

# Designing the Free Drugs List in Nepal: A Balancing Act Between Technical Strengths and Policy Processes

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*As more countries provide free health care, pharmaceutical reimbursement lists are becoming a concern, especially in low- and middle-income countries. In 2007, Nepal decreed that health is a human right and began basic health coverage for a target group of the poor, destitute, elderly, and disabled. The Ministry of Health and Population (MoHP) also provided 40 drugs without cost to all citizens through the Free Drugs List (FDL) program. The FDL was later expanded from 40 to 70 drugs; however, the process of review and update remains unclear. To propose a mechanism for future development of the FDL, we conducted a document review and in-depth consultations with representatives from the MoHP and the World Health Organization Country Office*

*during a workshop in Kathmandu. The FDL suffers from lack of an appropriate process, gaps between the listed drugs and Nepal's burden of disease, and no consideration of the unit costs or cost-effectiveness of drugs included in the list. We propose a new drug selection process that is a variant of the health technology assessment process. This process can be applied not only in Nepal but also in other resource-limited countries that wish to ensure their citizens' access to essential medicines through a pharmaceutical reimbursement list. **Key words:** essential medicines list; pharmaceutical reimbursement list; free health care; health care in low- and middle-income countries. (MDM Policy & Practice 2017;2:1-9)*

**I**t has been 40 years since the World Health Assembly first recommended that all countries should develop essential medicines lists (EMLs) to ensure free access to drugs that serve the basic and primary health care needs of their populations.<sup>1</sup> Since the World Health Organization (WHO) published the first model EML in 1977, the list has been updated every 2 years, most recently in 2015.<sup>2</sup> Drug inclusion criteria have shifted from being experience-based to evidence-based, and to include new considerations such as global disease burden and drug efficacy, safety, and cost-effectiveness.<sup>1</sup> Currently, at least 156 countries have developed national EMLs based on the WHO model,<sup>3</sup> although very few low- and middle-income countries (LMICs) have been able to successfully implement them in health care policy in an effective way.<sup>4-6</sup> LMICs are increasingly exploring and investing in health care reforms with a strong social and

political push toward achieving universal health coverage.<sup>7,8</sup> Consequently, the need to develop financially viable EMLs that accurately reflect the accessibility of medicines and address the unique health care needs of LMICs has become more pronounced.

Countries contend with several issues in developing their medicines lists. In the original development process, covered medicines were selected based on local experience rather than evidence such as disease prevalence and drug cost-effectiveness.<sup>9</sup> Decision makers and health care professionals are often wary of using the EMLs because they are unclear about the drug inclusion process and accuracy of the represented information.<sup>4</sup> According to the WHO, LMICs spend between 25% to 66% of their total health expenditure on procuring medicines, which is significantly more than the 15% to 30% expenditure typical of developed countries.<sup>10</sup> While developing reliable, evidence-informed EMLs is beneficial for all countries, due to the high health expenditures and high potential opportunity costs of investing in certain medicines, the need is even greater in LMICs. Likewise, in most cases there is no

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clear method to review or update the national EML in LMICs, making some of the published information outdated or misleading.<sup>4,6</sup> Even when a structured plan is in place for developing the EML, LMICs often lack the capacity to make evidence-informed decisions, especially when EML criteria include value-for-money and financial feasibility. New medicines and vaccines are becoming more and more costly, and most governments believe that the EML should be publicly funded.

Nepal is classified as a low-income country by the World Bank, with a health expenditure of US\$39 per capita in 2014.<sup>11</sup> The health care system is overseen by the Ministry of Health and Population (MoHP) and broken down into 8 central hospitals, 6 regional and sub-regional hospitals, 10 zonal hospitals, 78 district hospitals, 208 primary care centers, 1559 health posts, and, at the most basic level, 2247 sub-health posts.<sup>12</sup> In 2007, the country's interim constitution decreed that health care was a basic human right and that essential health care services should be provided for free to Nepalese citizens.<sup>13</sup> In 2008, six groups (poorer, poor, destitute and disabled people, senior citizens, and female community health volunteers) were targeted in hospitals with 25 beds or less; these groups receive the largest portion of the funds. In mid-January 2008, the Government of Nepal declared that essential health care services were to be provided free of charge at all health posts and

sub-health posts. Subsequently, free hospital care was implemented in 2009.

