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Understanding the Role and Use of Essential Medicines Lists

Introduction

Since the establishment of the concept of "essential medicines" by the World Health Organization (WHO), it has evolved and matured into a critically important element of national health system policies and practices. As the movement toward universal health coverage strengthens, so does the role of essential medicines as a key part of bringing to all people the health services they need without suffering financial hardship when paying for them.

As the WHO moves toward a revision of the model Essential Medicines List, it is timely to revisit the evolution of the list since 1977 and its use across a range of countries.

The purpose of this report is to:

- Summarize how the Essential Medicines List has changed between 1977 and 2013 and the process by which the model list is revised

- Describe the ways in which the WHO's list is used by national health systems in developing their own lists of essential medicines

- Review and compare the national lists for a range of countries and factors affecting local implementation

- Provide considerations for future revisions of the WHO model list

In reviewing national systems, a selection of middle- and low-income countries were selected from Asia, Africa and Latin America, including Brazil, China, India, Indonesia, Kenya, Malawi, the Philippines, South Africa, and Tanzania.

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Contents

Background

The concept of essential medicines was pioneered by the World Health Organization (WHO) in 1977 with the introduction of the first essential medicines list (EML). The list has been revised every 2 years since then.[1]

Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.[2] Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Although the WHO has defined the concept of EML and regularly publishes the updated lists, implementation of this concept is intended to be flexible and adaptable. The responsibility of determining exactly which medicines are regarded as essential is left to the discretion of the adopting nations based on their requirements.

The Model list of the WHO serves as a guide for the development of national and institutional EML. The concept of essential medicines has been accepted worldwide as a powerful tool to promote health equity and its impact is remarkable, as essential medicines are considered to be one of the most cost-effective elements in healthcare.

Usage of EML

The Model list serves as a baseline for further modification (addition and deletion of new medicines), selection of correct dosage strength, and form depending upon the national priority and available evidence. It can assist national decision-makers in managing costs by helping them identify priority medicines to meet their country's health needs.

The WHO EML has gained widespread acceptance among nations with 4 out of 5 countries having adopted a national list based on the WHO EML.[3] The list is now considered a cornerstone of national medicine policies. Some countries have provincial or state lists, in addition to the national list.

The concept of essential medicines has also been adopted by many international organizations, such as United Nations Children's Funds (UNICEF), Office of the United Nations High Commissioner for Refugees (UNHCR), Doctors without Borders (Médecins Sans Frontières), as well as by NGOs and international non-profit supply agencies.[4]
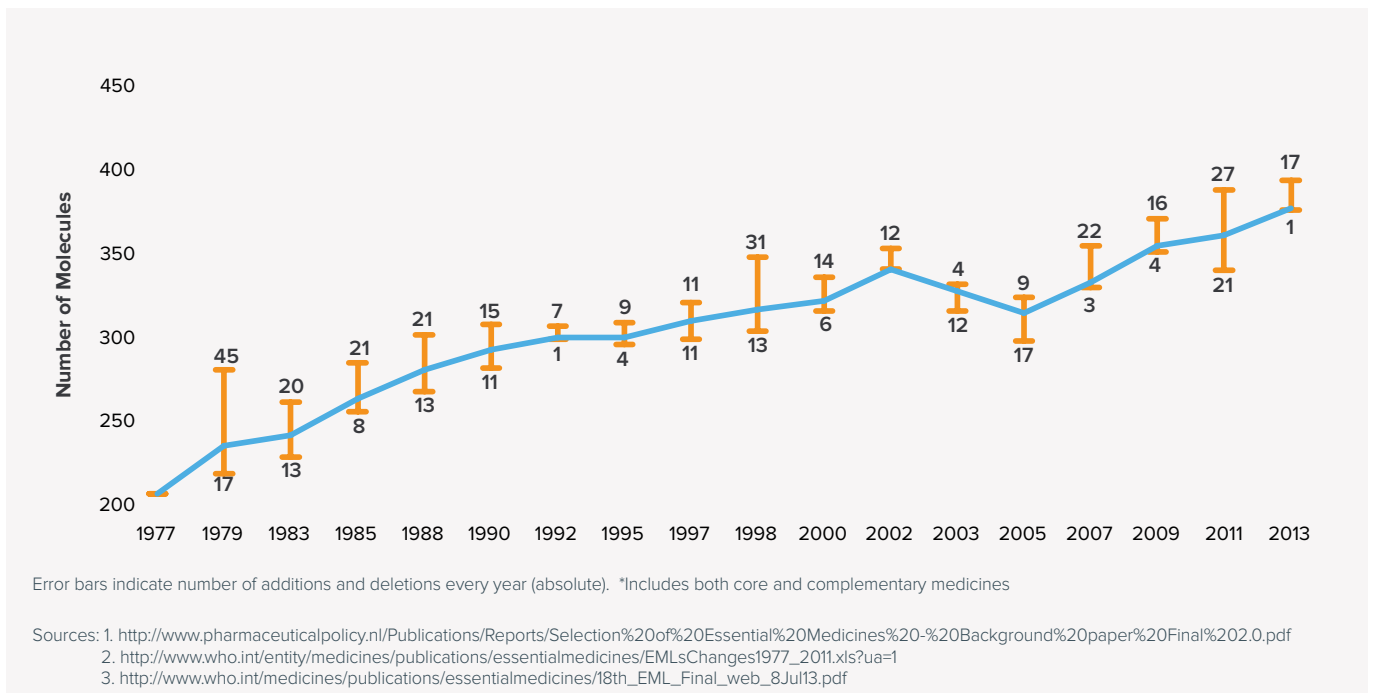
Evolution of WHO EML (1977-2013)

The WHO carries out regular updates of the EML to reflect evolving public health challenges, as seen, for example, from the addition of anti-retroviral medicines for HIV and formulations to treat non-communicable diseases.

Evolution of WHO EML in Terms of Drugs Added

The WHO EML has steadily grown in terms of the number of drugs included in the list with each update (See Exhibit 1). Initially in 1977, the WHO EML had 204 molecules and the current list of 2013 includes 374 unique molecules.[5, 6] The 2013 WHO EML has 431 molecules with duplications across indications and includes both core and complimentary medicines.

Exhibit 1: Evolution of the WHO EML with Number of Additions and Deletions[5, 6, 7]

Error bars indicate number of additions and deletions every year (absolute). *Includes both core and complementary medicines

Sources: 1. http://www.pharmaceuticalpolicy.nl/Publications/Reports/Selection%20of%20Essential%20Medicines%20-%20Background%20paper%20Final%202.0.pdf
2. http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1
3. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

Addition of new drugs is based on documented evidence of efficacy, relative efficacy, safety and comparative cost-effectiveness, while reasons for deletions include lack of proof of effectiveness, unacceptable side effects or availability of safer or more effective alternatives.
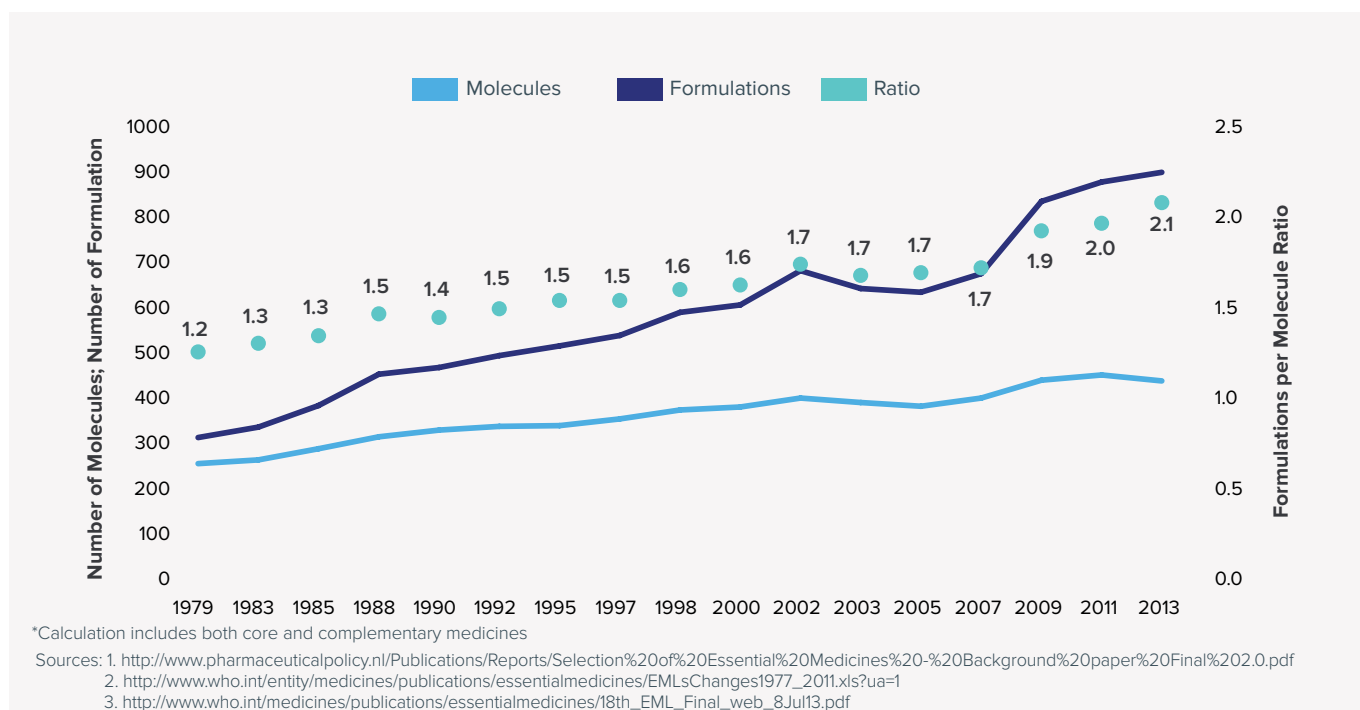
Among the most significant changes in the WHO EML since 1977 are the following:[7]

- Significant net change was observed in the 1979 list, probably since the list was in the process of being developed and established

- Addition of fixed dose combinations for tuberculosis to the list contributed to the significant change observed in 1998

- Addition of agents in 2003 is mainly attributed to the inclusion of anti-retroviral drugs to the EML

- Significant change observed in 2007 can be attributed to the inclusion of various newly developed vaccines to the list, including hepatitis A vaccine, rotavirus vaccine, etc.

Evolution of the WHO EML in Terms of Formulations per Molecule

Over time, the ratio between formulations and molecules has consistently increased, indicating more formulations per molecule are listed in the WHO Model EML (See Exhibit 2). This may be attributable to the fact that the longer a medicine is on the market, more formulations and dosage forms become available and that these may also be included in the WHO Model EML.

Exhibit 2: Formulation per Molecule Ratio[5, 6, 7]

*Calculation includes both core and complementary medicines

Sources: 1. http://www.pharmaceuticalpolicy.nl/Publications/Reports/Selection%20of%20Essential%20Medicines%20-%20Background%20paper%20Final%202.0.pdf
2. http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1
3. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
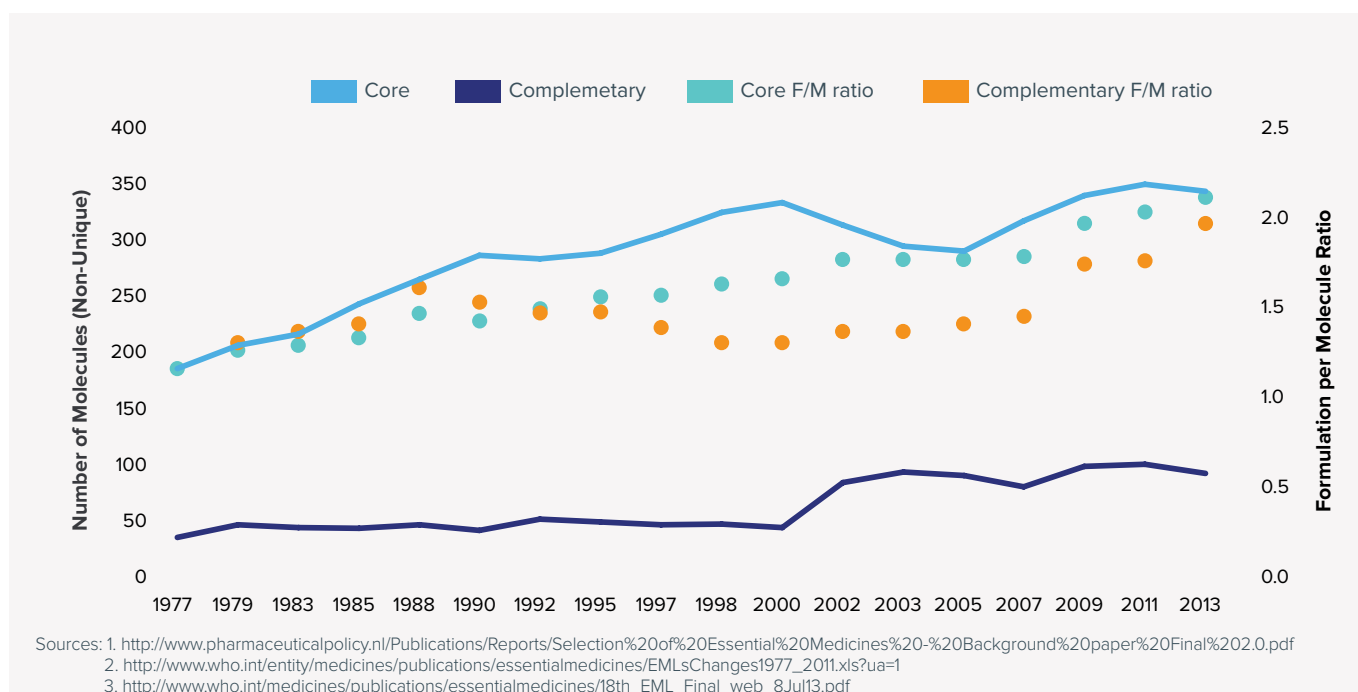
Evolution in Terms of Expansion of Core and Complementary Molecules

