

ISSN 0022-3859

Impact Factor® for 2010: 1.589

SETH GORDHANDAS SUNDERDAS  
MEDICAL COLLEGE  
1925



# Journal of Postgraduate Medicine

Official Publication of  
The Staff Society of the Seth GS Medical College and KEM Hospital, Mumbai, India

January-March 2012 | Volume 58 | Issue 1

[www.jpjgmonline.com](http://www.jpjgmonline.com)

# National list of essential medicines of India: The way forward

Manikandan S, Gitanjali B<sup>1</sup>

Department of  
Pharmacology, Indira  
Gandhi Medical College  
and Research Institute,  
<sup>1</sup>Jawaharlal Institute of  
Postgraduate Medical  
Education and Research,  
Puducherry, India.

**Address for correspondence:**  
Dr. B. Gitanjali,  
E-mail: gitabatman@gmail.  
com

Received : 03-08-11  
Review completed : 27-08-11  
Accepted : 05-12-11

## ABSTRACT

Essential medicines lists have been shown to improve the quality and cost-effectiveness of health care delivery when combined with proper procurement policies and good prescribing practices. The Ministry of Health, Government of India revised the National List of Essential Medicines of India (NLEMI 2011) in June 2011, eight years after the last revision. The NLEMI 2011 contains 348 medicines and was prepared over one and a half years by 87 experts. Though there are some positive aspects to the list such as the documentation of a detailed description of the revision process, inclusion of many experts from various fields in the review committee, well written description of the essential medicines concept and others, a critical review of the list reveals areas of major and minor concerns. Improper medicine selection like the inclusion of a nearly obsolete medicine such as ether, an anesthetic agent; non-inclusion of pediatric formulations; spelling errors; and errors in the strengths of formulations diminishes the significance of the NLEMI 2011. In its present form, the NLEMI 2011 did not align with the Indian Pharmacopoeia, and the National Health Programs as well as the National Formulary of India 2010. Formatting errors, non-inclusion of an index page, syntax and spelling errors may also undermine the usefulness of the NLEMI 2011 as a reference material. An urgent revision of the NLEMI 2011 is suggested so as to avert misinforming the wider international and local readers.

**KEY WORDS:** Essential drug list, essential medicines, formulary, rational use of drugs

## Introduction

Essential medicines are defined as those that satisfy the health care needs of the majority of a population.<sup>[1]</sup> This concept was defined in 1975 by the World Health Organization (WHO), and is based on the premise that a limited list of carefully selected medicines, will improve quality of health care, provide cost-effective health care and better management of medicines.<sup>[1]</sup> The first WHO Model list of essential medicines (EML) was published in 1977 with revisions every two years. This model EML provides a template and serves as a guide for countries to prepare their own lists. The seventeenth WHO model EML published in March 2011, is proof that the concept is still valid after nearly 34 years and continues to have many advantages when it is used appropriately and in conjunction

with standard treatment guidelines.<sup>[2]</sup> As of now, 134 countries in the world have their own EMLs.<sup>[2]</sup> The Government of India, recognizing the importance of the EML, prepared and published its first National Essential Drugs List in 1996, which was revised in 2003 as the National List of Essential Medicines.<sup>[3]</sup> The National List of Essential Medicines of India (NLEMI 2011) was revised recently<sup>[4]</sup> by the Ministry of Health and Family Welfare (MOHandFW), Government of India (GOI), in June 2011, nearly eight years after the previous list, on the directions of the Supreme Court of India.<sup>[5]</sup>

The 2003 National List of Essential Medicines, India came in for criticism due to errors of omission and typos.<sup>[6,7]</sup> There was a general expectation that the present list would be better than its predecessor<sup>[7]</sup> considering the fact that the preparation for the list started as early as 16 September 2009.<sup>[4]</sup> Though this list has gone through a more thorough process of revision as mentioned in the opening pages of the document,<sup>[4]</sup> and the fact that a large number of experts contributed to the list, the contents do not fulfill the rigorous standards expected in a national EML.