In the initial phases of addressing this goal, the Government of Nepal developed essential services programs and an EML to provide basic health coverage for a target group of the poor, destitute, elderly, and disabled in health posts and sub-health posts.<sup>13</sup> However, the EML only serves as a guide for health practitioners; there is no financial commitment from the government to provide the medicines and vaccines on the list, which means that they may not necessarily be free of charge or even available in public facilities. In 2009, the coverage was expanded so that all citizens would have access to 40 drugs on a separate list known as the Free Drug List (FDL). FDL differs from the EML in that the government has allocated resources in procuring these products for eligible health facilities. The few published studies evaluating the FDL noted several issues such as lack of appropriate process, obvious gaps in the listed drugs and Nepal's burden of disease, and also no consideration for unit costs or cost-effectiveness of drugs included in the list.<sup>13,14</sup> Despite these concerns, the FDL has recently been expanded from 40 to 70 drugs although the process of review or updating the list remains unclear.<sup>15</sup>

One way to address these issues is the use of health intervention and technology assessment (HTA) to inform health care programs under a universal health care scheme.<sup>16,17</sup> HTA assumes limited resources and aims to ensure the most beneficial allocation of these resources. It emphasizes stakeholder involvement, ensuring that all the necessary information is on hand from all areas to address issues. Although this process does not directly address procurement, delivery, and so on, it provides the basis for improvements in these areas, particularly since HTA seeks to allocate resources in areas of most need in the health system. It is assumed that many resource-limited countries are using resources inefficiently and that the creation of a list that considers not only safety, efficacy, and effectiveness but also cost-effectiveness, financial, social, and ethical implications will be instrumental in ensuring that the government can provide the medicines to which it has committed.

This article outlines an HTA-based process proposed for developing and updating the FDL in Nepal. We conducted a document review and in-depth consultations with representatives from Nepal's MoHP and the WHO Nepal Country Office. We propose a mechanism for future FDL development that aims to address the current barriers to

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successful use of the list in the country. This article is relevant to resource-limited settings that wish to develop sustainable, reliable, and effective EMLs that increase access to essential medicines using a more systematic, participatory, and transparent process.

## METHODS

### Document Review

A systematic review was conducted between February and March 2015 by searching MEDLINE to identify any publications that detailed the process of developing the FDL in Nepal. The search terms (Nepal) OR (low- and middle-income countries) OR (LMICs) OR (developing countries) AND (Free Drug List) OR (FDL) OR (essential medicines list) OR (EML) OR (essential medicines) were used as free text in the title, abstract, or keywords. Parameters were set that limited the publications to a time frame between January 2005 and March 2015 and to those written in the English language. In total, 125 reference abstracts were obtained from MEDLINE ( $n = 125$ ), which were then manually searched for relevance. A review of these documents revealed that none of them contained information about the selection process for medicines on the FDL.<sup>13,15</sup> An additional three documents were retrieved including an annual report from Nepal's Department of Health Services and an unpublished WHO status report for 2014–2015. The WHO report specifically stated that in their review of the current health system, the developmental process for the drugs selected to be freely distributed is unclear.<sup>15</sup>

### Consultation Workshop

As the goal of this work was to create a sustainable process for the FDL, involvement of the stakeholders was a key component to ensure policy relevance and feasibility in the local context. Accordingly, we interviewed WHO and MoHP representatives at a workshop held in Kathmandu in March 2015.