Core medicines are defined as efficacious, safe, and cost-effective medicines for priority conditions (based on current and future public-health relevance and potential for safe and effective treatment).[6]

The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed. In case of doubt, medicines may also be listed as complementary on the basis of consistent higher costs or less attractive cost-effectiveness in a variety of settings.[6]

Exhibit 3: Expansion of Core and Complementary Medicines and their Respective Formulation/Molecule Ratio[5, 6, 7]

Sources: 1. http://www.pharmaceuticalpolicy.nl/Publications/Reports/Selection%20of%20Essential%20Medicines%20-%20Background%20paper%20Final%202.0.pdf
2. http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1
3. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

There has been a consistent increase in the number of core medicines added to the WHO EML compared to the complementary medicines (See Exhibit 3). In the 2011 WHO EML, 100 of the total 445 medicines listed (22%) were listed as complementary with some appearing both on core and complementary lists.[5]

Trend for the Number of Medicines for Non-Communicable Diseases

There has been a consistent increase in the burden of non-communicable diseases (NCDs) in low- and middle-income countries despite availability of effective interventions.[8]

NCDs negatively impact individuals, family economic production and well-being, and have the potential to considerably undermine the macroeconomic development at a national level. It is estimated that the appropriate use of medicines alone can reduce up to 80% of the burden of NCDs in many countries.[8]

In 2005, based on the significant contribution to the global disease burden, the WHO identified specific NCDs such as cardiovascular diseases and stroke, diabetes mellitus, cancers, and chronic obstructive airway diseases, for prioritized targeting. Gradually, the WHO EML has been expanded to address other preventable and controllable disease areas, including overweight and obesity, misuse of tobacco and alcohol, injuries and mental health, and effects of unhealthy diet.[8]

Exhibit 4: Trend for the Number of Medicines for Non-Communicable Diseases[5, 6]

*Calculation includes both core and complementary medicines
Source: http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1
          http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
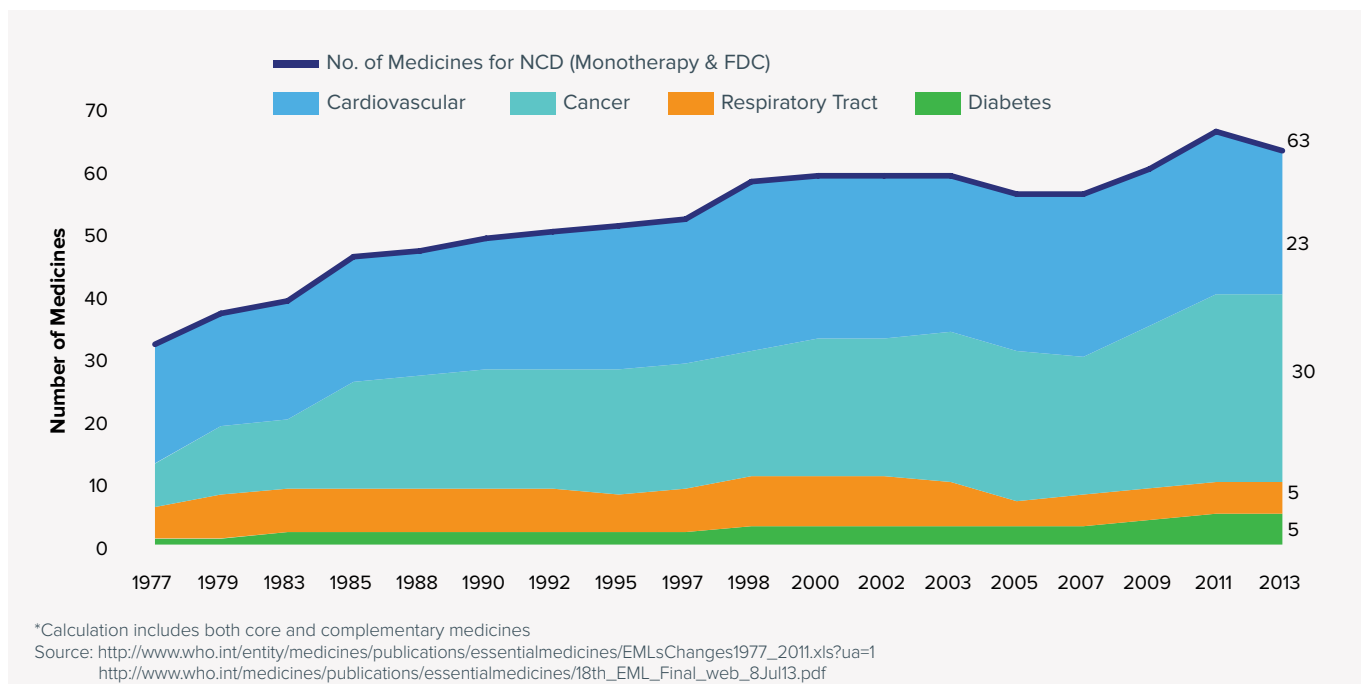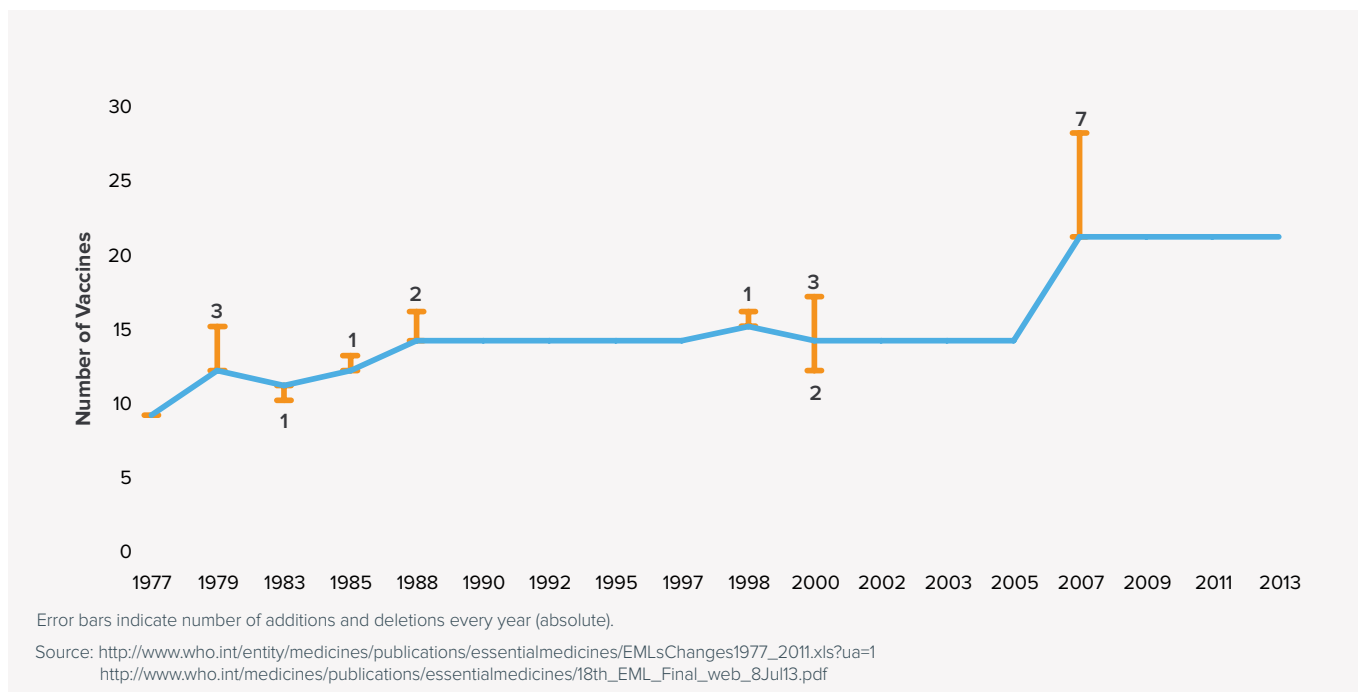
The importance of ensuring access to appropriate medicines for treating NCDs is reflected in the consistent increase in the number of medicines for NCDs in the WHO EML (see Exhibit 4). The ratio of medicines for NCD medicines to total number of medicines in the WHO EML is constant at ~15% from 1977 to 2013,[5, 6] despite projections by the WHO that NCDs are likely to contribute to 73% of death burden and 60% of the disease burden by 2020.[9]

Trend for Inclusion of Vaccines in the WHO EML

The WHO began the Expanded Program on Immunization (EPI) in 1974,[10] to cover six disease areas (diphtheria, pertussis, tetanus, poliomyelitis, tuberculosis, and measles) for which proven vaccines were available. The program has evolved in close collaboration with UNICEF, which continues to furnish vaccines and much of the associated necessary supplies and equipment.

Exhibit 5: Evolution of Vaccines in the WHO EML with Number of Additions and Deletions[5,6]

Error bars indicate number of additions and deletions every year (absolute).

Source: http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1
http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

On the recommendation of the WHO Global Advisory Group on Immunization, vaccines have been added through the years. The WHO EML added yellow fever vaccine (YF), Meningococcal vaccine and Influenza vaccine in 1979. Other additions include Poliomyelitis vaccine in 1985, Hepatitis B and Rubella vaccines in 1988 and Mumps vaccine in 2000. Seven vaccines were added in 2007, which included Cholera, Haemophilus influenza type B, Hepatitis A, Japanese Encephalitis (JE), pneumococcal, rotavirus, and varicella vaccines.[5, 6] (See Exhibit 5)

The selection of the original EPI vaccines was made on programmatic criteria rather than consideration of disease burden. A few vaccines, such as YF and JE, have regional importance based on prevalence. The WHO EML included JE after 27 years of inclusion of YF, even though there is no evidence that the disease burden of YF is greater than JE.

The need for consistent and standardized regimens determined the strategies selected by EPI. Adaptations over time, as new vaccines were developed and local needs changed, were slow, and the uptake of newer vaccines remains a major constraint in most developing countries, although support provided through the Global Advisory Group on Immunization (GAVI) has improved the situation.[11]

The WHO-UNICEF Effective Cold Store Management Initiative encourages countries to procure equipment and adopt management and training practices that fully protect vaccines in national and intermediate vaccine stores.[11]

Expansion in Terms of the Number of Agents Included within Therapy Classes

Additions and deletions across therapy areas in the EML reflect the evolving focus areas and public health challenges. Anti-infectives appear to be the area with the highest increase, presumably driven by the addition of therapies for evolving health concerns such as tuberculosis, malaria, and HIV. Anti-neoplastic agents, hormones, and vaccines are the other therapy areas with the highest number of drugs added to the original list. (See Exhibit 6)

Exhibit 6: Expansion of Therapy Classes[5,6,7]