## Evaluation of the NLEMI 2011

The list was accessed from the official website of the drug

Access this article online	
Quick Response Code:	Website: www.jpgmonline.com
	DOI: 10.4103/0022-3859.93258

regulatory authority of India, the Central Drugs Standard Control Organization ([www.cdsc.nic.in](http://www.cdsc.nic.in)), downloaded and reviewed by comparing it with the 17<sup>th</sup> Model WHO EML, March 2011,<sup>[8]</sup> the 3<sup>rd</sup> WHO Model EML for children, March 2011<sup>[9]</sup> and the National EML 2003.<sup>[3]</sup> The strengths and the weaknesses of the list were studied and the weaknesses were subjectively classified as major and minor, based on their potential to misinform the users such as prescribers, pharmacists, drug procurement managers and policy planners. The critique of the NLEMI 2011 is a personal viewpoint, based on our own understanding and perceptions of the essential medicines concept.

### **The Strengths of NLEMI 2011**

It is commendable that the NLEMI was revised after eight years of much delay. Many countries do not revise their lists regularly for want of expertise, financial constraints and motivation. The MOH and FW must be congratulated for seeing the revision through to the end. An additional strength of the document is that the process of revising the NLEMI was clearly transcribed in the executive summary as well as in a separate section of the document. This gives users a clear idea of how the revision was done and will serve as a reference for future revisions. Thirdly, NLEMI gives the names of all the additions and deletions as well as detailed lists of medicines in alphabetical order, classified therapeutic area- and category-wise. This will be helpful for those preparing lists at the state level to use when the category-wise classification is required, especially for procurement purposes. Fourthly, experts from nearly all specialties were included in the expert group for the preparation of the list. This would have helped to make sure that all the medicines required for the priority diseases in the country were included. Lastly, the executive summary, salient features of the NLEMI and the potential uses of the list have been well written, in simple language, to permit health care professionals, students and even others like health activists and media persons to understand what an essential medicines list is all about.

### **Weaknesses**

#### **Major weaknesses**

##### *Improper selection of medicines*

The very first medicine to be listed in the NLEMI India 2011 is 'ether' as a general anesthetic, meant to be used in secondary and tertiary facilities.<sup>[4]</sup> Ether is nearly obsolete as an anesthetic agent and was deleted from the 14<sup>th</sup> edition of the WHO Model list (2005). It is rather surprising that six years later, in 2011, the committee decided to list it in the NLEMI when none of the anesthesiologists (even in resource poor settings) would be comfortable using ether. Currently, ether is not even recommended as an anesthetic for animal experimentation<sup>[10]</sup> and should not have been listed. On the other side of the spectrum, one of the conspicuous absences in the list is the lack of a diuretic being mentioned under medicines used for cardiac failure.

Vitamin B<sub>12</sub> is available as cyanocobalamin and hydroxocobalamin for parenteral administration. Among these two, hydroxocobalamin is preferred because it is more

highly protein bound and therefore remains longer in the circulation.<sup>[11]</sup> WHO EML<sup>[8]</sup> and EMLc<sup>[9]</sup> have rightly included hydroxocobalamin, whereas NLEMI has cyanocobalamin in the list. Pyridoxine tablets (10 mg) have been included in the NLEMI under antianemic medicines. Pyridoxine is indicated for idiopathic sideroblastic anemia.<sup>[12]</sup> This is a rare disorder and drugs for such conditions need not be included in an essential medicines list under this section.

Under ophthalmological preparations (section 21) six anti-infective agents have been listed but acyclovir, an antiviral agent has been left out.<sup>[4]</sup> Incidentally the WHO Model EML 2011 lists just three, including acyclovir in this section.<sup>[8]</sup> Eight radiocontrast media have been listed in the NLEMI with all of them categorized for secondary and tertiary centers. Only three are listed in the WHO EML with another one under the complementary list.