With support from the WHO Nepal Country Office and Regional Office, a team of six members of Thailand's Health Intervention and Technology Assessment Program (HITAP) facilitated a 2½-day workshop at the request of Nepal's MoHP. Twenty-four local policy makers and technical experts attended the meeting including representatives from

the MoHP, Primary Health Care and Revitalization Division (PHCRD), Health Research and Social Development Forum, Nepal Health Research Council, Logistics Management Division, Epidemiology and Disease Control Division of the Department of Health Services, National Health Training Center, Department of Drug Administration (DDA), the Health Economics Unit of Bangladesh's Ministry of Health and Family Welfare, and the WHO. The objectives of the workshop were a) to learn in detail about the original process of developing the FDL as well as the current method of evaluating and updating it from the government officials charged with this task; b) to inform these same officials of the benefits and process of including health intervention technology assessment (HTA) evidence to inform the FDL; and c) to propose a new, transparent, evidence-based mechanism to create a sustainable FDL using input from the local participants. Decision makers from the high-level offices of the Nepalese Ministry of Health, such as the Director of the PHCRD and officials from the DDA, validated the results on the final day of the workshop.

## RESULTS AND DISCUSSION

### The Current Free Drugs List Process

The document review revealed that beyond the hospitals that provided free hospital care, nontargeted hospitals were to make 40 drugs<sup>20</sup> provided by the Logistics Management Division available free of charge to all patients. To respond to this need, 40 drugs were originally identified for the FDL for distribution in these hospitals and 30 more were added in 2014.<sup>18</sup> Currently, distribution is determined by facility category, with all drugs provided at district hospitals, 68 at primary health care centers, and 38 at health posts or HPs (and sub-health posts or sub-HPs, all of which are being upgraded to HPs).<sup>15</sup> There are two methods of drugs procurement—centrally and locally in individual districts. The government spends approximately 750 million Nepalese rupees (US\$7.5 million) on drugs every year (4.5% to 5% of the government health budget; laboratory drugs are not included).

The development process is unclear for the FDL and its 40 drugs. Per expert communication during the workshop, before the addition of the 30 new drugs, there was a revision of the FDL to include drugs for diabetes and hypertension in response to doctors' requests. Several drugs on the proposed

**Table 1** Comparison of the Nepal Essential Medicines List and the Nepal Free Drugs List<sup>15,20</sup>

	Nepal Essential Medicines List	Nepal Free Drugs List
First publication date	1986	2009
Purpose	“Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.”	“Provision of selected medicine free of cost at and below district hospital.”
Selection committee	<ul style="list-style-type: none"> <li>• Department of Drug Administration</li> <li>• Chief Drug Administrator</li> <li>• 14 specialist committees from 10 districts with specialties in general medicine, surgery, obstetrics and gynaecology, pediatrics, otolaryngology, psychiatry, anesthesia, tuberculosis, ophthalmology, oncology, orthopedics, dentistry, dermatology, and immunization</li> </ul>	<ul style="list-style-type: none"> <li>• Primary Healthcare Revitalization Division</li> </ul>
Payment mechanism	<ul style="list-style-type: none"> <li>• Hospital or public health office/facility budget, some of which is provided by the government</li> </ul>	<ul style="list-style-type: none"> <li>• Government budget</li> </ul>
Type of facility drugs are available in	<ul style="list-style-type: none"> <li>• District hospitals</li> <li>• District public health offices</li> <li>• Referral hospitals</li> </ul>	<ul style="list-style-type: none"> <li>• Health posts</li> <li>• Sub-health posts</li> </ul>
Inclusion of drugs	<ul style="list-style-type: none"> <li>• Results from expert review and consultation</li> </ul>	<ul style="list-style-type: none"> <li>• Drugs should be based on the Nepal Essential Medicines List, though a number are not included (amlodipine tablets, indomethacin tablets, and neomycin ointment)</li> <li>• Process unknown</li> </ul>

Source: *Draft Report on Medicines in Healthcare Delivery, Nepal: A Situational Analysis* and the fourth revision of the National List of Essential Medicines, Nepal.