Sources: 1. http://www.pharmaceuticalpolicy.nl/Publications/Reports/Selection%20of%20Essential%20Medicines%20-%20Background%20paper%20Final%202.0.pdf
2. http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1
3. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
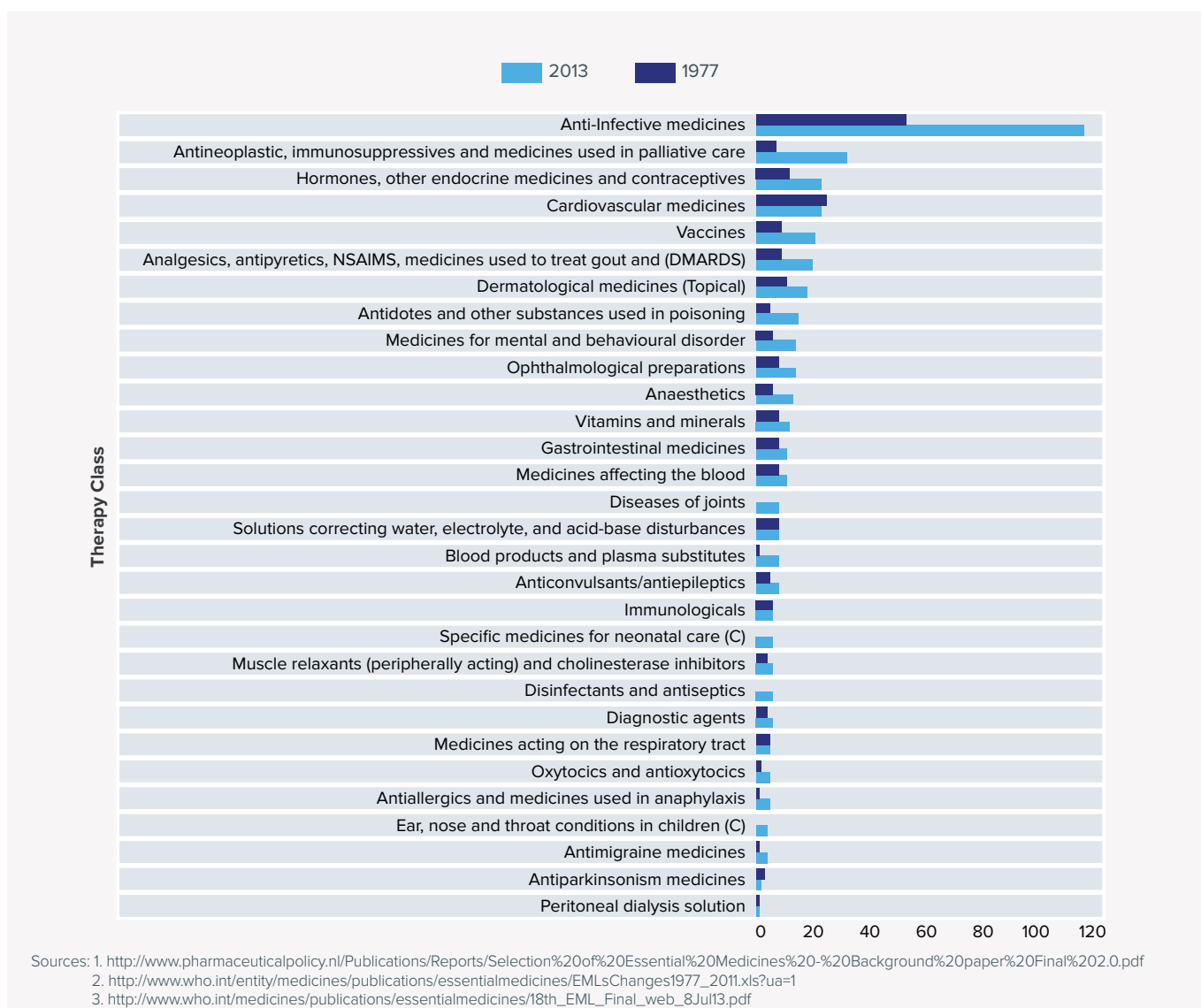
Approach for Revising/Updating the WHO Model EML
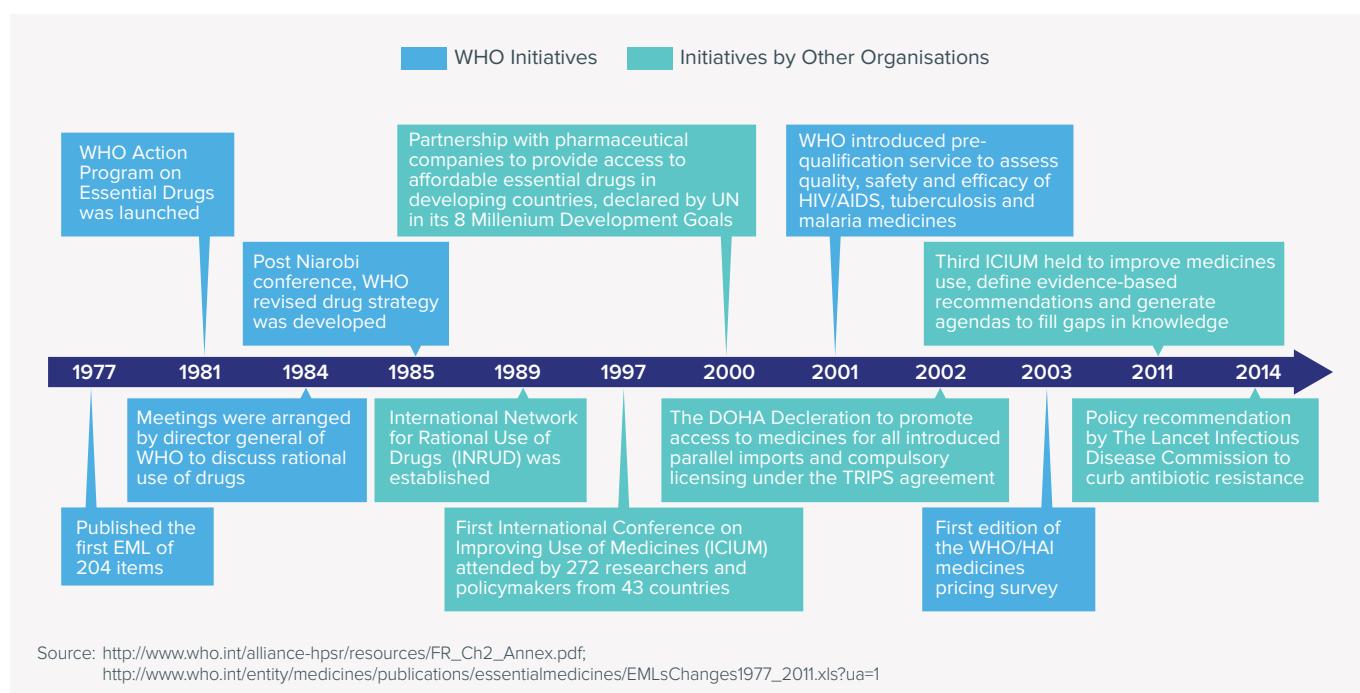
Evolution of Approach Used

While the structure of the WHO Model EML has remained largely unchanged since it was first published in 1977, the process for creation of the WHO Model EML has evolved from being experience-based in the early years to evidence-based guidelines.[12]

Pre-1999, an experience-based approach was considered for addition or deletion of molecules for preparing the WHO EML. In 1999, the Expert Committee recommended moving from experience-based approach to one that was evidence-based and modifications to the methodology were developed. Post 2002, an evidence-based approach was adopted, including evidence for public-health relevance, efficacy, and cost-effectiveness.[13] The guidelines are now prepared with inputs from different stakeholders present in the expert committee.

Among the notable changes in the WHO EML since its inception are the following:[7]

- Use of the term "Essential Medicines" as an alternative to "Essential Drugs," reflecting the common use of the term "medicines" to describe pharmaceutical preparations used in clinical practice

- Evolution from being experience-based to evidence-based

- Introduction of a more rationalized selection process where research evidence was relied upon for evaluating comparative benefit and safety of specific medicines

- Use of a comparative cost-effectiveness approach which is presented as a range of cost per routine outcome (e.g., cost per case, cost per cure, cost per month of treatment) compared to older methods where cost of the total treatment was taken into account.

Exhibit 7: A Timeline Depicting Some Important Events of Essential Medicine[5,14]

Source: http://www.who.int/alliance-hpsr/resources/FR_Ch2_Annex.pdf;
http://www.who.int/entity/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls?ua=1

Over the course of time, a number of challenges were addressed in the selection process of essential medicines (See Exhibit 7). A significant inclusion was the Essential Medicines List for Children (EMLc) in 2007[15] which is separate from the essential medicines list for adults. The EMLc specifically incorporates pediatric dosage forms, e.g., suspensions, chewable tablets, disintegrating tablets.

Outcomes of the Nairobi Conference[16]

The Nairobi conference, which was held from November 25–29, 1985, is considered a landmark event in the evolution of the Model EML. The conference brought together NGOs, industry, and government representatives and resulted in the development of WHO's revised drug strategy, which puts emphasis beyond the mere selection of drugs, to focus on procurement, distribution, rational use, and quality assurance for the public sector (see Exhibit 8).

The key suggestions from the conference included:

- Formulation and implementation of a National Drug Policy as an integral part of the national health policy for attaining the goal of health for all by 2000

- Drug regulation through the formulation of a drug regulatory body

- Adoption of an ethical code for drug promotion with emphasis on the responsibility of the pharmaceutical industry for complying with standard established criteria to avoid different standards in different countries

- Providing information on the national drug policy with implementation of a system that provides impartial and objective information on drugs for policy-makers, patients, and, prescribers

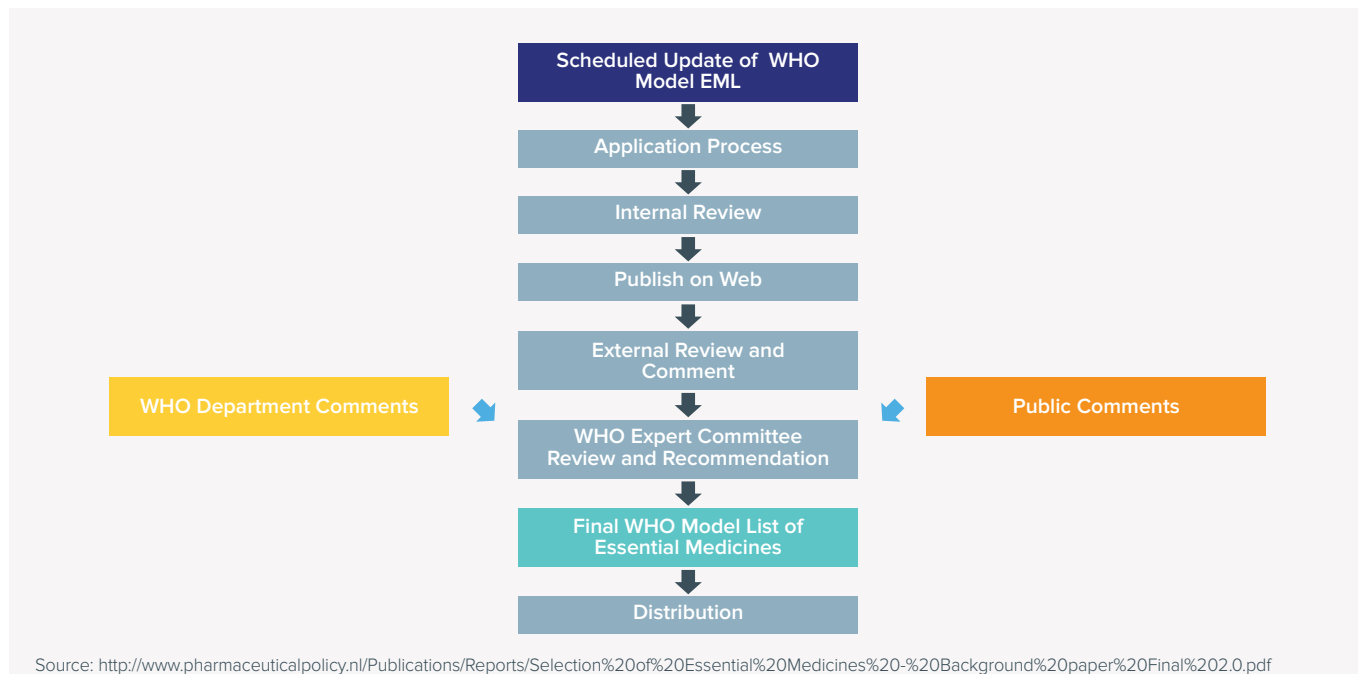- Appropriate national legislation for ensuring rational drug use

Exhibit 8: Key Responsibilities of Different Stakeholders as Defined at the Nairobi Conference[16]	
Stakeholders	**Key Responsibilities**
Government	· Establish a national drug policy and implement it with the national health policy · Create awareness of essential drug list among health personnel and public · Increase registration of acceptable and safe drugs by setting up or strengthening drug regulatory authority
Pharmaceutical Industries	· Provide complete and unbiased product information to all concerned – governments, prescribers and consumers · Comply with established drug promotional criteria and adopt ethical code for drug promotion · Respond to the need of developing countries for low-cost drugs · Develop new drugs in neglected fields with high unmet needs
Prescribers	· Prescribe rationally in conformity with health, as well as social and economic criteria · Provide transparent and accurate information on healthcare and drug therapy to patients and public · Insist on being provided with truth
Universities and teaching institutions	· Improve training of health workers in healthcare in general and in rational use of drugs · Introduce the concept of essential drugs · Provide continuing education for health care providers · Provide general education on proper health care and drug therapy also to those not training as health workers
Public, patient and consumer	· Improve the relevance and quality of information for the public · Share responsibility with govt. and non-govt. organizations for the education of consumers on drug matters · Support essential drug program · Demand compliance with established criteria for drug advertising and draw attention of the health authorities to suspected infringements
The mass media	· Provide relevant and balanced information on health matters, including drug therapy · Share in public education on the proper use of drug therapy · Favorable publicity to be given to those who comply with ethical criteria for drug advertising and unfavorable publicity to those not complying

Source: http://apps.who.int/medicinedocs/en/d/Js17054e/

Current Process and Steps in Updating WHO Model EML[7]

Exhibit 9: Current Process and Steps in Updating WHO Model EML

Source: http://www.pharmaceuticalpolicy.nl/Publications/Reports/Selection%20of%20Essential%20Medicines%20-%20Background%20paper%20Final%202.0.pdf

The WHO has adopted an evidence-based approach for the selection of medicines when updating the WHO EML (See Exhibit 9). The selection of essential medicines depends on several factors, including the disease burden, sound and adequate data on the efficacy, safety, and comparative cost-effectiveness of available treatments. In case of unavailability of adequate scientific evidence on the current treatment of priority disease, the Expert Committee either waits for more evidence or chooses to make recommendations based on expert opinion and experience.

Applications for inclusion, change or deletion of a medicine in the WHO Model List of Essential Medicines are submitted by or through relevant departments in the WHO to the secretary of the WHO Expert Committee. There are 15 questions to be addressed completely in applications, related to disease burden, efficacy, safety, comparative cost-effectiveness, and product-specific considerations.[17]

The committee members are selected by the Director General from the WHO Expert Advisory Panels. Around 8-12 members are selected based on equitable geographical representation, gender balance and professional competencies.[11]

The application should be received at least four months before the meeting of the Expert Committee. All the application reviews and comments are posted on the webpage and checked by the Secretary of the Expert Committee for completeness. The final result is summarized in the Expert Committee report and published as a WHO Technical Report Series.

Patient advocacy groups are invited to comment on applications and draft recommendation but are not included in the decision-making parts of meetings of the Expert Committee.

Use of WHO Model EML and Implementation by National Health Systems

A country's national EML is a government-approved selective list of medicines that guides the procurement and supply in the public sector, reimbursement schemes for medicine costs, medicine donations, and local production. It is a cost-effective means of providing guidance toward safe, effective treatment for the majority of communicable and non-communicable diseases.

Nearly all developing countries (95%) have a published national EML, of which 86% have been updated in the past five years.[18] Some countries also adopt EMLs at a sub-national or state/province level depending on regional requirements and priority health needs. A few developed countries formally use the WHO Model EML as guidance in the development and implementation of their pharmaceutical policy.

While the WHO Model EML serves as a guide for the development of national and institutional EMLs, the final list is decided based on regional factors such as patterns of prevalent diseases; availability of medicines, treatment facilities and personnel; affordability; and genetic, demographic, and, environmental factors.

Standard treatment guidelines, national expenditure on essential medicines, and procurement practices are some of the factors ensuring optimum utilization of the national EML. Relevant regional treatment practices also need to be considered. For example, in China where traditional medicine is widely practiced, a separate medicines list is published to address this area.

