



A comparative review on national list of essential medicines, India (NLEMI 2011) v/s WHO essential drug list 2013

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ABSTRACT

Essential medicines lists form the basis to improve the quality and cost effectiveness of health care delivery when taken together with proper procurement policies and good prescribing practices. The Ministry of Health, Government of India revised the National List of Essential Medicines 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. It is commendable that there are various positive aspects to the list such as 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; however a critical review of the list reveals areas of major and minor concerns. So there is a need of thorough comparison and critical review of the NLEMI 2011 with WHO Essential drug list, 2013 and its compliance with the National Health Programs as well as the National Formulary of India 2010.

Key words: Essential medicines, National list of essential medicines (NLEM), Ministry of Health and Family Welfare (MOHFW), World Health Organisation (WHO) Essential drug list.

INTRODUCTION

*"The Alma-Ata declaration during the International Conference on Primary Health Care in 1978 reaffirms that health is a fundamental human right and the attainment of the highest possible level of health is a most important worldwide social goal. The Alma Ata declaration has outlined the eight essential components of primary health care and provision of essential medicines is one of them. Medicines are integral part of the health care and the modern health care is unthinkable without the availability of necessary medicines. They not only save lives and promote health, but prevent epidemics and diseases too. The medicines are undoubtedly one of the weapons of mankind to fight disease and illness. Accessibility to medicines is too the fundamental right of every person."*¹

Essential medicines, as defined by the World Health Organization (WHO) are "those drugs that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford."²

The WHO has published a model list of essential medicines. Each country is encouraged to prepare their own lists taking into consideration local priorities. At present over 150 countries have published an official essential medicines list and India is one of the countries. The WHO List contains a core list and a complementary list.³

The National list of essential medicines NLEM (2011) has indeed surpassed various flaws post its revision and the job done by experts is worthy of appreciation but there are certain points which we found were overlooked and, being dutiful pharmacist we take this as an opportunity to highlight these points, such as:

- Certain important categories of drugs like Protease inhibitors (under Antiviral), Antispasmodics, etc. Were found to be missing
- Inclusion of an obsolete anaesthetic agent; Ether
- Absence of vaccines for some special groups like Mumps, etc.

All these and many other points are discussed in detail later in this article in positive light to make

this list even better, which is the sole objective of this review.

The content of WHO list and concept of National list of essential medicines: The aim of WHO is to present a list of minimum medicine needs for a basic health care system, listing the most efficacious, safe and cost-effective medicines for priority health conditions. Essential medicines are selected on the basis of current scenario of health and prevalent diseases as well as estimated future public health relevance. Drug that holds potential for safe and cost-effective treatment is included. ⁴

The National list of essential medicines is one of the key instruments in balanced healthcare delivery system of a country which includes accessible, affordable quality medicine at all the primary, secondary, tertiary levels of healthcare. Realizing this GOI, MOHFW decided to have its own essential medicines list. The first National List of Essential Medicines of India was prepared and released in 1996. This list was subsequently revised in 2003.⁵

COMPARATIVE ANALYSIS OF WHO LIST (2013) V/S NLEM (2011)

S. No.	Name of the Section	Drugs present in WHO List (2013) but not in NLEM(2011)	Drugs present in NLEM(2011) but not in WHO list (2013)	Drugs Common in both lists
1	Anaesthetics			
1.1	General anaesthetics and oxygen	Ephedrine	Ether Sevoflurane Propofol Midazolam	Halothane Ketamine NitrousOxide Oxygen Thiopentone
1.2	Local Anaesthetics		EMLA Cream	Bupivacaine Lignocaine hydrochloride
1.3	Preoperative Anaesthetics	Chloralhydrate		Atropine Diazepam Morphine Promethazine Midazolam
2	Medicines for pain and palliative care			
2.1	NSAIDS		Diclofenac	Acetyl Salicylic acid Ibuprofen Paracetamol
2.2	Opioid Analgesics	Codeine Pethidine	Tremadol Fentanyl	Morphine
2.3(2.4)	Drugs for palliative care/ drugs to treat gout and DMAs in RA	Amitriptyline Cyclizine Dexamethasone Diazepam Fluoxetine Haloperidol Docusate Hyoscine	Allopurinol Colchicine Azathioprine Methotrexate	