free list of 70 drugs are not on the more general national EML, including amlodipine tablets, indomethacin tablets, and neomycin ointment (Table 1). Given that the current government expenditure on drugs remains low, approximately US\$1.5 per capita in 2011, the FDL should be expanded in a systematic way to account for additional costs of expansion. The stakeholders during the workshop indicated that a robust development process for the FDL would ensure effective and feasible implementation and impact.<sup>15</sup>

### Barriers of the Implementation of the FDL

The analysis of the existing FDL shows room for improvement. Without broad stakeholder ownership, there is a risk of limited acceptance and use of the FDL. Furthermore, the acceptance of the FDL requires sufficient dissemination and

communication of the process and results. There are also uncertainties regarding the availability of financial resources for procuring the drugs, as a cost and budget impact analysis was never conducted.

The current FDL is impractical for health care practitioners and users, because of insufficient linkage between the needs of the country and the formulation of the reimbursement list. First, there are concerns about the FDL addressing the burden of disease, which has transitioned from previously high prevalence of communicable diseases to more noncommunicable diseases in recent years. Thus, the FDL responds to some of the most pressing health burdens of the country but is not comprehensive. Of the 20 diseases that had the highest percentages of premature death and years lived with disability in 2010 in Nepal, 12 have medicines as the first-line treatment but only 10 are included in the FDL: anxiety disorders and migraine are not.

Pharmacologic (25 classes)	Disease (13 classes)	Drug Structure (2 classes)
Antacid Antibacterial Antibiotic Anti-diabetic Antidote Anti-epilepticus Antifungal Antihelmitic Antihistamine Antihypertensive Antipoisonous Antiprotozoal Antiseptics Antispasmodic Antiviral Bronchodilator Diuretic Electrolyte Fluid and electrolyte substitution Local anaesthesia Nonsteroidal anti-inflammatory drug Steroid Topical antibiotic Tranquilizer Vitamin supplement	Allergy Anaphylactic shock Anomia Antiseptic Antithyroid Eczema Gout High altitude sickness Mental stimulant Psychotic drug Scabies Sunburn Ulcer healing	Benzodiazepine Cardiac glycoside

Figure 1 Free Drugs List classification system: Nepal's Free Drug List

Second, some drugs that could greatly improve public health are currently excluded from the list. The FDL limits choices for practitioners. For example, only the tablet form (no nebulizer or inhaler) of salbutamol is available for chronic obstructive pulmonary disease or asthma. However, the 2009 WHO EML states that the tablets should only be used when nebulizers and inhalers are not feasible.<sup>21,23</sup> The tablet has since been excluded from the WHO lists.<sup>23</sup> The inhaler is more effective and has fewer side-effects; the nebulizer is necessary for emergency situations. Having only one treatment option limits the ability of providers to respond to patient needs.

Third, unlike Thailand's or the WHO's EMLs that use uniform nomenclature to classify drugs, the FDL in Nepal uses a mixed system for classification

(Figure 1). Medicines are variously classified by pharmacologic, disease, or drug structure properties. The FDL's mixed system could be confusing for primary health care practitioners to use and obstructive to promoting the rational use of essential drugs. This is especially true as medications are added to the list and others are removed, because some drugs that are not explicitly classified by disease could be used for a number of disease conditions. For example, in the current FDL, antibiotics were classified by pharmacologic class which does not provide practitioners any information regarding the diseases that those antibiotics treat. There is no clear indication that certain antibiotics could be used for respiratory tract infections but not for gastrointestinal or wound infections.