Regular update of the national list ensures continuing relevance to the current health scenario. The process for the list revision involves a number of stakeholders including prescribers, academics, health facilities, civil society, etc. to ensure diversity in views and widest acceptance.

Changes in the structure of the list and categorization of drugs are the most commonly seen modifications for adaptation at the national level. For example, the WHO EML includes anti-diabetic agents such as insulin and metformin in the category "Medicines Used for Diabetics," while national lists for India and China include it under "Hormones, Other Endocrine Medicines and Contraceptives" and "Hormones and Endocrinal Agents" respectively.

Also, the WHO Model list contains only the names of medicines and recommended formulations and strengths, while the lists for some of the countries also include the recommended standard treatment guidelines for the specific indication in an attempt to align the EML with the country-specific standard treatment guidelines.
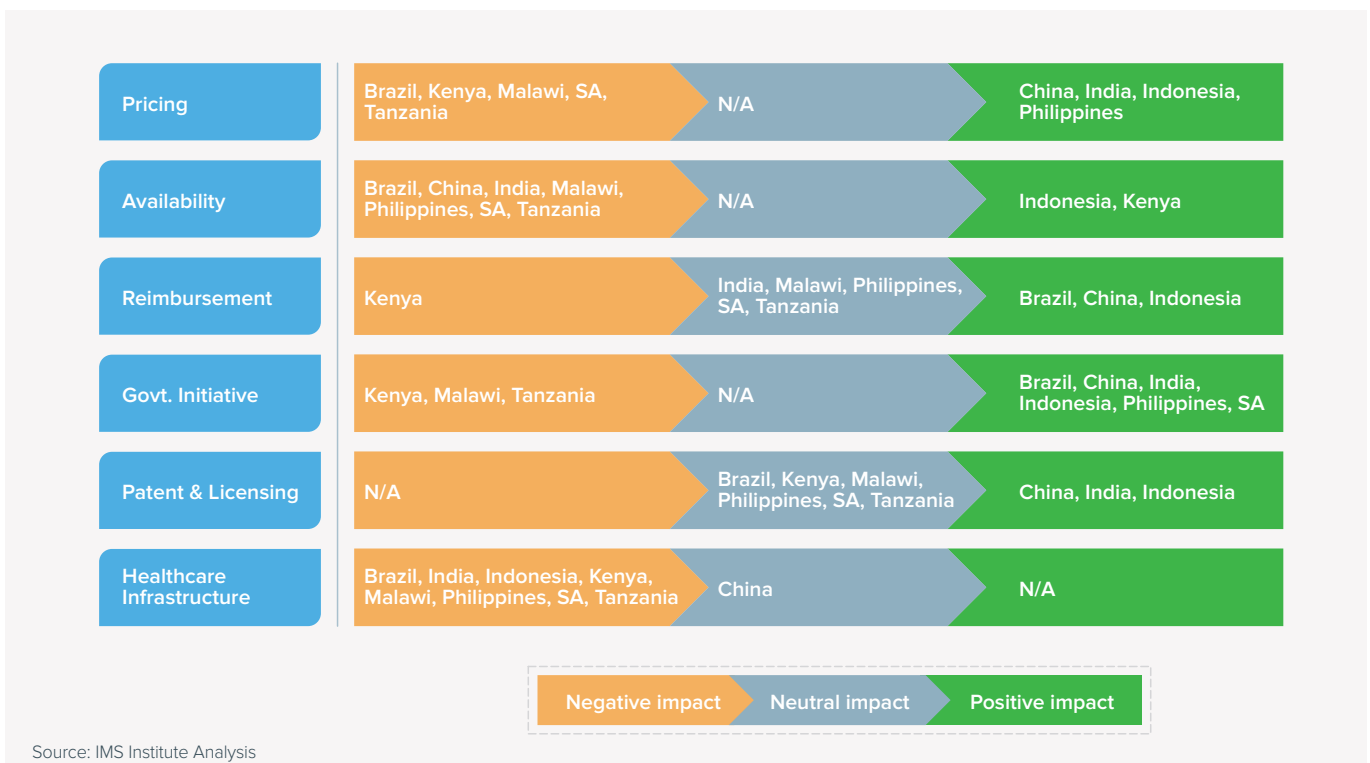
Factors Affecting the Implementation of EML on Country Level

Pricing policy, availability of essential medicines, reimbursement scenario, government initiatives supporting implementation, patent and licensing scenario, and healthcare infrastructure are the key factors affecting implementation of EMLs at a country level.

A number of studies have been undertaken to examine the extent to which country EMLs are being utilized and the impact of a range of factors that can positively or negatively influence implementation of the EML.

The impact of each factor varies depending on the scenario in the country evaluated (See Exhibit 10). For example, while the ceiling on drug price has a positive impact on the implementation in India, the lack of any such regulation results in a negative impact in Malawi.

Exhibit 10: Factors Affecting the Implementation of EML on a Country Level

Factor	Negative impact	Neutral impact	Positive impact
Pricing	Brazil, Kenya, Malawi, SA, Tanzania	N/A	China, India, Indonesia, Philippines
Availability	Brazil, China, India, Malawi, Philippines, SA, Tanzania	N/A	Indonesia, Kenya
Reimbursement	Kenya	India, Malawi, Philippines, SA, Tanzania	Brazil, China, Indonesia
Govt. Initiative	Kenya, Malawi, Tanzania	N/A	Brazil, China, India, Indonesia, Philippines, SA
Patent & Licensing	N/A	Brazil, Kenya, Malawi, Philippines, SA, Tanzania	China, India, Indonesia
Healthcare Infrastructure	Brazil, India, Indonesia, Kenya, Malawi, Philippines, SA, Tanzania	China	N/A

Source: IMS Institute Analysis

Pricing

Pricing has a high impact on the implementation of an EML for most of the countries. High drug prices decrease affordability and have a negative impact on low income countries such as Kenya, Malawi and Tanzania where there is less government control on drug pricing. Middle income countries such as the Philippines, India, and Indonesia have shown positive impact because of initiatives taken by the government to control high drug prices by adopting price ceilings.

Availability

Availability of essential medicines appears to be a challenge across most countries evaluated. Of the countries reviewed, availability of essential medicines in Indonesia is higher and has a positive impact on EML implementation. Lack of systematic procurement, supply, and distribution systems and poor demand management are the key resons for low availability.

Reimbursement

The impact of reimbursement appears to be neutral in most countries. The reimbursement scenario in Indonesia appears to have a positive impact on EML implementation as patients are being enrolled in the national reimbursement scheme, which is aimed at achieving 100% enrollment by 2019.[19] The reimbursement conditions in China also appear to be very supportive of EML implementation with coverage under the three health insurance schemes estimated to be at a level of 95% of the population.[20]

Government Initiative

Most governments are attempting to increase the implementation of their EML. However, lack of sufficient planning and support to the government initiatives in low income countries are barriers to effective implementation of the EMLs. In Indonesia, the government is planning to lift import duties for raw materials, which in turn is expected to reduce the drug prices by at least 5%.[21] The Brazilian Government, meanwhile, has introduced a network of 550 popular pharmacies providing free of charge essential drugs.[22]

Patent/Licensing

The role of patents and efforts at licensing medicines – both voluntary licensing by patent holders and national imposition of compulsory licensing – as well as parallel imports, are mechanisms cited as important considerations for those patent-protected drugs included on EMLs. However, the effect to date on implementation of EMLs at a national level does not appear to be significant in most of the countries reviewed. In countries like India, Indonesia, and the Philippines, the government has initiated compulsory licensing and price control to ensure better affordability and availability, while the long-term impact and sustainability of these mechansims is unclear.

Healthcare Infrastructure

The status of healthcare infrastructure is a major concern with respect to implemention of EMLs in most of the countries evaluated. Drug shortages appear to be a common problem likely caused by scarcity of funds as well as poor management of procurement and distribution. This may force patients to purchase medicines through private channels resulting in increased out-of-pocket expenses. Stock-outs are a common scenario in the African nations such as Malawi and Tanzania. Lack of qualified staff and limited capacity in public hospitals are compounding factors negatively affecting implementation.

Access to Essential Medicines in Public and Private Health Facilities

Although the percentage of population with access to essential medicines has improved over the years, the number of people without access is still high. Surveys have been conducted in multiple countries using the WHO/HAI methodology for measuring medicine availability, price, affordability, and price components (See Exhibit 11). A survey conducted in 27 developing countries in 2007 revealed that the average availability of essential medicines in the public sector was only 34.9%, while availability in the private sector was 63.2%.[23] In 2008, another study conducted in 36 developing and middle income countries showed that the average public sector availability of generics ranged from 29.4% to 54.4%.[24] Further surveys conducted across 23 countries revealed that implementation of EMLs has resulted in higher availability of essential medicines compared to non-essential medicines; however, there is still a need for government support as availability in the public sector is less compared to the private sector in low and lower middle income countries.[25]

Low availability of essential medicines in the public sector is often caused by a lack of public resources due to underfunding or under-budgeting, inaccurate demand forecasting, and inefficient public sector procurement and distribution of medicines. This compels patients into the private sector, where availability of medicines is relatively high but more costly.

Exhibit 11: Median Availability of Selected Generics in Public and Private Health Facilities Across Low and Middle Income Level Countries[26, 27]

* Above data is sourced from surveys conducted using the WHO/HAI standard methodology between 2001 and 2012; data for Malawi and Brazil is sourced from review articles which have studied availability of selected essential medicines, while those for other countries have been taken from the WHO website, which studied availability of selected generics
* Availability of generics in private and public sectors has been considered here as a surrogate measure of availability of essential medicines since >95% of essential medicines are off-patent generic agents
* Availability for essential medicines with 'lowest price generics' is considered as >90% medicines in the EML are generics
* No appropriate data point available for the public sector in South Africa
Sources: 1. http://apps.who.int/gho/data/node.wrapper.MEDS-2&menu=hide   2. http://www.who.int/bulletin/volumes/85/4/06-033647.pdf

Comparison Across Countries

The cross-country comparison of selected countries reveals a high level of disparity between the country EMLs and the WHO EML in terms of the number of molecules and the focus given to particular therapy areas (See Exhibit 12). While this indicates significant differences, it does not provide underlying causes of these differences.

Exhibit 12: Comparison of Medicines for Selected NCDs and CDs

Note: For South Africa, the hospital list was considered since it has a higher number of drugs and was also recently updated. The Hospital EML is integrated with the standard treatment guidelines and includes supportive drugs for all indications, ex. simvastatin is included under diabetes. *Calculation includes both core and complementary medicines

Source: IMS Institute Analysis
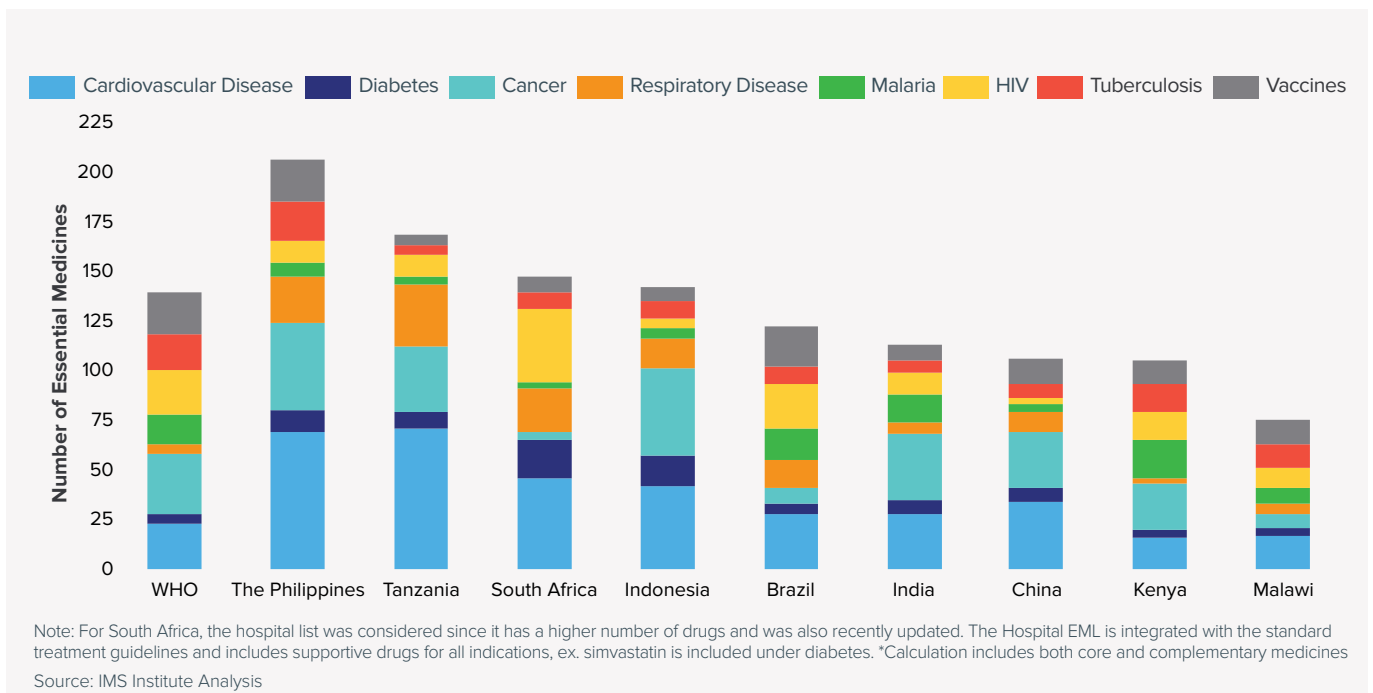
Contribution of Selected NCD and CD medicines

Exhibit 13: Percentage Contribution of Selected NCD and CD Medicines									
	WHO	The Philippines	Tanzania	SA	Indonesia	Brazil	India	China	Kenya	Malawi
NCD	15%	20%	23%	15%	25%	11%	19%	22%	14%	10%
CD	13%	5%	3%	8%	4%	10%	8%	4%	14%	9%