		Lactulose Loperamide Metoclopramide Ondansetron Senna Midazolam		
3	Anti allergic and medicines used in anaphylaxis	Loratadine	Sulfasalazine Hydroxychloroquine Leflunomide Dexchlorpheniramine maleate Pheniramine maleate Promethazine Citrizine	Adrenaline Chlorpheniramine Dexamethasone Hydrocortisone Prednisolone
4	Antidotes and other substances used in poisoning			
4.1	Non-specific	Ipecacuanah		Activated Charcoal
4.2	Specific	DL-Methionine Potassium ferric hexacyanoferrate Sodium EDTA	Specific Anti-snake venom Flumazenil Pralidoxime chloride	Atropine Ca-gluconate Desferrioxamine Methylene blue Penicillamine Dimercaprol Sodium nitrite Sodium thiosulphate Naloxone N-acetyl cysteine
5	Anticonvulsants/ Antiepileptic	Ethosuximide Clonazepam	Lorazepam	Carbamazepine Diazepam Magnesium sulphate Phenobarbitone Phenytoin Valproic acid
6	Anti infective medicines			
6.1	Anthelmintics	Levamisole Mebendazole	Piperazine	Albendazole
6.1.1	Intestinal anthelmintics	Niclosamide Praziquantel Pyrantel Ivermectin		
6.1.2	Antifilarials	Suramin sodium		Diethyl carbamazine

		Triclabendazole		
6.1.3	Antitrichosomals and Antitrematode medicines	Oxamniquine		Praziquantel
6.2	Antibacterials			
6.2.1	Beta lactam medicines	Benzylpenicillin Phenoxy methylpenicillin Procaine benzylpenicillin Imipenam+Cilastatin Ceftazidime Cefazoline Cefalexine Cefazoline	Cefotaxime Cephalexine Cefixime	Amoxicillin Ampicillin Benzathine benzylpenicillin Cloxacillin Amoxicillin+Clavulonic acid Ceftriaxone
6.2.2	Other antibacterials	Chloramphenicol Nalidixic acid Spectinomycin Trimethoprim Clindamycin	Amikacin Azithromycin	Ciprofloxacin Doxycycline Erythromycin Gentamycin Metronidazole Nitrofurantoin Sulfadiazine Co-trimoxazole Vancomycin
6.2.3	Antileprosy drugs	Thiacetazone		Clofazimine Dapsone Rifampicin
6.2.4	Antitubercular drugs		Oflaxacin	Ethambutol Isoniazid Pyrazinamide Rifampicin Streptomycin
6.3	Antifungals	Flucytosine Potassium iodide	Clotrimazole	Amphotericin-B Fluconazole Griseofulvin Nystatin
6.4	Antivirals			
6.4.1	Antiherpes			Acyclovir
6.4.2	Antiretrovirals			
6.4.2.1	Nucleotide reverse transcriptase	Abacavir Emtricitabine	Nevirapine	Didanosine Lamivudine

	inhibitors	Tinofovir disoproxil fumarate		Stavudine Zidovudine Efavirenz Nevirapine
6.4.2.2	Non-nucleotide reverse transcriptase inhibitors		Nelfinavir	Indinavir Saquinavir Ritonavir
6.4.2.3	Protease inhibitors	Atazanavir Lopinavir Oseltamivir Ribavirin Pegylated interferon alpha (2a or 2b)		
6.5	Antiprotozoal			
6.5.1	Antiamoebic and Antigiardiasis	Meglumine ontimoneate		Diloxanide Metronidazole
6.5.2	Antileishmaniasis	Paromomycin Miltefosine	Pentamidine isothionate	Sodium stibagluconate Amphotericin B
6.5.3	Antimalarial			
6.5.3.1	Curative	Amodiaquine Artemether Lumefantrine Doxycycline	Clindamycin	Artesunate Pyremethamine Sulfadoxine Quinine Primaquine Mefloquine
6.5.3.2	Prophylaxis	Chloroquine Doxycycline Proguanil		Chloroquine Mefloquine
6.5.4	Antipneumocystosis and Antitoxoplasmosis	Pyremethamine Sulfadiazine		Pentamidine Co-trimoxazole
6.5.5	Antitrypanosomals		Section absent	
6.5.5.1	African Trypanosomiasis	Pentamidine Suramin sodium Eflornithine Milarsoprol Nifurtimox		
6.5.5.2	American trypanosomiasis	Benznidazole Nifurtimox		

