



An Analytical Study of the Essential Medicine list of Kerala and Tamil Nadu.

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ABSTRACT

Plan: Through this study, the authors have critically analyzed the Essential Medicine List of Tamil Nadu (TN-EML) and Essential Medicine List of Kerala (KL-EML) and compared them with National List of Essential Medicines India (NLEMI). A questionnaire which includes; how frequently the list is modified? What are the criteria for addition and deletion of items? What method is adopted for the publication and popularization of the EML? What is the constitution of the Committee entrusted with the responsibility of EML revision? Which state does have the highest number of items? How the list is categorized? Are there obsolete items in the EML? Is the EML supported by Standard Treatment Guidelines? Is there redundant exclusion of child friendly dosage forms of the items? , are planned to discuss in the present study.

Methodology: Analytical study of Essential Medicine List of Tamil Nadu, Kerala in comparison with National List of Essential Medicines India.

Outcome: The KL-EML just lists all the essential medicines. It does not classify them into various therapeutic classes as done by TN-EML and NLEMI. The common therapeutic categories include most of the drugs in all the 3 lists. There is a need for certain add-on drugs like antidotes and pediatric dosage forms in TN EML and KL EML.

Keywords: Essential Medicine List (EML) , Kerala Medical Services Corporation Ltd (KMSCL), Tamil Nadu Medical Services Corporation(TNMSC),National List of Essential Medicine India (NLEMI)

1. INTRODUCTION

In October 1977, World Health Organisation (WHO) produced the first Model List of Essential Drugs and in 1978, the Declaration of Alma Ata identified “provision of essential drugs” as one of the eight elements of primary health care. WHO defined “The Essential medicines are those that satisfy the priority health care needs of the population”.



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They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.” The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations and it should be updated regularly¹.

In India, there were more than 70,000 drug formulations available in the market and most of them are unnecessary, hazardous and marginal remedies. The irrational drug use is directly related to the number of brands available in the market and their promotion. Third world countries including India are the dumping grounds mostly because of poor drug control or regulatory mechanisms. Struggle for essential drugs in keeping with morbidity pattern of our country started as early as 1901 with the setting up of Bengal Chemical and pharmaceutical industry at Calcutta by scientist of repute Dr. P.C.Roy. The struggle for availability of common essential drugs started in 1944 to 45 during the post famine epidemics. The supply of essential drugs was inadequate to meet even 20% of the demand. The government of India constituted Hathi Committee in 1975 provided some recommendations, some of which have been achieved, such as self-sufficiency in medicines. Recognizing the importance of the Essential Medicine List (EML), the first EML was developed in 1996, but was not implemented for procuring drugs and no Standard Treatment Guidelines (STG) were drawn up². The list was revised in 2003 and the next revision was carried out on June 2011. The National List of Essential Medicines of India (NLEM) has been useful in advancing medicine in the health sector. It has also helped to prevent irrational combination drugs and ineffective ones.

In India, health is the individual responsibility of each state. Many states have developed their formulary based on the list of essential drugs. The NLEMI serves as a model list and is adapted to reflect the health status, morbidity patterns, financial and other logistic requirements for procuring and transporting medicines within the state. Tamil Nadu is the first state to develop the essential list as early as in 1994; the state has also streamlined the procurement and distribution of the same through Tamil Nadu Medical Services Corporation Ltd. (TNMSC) which is being looked upon as a model by other state governments. TNMSC finalize the EML every year by getting the requirements of the Government Medical Institution situated throughout the state and these requirements are placed in the month of November every year. Apart from regularly publishing EML, TNMSC provides copies of the EML to all government Doctors, Pharmacist and Nursing staff.

The Government of Kerala sanctioned a Hospital Formulary for Medical Colleges in the state of Kerala containing 236 drugs. The first hospital formulary for a government medical college in the country was published in 1997 under the department of hospital and clinical pharmacy, Govt. Medical College Hospital, Trivandrum. Unfortunately there was no revision for this Hospital formulary and later, the establishment of Kerala Medical Services Corporation Ltd (KMSCL) in 2008 paved the way for publishing EML and they finalize EML every year. KMSCL could not give much attention and care for the activities like publication of EML in booklet form every year and make it available to all health centers.