Source: IMS Institute Analysis

With the increasing burden of non-communicable diseases (NCDs), low- and middle-income countries have included a higher share of NCD medicines in the country EMLs. Countries such as Indonesia, Tanzania, China, and the Philippines have a higher percentage of the medicines for NCDs compared to the WHO EML, while Malawi and Brazil appear to have less focus on the inclusion of medicines for NCDs (See Exhibit 13). The Philippines and Brazil have a similar number of vaccines as compared to the WHO EML, while other countries have fewer number of vaccines (See Exhibit 12).
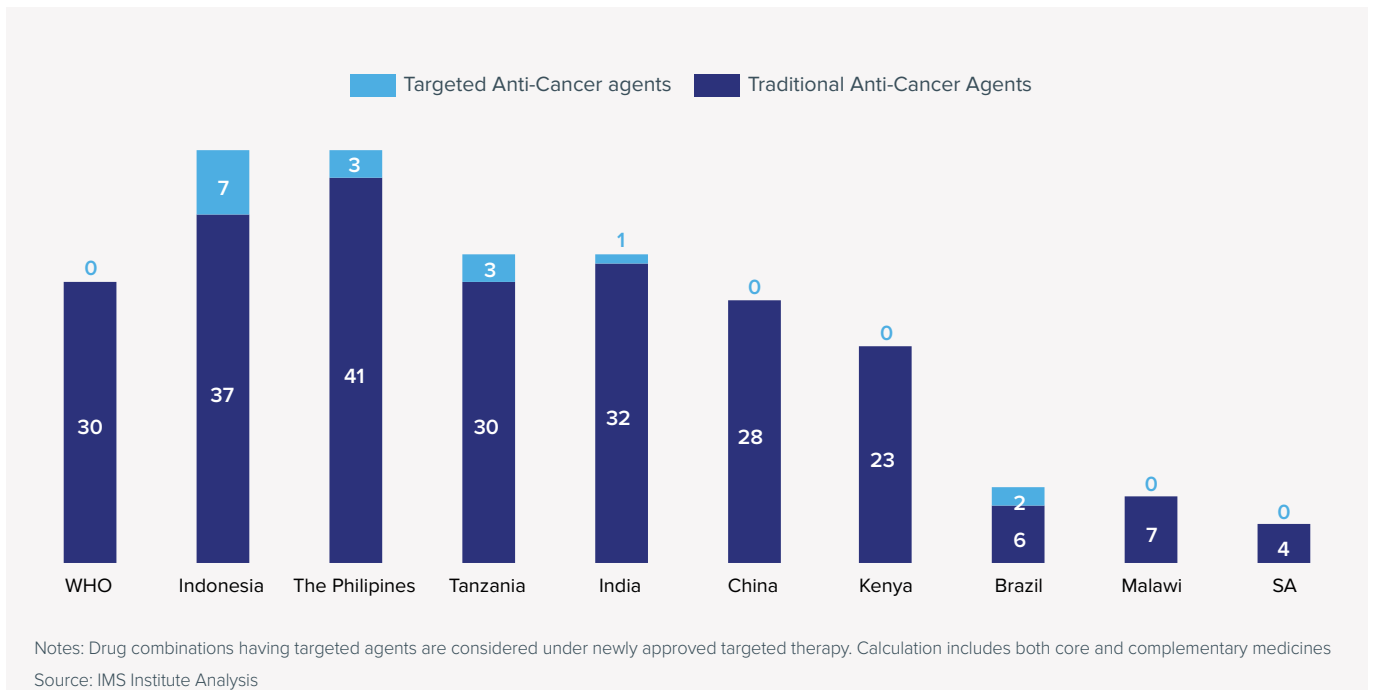
As compared to other evaluated countries, Kenya and Brazil have a considerably higher percentage of medicines for communicable diseases, whereas the other countries have fewer medicines in this category. Of the reviewed NCDs and CDs, cardiovascular medicines form the largest therapy class followed by cancer medicines in all countries evaluated except for India, Kenya and Indonesia, where cancer is the leading therapy class followed by cardiovascular medicines.

In a comparison within the countries evaluated, South Africa and Brazil have the highest number of drugs for HIV in the country EMLs; The Philippines has the highest number of tuberculosis medicines and vaccines; and Kenya, Brazil and India have the highest number of anti-malarial medicines (See Exhibit 12).

Inclusion of Newer Cancer Drugs in the WHO Model EML

The WHO Model EML has fewer cancer medicines compared to some of the countries evaluated (See Exhibit 14). While new generation anti-cancer agents such as trastuzumab, imatinib and rituximab are present in some of the country EMLs, they are absent in the WHO Model EML. All the 30 agents included in the current WHO Model EML are traditional anti-cancer agents (See Exhibit 14). The proposed list of cancer medicines to be evaluated for 2015 revision has an additional 22 anti-cancer agents, including new-generation, patented agents.

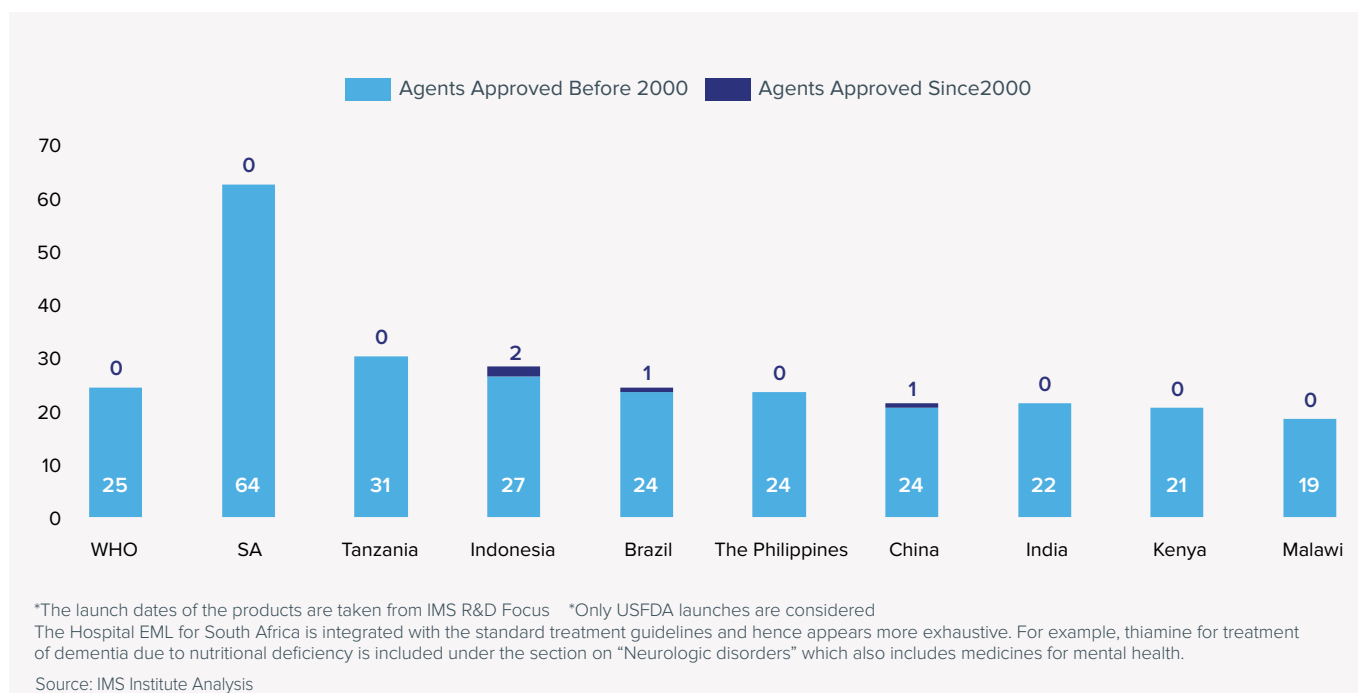## Exhibit 14: Inclusion of Newer Cancer Drugs in the WHO Model EML

Notes: Drug combinations having targeted agents are considered under newly approved targeted therapy. Calculation includes both core and complementary medicines
Source: IMS Institute Analysis

Inclusion of Newly Approved Mental Health Drugs in the WHO Model EML

While the number of drugs for mental health appear to be in the similar range across the WHO EML and the country EMLS, the WHO Model EML does not include any mental health medicines approved after 2000. Similarly, most of the country EMLs have also not included any drugs approved after 2000 (See Exhibit 15). Indonesia, Brazil, and China are the only exceptions. While Indonesia has included clobazam and carbidopa + entacapone + levodopa in the EML, Brazil and China have ziprasidone and aripiprazole, respectively.

Exhibit 15: Inclusion of Newly Approved Mental Health Drugs in the WHO Model EML

Agents Approved Before 2000   Agents Approved Since 2000

	WHO	SA	Tanzania	Indonesia	Brazil	The Philippines	China	India	Kenya	Malawi
Since 2000	0	0	0	2	1	0	1	0	0	0
Before 2000	25	64	31	27	24	24	24	22	21	19

*The launch dates of the products are taken from IMS R&D Focus   *Only USFDA launches are considered
The Hospital EML for South Africa is integrated with the standard treatment guidelines and hence appears more exhaustive. For example, thiamine for treatment of dementia due to nutritional deficiency is included under the section on "Neurologic disorders" which also includes medicines for mental health.

Source: IMS Institute Analysis

The WHO vs. Country-Level Comparison of Oral Anti-Diabetic Drugs

Below is the comparison of oral anti-diabetic agents across the countries and the WHO. A total of 12 molecules are used in one or more EMLs, though only three are included in the WHO model list. While all countries studied include metformin in their EML for diabetes, each of the other agents has more selective representation on country lists (See Exhibit 16). Beyond these oral anti-diabetic agents, insulin's indispensible nature is recognized by its inclusion in the WHO EML and other country EMLs.

Exhibit 16: WHO vs. Country-Level Comparison of Oral Anti-Diabetic Drugs										
Product	WHO	Indonesia	The Philippines	China	Tanzania	SA	Brazil	India	Kenya	Malawi
Acarbose		✔	✔	✔						
Chlorpropamide		✔	✔		✔					
Glibenclamide		✔	✔	✔	✔	✔	✔	✔	✔	✔
Gliclazide	✔	✔	✔		✔	✔	✔			
Glimepiride		✔		✔						
Glipizide		✔	✔	✔	✔					
Gliquidone		✔								
Glucagon	✔		✔			✔		✔		
Glyburide				✔						
Metformin	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
Pioglitazone		✔								
Rosiglitazone			✔							

*Only Oral Hypoglycemic agents have been considered for analysis

Source: IMS Institute Analysis

- Prevalence estimates of diabetes among adults aged between 20 and 79, in 2010 was nearly the same for China, South Africa, and Indonesia;[28] however, the number of diabetes drugs included in EMLs varies widely – from nine in Indonesia, to six in China and four in SA

- Compared to the WHO EML, Indonesia has a higher number of drugs in the diabetes section including pioglitazone which belongs to a new class of oral anti-diabetic (9 in Indonesia vs. 3 in the WHO)

- As of 2011, glibenclamide, glucagon, and metformin were included in the WHO EML. Gliclazide was added in 2013. Even though glibenclamide is mentioned in the 2013 WHO EML, it is not listed along with the other medicines; only a note mentioning that it is not recommended for patients above 60 years[5]

- Kenya and Malawi have only two drugs, glibenclamide and metformin, listed for diabetes

- First generation anti-diabetic drugs, metformin and glibenclamide, are included in the EML for most countries

Country-Specific Case Studies

Brazil

Brazil published its first EML in 1964 (known as RENAME – the Basic Value and Priority Biological Products and Materials for Use Pharmaceutical Human and Veterinary), 13 years before the initial recommendation made by the WHO in 1977.[29] This EML not only covers assistance for primary care but also covers treatment options for health situations of medium and high complexity.

The selection of medicines in RENAME is based on national health priorities, as well as the safety, efficacy, and availability of products.

Process used for Brazil EML:

The Brazilian EML (RENAME 2012) has adopted the classification of drugs into therapeutic classes from the WHO EML. The selection of the medicines meets the orientation of the WHO EML but consists of drugs effectively suited for Brazil epidemiological conditions.

The Brazilian committee has considered the 16th WHO Model EML (2009) for children as a guideline to create its own pediatric list (RENAME pediatric).[29] After the analysis they made certain adjustments to the WHO list, for example, Drugs Pharmaceutical form of review and/or concentration and/or composition. There is a limitation of adjustment in the RENAME list due to a lack of drugs with registration in Brazil for use in pediatrics or lack of presentations for pediatric use traded in the country. Due to these challenges the Brazilian committee decided to wait for better evidence before making their selection.