7	Anti migraine			
7.1	Acute attack	Ibuprofin	Dihydroergotamin	Acetyl salicylic acid Paracetamol
7.2	Prophylaxis			Propranolol
8	Antineoplastics and Immunosuppressive medicines			
8.1	Immunosuppressive medicines			Azathioprine Cyclosporine
8.2	Cytotoxic drugs	Allopurinol Calcium folinate Chlormethine Cytarabine Dactinomycin Levanusole	Actinomycin D Alpha interferon Busulphan Cytosine arabinoside Danazol Flutamide Folinic acid Gencitabine HCl Melphalan Mitomycin-C Paclitaxel Carboplatin Ifosfamide Mesna Oxaliplatin Imatinib Raloxifene	Bleomycin Cyclophosphamide Cysplatin Doxorubicin Etoposide 5-Fluorouracil Asparaginase Mercaptopurine Methotrexate Procarbazine Vincristine Vinblastine Dacarbazine Daunorubicin Chlorambucil
8.3	Hormones and Antihormones	Dexamethasone Hydrocortisone Methylprednisolone		Prednisolone Tamoxifen
8.4	Medicines used in palliative care	Azathioprine Sulfasalazine Chloroquine	Morphine sulphate Ondansetron Filgrastim	Allopurinol
9	Anti parkinsonism	Biperiden	Bromocriptine mesylate Trihexyphenidyl HCl	Levodopa+ Carbidopa
10	Medicine affecting the blood			

10.1	Antiamaemia medicines		Pyridoxine Cyanocobalamine	Ferrous salt+Follic acid Iron duxtran
10.2	Drugs affecting coagulation		Enoxaprin	Heparin sodium Phytomenadione Protamine sulphate Warfarin
10.3	Other medicines for haemoglobinopathies	Deferoxamine Hydroxycarbamide	Section absent	
11	Blood Products and plasma substitutes	RBCs, Platelet concentrates, Whole blood Human normal immunoglobulin Hydroxycobalamin	Dextran 40 Hetastarch Polygeline Albumin Cryoprecipitate Platelet rich plasma	Fresh frozen plasma Dextran 70 Factor VIII Factor IX
12	Cardiovascular drugs			
12.1	Antianginal drugs	Bisoprolol Virapamil	Acetyl salicylic acid Diltiazem Isosorbate dinitrate Metoprolol Clopidogril	Glyceryl trinitrate Isosorbide dinitrate
12.2	Antiarrhythmic drugs	Atenolol Dgoxin Epinephrine Isoprenaline Quinidine	Adenosine Amiodarone Diltiazem Esmolol	Lignocaine Procainamide Virapamil
12.3	Antihypertensive drugs	Bisoprolol Captopril Hydralazine Reserpine Prazosin	Enalapril maleate Losartan Hydrochlorthiazid	Atenolol Methyldopa Nefidipine Sodium nitroprusside Amlodipine
12.4	Drugs used in Heart failure	Bisoprolol Enalapril Furosemide Spironolactone Hydrochlorthiazide	Dobutamine	Digoxin Dopamine
12.5	Antithrombotic drugs		Heparin Urokinase	Acetyl salicylic acid Streptokinase

