Updating National Essential Medicine Lists

A Step-by-Step Advocacy Guide

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ACRONYMS AND ABBREVIATIONS

EML	Essential Medicines List
MOH	Ministry of Health
RMNCH	Reproductive, Maternal, Newborn, and Child Health
UNCOLSC	UN Commission on Life-Saving Commodities for Women And Children
USAID	United States Agency for International Development
WHO	World Health Organization

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BACKGROUND

In 2012, the UN Commission on Life-Saving Commodities for Women and Children (UNCOLSC) identified 13 overlooked reproductive, maternal, newborn, and child health (RMNCH) commodities[1] for safeguarding the health and well-being of the world's women, newborns, and children. According to the Commission, if these 13 commodities were more widely available and properly used, they could save the lives of more than 6 million women and children per year (UNCOLSC, 2012). The UNCOLSC identified key areas of action to ensure their widespread availability and use in low- and middle-income countries. One priority area is ensuring these commodities are included in national essential medicines lists (EMLs), as one step towards ensuring their availability in the public health sector.

In some countries, national EMLs are not regularly updated and do not include key RMNCH commodities—even when there is a solid evidence base for their effectiveness and safety. An analysis in 2012 (Hill et al, 2012) showed that essential medicines for women and children are not universally listed in national EMLs. For example, magnesium sulfate—a medicine proven effective in preventing pre-eclampsia and treating eclampsia—appeared on the essential medicines lists of only 50% of countries surveyed.

The World Health Organization (WHO) defines essential medicines as those that meet the priority health needs of a given population. These medicines are identified as essential because they meet specific criteria, including:

- Relevance to public health/prevalence of disease
- Evidence of efficacy and safety
- Costs and cost-effectiveness

According to WHO, essential medicines must be available "at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford." (WHO, 2015) The WHO developed its Model List of Essential Medicines to guide national governments in selecting those medicines and technologies that best address public health needs. Every two years, WHO convenes an expert committee to update the model list to review new evidence and developments in relation to medicines that will best address public health needs The WHO Model List forms the basis of national medicine policy in many countries, and governments often refer to WHO recommendations when making decisions on which medicines to prioritize in their national lists (IMS Institute for Healthcare Informatics, 2015).

A country's national EML is a selective list of medicines and technologies approved by the government for use in the public health sector (IMS, 2015). National EMLs are often used by governments to guide purchase of priority health commodities. Some countries have also adopted EMLs at a sub-national or state/province level as part of decentralizing health services. Together with standard treatment guidelines, EMLs often serve as the basis for education and training for health providers and for educating the public about the use of medicines and technologies (PATH, 2006). A country's EML reflects a government's commitment to ensuring

[1] The 13 commodities include emergency contraceptive pills, female condoms, and contraceptive implants; oxytocin, misoprostol, and magnesium sulfate; antenatal corticosteroids, chlorhexidine, injectable antibiotics, and resuscitation equipment; amoxicillin, oral rehydration salts, and zinc.

that quality health commodities are available and accessible to the population, and can serve an important tool for advocacy.

An EML review committee, most often appointed by the ministry of health (MOH), is responsible for identifying which commodities to add to (or remove from) the national EML. The committee members include representatives from procurement and supply chain, public health, and medicine (PATH, 2006). WHO recommends that the EML, along with standard treatment guidelines and the national formulary, be regularly updated (at least every other year) and that there be regular monitoring to assess availability and use of essential commodities (PATH, 2006).

PURPOSE OF THIS GUIDE

This guide provides national stakeholders and advocates with information and guidance to update the national EML to include a new commodity, a new indication, or a new formulation based on the available evidence and based on country need and disease burden. While the actors, timeline, and process may vary from country to country, this guide presents the broad steps involved in revising an EML for any health commodity. Additional resources and a glossary are included to provide supplemental information and to clarify key terms.

STEPS FOR UPDATING EML

1 Obtain a copy of the most recent EML.

Country EMLs can be accessed through the WHO website: http://www.who.int/selection_medicines/country_lists/en/. Confirm that this is the latest version. You may need to contact the Ministry of Health to obtain the most recent version of the EML.

Confirm whether the commodities of interest are included, and determine if a specific medical indication is identified. Often commodities are listed in the EML without a specified indication. In these cases, it may be helpful that any update of the EML include the evidence-based indication(s) that is most relevant based on a country's disease burden.

2 Coordinate and work with partners in-country.

Identify the key partners who could contribute to the EML review by providing support, additional knowledge and resources, and credibility and influence

Specify the partner who will take the lead in gathering information, and meeting with key officials and EML review committee members.

3 Determine the process for updating the EML.

Identify and meet with key officials and decision makers who are part of the EML review committee, and who make decisions regarding the update.