Comparison of the Brazil's EML and WHO's current EML: (See Exhibit 17)

- The Brazil EML has more unique molecules compared to the WHO EML (468 vs. 374)
- The number of medicines for non-communicable diseases is lower in the Brazil EML compared to the WHO EML (55 in Brazil vs. 63 in the WHO)
- The Brazil EML specifies fewer drugs for the Cancer category compared to the WHO EML (8 in Brazil vs. 30 in the WHO)
- The Brazil EML has a higher number of CVS drugs (28 in Brazil vs. 23 in the WHO)
- The Brazil EML includes fewer number of tuberculosis drugs (9 in Brazil vs. 18 in the WHO)
- There is a significant similarity with respect to the number of vaccines and the choice of inclusion of the vaccines in the two EMLs. 17 out of 20 vaccines in Brazil EML are similar to the WHO EML

Exhibit 17: Summary of Similarities & Differences between the WHO & Brazil EML[6, 30]						
Disease Areas	WHO EML	Brazil EML	Percentage share (%)	Number common to both lists	Present in Brazil NLEM, absent in WHO EML	Present in WHO EML, absent in Brazil NLEM
Non-Communicable Diseases (NCDs)	**63**	**55**	**11%**	**18**	**37**	**45**
Cardiovascular Diseases	23	28	6%	10	18	13
Diabetes	5	5	1%	3	2	2
Cancer	30	8	2%	2	6	28
Respiratory Diseases	5	14	3%	3	11	2
Communicable Diseases (CDs)	**55**	**47**	**10%**	**29**	**18**	**26**
Malaria	15	16	3%	8	8	7
HIV	22	22	5%	13	9	9
Tuberculosis	18	9	2%	8	1	10
Vaccines	**21**	**20**	**4%**	**17**	**3**	**4**
Others	**292**	**362**	**75%**	**81**	**281**	**211**
Total	**431***	**484***	**100%**	**145***	**339***	**286***

*Total number of drugs includes duplicates across different indications

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://pfarma.com.br/noticia-setor-farmaceutico/carreira-farmaceutica/1541-download-rename-2013.html

Assessment of Current Implementation and Specific Mechanisms Impacting Implementation

Despite the government's initiatives for ensuring implementation, problems regarding high prices, poor availability in public sector facilities and low affordability persist.

Healthcare is a constitutional right in Brazil and the state has committed itself to guaranteeing access to health services. Public healthcare is provided through the National Health Care System, known as Unified Health System – SUS and more than 75% of the country's people rely exclusively on it for their healthcare coverage.[31] Yet, the government accounts for only 44% of the country's total healthcare spending. The remaining 56% is private, and of that, two-thirds is paid out-of-pocket by consumers.[32]

The range of products stocked by most public hospitals has traditionally been limited by a combination of funding issues, supply problems and a restrictive approach to updates of the EML. Public sector availability of generics or similar medicines is lower than expected, and consequently, patients resort more often to purchasing medicines in private pharmacies, thus impacting the affordability of medicine.

China

The first EML was published by the Ministry of Health (MOH) in 1982. By 2004, the EML included 2,033 products, including 1,260 Chinese herbal preparations and 773 chemical and biological medicines.[33] The latest EML of China was published in 2012.[34]

Process used for China EML:

The MOH is responsible for the selection of essential medicines for inclusion in the national essential drugs list. The MOH forms a committee consisting of experts in the field of medicine, pharmaceutical economics, pharmacy, health insurance, health management, and pricing. These experts are divided into two mutually exclusive groups, a consult group and a review group.[35] The consult group evaluates medicines and proposes their opinions on the medicines before forming candidate lists, while the reviewing group votes on the candidate list and determines the draft list. The draft list receives comments from government departments before being handed over to managing authority for final approval. The Chinese selection system also accepts suggestions from the public and stakeholders for changes to the list.

The Provincial government has the authority to include more medicines at the provincial level and publish a provincial list, transfer the power of selection to municipal governments while setting upper limit or range or opt to not conduct provincial selection. However, Provincial governments cannot remove medicines already included in the national list.[36]

Comparison of China's EML and WHO's current EML: (See Exhibit 18)

- China's EML has fewer unique molecules compared to the WHO EML (342 vs. 374)
- The number of medicines for non-communicable diseases is higher in China's EML compared to the WHO's EML (80 in China vs. 63 in the WHO)
- China's EML has 28 drugs for cancer, including 15 drugs similar to the WHO
- The China EML has a higher number of CVS drugs (34 in China vs. 23 in the WHO)
- There is a significant difference in the number of drugs for communicable diseases between the lists. The China EML has considerably fewer drugs for TB (7 in China vs. 18 in the WHO), malaria (4 vs. 15), and HIV (3 vs. 22)
- There is a higher number of drugs for non-communicable diseases compared to communicable diseases (80 for NCDs vs. 14 for CDs)

Exhibit 18: Summary of Similarities & Differences between the WHO & China EML[6, 34]						
Disease Areas	WHO EML	China EML	Percentage share (%)	Number common to both lists	Present in China NLEM, absent in WHO EML	Present in WHO EML, absent in China NLEM
Non-Communicable Diseases (NCDs)	**63**	**80**	**22%**	**31**	**49**	**32**
Cardiovascular Diseases	23	34	10%	11	23	12
Diabetes	5	8	2%	2	6	3
Cancer	30	28	8%	15	13	15
Respiratory Diseases	5	10	3%	3	7	2
Communicable Diseases (CDs)	**55**	**14**	**4%**	**10**	**4**	**45**
Malaria	15	4	1%	4	0	11
HIV	22	3	1%	1	2	21
Tuberculosis	18	7	2%	5	2	13
Vaccines	**21**	**13**	**4%**	**13**	**0**	**8**
Others	**292**	**249**	**70%**	**80**	**169**	**212**
Total	**431***	**356***	**100%**	**134***	**222***	**297***

*Total number of drugs includes duplicates across different indications

**Analysis does not include traditional Chinese medicine

For Vaccines –NIP – National Immunization Program was referred to get the names of the Vaccines. Immunologicals are added in vaccines category. Also, Combination vaccines are divided into mono vaccines.

Sources:

1.http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://itrade.gov.il/china-en/2013/04/23/national-essential-medicine-list-2012-edition-released/

In China EML, the number of traditional medicines increased from 102 in 2009 to 203 in 2012.[37] Among 13 provinces that have published their PEDL since March 2013, four – Shanghai, Shaanxi, Jilin and Hunan – made no additions to the 2012 NEDL, and the other nine added an average of approximately 250 molecules (in a range from 57 to 535). Roughly half of the molecules in the nine newly-announced PEDLs are TCM products. Among the Western medicine molecules, 6%–37% (23% on average) are in the portfolios of leading multiple national corporations.[38]

Assessment of Current Implementation and Specific Mechanisms Impacting Implementation

The national EML has become more important in China since 2009 with the expansion of coverage and increase in reimbursement levels as all essential medicines are included in the insurance reimbursement lists, and their prices are much lower compared with non-essential medicines. The current EML is the first part and intended for primary care. The second part of the EML for secondary hospitals is yet to be released.

Insurance coverage is high, and almost 96% of the population is covered by the three basic medical insurance plans and there are plans to gradually improve the reimbursement coverage under the basic plans.[39]

In terms of healthcare infrastructure, while public institutions are likely to continue as the main providers of hospital care, greater participation of the private sector will be encouraged.

Drugs included in the Essential Drugs List and the National Reimbursement Drugs List are subject to price ceilings to ensure affordability of these medicines.

India

The first National List of Essential Medicines (NLEM) was introduced in 1996 with 2 subsequent revisions in 2003 and 2011.[40]

Process used for India EML:

The Indian NLEM is reviewed in consultation with experts for discussion on evidence-based criteria for addition and deletion of medicines from the NLEM. This is followed by therapeutic area wise group discussion by clinicians, pharmacologists, pharmacists, scientists, and regulators. The updated list is then presented for an open-house discussion, and the draft is forwarded to NLEM for considerations with NLEM core committee after modifications.[40]

Comparison between India's EML and WHO's current EML: (See Exhibit 19)

- The Indian EML has fewer unique molecules compared to the WHO EML (352 vs. 374)

- The number of medicines for non-communicable diseases is higher in the Indian EML compared to the WHO EML (74 in India vs. 63 in WHO) while the reverse is true in case of communicable disease (31 in India vs. 55 in the WHO)

- While the number of anti-cancer drugs are similar between the lists of the WHO and India (33 vs. 30), there are 18 anti-cancer drugs which are present in the Indian EML but absent from the WHO EML. As in the WHO EML, most drugs in the Indian EML are generic agents. However, a key difference is the inclusion of imatinib in the Indian EML. While this drug has been on the market for over a decade for CML and is accepted as a standard of care for chronic myeloid leukemia, it is still not included in the WHO EML. Application for inclusion in 2015 EML revision is to be evaluated this year

- The WHO EML provides fixed-dose combination drugs for tuberculosis, whereas the Indian EML only gives the names of individual drugs

- Indian EML has a higher number of drugs for non-communicable diseases compared to communicable diseases (74 for NCDs vs. 31 for CDs)

The Indian NLEM is not considered comprehensive and several issues have been identified such as non-inclusion of pediatric formulations, errors in the strengths of formulations for drugs included, omission of important oral anti-diabetic medicines such as glimeperide and glicazide.

Assessment of Current Implementation and specific mechanisms impacting implementation:

The current level of implementation appears to be poor with factors such as poor medicine supply and distribution systems, insufficient health facilities and staff, low investment in health, the high cost of medicines adversely affecting the availability of medicines, and lack of confidence in the quality of medicines supplied through the public healthcare system.

Most patients either choose or are forced to seek treatment in private clinics and hospitals due to inadequate healthcare infrastructure. An estimated 80% of outpatient consultations and 60% of inpatient treatments take place in private facilities and only 22% of the population has access to public healthcare.[41] Also, there is a considerable variation between rural and urban areas in terms of healthcare infrastructure and access to healthcare services due to the disparity in healthcare services, which are skewed towards urban centers.

Exhibit 19: Summary of Similarities & Differences between the WHO & India EML[6, 40]						
Disease Areas	WHO EML	India EML	Percentage share (%)	Number common to both lists	Present in India NLEM, absent in WHO EML	Present in WHO EML, absent in India NLEM
Non–Communicable Diseases (NCDs)	**63**	**74**	**19%**	**29**	**45**	**34**
Cardiovascular Diseases	23	28	7%	10	18	13
Diabetes	5	7	2%	3	4	2
Cancer	30	33	9%	15	18	15
Respiratory Diseases	5	6	2%	1	5	4
Communicable Diseases (CDs)	**55**	**31**	**8%**	**14**	**17**	**41**
Malaria	15	14	4%	2	12	13
HIV	22	11	3%	7	4	15
Tuberculosis	18	6	2%	5	1	13
Vaccines	**21**	**8**	**2%**	**5**	**3**	**16**
Others	**292**	**270**	**70%**	**108**	**162**	**184**
Total	**431***	**383***	**100%**	**156***	**227***	**275***

*Total number of drugs includes duplicates across different indications

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://www.who.int/selection_medicines/country_lists/India_NLME_2011.pdf?ua=1

Funding issues and shortcomings in procurement and distribution systems result in poor supply of essential medicines. Shortages are a particular issue in public health centers, but also affect availability in government hospitals, where patients are sometimes forced to purchase products from alternative sources.

The Government of India is currently negotiating with the pharmaceutical industry to lower the cost of essential drugs. In 2014, the government extended the price control to products beyond the list of EML for over 100 cardiovascular and diabetes drugs.[41] The appropriate approach to compulsory licensing – in accordance with the provisions of the Agreement on the Trade–Related Aspects of Intellectual Rights (TRIPS) – is also under review and discussion.

Indonesia

The National List of Essential Medicines in Indonesia was first introduced in 1978. The NLEM, which is named as DOEN, is revised periodically every three to four years.[42]

Process used for Indonesia EML:

The FORNAS (National Formulary) for Indonesia is developed through an expert committee. There is a high level of similarity in the national process and the WHO EML process. The FORNAS takes the DOEN as the reference and expands it into a larger list.

A survey conducted by the WHO in 2007 for the selection process of essential medicines revealed that the aspect of transparency in the process was not sufficient. After that the selection of expert panel members has been tightly scrutinized, including valuation against conflict of interest. Transparency is also displayed with descriptions of arguments on why a medicine must be deleted from or be added to the prior version.[42]

The WHO's EMLc has been used as one of the guidelines for selecting medicine for children including its formulation. The guidelines used for donation of medicines fulfill the requirements as described in the WHO Guidelines for Medicines Donations 1999. Medicines which are submitted, but not included in the WHO's EML are specifically scrutinized.[42]

Comparison between Indonesia's EML and WHO's current EML: (See Exhibit 20)

- Indonesia's EML has fewer unique molecules compared to the WHO EML (323 vs. 374)

- The Indonesia EML has a significantly higher number of drugs compared to WHO EML for cardiovascular diseases (42 in Indonesia vs. 23 in the WHO), medicines for respiratory diseases (15 in Indonesia vs. 5 in the WHO) and cancer (44 in Indonesia vs. 30 in the WHO)

- A significant number of cardiovascular, respiratory, and cancer drugs present in Indonesia's EML do not feature in the WHO EML

- There is a difference in the number of drugs for communicable diseases between the lists. Indonesia's EML has considerably fewer drugs for HIV (5 in Indonesia vs. 22 in the WHO), malaria (5 in Indonesia vs. 15 in the WHO) and tuberculosis (9 in Indonesia vs. 18 in WHO)

- There is a higher degree of focus on non-communicable diseases compared to communicable diseases (119 for NCDs vs. 19 for CDs) in Indonesia's EML

- A notable difference between Indonesia's EML and the WHO's EML is the inclusion of imatinib, rituximab, and trastuzumab in Indonesia's list for the treatment of cancer.

Exhibit 20: Summary of Similarities & Differences between the WHO & Indonesia EML[6, 42]						
Disease Areas	WHO EML	Indonesia EML	Percentage share (%)	Number common to both lists	Present in Indonesia EML, absent in WHO EML	Present in WHO EML, absent in Indonesia EML
Non-Communicable Diseases (NCDs)	**63**	**116**	**25%**	**37**	**79**	**26**
Cardiovascular Diseases	23	42	9%	13	29	10
Diabetes	5	15	3%	3	12	2
Cancer	30	44	9%	18	26	12
Respiratory Diseases	5	15	3%	3	12	2
Communicable Diseases (CDs)	**55**	**19**	**4%**	**17**	**2**	**38**
Malaria	15	5	1%	5	0	10
HIV	22	5	1%	4	1	18
Tuberculosis	18	9	2%	8	1	10
Vaccines	**21**	**7**	**1%**	**7**	**0**	**14**
Others	**292**	**329**	**70%**	**195**	**134**	**97**
Total	**431***	**471***	**100%**	**256***	**215***	**175***

*Total number of drugs includes duplicates across different indications

Sources:
1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf
2. "National List of Essential Medicines (NLEM), 2014 - Indonesia"

Assessment of Current Implementation and specific mechanisms impacting implementation:

Despite the operational problems in implementation of Indonesia's National Formulary, FORNAS, the government appears to be committed to improve the level of implementation. Some challenges include difficulties in price setting through tenders, inability to forecast drug consumption, lack of private drug reimbursement, etc.