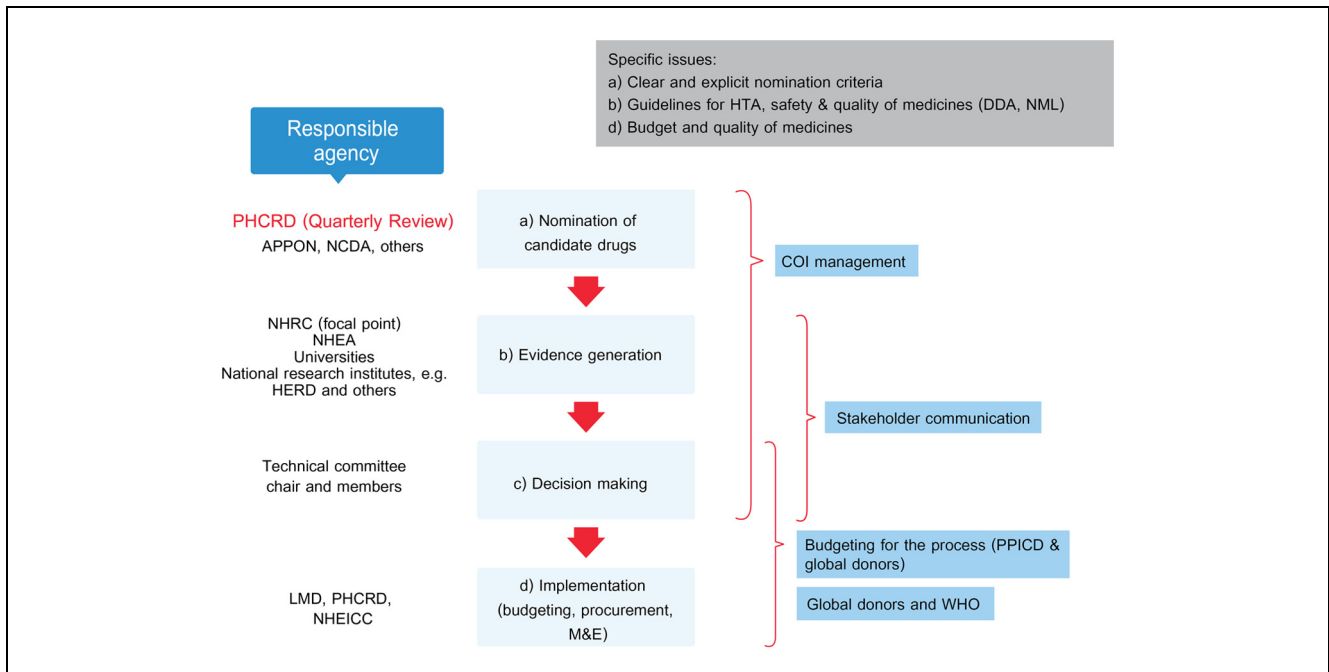


Figure 2 The proposed drugs selection process for the Nepal Free Drugs List.

Note: APPON = Association of Pharmaceutical Producers of Nepal; COI = conflict of interest; DDA = Department of Drug Administration; HERD = Health Research and Social Development Forum; LMD = Logistics Management Division; M&E = Monitoring and Evaluation; NCDA = Nepal Chemists & Druggists Association; NHEA = Nepal Health Economics Association; NHEICC = National Health Education, Information, and Communication Center; NHRC = Nepal Health Research Council; NML = National Medical Laboratory; PHCRD = Primary Health Care Revitalization Division; PPICD = Policy Planning and International Cooperation Division; WHO = World Health Organization.

This system could also result in the irrational use of medicines. A physician might use different medicines under the drugs structure and the pharmacologic categories to treat the same disease when there should be a clearly outlined prescription for first-line and second-line treatments as well as the various alternative choices within each line. Other countries' EMLs, such as Thailand's National List of Essential Medicines (NLEM), use the disease classification, which is divided into 17 disease classes and 86 subcategories. This allows drugs to be listed with multiple indications and under several disease classes without overlapping each other, which is easier for practitioners.

Workshop participants recognized that a health technology assessment (HTA) approach could meet the needs of the MoHP in expanding access to essential health services for Nepal's citizens. They identified several barriers to using HTA to inform Nepal's FDL development: lack of formal structure for updating the list, lack of skilled HTA researchers, inadequate linkage between policy making and research, different needs for different geographic

and socioeconomic groups, no standard methodology for HTA, inadequate quality of drugs, lack of research focusing on the FDL, lack of policy on pharmaceutical outlets in health facilities, bureaucratic process of drugs approval, and financial limitations. They also identified conducive factors: political commitment, legislation to support the process decided upon for the FDL, current health system reform initiatives, availability of some data for preliminary HTA work, and the existence of local capacity and/or organizations that can be trained for HTA work.