12.6	Lipid lowering agents	Simvastatin	Atorvastatin	
13	Dermatological drugs			
13.1	Antifungal drugs	Sodium thiosulphate Selenium sulphide Terbinafene Potassium permanganate		Meconazole
13.2	Antiinfective drugs	Mupirocin	Acyclovir Framycetin sulphate Povidine iodine	Gentian violet Neomycin+Bacitracin Silver sulfadiazine
13.3	Antiinflammatory and antipruritic	Hydrocortisone		Betamethasone Calamime
13.4	Drugs affecting skin proliferation and differentiation	Benzoyl peroxide Fluorouracil Podophyllum resin Urea	Glycerine	Coal tar Dithranol Salicylic acid
13.5	Scabicides and pediculicides			Benzyl benzoate Permethrin
13.6	Astringent	Aluminium diacetate	Zinc oxide	
14	Diagnostic agents			
14.1	Ophthalmic drugs		Lignocaine	Fluorescein Tropicamide
14.2	Radiocontrast media	Amidotrizoate Iohexol	Calcium ipodate Meglumine iothalamate Sodium meglumine diatrizoate Sodium iothalamate	Barium sulphate Ipanoic acid Propylidone Meglumine iotroxate
15	Disinfectants and antiseptics			
15.1	Antiseptics		Acriflavin+Glycerine Benzoin compound Cetrimide Gentian violet Hydrogen peroxide	Chlorhexidine Povidone iodine Ethanol
15.2	Disinfectants	Chlorine base compound Chloroxlenol	Bleaching powder Formaldehyde solution Potassium	Glutral

16	Diuretics	Amiloride	permanganate	Furosemide Hydrochlorthiazide Mannitol Spironolactone
17	Gastrointestinal drugs			
17.1	Antacids/Antiulcer	Cimetidine	Omeprazole Ranitidine Pantoprazole Famotidine Domperidone Ondansetron	Aluminium hydroxide Magnesium hydroxide (NLEM has the combination)
17.2	Antiemetics			Metaclopramide Promethazine
17.3	Antiinflammatory drugs	Hydrocortisone		Sulfasalazine
17.4	Laxative	Senna	Bisacodyl Ispaghula	
17.5	Antispasmodic	Dicyclomine hydrochloride Hyoscine butyl bromide	Section absent	
17.6	Drugs for Diarrhoea			
17.6.1	Oral dehydration salts			ORS
17.6.2	Antidiarrhoeal drugs	Codeine	Zinc sulphate	
18	Hormones, other endocrine drugs and contraceptives			
18.1	Adrenal hormones and synthetic substitutes	Fludrocortisone	Methylprednisolone	Dexamethasone Hydrocortisone Prednisolone
18.2	Androgens			Testosterone
18.3 18.3.1	Contraceptives Hormonal contraceptives	Levonorgestrel	Hormone releasing IUDs	Ethinylestradiol+ Levonorgesrin Ethinylestradiol+ Norethisterone
18.3.2	Injectable contraceptives	Estradiol cypionate+ medroxyprogesterone		

18.3.3	Intrauterine devices	ne acetate Noethisterone enantate		IUD containing Copper
18.3.4	Barrier methods	Diaphragms		Condoms
18.3.4	Implantable contraceptives	Levonorgestrel releasing implants	Section absent	
18.4	Estrogens			Ethinyl estradiol
18.5	Drugs used in diabetes mellitus			
18.5.1	Insulins and other Antidiabetic drugs	Gliclazide	Premix insulin	Glibenclamide Insulin injection Intrmediate acting insulin Metformin
18.5.2	Drugs for hypoglycaemia		25% Dextrose	Glucagon
18.6	Ovulation inducers			Clomifene
18.7	Progestogens		Norethisterone	Medroxyprogesterone acetate
18.8	Thyroid and antithyroid drugs	Propyl thiouracil Lugol's solution Potassium iodide	Carbimazole Iodine	Levothyroxine
19	Immunologicals			
19.1	Diagnostic agents			Tuberculin, Purified protein derivative
19.2	Sera and immunoglobins	Immunoglobulin, human normal		Anti D-immunoglobulin Anti tetanus immunoglobulin Antivenom sera Diphtheria antitoxin Rabies immunoglobulin
19.3	Vaccines			
19.3.1	For universal immunisation	Pertussis vaccine Tetanus vaccine		BCG vaccine DPT vaccine Hepatitis B vaccine Measles vaccine Poliomyelitis vaccine
19.3.2	For specific group of individuals	Influenza vaccine Meningococcal meningitis	Rabies vaccine Tetanus vaccine	