The EML and public sector healthcare implementation is done through a tripartite mechanism. The MoH forms the FORNAS through an expert committee across various disease areas, the LKPP procures the drugs in the FORNAS through a tender process and the BPJS is a reimbursing organization and manages providers.[42]

Patients continue to fund a substantial proportion of the healthcare bill with out-of-pocket payments accounting for approximately 45% of all healthcare spending.[43] While the government is planning to roll out the National Health Insurance (NHI) system progressively over the next 5 years, with the objective of covering the total population in 2019,[43] the ability of the government to fund NHI over the long-term remains the subject of considerable doubt.

Availability of healthcare infrastructure is varied and fragmented across the island nation. Poor healthcare infrastructure results in low utilization of health services, with access often determined by a mix of income and location as well as insurance status.

Indonesia initiated the compulsory licensing process in 2004 creating agreements with major pharmaceutical companies to reduce prices and make the drugs affordable to the larger population.[44] Drug pricing for patent originators is through case by case negotiation and through tender for off patent generics. Discussions with pharmaceutical manufacturers regarding voluntary licensing arrangements are ongoing as a means to increase the availability of essential medicines in a sustainable framework.

Kenya

The first Kenya Essential Medicines List (KEML) was introduced in 1981 with 2 subsequent revisions in 2003 and 2010.[45]

Process used for Kenya EML:

Although Kenya has the EML, the responsibility for managing this function has not been clearly defined. Furthermore, there are no written standard operating procedures to guide the development and maintenance of the KEML. The National Medicines and Therapeutic Committee has now been mandated to lead the review and revision of future editions of KELM guided by feedback, amendments requested by users, changes in the WHO Model lists and results of other health research.[46]

Comparison between Kenya's EML and WHO's current EML: (See Exhibit 21)

- The KEML has fewer unique molecules compared to the WHO EML (285 vs. 374)

- The number of medicines for communicable and non-communicable diseases is nearly the same (46 for NCDs vs. 47 for CDs) in the Kenya EML

- There are fewer medicines for non-communicable disease in the Kenya EML compared to the WHO EML (46 in Kenya vs. 63 in WHO)

- 12 cancer drugs present in the Kenyan EML do not feature in the WHO EML

- The Kenyan EML has a lower number of drugs compared to WHO EML for cardiovascular disease (16 in Kenya vs. 23 in WHO) and for cancer (23 vs. 30)

- **Assessment of Current Implementation and specific mechanisms impacting implementation:**

The level of implementation appears to be poor due to factors such as:

Poor supply system – In Kenya's drug supply system, the drugs are procured by Kenya Medical Supplies Agencies (KEMSA), which sources from other countries. The system is rigid and unable to cope with health facilities' varied needs

Frequent stock outs – Out of 343 items on KEDL, KEMSA procures only 117 selected items, based on available funds. Also, KEMSA does not provide any incentives to procure pandemic drugs from local pharma to ensure sustainable supply source.[47]

Budgetary constraints – Funding of public hospitals coming from the government allocations are not adequate for sustaining quality healthcare.

Poor policy and guideline dissemination, differential pricing and inappropriate selection of medicines are other factors impacting implementation. The government plans to invest in health technology assessment systems to strengthen the development processes of EML, clinical guidelines and national formulary.

					Present in Kenya NLEM, absent in WHO EML	Present in WHO EML, absent in Kenya NLEM
Disease Areas	**WHO EML**	**Kenya EML**	**Percentage share (%)**	**Number common to both lists**		
Non-Communicable Diseases (NCDs)	63	46	14%	35	11	28
Cardiovascular Diseases	23	16	5%	12	4	11
Diabetes	5	4	1%	2	2	3
Cancer	30	23	7%	18	5	12
Respiratory Diseases	5	3	1%	3	0	2
Communicable Diseases (CDs)	55	47	14%	26	21	29
Malaria	15	19	6%	5	14	10
HIV	22	14	4%	10	4	12
Tuberculosis	18	14	4%	11	3	7
Vaccines	21	12	4%	8	4	13
Others	292	220	68%	138	82	154
Total	431*	325*	100%	207*	118*	224*

Exhibit 21: Summary of Similarities & Differences between the WHO & Kenya EML[6, 45]

*Total number of drugs includes duplicates across different indications

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://apps.who.int/medicinedocs/documents/s18694en/s18694en.pdf

Malawi

The latest edition of Malawi Standard Treatment Guidelines (MSTG) incorporating Malawi Essential Medicines List (MEML) was published in 2009. It provides prescribers and dispensers with the currently recommended treatment as well as preventative schedules for most common disease states found in the country. The EML was first published in 1991, with revisions in 1993, 1998 and 2009.[48]

Process used for Malawi's EML:

The Malawi Standard Treatment Guidelines are developed by the Ministry of Health and all its partners in clinical and pharmaceutical sectors. For the revision of these guidelines, the Government of Malawi is supported by the WHO, MSH/SPS, World Bank, Pharmaceutical organizations and individuals.

The Malawi Essential Drugs Program (MEDP) was established in 1988 as an integral part of the activities of the Ministry of Health, Pharmaceutical Services Department.[49]

Comparison between Malawi's EML and WHO's current EML: (See Exhibit 22)

- The Malawi EML has fewer unique molecules compared to the WHO EML (318 in Malawi vs. 374 in WHO)

- Fewer molecules for non-communicable diseases are included in the Malawi EML compared to the WHO EML (33 in Malawi vs. 63 in WHO)

- The Malawi EML has fewer cancer drugs compared to WHO EML (7 in Malawi vs. 30 in WHO)

- There is a significant difference with respect to drugs included for non-communicable diseases between the lists. Out of 33 NCDs medicines in the Malawi EML, only 17 are similar between the WHO EML and Malawi EML

- There is equal focus on non-communicable diseases and communicable diseases (33 for NCDs vs. 30 for CDs) in the Malawi EML

- Out of 30 drugs present for treatment of Communicable Diseases in Malawi, 27 are similar to WHO EML

Assessment of Current Implementation and Specific Mechanisms Impacting Implementation

The current level of implementation appears to be poor with factors such as poor medicine supply and distribution systems, stock-out situations, unavailability of free medicines and the high cost of medicines in private sector adversely affecting the implementation.

Severe stock-outs have been a major barrier in the availability of essential medicines in Malawi. In 2013, on average, 75% of facilities have experienced significant drug stock-outs with the majority stock-outs of antibiotics, HIV test kits, and vaccines in the clinics.[50] Reasons for this include insufficient deliveries from the Regional Medical Store and differences between the information recorded on the Stock Cards at the health centers and that recorded in Patient Records. The availability and cost of medicines varies between districts leading to inequity of service delivery. Efforts have been made to strengthen the Central Medical Store (CMS) in Malawi. The CMS, established in 1968, is responsible for the procurement and supply of medicines and medical products for the government. However, in practice it does not appear to have the full confidence of key stakeholders.

Exhibit 22: Summary of Similarities & Differences between the WHO & the Malawi EML[6, 48]						
Disease Areas	WHO EML	Malawi EML	Percentage share (%)	Number common to both lists	Present in Malawi NLEM, absent in WHO EML	Present in WHO EML, absent in Malawi NLEM
Non-Communicable Diseases (NCDs)	**63**	**33**	**10%**	**17**	**16**	**46**
Cardiovascular Diseases	23	17	5%	9	8	14
Diabetes	5	4	1%	2	2	3
Cancer	30	7	2%	4	3	26
Respiratory Diseases	5	5	1%	2	3	3
Communicable Diseases (CDs)	**55**	**30**	**9%**	**27**	**3**	**28**
Malaria	15	8	2%	6	2	9
HIV	22	10	3%	10	0	12
Tuberculosis	18	12	3%	11	1	7
Vaccines	**21**	**12**	**3%**	**10**	**2**	**11**
Others	**292**	**271**	**78%**	**76**	**195**	**216**
Total	**431***	**346***	**100%**	**130***	**216***	**301***

*Total number of drugs includes duplicates across different indications
For Vaccines – Combinations of vaccines are broken to mono vaccines

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://apps.who.int/medicinedocs/documents/s18801en/s18801en.pdf

The cost of innovator products in the private sector is approximately three times higher than generics in Malawi.

In 2011, the Malawi Ministry of Health committed to provide free essential medicines to patients at all public health facilities in order to ensure equitable access to healthcare. The country spends about 30% of the national health budget on drugs.[50] Lack of free essential medicines in government clinics and hospitals is observed due to a combination of poor investment in personnel and infrastructure, inadequate resources, corruption and mismanagement.

The Philippines

The national essential medicine list of the Philippines is also known as Philippine National Drug Formulary (PNDF), and was most recently updated in 2008. This 7th edition includes a total of 627 medicines, including 351 in the core list and 276 in the complementary list.[51]

Process used for the Philippines EML:

The PNDF is revised by a consultative and participative process through regular meetings among members of National Formulary Committee (NFC).[51] This is followed by a series of deliberation meetings with different panels of experts from medical schools, Philippine Medical Association, various specialty and subspecialty societies, and government and private hospitals. Inputs from pharmaceutical companies and recommendations of other stakeholders are also considered.

The medicines for the list are selected on the basis of due regard to public health relevance, evidence of efficacy and safety and comparative costeffectiveness.[51]

The national list of essential medicines is a subset of registered medicines divided according to different levels of care.[51]

Comparison between the Philippines' EML and WHO's current EML: (See Exhibit 23)

- The Philippines EML has significantly higher number of unique molecules as compared to the WHO EML (627 in the Philippines vs. 374 in WHO)

- The Philippines EML has a significantly higher number of drugs compared to the WHO EML for all NCDs evaluated: cardiovascular diseases (69 in the Philippines vs. 23 in WHO), medicines for respiratory diseases (23 in the Philippines vs. 5 in WHO), cancer (44 in the Philippines vs. 30 in WHO), and medicines for diabetes (11 in the Philippines vs. 5 in WHO)

- A significant number of cardiovascular, respiratory, cancer and diabetes drugs present in the Philippines EML do not feature in the WHO EML

- A major difference in the list of drugs for treatment of cancer was the inclusion of imatinib, rituximab and trastuzumab in the Philippines EML. While these drugs have been on the market for a long time and are accepted as a standard of care, they are currently not included in the WHO EML

- There is a difference in the number of drugs for communicable diseases between the lists. The Philippines EML has considerably fewer drugs for HIV (11 in the Philippines vs. 22 in WHO) and malaria (7 in the Philippines vs. 15 in WHO)

- There are higher number of medicines for non-communicable diseases compared to communicable diseases (147 for NCDs vs. 38 for CDs) in the Philippines EML

A major revision in the 2008 edition was the incorporation of the WHO listing of immediate release solid oral dosage forms of multisource (generic) pharmaceutical products/active ingredients which should be subjected to in-vivo bioequivalence studies.[51]

Exhibit 23: Summary of Similarities & Differences between the WHO & the Philippines EML[6, 51]					
Disease Areas	**WHO EML**	**The Philippines EML**	**Percentage share (%)**	**Number common to both lists**	**Present in the Philippines EML, absent in WHO EML**	**Present in WHO EML, absent in the Philippines EML**
Non-Communicable Diseases (NCDs)	63	147	20%	50	97	13
Cardiovascular Diseases	23	69	10%	20	49	3
Diabetes	5	11	2%	4	7	1
Cancer	30	44	6%	21	23	9
Respiratory Diseases	5	23	3%	5	18	0
Communicable Diseases (CDs)	55	38	5%	30	8	25
Malaria	15	7	1%	7	0	8
HIV	22	11	2%	9	2	13
Tuberculosis	18	20	3%	14	6	4
Vaccines	21	21	3%	18	3	3
Others	292	516	71%	185	331	107
Total	431*	722*	100%	283*	439*	148*

*Total number of drugs includes duplicates across different indications

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://www.who.int/selection_medicines/country_lists/PhillipinesEML2008.pdf?ua=1

Assessment of Current Implementation and specific mechanisms impacting implementation:

The level of implementation appears to be improving in the Philippines driven by government initiatives, reimbursement support, insurance, and attempts to improve supply, distribution, use, and acceptance of generic drugs and medicines. The government's stated aim is to increase access to essential medicines to 80% of the population by 2016 from 25% in 2010.[52]

However, there is considerable variation between rural and urban areas in terms of healthcare infrastructure and availability of medicines. Government hospitals are currently struggling to meet the growing demands from the population but are short of finance, resources, equipment and adequate stocks of essential medicines.

The Philippines signed The Universally Accessible Cheaper and Quality Medicines Act in June 2008 to control high drug prices, allowing the government to issue compulsory licenses and broaden the parallel importation provision in an attempt to improve access to essential medicines. However, in the absence of regulation for pricing, there is a lack of transparency and varied application of mark ups at present.[52]

South Africa

South Africa's Department of Health published its first EML for Primary Health Care (PHC) in 1998 followed by the list for hospital use in the same year. The hospital list has been updated two times since then, first in 2006 and subsequently in 2012.[53]

Process used for South Africa EML:

The selection criteria of drugs for the EML are based on the WHO guidelines. South Africa did not have a concept of EML prior to the government appointment of a National Essential Drugs List Committee in 1995. The committee includes pharmacists, general practitioners, medical specialists, pharmacologists and public health experts. The initial medicine list is drawn from the most prevalent conditions at the primary care level and the draft list is widely circulated for comments. Standard treatment guidelines are then prepared and an EML is derived.[54]

Comparison between South Africa's EML and WHO's current EML: (See Exhibit 24)

- The South African EML has fewer unique molecules compared to the WHO EML (339 in South Africa vs. 374 in WHO)

- The number of medicines for non-communicable disease is higher in South African EML compared to the WHO EML (91 in South Africa vs. 63 in WHO) and also within their own EML (91 for NCD vs. 48 for CD)

- There is a significantly greater number of drugs for diabetes in South African EML compared to the WHO EML (19 in South Africa vs. 5 in WHO)

- The number of drugs for cancer is significantly less compared to WHO (4 in South Africa vs. 30 in WHO)

- The is no BCG vaccine listed in the South African EML

Assessment of Current Implementation and Specific Mechanisms Impacting Implementation:

A medicine's inclusion in the essential list does not ensure access across public and private facilities. Affordability and availability are the key barriers to access essential medicines. The generic substitution policy has not been effectively implemented by the government despite there being provision to do so.