### Future Proposal of FDL

Based on the results of the workshop, we propose four steps for the FDL development: a) the nomination of candidate drugs, b) evidence generation, c) decision making, and d) implementation (Figure 2).

First, the nomination of the candidate drugs should be linked to the routine quarterly health care review by the PHCRD, where stakeholders and experts from the district, regional, and central levels

give updates on the status and needs of lower level hospitals. This review captures the viewpoints of potential users of the FDL including primary health care workers. Representatives of associations of international and domestic pharmaceutical companies (e.g., the Association of Pharmaceutical Producers of Nepal and the Nepal Chemists & Druggists Association) should take part in the nomination process. Because these companies have up-to-date knowledge of the constantly evolving field of pharmaceuticals, they could play an important role in suggesting the withdrawal of drugs that have been proven to be unsafe, outdated, or unavailable. However, they would not be allowed to participate in the final decision making due to their vested interest in promoting their own products. This involves them in the national process as a stakeholder but limits their potential influence. The stakeholders could further improve the process in the future by including other groups such as patients and community members.

Second, the Nepal Health Research Council (NHRC) should be the focal technical body for HTA evidence generation. NHRC should establish a standard protocol for conducting HTA in Nepal to ensure quality and comparability of studies. They will collaborate with other local scholars and agencies such as Nepal Health Economics Association, universities, and research groups such as Health Research and Social Development Forum. The National Medical Laboratory of the Department of Drug Administration (DDA) should be the focal point for pharmacovigilance and providing input about drug safety and quality for coverage decisions.

Third, a technical committee should be established for considering evidence and advising the Secretary of the Ministry of Health and Population regarding the FDL's coverage. The Director General of the Department of Health Services was proposed to chair this committee, with the following members' organizations: academics, the National Consumer Forum, the NHRC, DDA representatives, the PHCRD, the National Planning Commission, the Ministry of Finance, the Policy Planning and International Cooperation Division (PPICD), and the National Medical Council. This committee should meet once a month and oversee not only the inclusion or exclusion of drugs but also work closely with agencies responsible for communication and advocacy of the use of the FDL among practitioners, drug procurement, and monitoring and evaluation. A secretariat should be appointed to facilitate the process and assist the committee in conducting the work

required. Fourth, several agencies were identified to be responsible for the implementation of the FDL including the Logistics Management Division for drug procurement, PHCRD for general oversight on the implementation process, and the National Health Education, Information, and Communication Center to communicate with stakeholders.

This process will require financial resources, estimated at US\$200,000, for which PPICD should earmark a yearly budget. This FDL development mechanism will be of interest to other overseas development agencies because it can ensure good governance, is based on evidence-informed policy development that meets local need, and promotes the sustainable development of the health system in Nepal. This plan should therefore be shared with other international partners.

## CONCLUSION

The FDL serves as a foundation for the provision of government-funded drugs to address the needs of the Nepalese society. Its long-term sustainability, however, faces challenges in terms of acceptance, drug procurement, doctor or practitioner use, rational drug use, and costs. These issues result from a lack of a systematic, evidence-informed, and participatory mechanism of drug selection and concomitant budget impact analysis. The proposed drug selection process, which will help address these issues, is a variant of HTA.

HTA processes for drug selection have been successful elsewhere. Thailand's NLEM selection process begins with topic nomination and selection with the participation of relevant stakeholders, economic evaluation, an appraisal, and submission to policy makers. The results of previous HTAs have been used to inform price negotiations for the NLEM. An example is the reduction of the price of oxaliplatin from 8,000 Thai baht to 2,500 Thai baht through negotiations. The original price of oxaliplatin was not cost-effective; however, with evidence of the affordable price for the Thai context, the stakeholders could negotiate a lower price, resulting in a potential savings of 152 million Thai baht for the government. Taken collectively, economic evaluations and budget impact analysis for price negotiations save the Thai government approximately one billion Thai baht annually.<sup>19</sup> Similarly, implementing this process in Nepal would allow the use of evidence in price negotiations with local and international drug industries, giving the government

the chance to avoid overspending on necessary drugs and reallocate resources to the budget for other drugs to be procured and programs being implemented.