##### *Improper principles of medicine selection*

Medicines have been included not taking into account the principles of selection of essential medicines. For example, under gastrointestinal medicines, pantoprazole and famotidine have been added when omeprazole and ranitidine are already on the list. Similarly, oxaliplatin has been added when cisplatin is already in the list. Including medicines of the same class which have no major advantages in efficacy and safety is against the principles of selection.<sup>[11]</sup> The section on antiallergics and medicines used in anaphylaxis lists pheniramine, chlorpheniramine and dexchlorpheniramine, all three with a similar pharmacological profile. As if these were not enough, cetirizine has also been added. It is also the same with prednisolone acetate and prednisolone sodium phosphate (ophthalmological agents); both are used for the same indications and neither has any advantage over the other.

##### *Non-alignment of the NLEMI with the National Health Programs and the National Formulary of India*

The preamble states that the medicines used in the various national health programs are addressed in the list.<sup>[4]</sup> Table 1 shows a few examples where this is not the case. The formulation and strengths of medicines listed in the NLEMI are different from those mentioned under some of the national health programs in India and the guidelines of the integrated management of neonatal and child illnesses (IMNCI).<sup>[13]</sup>

Medicines for tuberculosis are recommended to be administered as fixed dose combinations (FDCs) in the revised national TB control program (RNTCP), by the WHO. None of the FDCs have been included in the NLEMI. The WHO Model EML includes five FDCs of antituberculosis medicines.<sup>[8]</sup> Therefore, the list fails to provide harmonization in terms of listing the medicines in the national health programs.

The executive summary on page 7 states that the revision of the NLEMI was based on the National Formulary of India (NFI) 2010<sup>[14]</sup> and the Indian Pharmacopoeia 2010.<sup>[15]</sup> However, some of the medicines in the NLEMI do not figure in the NFI and vice versa. Zinc sulfate syrup 20 mg/5ml which is listed in the NLEMI is not mentioned in the NFI.<sup>[14]</sup> Incidentally, the NFI does not list any zinc sulfate formulation, though it is one of

the medicines used in the management of diarrhoea in children and is supplied to all sub-centers under the National Rural Health Mission.<sup>[13]</sup> The Indian Pharmacopoeia (I.P) 2010 too does not describe standards for zinc sulfate syrup or tablets.<sup>[15]</sup> The NFI lists and describes benzyl penicillin, procaine benzyl penicillin and chloramphenicol which have been deleted from the NLEMI while there is no description of ether, sevoflurane and oxaliplatin which figure in the NLEMI. Hence there is no evidence of the NLEMI being *in sync* with the NFI and I.P 2010.

#### Lack of uniformity in expressing strengths of medicines

The strength of drug in the formulation is not expressed in a uniform manner throughout the list. For drugs which are available as solution for injection, the standard convention is to express the strength as 'per ml'. The WHO Model lists follow this convention.<sup>[8,9]</sup> NLEMI 2011 follows multiple formats for expressing the strength of injectable, viz – 'per ml', 'per 2 ml' (e.g. amikacin), 'per 5 ml' (e.g. 5-fluorouracil, paclitaxel, sodium nitroprusside). Adding to the confusion, for some drugs (e.g. cisplatin, cytosine arabinoside) it is expressed as 'per

vial'. Similarly for the liquid oral dosage forms, the strength is expressed in two different ways – 'per 5 ml' and 'per ml'. Even though these inconsistencies look trivial, they are dangerous as it can lead to errors in dose of drugs prescribed which may cause treatment failure or toxicity.

#### Errors of medicine formulation strengths

NLEMI 2011 claims (in Page 15) that it is a reference document for correct dosage form and strength for prescribing. However, there are errors in both dosage form as well as its strength. A few of the errors in strength are given in Table 2.

#### Incomplete medicine information

For many drugs the information provided under some columns remain incomplete. Section 26 includes oral rehydration salts (ORS) for which the strength is mentioned as 'As per IP'. As there are many types of ORS (low osmolality, rice based and high osmolality), the exact constituents should be specified. This point too has been highlighted in the commentary on NLEM 2003,<sup>[6]</sup> but has not been rectified in this list.