Inadequacy of skilled resources for healthcare, including pharmacists and pharmacy technicians has always been a challenge in Sub Saharan African countries. There is also lack of adequate financing and coordination with international aid sources, resulting in reduced access to medicines. The public sector healthcare infrastructure that serves more than 80% of the population is under-resourced and has a negative impact on EML implementation.[56]

					Present in South Africa NLEM, absent in WHO EML	Present in WHO EML, absent in South Africa NLEM
Exhibit 24: Summary of Similarities & Differences between the WHO & South Africa EML[6, 55]						
Disease Areas	WHO EML	South Africa EML	Percentage share (%)	Number common to both lists	Present in South Africa NLEM, absent in WHO EML	Present in WHO EML, absent in South Africa NLEM
Non-Communicable Diseases (NCDs)	**63**	**91**	**15%**	**22**	**69**	**41**
Cardiovascular Diseases	23	46	7%	15	31	8
Diabetes	5	19	3%	3	16	2
Cancer	30	4	1%	3	1	27
Respiratory Diseases	5	22	4%	1	21	4
Communicable Diseases (CDs)	**55**	**48**	**8%**	**18**	**30**	**37**
Malaria	15	3	0%	2	1	13
HIV	22	37	6%	10	27	12
Tuberculosis	18	8	1%	6	2	12
Vaccines	**21**	**8**	**1%**	**4**	**4**	**17**
Others	**292**	**470**	**76%**	**157**	**313**	**135**
Total	**431***	**617***	**100%**	**201***	**416***	**230***

*Total number of drugs includes duplicates across different indications

Note: The hospital list was considered against primary healthcare list for comparison since it has more number of drugs and also was recently updated. The hospital EML is integrated with the standard treatment guidelines.

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://www.kznhealth.gov.za/pharmacy/edladult_2012.pdf

Tanzania

Tanzania introduced the first National Essential Medicines List (NEML) in 1991 accompanied by Standard Treatment Guidelines (STG), the second edition followed in 1997 and the third in 2007. The fourth edition was launched in May 2013, and included a new section on symptoms and syndrome.[57]

Process used for Tanzania EML:

The NEML attached to the STG retains its purpose of identifying medicines that are considered essential for the treatment of common disease conditions in Tanzania. A baseline survey of the pharmaceutical sector in Tanzania (2002) revealed that most of the drugs prescribed (98.5%) were included in the NEML.[58]

Comparison between Tanzania's EML and WHO's current EML: (See Exhibit 25)

- Tanzania's EML has more unique molecules compared to the WHO's EML (440 in Tanzania vs. 374 in WHO)

- The number of NCD medicines is higher in the Tanzania's EML compared to the WHO EML (146 in Tanzania vs. 63 in WHO). Of these, at least 116 medicines are present in the Tanzania EML and absent from the WHO EML

- A similar number of cancer drugs are included in both lists (30 in WHO vs. 36 in Tanzania), however only eight molecules are in common

- The Tanzania EML has a higher number of drugs for respiratory conditions compared to the WHO EML (31 in Tanzania vs. 5 in WHO)

Assessment of Current Implementation and specific mechanisms impacting implementation:

Prices of medicines in private health facilities are usually higher than the public and mission sectors. Price controls on essential medicines only takes place through the Medical Stores Department (MSD) tender procedures, but this price control does not guarantee that consumers can access the medicine at the lower price. This also contributes to the fact that medicines are more available in private sector health facilities than in the public and mission sectors. Insufficient stock is also a major issue in Tanzania. A study covering 923 public health facilities (hospitals, health centers and dispensaries) conducted by the Ifakara Health Institute in 2012 found high levels of stock-outs, with only 37% of public facilities, on average, being in stock for any given drug from a set of 14 essential tracer medicines. MSD is the main supplier of medicines to public health facilities and other faith-based organizations but shows insufficiency in the procurement of medicines.[59]

Another factor that affects the implementation of EML is its revision cycle. There is a significant gap in the revision cycle of the NEML and STG leading to treatment regimens becoming outdated and prescribers losing confidence in them.[60] The local government has taken some steps to increase the access and availability of essential medicines in the country. Accredited Drug Dispensing Outlets (ADDOs) were established by the Tanzanian FDA in 2003. The national essential drugs program criteria ensures that staff from small, privately operated retail outlets were trained to sell a list of essential medicines, including selected prescription drugs.

Exhibit 25: Summary of Similarities & Differences between the WHO & Tanzania EML[6, 57]						
Disease Areas	WHO EML	Tanzania EML	Percentage share (%)	Number common to both lists	Present in Tanzania NLEM, absent in WHO EML	Present in WHO EML, absent in Tanzania NLEM
Non–Communicable Diseases (NCD)	**63**	**143**	**23%**	**30**	**113**	**33**
Cardiovascular Diseases	23	71	12%	17	54	6
Diabetes	5	8	1%	3	5	2
Cancer	30	33	5%	8	25	22
Respiratory Diseases	5	31	5%	2	29	3
Communicable Diseases (CD)	**55**	**20**	**3%**	**16**	**4**	**39**
Malaria	15	4	1%	3	1	12
HIV	22	11	2%	8	3	14
Tuberculosis	18	5	1%	5	0	13
Vaccines	**21**	**5**	**1%**	**4**	**1**	**17**
Others	**292**	**445**	**73%**	**136**	**309**	**156**
Total	**431***	**613***	**100%**	**186***	**427***	**245***

*Total number of drugs includes duplicates across different indications

Sources:

1. http://www.who.int/medicines/publications/essentialmedicines/18th_EML_Final_web_8Jul13.pdf

2. http://apps.who.int/medicinedocs/documents/s20988en/s20988en.pdf

Considerations for Future Revisions of the WHO Model EML

While the WHO Model EML is now an established ideal for developing national EMLs, challenges persist in terms of its adaptation to nation-specific scenarios, and its effective implementation driven by availability, access, and affordability, as well as measuring cost-effectivness. As the next revision of the WHO Model EML approaches in 2015,[61] a number of areas are of growing relevance and importance, and reflect the changing role of and demand for medicines globally.

EML and Universal Health Coverage

As the United Nations wraps up the Millennium Development Goals (MDG) program in 2015,[62] Universal Health Coverage offers a way of sustaining gains and protecting investments achieved in the current set of health-related MDG.

The goal of universal health coverage is to ensure that all people obtain necessary health services without suffering financial hardship when paying for them. This concept is based on the 1948 WHO Constitution, which declares health a fundamental human right and commits to ensuring the highest attainable level of health for all.[62]

The impact of Universal Health Coverage (UHC) on a population's health and its importance in ensuring sustainable development and reduction of poverty and social inequities is well established. UHC is the hallmark of a government's commitment to improve the well-being of all its citizens. An efficient health system, affordability and accessibility to essential medicines, and availability of trained health workers are important for achieving the objective of universal health coverage.

The concept of EML is closely linked to universal health coverage, and the availability of essential medicines is a measure of successful implementation of universal health coverage. Most countries aiming to implement UHC attempt to provide access to at least essential medicines in the national list and since the national list is usually adapted from the WHO Model list, the selection of medicines for the WHO Model list is critical and should reflect country-level requirements at least on a broader level.

However, comparison across the selected countries indicates significant disparity between the WHO Model EML and the country-specific lists. While all 9 countries evaluated include additional agents in their lists compared to the WHO EML, there were a significant number of drugs which featured on the WHO list but not on the country lists, indicating a lack of "acceptance" of the WHO list. While some of this difference is due to disease prevalence and local prioritization, other reasons for this are unclear. As the number of medicines on the WHO list increases and broadens, it may be helpful to differentiate a core set of medicines that the WHO believes should be a priority for all countries from those medicines that may be a priority depending upon local disease prevalence and conditions. Further evaluation, in terms of WHO's approach for the Model EML and countries' perspectives for adaptation, is necessary to understand and address this scenario and guide future revisions.

Ensuring Continuing Relevance with Disease Treatment Evolution and Emergence of Innovative Therapy Options

Currently, generics comprise approximately 95% of the medicines in the WHO EML.[63] There appears to be a major lag in terms of including newer medicines in the list. The category of anti-neoplastic agents is a key example for this. Even as newer medicines such as imatinib, rituximab, and trastuzumab have drastically changed the way cancer is now managed, these medicines fail to find a mention in the current WHO EML, even as they are included in country lists. The approach for including medicines in the WHO EML will need revisiting to ensure relevance with the advances in medicine, and medicines' selections need to be updated in a timely manner to reflect new therapeutic options and changing therapeutic needs.

According to the Global Burden of Disease report, mortality due to communicable diseases is expected to decrease significantly by 2020, while the proportion of deaths due to non-communicable diseases is projected to increase from 55% in 1990 to 73% in 2020.[64] This change in disease burden combined with an increase in life expectancy makes it imperative for the EML updates to be in line with the changing requirements.

Intellectual Property Rights, Trade laws, and WHO EML

The impact of the patent laws and TRIPS agreement on access to essential medicines has been a much discussed topic in recent years. While the Doha declaration provides solutions to ensure access to medicines as priorities, the WHO too attempts to provide appropriate technical assistance and country support to Member States for promoting implementation of the TRIPS Agreement, consistent with the protection of public health and promotion of access to medicines in line with the Doha declaration.

A database analysis, published in 2012, on the trends in compulsory licensing since Doha Declaration revealed that most compulsory licensing episodes occurred between 2003 and 2005, involved drugs for HIV/AIDS, and occurred in upper-middle-income countries (UMICs) with significant activity by Thailand. The analysis found that while the intention of the Doha Declaration was to ensure access and availability of medicines, a higher level of compulsory licensing activity was observed in the upper-middle income countries rather than the intended beneficiaries, viz. the poorer countries. The authors hypothesized that this could be due to better ability of UMICs to withstand political pressures and threats of retaliatory actions compared to poorer nations.[66]

It appears that the Doha Declaration is unlikely to have significant impact on access to pharmaceuticals for communicable diseases other than HIV/AIDS in developing and low-income countries.

The current WHO EML includes very few patent protected products resulting in limited access to many life-saving drugs that typically have relatively high costs. Even as the WHO evaluates inclusion of several patented agents for its 2015 revision, a broader initiative might be required across countries and in partnership with all stakeholders, including industry to ensure that patents and price do not become barriers to access for life-saving medicines.

Procurement and regulatory systems

While the WHO provides independent data and technical support to countries to help with the issue of intellectual property rights, ensuring access to medicines is the duty of the national government. Poor infrastructure and issues with procurement and supply are key factors negatively affecting the implementation of the national EMLs in many countries. Shortages of essential medicines in public health facilities are a major issue in many of the low and middle-income countries. For example, 75% of the facilities are thought to have experienced significant drug stock-outs in recent years in Malawi despite the formal policy commitment to free essential medicines.[66]

Procurement and supply of essential medicines in low and middle-income countries is often affected by the political climate of the country as well as patronage dynamics and corruption. In addition to these, finance, technology, infrastructure, and IP constrains are other bottlenecks for the production and procurement of essential medicines. While the WHO does provide guidance in this respect, the onus for action ultimately rests with the individual countries.

Pricing and Reimbursement

Cost of medicines is often a major strain on the patient's financial resources. In the absence of comprehensive reimbursement system and insurance coverage, out-of-pocket payment is often adopted for accessing healthcare services and eventually patients have to bear the financial burden.

While countries such as China and Indonesia are moving towards total coverage and reimbursement with Universal Health Coverage, this is still a distant dream for countries such as Malawi.[39, 43]

Initiatives to ensure access to essential medicines are being taken up worldwide, with the WHO providing technical guidance and inputs, as appropriate. WHO's support of programs such as universal health coverage and the Doha Declaration are evidence of the agency's commitment towards improving access. However, much needs to be done at the country level in terms of implementing the agency's suggestions and inputs to make sure that benefits reach patients in need and the aim of "health for all" is achieved.

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About the Institute

The IMS Institute for Healthcare Informatics leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved patient care. With access to IMS Health's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using IMS Health information and expertise to support the advancement of evidence-based healthcare around the world.

Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

The IMS Institute for Healthcare Informatics

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About IMS Health

IMS Health is a leading global information and technology services company providing clients in the healthcare industry with comprehensive solutions to measure and improve their performance. End-to-end proprietary applications and configurable solutions connect 10+ petabytes of complex healthcare data through the IMS One™ cloud-based master data management platform, providing comprehensive insights into diseases, treatments, costs and outcomes. The company's 15,000 employees blend global consistency and local market knowledge across 100 countries to help clients run their operations more efficiently. Customers include pharmaceutical, consumer health and medical device manufacturers and distributors, providers, payers, government agencies, policymakers, researchers and the financial community.

As a global leader in protecting individual patient privacy, IMS Health uses anonymous healthcare data to deliver critical, real-world disease and treatment insights. These insights help biotech and pharmaceutical companies, medical researchers, government agencies, payers and other healthcare stakeholders to identify unmet treatment needs and understand the effectiveness and value of pharmaceutical products in improving overall health outcomes. Additional information is available at www.imshealth.com.

Mobile

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