The findings of this study are in line with recommendations and conclusions from two other studies that evaluated the national reimbursement lists of other LMICs, namely, India<sup>4</sup> and Tanzania.<sup>9</sup> In India, the first National Essential Drug List was created in 1996, then updated in 2003 and renamed the National List of Essential Medicines, and finally revised once again in 2011, becoming the National List of Essential Medicines in India (NLEMI).<sup>22</sup> The study by Manikandan and Gitanjali analyzes the process of updating the NLEMI and presents the results of the 2011 revision. A major difference between the study in India and this study was that there was clear, published information about the development mechanism for the NLEMI, which allowed the authors to provide detailed feedback on its strengths and weaknesses. Despite this, the authors still found issues similar to those reported in Nepal including the inclusion of outdated or obsolete medicines, improper methods of medicine selection, and an omission of treatments that were necessary to address the disease burden in India.<sup>4</sup> These findings highlight the importance of developing a strong foundation for evidence generation and clearly assigning tasks to different organizations within the health care system to develop EMLs that are verifiable and accurate.

The second study evaluated the process of selecting medicines for Tanzania's National Essential Medicines List and determined that, like in Nepal, most drugs are included on the list based on expert opinions rather than evidence. Although cost-effectiveness analysis is considered an important criterion in the process, it is not utilized. Mori and others concluded that this lack of evidence could result in the adoption of policies that are ineffective and costly, and recommend that evidence-based criteria should be implemented for proper resource allocation.<sup>9</sup> While both studies emphasize the importance of developing an evidence-based process for EMLs, neither of them outline a mechanism for its development. The mechanism presented in this article provides useful information in Nepal's context, but it can also be adapted as a model for other LMICs striving to create sustainable and reliable EMLs.

The primary weakness of this study is that the researchers could only find data sources for the systematic review in English as none of them spoke the local language. This limited the ability to collect

information from Nepali databases and publications. It also placed constraints on who could participate in the information generation workshop because the meeting was conducted in English. However, information about Nepal's health care system and process for developing the FDL was collected during the workshop. These data are more accurate and current than information obtained from online sources because the participants of the workshop were the organizations responsible for making health care policy and generating the FDL in Nepal. The language barrier did not affect participation at the workshops as representatives from all the relevant agencies could speak and understand English fluently.

In this article, the most visible aspect of the HTA process proposed is cost-effectiveness. It is only one part of the HTA process, which also considers distributional concerns, physician autonomy, and legal and budget implications. Governments should also be concerned with rare diseases in vulnerable populations, minority issues, and other ethical problems; however, there must be explicit social and ethical criteria that are widely accepted and applied across the board to justify investment in cost-ineffective medicines. As such, a governing body representing different social viewpoints should be included in the process. Similarly, standard treatment protocols may be useful but could limit the doctor's ability to address patient concerns. On the other hand, when each physician prescribes any type of treatment, spending may be skewed toward certain diseases at the expense of other diseases (and patients' lives). A balance needs to be struck so that physicians can prescribe treatments that also fit within the government's ability to pay. Another issue is to ensure that spending on health is adequate (especially given the often low spending on health in LMICs). With information on health needs and cost-effectiveness of the programs, stakeholders could advocate for more budget allocation to health. The Nepal FDL mechanism proposed in this article can be adapted in other developing countries. In the past two decades, global development partners such as the Global Fund, the Global Alliance for Vaccines and Immunization, and the US President's Emergency Plan for AIDS Relief have set out short-term priorities in the countries they work in. If these development partners want to work toward sustainable development, they must invest in in-country capacity for evidence generation for health care priority setting.



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