Ascertain the timing and timeframe for the next EML update. EMLs should be updated regularly and the timing is often determined by the EML committee.

Determine requirements and process for the addition of new commodities (or a change in formulation or indication) to the national EML.

4 Gather research and evidence needed for submission/request to the EML review committee.

This may include:

Identify the commodity's International Nonproprietary Name (INN) (also known as the generic name). The INN identifies the active pharmaceutical ingredient that is globally recognized and is public property as well as other names available in the market. A listing of INNs is available:
http://www.who.int/medicines/services/inn/en/

Identify the clinical condition for which the commodity is intended to diagnose, treat, or improve upon. Some medicines can have more than one indication, which means that the medicine can be used to address more than one disease or illness.

Specify the burden of disease, either at the global level or in the national context, related to the clinical condition.

Provide the dosage, route of administration, and formulation based on current evidence and global recommendations. If applicable, use the World Health Organization (WHO) Model Essential Medicines List to develop these recommendations.

Provide clinical and programmatic evidence (from research studies, clinical trials or other sources) which support the use of the commodity for the given indication.

Evidence is required in support of a commodity's:
- Relative efficacy
- Relative safety
- Acceptability among the target population
- Relative cost (compared to a medicine already listed for the same indication)

Evidence can include global, regional or local data from:
- Literature reviews
- Published systematic reviews
- Single articles concerning randomized controlled trials
- Case reports
- Observational studies
- Global recommendations
- Policies and guidelines, for example the 19th WHO Model List of Essential Medicines (April 2015)

5 Compile a dossier of the available evidence, based on the requirements of the EML review committee, and submit to the committee, based on the deadline set.

6 In coordination with the EML committee and MOH stakeholders, develop a dissemination plan to share the outcomes and decisions of the EML committee.

Once the EML is updated, share it widely with key stakeholders, including ministry of health officials, procurement officers, national health professional associations, and health care providers, among others, in printed and electronic formats. Dissemination plans can include an official launch event, media coverage, and sub-national meetings to share the outcomes with provincial- and district-level health teams. Ensure that the EML is published on a public web site.

Develop a brochure or pamphlet, in printed and electronic format, to summarize relevant information that can be shared with a wide audience

7 Follow-up through ongoing monitoring and evaluation to ensure that EML updates are fully implemented and leads to the availability and use of the commodity(ies).

Specifically, ensure that:

National procurement authorities take steps to ensure that the commodity is procured in the right dosage and formulation based on the indication(s) specified in the EML

National resource allocations support the right amount of quantities needed for the indication(s) and regimen specified

Standard treatment guidelines and pre- and in-service training curricula reflect the updated national EML (if needed)

Health care workers are trained on proper use.

CONCLUSION

National EMLs often specify which commodities the public health sector will procure for use in the health system. EMLs are used by governments to purchase and distribute priority health commodities, and they can also help in identifying quality assured and cost-effective products. However, country-level EMLs are not always regularly updated with newer or less well-known technologies, even though these products have been included on the WHO Model EML. Concerted effort by many partners is needed to ensure that national EMLs are revised periodically to reflect emerging health priorities, and to reflect updates in the evidence.

Beyond the national EML itself, advocacy is required to ensure that countries are indeed providing a reliable, high-quality supply of key health commodities. Work on EMLs is a starting point that needs to be linked with other efforts, including sound supply chains, training, and on-going monitoring and evaluation.

GLOSSARY

Dosage	The amount of a medicine that should be taken during a specific period of time.
Formulation	The specific state (solid, semisolid or liquid) in which a medicine is supplied to a patient.
International Nonproprietary Name	Identifies the active pharmaceutical ingredient, also known as a generic name.
National Formulary	Manual containing pharmacological information about selected medicines and commodities. In some countries the national EML and formulary are identical.
Quality-assured	A range of factors (including development, quality control, production, distribution, and inspections) that determine the quality of a product.
Standard Treatment Guidelines	A set of written standards systematically developed and designed to assist health providers and patients in making decisions about appropriate care for specific clinical conditions.
Systematic review	A review of the evidence to identify, select, and critically appraise primary research.

ADDITIONAL RESOURCES: FOR MORE INFORMATION

Searchable Database of national EMLs for 13 New or Underutilized Family Planning and Maternal Health Commodities

WHO List of Country Essential Medicine Lists

World Health Organization Global Essential Medicine List (updated: April 2015)

Case studies of successful changes to EML:

- Burkina Faso: Advocacy success story: Burkina Faso broadens access to misoprostol, an essential maternal health medicine
- Pakistan: Building the Momentum: Misoprostol for Postpartum Hemorrhage in Pakistan
- Malawi: Increasing access to key reproductive health and newborn commodities in Malawi

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