The objectives of the present study are

1. To critically evaluate the EML of Kerala and Tamil Nadu and compare with NLEMI.
2. To find out which state is having the highest number of items and how the list is categorised, are there obsolete items in the EML, how frequently list is modified, criteria for the addition and deletion of medicines, Methods adopted for the publication and popularization of the EML.
3. To find out whether EML is supported by STG and if there is redundant exclusion of child friendly dosage forms in EML.
4. To find out to what extent these EMLs comply with the WHO Model List of Essential Medicines.

2. METHODOLOGY

Our study is a comparative analytical study. By selecting the published list of NLEM 2011 and EML 2011-12 of Tamil Nadu and Kerala which were downloaded from their official websites through the sources such as The Central Drugs Standard Control Organization, KMSCL and TNMSCL. The lists were assessed and evaluated and checked for the compliance with WHO Model List of Essential Medicines. Published articles and literatures in various scientific and professional publications were reviewed based on the aims and objectives of the study. The primary purpose of NLEM is to promote rational use of medicines considering the three important aspects i.e. cost, safety and efficacy. Furthermore it promotes prescription by generic names. Comparison was made between the 17th edition of TN- EML and 4th Edition of Kerala- EML

3. RESULTS & DISCUSSION.

It is observed that the total number of drugs present in the National List of Essential Medicines (NLEM), TamilNadu Essential Drug List (TN EML), Kerala Essential Drug List (KL EML) are 348, 260, 287 drugs respectively. One hundred and sixteen drugs were found to be common in three lists. Number of drugs that are not present in TN EML and KL EML when compare with NLEM are 158 drugs.

The three lists were compared with the WHO model list⁶ and observed that WHO list contains 362Medicine out of that 124 medicines were not present in NLEMI, Tamil Nadu EML and Kerala EML. Tamil Nadu and Kerala finalize their EML every year, where as NLEMI was revised only two times.

Criteria for modifying the NLEMI was done through experts from different disciplines, from medical and pharmaceutical institutes and hospitals, from across the country and states specifically gave the reasons or evidence which guided their decision regarding addition/deletion/alteration.

A table showing the comparison of Kerala EML and Tamil Nadu EML with NLEMI.^{3,4,5}

No.	Drug class	NLEM	KL EML	TN- EML	Comments
1	Anaesthetics	18	12	11	Ether is listed in NLEM; it's nearly an obsolete as an anesthetic agent. Oxygen is included only in NLEMI not in another 2 list.
2	Anti infectives	64	35	38	Anti fungals, anti retro virals do not have either dose or dosage form appropriate for children.
3	NSAIDs	14	11	13	Morphine, Azathioprine were not listed in KL-EML, Tramadol, Allopurinol, Sulfasalazine were not included in TN-EML.
4	Cardio vascular drugs	27	19	20	Amiodarone, Verapamil were not listed in KL-EML, Sodium Nitropruside, Losartan potassium were not in TN- EML, Urokinase, Procainamide, Esmolol were not in both KL & TN list
5	Gastrointestinal drugs	16	19	12	The presence of 4 anti ulcer drugs in NLEMI, such as Famotidine, Ranitidine, Omeprazole, Pantaprazole .In KL EML Ranitidine, Pantaprazole, Omeprazole and Rabeprazole were present, including medicines of the same class which have no major advantage.Zinc Sulphate which is used for pediatric diarrhea is included only in NLEMI.
6	Anti Convulsants	7	11	4	Lorazepam is not present in TN EML
7	Hormones other endocrine drugs & contraceptives	24	12	3	NLEMI includes premix insulin (30:40) inj, but it is not specified which of the two insulin preparations are mixed in this.
8	Antidotes & other Substances used in poisoning	7	7	1	Activated charcoal and other major antidotes are not included in TN EML.
9	Solutions correcting water electrolyte & acid base disturbances	10	11	10	N/2 Saline and N/5 Saline not available in KL and TN- EML.
10	Vitamins & minerals	10	8	11	Zinc tablets were present in TN- EML
11	Psychotropic drugs	10	14	15	Olanzapine in not listed in TN -EML
12	Drugs acting on the respiratory tract	6	11	8	Codeine is not included in both KL and TN EML.
13	Muscle Relaxants & cholinesterase inhibitors	5	12	4	Vecuronium, Pyridostigmine were not listed in both KL & TN EML
14	Dermatological drugs	16	17	8	Calamine, Benzyl benzoate not listed in TN-EML, Coal tar, Dithrenol, Permethrin were not listed in both lists
15	Other category drugs	114	88	102	More than 25 medicines were not listed in both KL & TN EML
	Total drugs	348	287	260	82.47% drugs in KL -EML and 74.71% drugs in TN EML were present in NLEMI.

