplinary approaches; iv) develop facilities catering to special needs and vulnerabilities.

Acceptability

Medicines may be available, accessible, and affordable, but people might still choose not to use them due to concerns about acceptance. In a review of female condom usage, factors influencing acceptability included male partner opinions, functionality, condom appearance, and ease of access.[69] As these users became more familiar with the condoms, acceptability increased. For the human papillomavirus (HPV) vaccine, concerns about safety, effectiveness, and self-perception of risk reduced acceptance.[69] People with higher incomes living in urban areas were less likely to receive the HPV vaccine, as they tended to refuse it.[72] Another review examined women's acceptance of mifepristone and misoprostol for medical abortions and their effectiveness.[59] In one study, fear of chemotherapy also reduced access to medicines.[70] These findings carry several policy implications.

Considering product acceptability before a product enters the market is vital to ensure that it meets the needs and preferences of potential users. By consulting potential users, policymakers and manufacturers can capture insights and improve the design and desirability of intervention programs and policies. Intentional engagement with would-be end-users can lead to more successful implementation of healthcare interventions and greater satisfaction among patients.

Countries must learn from Brazil's pursuit of several strategies to improve access to medicines for its population, including establishing a universal healthcare system, promoting domestic pharmaceutical industrialization, strengthening healthcare infrastructure, developing subsidy programs, increasing transparency, supporting product development partnerships, implementing the Essential Medicines Policy (EMP) to improve the provision and use of pharmaceuticals, creating municipal essential medicines lists (MEML) to evaluate the effects of the EMP on the procurement and availability of medicines, and implementing the Pharmacy Network of Minas program to promote improvements in essential medicine availability.[73,74,75] However, entrenched inequalities within and between states have affected healthcare utilization and resulted in very different procurement prices, particularly affecting the purchasing capacity of smaller states[73] As observed in Brazil, access to medicines is associated with social, economic, and health perception factors.[76] Therefore, educational strategies are key to improving access to medicines.[77]

Strengths and limitations of the study

This study has four main strengths. Its reliance on a constructivist approach enabled a review that brings out the nuances of contextual differences. Second, the focus on systematic reviews allowed for a synthesis of evidence from rigorous studies. Third, limiting the articles to those published within three years ensured that the evidence was current and applicable given the coincidence with the advent of the COVID-19 pandemic. Lastly, this appears to be the first study that aggregated evidence from papers that focused on distinct health conditions or programs. One strength, however, can be viewed as a weakness. This study excluded primary studies and other forms of evidence such as grey literature. Grey literature would have offered a view into how ministries and individual organizations working with governments view access to medicines. Primary studies would have provided even more contemporary and contextual evidence. Acknowledging this weakness informs our suggestions for future research areas.

Future research priorities

Researchers must seek evidence to inform cross-sector strategies[45] and use mixed-methods studies to evaluate programs.[63] Such research can help explicate why some researchers could not explain why medical services increased in China following a new policy on medicine markups.[53] We must collect more data on the factors influencing access to medicines in LMICs[38,41,] and assess vulnerability and power distribution when analyzing these factors.[42] Several authors agree on the need for more research in LMICs to generate evidence on general or specific components of access to medicines.[38,41,78] Countries should encourage and reward researchers who conduct research in local contexts.

Conclusions

Policymaking requires context because healthcare reform is more political than technical.[67] Breaking medical care barriers requires sociocultural knowledge, but empirical public health research ignores sociopolitical contexts.[80] Issue framing is important because organization frames strengthen meaning by emphasizing one evaluative dimension and elevating it above other valued goals, such as prioritizing access to life-saving medicines over intellectual property rights.[81] Communication is, therefore, vital because learning about a policy's positive and negative outcomes can

increase or decrease support for the policy.[82]

Policy failure can result from policy ideas and implementers' assumptions clashing.[83] Removing user fees lowers household health spending and increases poor people's use of formal healthcare, but Africa's political and institutional challenges make fee removal difficult. Investing in primary care and removing barriers increases equity.[56] Furthermore, policies that define the maximum price charged to the government and that establish or encourage health technology assessment agencies can be part of the discussion, as they can help improve access to medicines in LMICs. These policies can be adopted to regulate medicine prices and ensure the rational use of medicines based on evidence and cost-effectiveness.

In summary, to effectively improve access to medicines in LMICs, policymakers must consider the complex interplay of various factors and develop multipronged strategies that address the unique challenges faced by their populations. LMIC governments can work towards reducing social inequities and health disparities while ensuring equitable access to essential medicines for all. Policies that guarantee a qualified workforce should be discussed, as these can influence rational use. This can involve investing in the training of healthcare professionals, implementing strict regulations to promote rational prescribing and dispensing practices, and monitoring the performance of health institutions to ensure quality service delivery. To address these policy implications, LMIC governments should consider developing policies that target the specific barriers faced by different population groups by implementing targeted health education campaigns to raise awareness about the importance of medicine access and adherence, training healthcare providers in culturally competent care, and addressing the stigma around certain health conditions. Pricing and financing policies should increase coverage for vulnerable groups[83] by subsidizing products.[35]

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