**Table 1: Differences in the formulations and strength of medicines in the NLEMI 2011 and the national health programs**

Program	Medicines present in the National Health Program	Medicines present in the NLEMI 2011	Remarks
National nutritional anemia prophylaxis program (as per IMNCI*)	1. Ferrous sulfate 100 mg and folic acid 100 mcg (20 mg elemental iron) as pediatric tablet 2. Ferrous fumarate 100 mg and folic acid 0.5 mg per 5 ml (20 mg elemental iron per ml) 3. Ferrous ammonium citrate 20 mg of elemental iron and folic acid 0.2 mg per 1 ml as drops.	1. Ferrous sulfate / ferrous fumarate tablets, oral solution 60 mg elemental iron and 25 mg elemental iron /ml 2. Folic acid tablets 1 mg, 5 mg	The combination of iron and folic acid is not included in NLEMI. The strength is different and the drops are not in the list
National diarrheal disease control program (as per IMNCI*)	Dispersible zinc tablets 20 mg	Zinc syrup 20 mg/5ml	Solid oral dosage formulations of zinc should have been included
Vitamin A prophylaxis program (as per IMNCI*)	Vitamin A syrup 100,000 IU/ml	Vitamin A tablets (5000 IU); Capsules (50000 IU, 100000 IU) Injection 50,000 IU/ml	Liquid oral formulation should have been included
IMNCI guidelines for pneumonia	Amoxycillin - tablet 150 mg and syrup 125mg/5ml  1. 20 mg trimethoprim + 100 mg Sulfamethoxazole (as pediatric tablet) 2. 40 mg trimethoprim +200 mg sulfamethoxazole per 5 ml as syrup	Amoxycillin powder for suspension (125mg/5ml) Capsules 250 mg and 500 mg  Cotrimoxazole 80 mg + 400 mg, 160 mg + 800 mg (tablets); 40 mg + 200 mg/5ml (suspension)	Solid oral dosage form for children is not included  Solid oral dosage form for children is not included.

\*IMNCI is integrated management of neonatal and childhood illness

**Table 2: Errors in the strength of formulations of the NLEMI 2011**

Name of medicine	Formulation	Strength as given in NLEMI	Correct strength
Cetirizine	Syrup	5 mg/ml	5 mg/5ml or 1 mg/ml
Ondansetron	Syrup	2 mg/ml	2 mg/5ml
N-acetylcysteine	Injection	200 mg/ml (5 ml)	200 mg/ml in 5 ml or 10 ml ampoule
Mesna	Solution for injection	200 mg	200 mg/2ml or 100 mg/ml
Filgrastim	Injection	1 ml vial	300 µg/ml
Amoxicillin + clavulanic acid	Tablet	625 mg	500 mg + 125 mg
Amoxicillin + clavulanic acid	Injection	600 mg, 1.2 gm	500 mg + 100 mg, 1000 mg + 200 mg
Lignocaine	Injection	1-2% (in page 34 of NLEMI)	1%, 2%
Fentanyl	Injection	50 µg/ml	50 µg/ml

Similarly, NLEMI 2011 includes premix insulin (30: 70) injection, but it is not specified which of the two insulin preparations are mixed in this. The commercially available premix insulin contains either regular insulin (30%) or any one rapid acting analog (insulin lispro or insulin aspart) along with NPH insulin (70%). The exact preparation of insulin recommended in this premix insulin should be specified.

#### *Non-inclusion of pediatric formulations*

Many drugs have formulations to suit different adult doses. For example, fluconazole tablets are available in four different strengths (50 mg, 100 mg, 150 mg and 200 mg) for adults in the list. But there is no dose / dosage form for children. Many drug groups – benzodiazepines (diazepam, midazolam), opioids (morphine), antibiotics (doxycycline, metronidazole), antifungals (fluconazole, griseofulvin, nystatin) and antiretrovirals (lamivudine, stavudine, zidovudine, efavirenz) do not have either the dose or dosage form appropriate for children. This was a major limitation of NLEM 2003<sup>[6]</sup> which has not been addressed in this list.