20	Muscle relaxants (peripherally acting) and cholinesterase inhibitors)	Mumps Rubella Typhoid Yellow fever Varicella Japanese encephalitis Pneumococcal Alcuronium Suxamethonium	Atracurium Succinyl choline chloride	Neostigmine Pyridostigmine Vecuronium
21	Ophthalmological preparations			
21.1	Antiinfective agents	Acyclovir Azithromycin Ofloxacin Iodoxuridine Silver nitrate Tetracycline	Chloramphenicol Ciprofloxacin Miconazole Povidone iodine Sulfacetamide sodium	Gentamycin
21.2	Antiinflammatory agents			Prednisolone
21.3	Local anaesthetics			Tetracaine
21.4	Miotics and antiglaucoma drugs	Acetazolamide Latanoprost	Betaxolol hydrochloride Homatropine Phenylephrine	Pilocarpine Timolol
21.5	Mydriatics	Epinephrine	Homatropine Phenylephrine	Atropine
21.6	Anti vascular endothelial growth factor	Bevacizumab	Section absent	
21.6	Ophthalmic surgical aids	Section absent	Methylcellulose	
22	Oxytocics and antioxytocics			
22.1	Oxytocics		Mefipristone Misoprostal	Oxytocin Ergometrine
22.2	Antioxytocics		Terbutaline sulphate Betamethasone	Nifedipine
23	Peritoneal dialysis solution			Intraperitoneal dialysis solution
24	Drugs for mental			

	and behavioural disorders			
24.1	Drugs used in psychotic disorders	Fluphenazine Risperidone Clozapine	Olanzapine	Chlorpromazine Haloperidol
24.2	Drugs for mood disorders			
24.2.1	Antidepressants		Imipramine	Amitriptyline Fluoxetine hydrochloride
24.2.2	Drugs for bipolar disorder	Carbamazepine		Lithium carbonate Valproic acid
24.3	Drugs for anxiety disorders			Diazepam
24.4	Drugs for OCD and panic attack	Clomipramine	Alprazolam Fluoxetine hydrochloride	
24.5	Drugs for disorders due to psychoactive substance use	Nicotine replacement therapy Methadone	Section absent	
25	Drugs acting respiratory tract			
25.1	Antiasthmatic	Aminophylline Epinephrine Budesonide	Hydrocortisone sodium	Beclomethasone Salbutamol Ipratropium
25.2	Antitussives	Section absent	Codeine phosphate Dextromethorphan	
26	Solutions correcting water and electrolyte balance			
26.1	Oral	Potassium chloride		ORS
26.2	Parenteral	Compound solution of sodium lactate	N/2 saline N/5 saline Ringer Lactate	Glucose Glucose with NaCl Potassium chloride Sodium bicarbonate
26.3	Miscellaneous		Calcium carbonate	Water for injection
27	Vitamins and Minerals	Iodine		Ascorbic acid Nicotinamide

				Pyridoxine Vitamin A/ Retinol Vitamin D Riboflavin Thiamine Calcium gluconate
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A comparative analysis of WHO Model list of Essential medicines (2013) v/s NLEM (2011):

On comparison of **National list of Essential Medicines (NLEM 2011)** with **WHO Model List of Essential Medicines (2013)** listed above, we observed that national list of our country is quite appreciable as it has been very much made on the lines of WHO model list, however, certain noticeable differences came into sight on a deeper analysis. With due regards to the committee that revised the national list we take this as our duty to bring these points of difference in light. As we know that NLEM forms the basis for deciding various national drug policies and drugs/medicines play an important role in framing the economy of our country, it is worthy enough and important to look into these differences analytically.