#### **Minor weaknesses**

##### *Spelling errors and other mistakes*

There are many spelling mistakes in the name of drugs. The notable errors include ‘clavulinic acid’, ‘cetrizine’, ‘ferrous fumarate’, ‘theophylline’, ‘colchicin’ and ‘hydrochlorthiazide’. These mistakes should be corrected as NLEMI 2011 is a reference document. In section 21 (ophthalmological preparations), tropicamide and lignocaine have not been listed under mydriatics and local anesthetic agents respectively but have been listed under diagnostic agents in Section 14.1. Flutamide is listed under cytotoxic medicines. It should be moved to the next section (hormones and antihormones).

The title page of NLEMI 2011 has three error alerts in the table of contents. These may have crept into the document during its preparation in PDF format. It would have been desirable for someone to have proofread the document carefully before uploading. Lack of alignment makes it difficult to decipher which form corresponds to which strength.

The list is arranged in four columns. The third column is titled ‘Route of administration’. But under this column, only the formulations are listed (e.g. tablets, injection, syrup and cream, etc.), not the route. This makes the title of the column inappropriate. Furthermore, meaningless sentences and inappropriate terms like ‘Is this commonly used?’ (Page 34) and ‘levonorgestrol releasing’ (Page 66) in this column is likely to confuse users.

In every section / subsection, the newly added medicines are mentioned separately. This kind of format is not needed as the list of newly added medicines is mentioned separately at the beginning (Pages 27 and 28). Moreover in many sections (e.g. Sections 1.1, 2.2, 4.2, 8.2) the newly added medicines are not listed alphabetically. This makes searching difficult. The lack of index makes this document less user friendly.

#### *Incorrect statistics*

NLEMI 2011 states (in Page 11) that it has a total of 348 medicines (excluding repetitions) and provides an alphabetical list of medicines at the end. In this list, betamethasone and betamethasone dipropionate are counted as two different drugs. Similarly lignocaine and lignocaine hydrochloride; polyvalent antsnake venom and specific antsnake venom (polyvalent solution / lyophilized polyvalent serum); prednisolone and prednisolone acetate are counted as different drugs, whereas isosorbide 5 mononitrate and isosorbide dinitrate which are two different drugs are counted as a single drug. This has led to an incorrect total, and hence, the category wise statistics given in the document is also erroneous.

The document also states that 47 medicines have been deleted, 43 medicines have been added and provides the list of additions and deletions (in Pages 27 – 31). Medicines which were present in NLEM 2003<sup>[3]</sup> (e.g. allopurinol, betamethasone and diazepam) are erroneously listed as new additions in NLEMI 2011. Moreover, medicines listed in NLEMI 2011 were erroneously included in the list of deletions (e.g. chloramphenicol – Page 72). Hence, the statistics of drug count provided in the NLEMI 2011 are unreliable.

#### *Lack of official endorsement of the document*

Though the list can be accessed from the official website of the Ministry of Health, Government of India website ([www.mohfw.nic.in](http://www.mohfw.nic.in)) or from the official website of the drug regulatory authority of India, the Central Drugs Standard Control Organization ([www.cdsc.nic.in](http://www.cdsc.nic.in)), the document has no official seal or indication that this list is endorsed by the MOH and FW, GOI. The edition or the month in which it was released is not mentioned. It is imperative that the list states upfront that it is indeed the official NLEMI because if this list is going to be used as a model for the state EMLs there should be a seal of authority. Incidentally, the 2003 list contains the government seal in the cover page. This feature should not have been deleted.

### **The Way Forward**

The objective of this paper is not to give a comprehensive list of errors in the NLEMI but to inform readers that there are major concerns with the list in its present form. In trying to find out where it went wrong, it is inevitable that the process which went into the preparation of the of the 17<sup>th</sup> WHO Model list which was prepared in Accra, Ghana, in March 2011 will be compared with this list. With just about twenty of the world’s topmost experts, selected from different countries, the expert committee sat for just five working days to finalize the list and came out with a near-perfect document. The Indian list, by contrast, which was prepared by 87 experts over a long period of time, falls short of its objectives. In order to avert such weaknesses perpetrated by the NLEMI-2011, an important document like this should be made available to the general population to read and to offer useful suggestions before the final draft is released as a reference document. It is still not too late to do this. The committee may also send the list for review to international experts on essential medicines. This will go a long way in further ensuring quality.