On closely examining all the sections of both the lists it was found that there are various sections (drug categories) missing in our national list:

- a) Protease inhibitors a subcategory of Antiviral drugs (Atazanavir, Lopinavir, etc.)
- b) Drugs for haemoglobinopathies (Deferoxamine, Hydroxycarbamide)
- c) Antispasmodics (Dicyclomine, Hyoscine)
- d) Implantable contraceptives
- e) Nicotine replacement therapy
- f) Oxytocics (Misoprostal, Mefipristone)
- g) Opioid analgesics
- h) Drugs to treat Trypanosomiasis

The very first medicine to be listed in the NLEM India 2011 is 'ether' as a general anaesthetics, meant to be used in secondary and tertiary facilities. Ether is nearly obsolete as an anaesthetics agent and was deleted from the 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 NLEM when none of the anaesthesiologists (even in resource poor settings) would be comfortable using ether.⁹ 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. Therefore, the list fails to provide harmonization in terms of listing the medicines in the national health programs.⁹

Vitamin B12 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. WHO EML has rightly included hydroxocobalamin, whereas NLEM has cyanocobalamin in the list. Pyridoxine tablets (10 mg) have been included in the NLEM under antianemic medicines. Pyridoxine is indicated for idiopathic sideroblastic anaemia. This is a rare disorder and drugs for such conditions need not be included in an essential medicines list under this section.⁹

Apart from this, there are various specific drugs in certain categories that have not been given the status of essential medicines despite them being present in WHO list, for example, **Propyl thiouracil** and **Lugol's solution** for treatment of thyroid disorders. There are various vaccines for treatment of specific groups that are absent from NLEM, like **Influenza, Mumps, Rubella, Varicella, Pneumococci**, etc.^{5,8}

WHO recommends the use of **Loratidine** as an essential medicine under the category of antiallergics but NLEM does not have it; instead it has **Citrizine** – a drug whose use is banned in various countries.⁵

WHO list includes Antivascular endothelial growth factor-**Bevacizumab** whereas there is not even a mention of any such category in NLEM.⁸ However, the absence of certain categories from NLEM is justifiable, such as Antitrypanosomiasis drugs (Trypanosomiasis is not prevalent in India) and opioid analgesics- **Codeine** and **Pethidine** (NLEM has **Fentanyl** and **Tramadol**, instead) due to drug abuse and Narcotics Act but paradoxically, Antitussives are present in NLEM and the prominent drugs of this category are **Codeine** and **Dextromethorphan** (present in

cough syrups; a formulation very common for drug abuse).⁹

Similarly, WHO lists out Methadone to be used as drug to treat disorders due to overuse/abuse of psychoactive substances like Nicotine (Nicotine replacement therapy) but NLEM has no such category and it is needless to mention that how important this category is for India where a big section of population consumes tobacco and suffers from its abuse.¹⁰

There are certain sections of drug present in WHO but absent in NLEM, such as

- a) Section 28: Ear, Nose and Throat medicines in children (Acetic acid, Budesonide, Ciprofloxacin)
- b) Section 29: specific medicines for neonatal care (Caffeine citrate, Prostaglandin E)

In 2013 WHO has also published a separate list of essential medicines for children but no such national list has been published that deals with the paediatric drugs.¹¹

CONCLUSION

On the basis of comparative analysis it the study observed that NLEM lacks some important drugs

that are present in WHO list and there are certain drugs which are not included in WHO list but present in NLEM. Hence the national list needs a revision by the experts from the field of Pharmacology and the experts of drug market, as the general capital of market is a very important point when any drug is chosen to be included in the list of essential medicines. The World Medicines Situation Report 2004 of the World Health Organization (WHO) pointed out that approximately 67% of the population lives without an access to essential medicines. India is reckoned among the global leaders in the manufacturing of generic medicines. However, it is also held that the largest number of population in India is living without having an access to basic medicines. For meeting the requirements of medicines at reasonable prices as also for strengthening of the indigenous manufacturing capacity and capability, the Government has over the years, formulated policies and issued drug price control orders from time to time. Currently, National Pharmaceuticals Policy, 2005 has been drafted with key objectives of price regulation of the essential medicines, availability of good quality medicine, higher investment for increased production, emphasis on drug research and development and promoting good manufacturing practice in domestic pharmaceutical companies.

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