We, in India need to introspect on the quality of documents prepared at great expense to the exchequer and to analyze what goes wrong not just once but every time.<sup>[6,7]</sup> Greater accountability of those involved in preparing the list is also called for. A method for recording and dealing with potential conflicts of interest of members of the committee revising the list should be in place. It is high time the health professionals in India demand and accept nothing less than a list which is free from errors and will satisfy the health care needs of the majority of our population.

### References

1. The selection of essential medicines. WHO Policy perspectives on Medicines. Geneva: World Health Organization; Jun 2002.
2. Country pharmaceutical situations. Fact Book on Level 1 indicators. 2007. World Health Organization, Geneva, 2009. Available from: [http://www.who.int/medicines/technical\\_briefing/tbs/WHO\\_EMP\\_MPC\\_2010\\_1full.pdf](http://www.who.int/medicines/technical_briefing/tbs/WHO_EMP_MPC_2010_1full.pdf) [Last cited on 2011 Jul 25].
3. National list of essential medicines 2003. Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, New Delhi. Available from: [http://www.searo.who.int/LinkFiles/Essential\\_Drugs\\_and\\_Medicines\\_India.pdf](http://www.searo.who.int/LinkFiles/Essential_Drugs_and_Medicines_India.pdf) [Last cited on 2011 Jun 23].
4. National list of essential medicines of India 2011. Available from: <http://www.cdsc.nic.in/> [Last cited on 2011 Jun 23].
5. Sinha K. New essential drugs list finalized after eight years. Times of India. June 11 2011. Available from: [http://www.articles.timesofindia.indiatimes.com/2011-06-11/india/29646861\\_1\\_essential-medicines-nlem-new-cancer-drugs](http://www.articles.timesofindia.indiatimes.com/2011-06-11/india/29646861_1_essential-medicines-nlem-new-cancer-drugs) [Last cited on 2011 Jun 23].
6. Manikandan S. A critical look at the national essential medicines list of India 2003. *J Pharmacol Pharmacother* 2010;1:75-7.
7. Gitanjali B. The national essential medicines list of India: Time to revise and purge the mistakes. *J Pharmacol Pharmacother* 2010; 1:73-4.
8. WHO model list of essential medicines, 17<sup>th</sup> list (March 2011). Available from: <http://www.who.int/medicines/publications/essentialmedicines/en/index.html> [Last cited on 2011 Jun 23].
9. WHO model list of essential medicines for children, 3<sup>rd</sup> list (March 2011). Available from: <http://www.who.int/medicines/publications/essentialmedicines/en/index.html> [Last cited on 2011 Jun 24].
10. Committee for the Purpose of Control and Supervision of Experiments on Animals. CPCSEA guidelines for laboratory animal facility. *Indian J Pharmacol* 2003;35:257-74.
11. Masters SB. Agents used in anemias; Hemotopoietic growth factors. In: Katzung BG, Masters SB, Trevor AJ, editors. *Basic and clinical pharmacology*. 11th ed. 2009. p. 569-86.
12. *British national formulary*. 58<sup>th</sup> ed. London: BMJ Group and RPS Publishing; 2009. p. 517.
13. *Integrated management of neonatal and childhood illness. Physician Chart Booklet*. New Delhi: Ministry of Health and Family Welfare, Government of India; 2009.
14. *National Formulary of India*. 4<sup>th</sup> ed. Government of India, Ministry of Health and Family Welfare. India: Indian Pharmacopoeia Commission; 2010.
15. *Indian Pharmacopoeia*. Government of India, Ministry of Health and Family Welfare. Ghaziabad: Indian Pharmacopoeia Commission; 2010.

**How to cite this article:** Manikandan S, Gitanjali B. National list of essential medicines of India: The way forward. *J Postgrad Med* 2012;58:68-72.

**Source of Support:** Nil, **Conflict of Interest:** None declared.