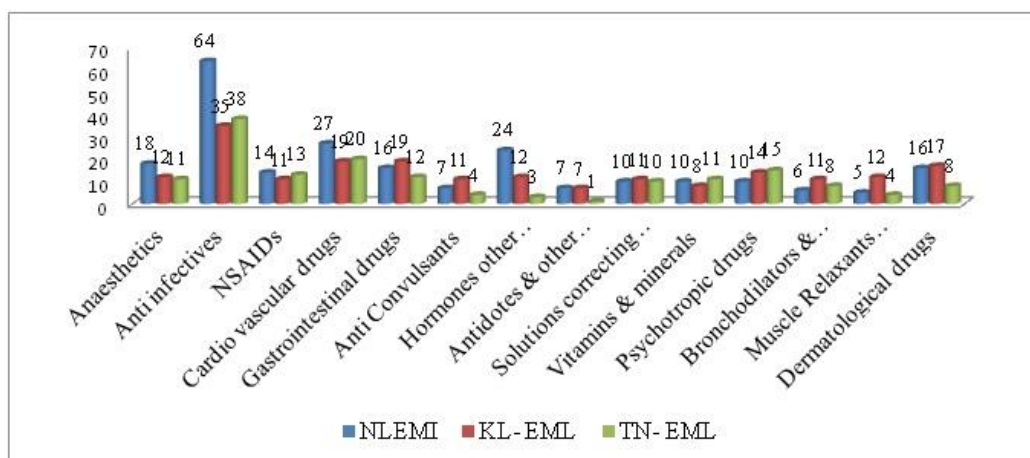
The TN EML was published and made available to all public hospitals in the state. It was the result of a well thought and properly designed plan that the essential drugs list was prepared before starting the logistics management by the Corporation. Since 1995, the EDL is published every year and made available to all the stakeholders in the state. A Committee consisting of Professors of various clinical disciplines including medicine, pharmacology, an expert from World Health Organization (WHO), health secretary and the managing director of TNMSC was constituted to finalize the essential drug list. Later the state drugs controller was also included in the in the Committee. The WHO essential drugs list is taken as the model for the preparation of the EDL of TNMSC. After detailed discussions and deliberations, based on the morbidity pattern and the prevailing diseases calendar in different parts of the state, the Committee finalized an essential drug list consisting of 240 generic medicines.

They have also conducted a 'Vital Essential and Desirable' analysis (a well accepted inventory control technique used in medicine management) and listed the items into three categories - Vital, Essential and Desirable⁷. Only very few combination drugs were included in the list and the concept of single drug ingredient was adopted by the Committee at the time of finalizing the list⁸. However, the TNMSC could not or rather it did not try to convert the essential drug list in the form of a scientific Hospital or State Formulary. But development of handbook for pharmacists and regular publication of newsletter for healthcare professionals helped promoting the concept of rational drug use. The TNMSC entrusted the responsibility of publication of the hand book for pharmacists to a private pharmacy college in the state and the authors have written it in a professional manner.

The KMSCL finalizes the EDL every year. The first EDL was published in 2008 containing 527 items of medicines, sutures, surgical and other hospital items including detergents and chemicals. The number of drugs presented in each category was shown in Figure 1. The annual indents are prepared by the DHS and DME and the Corporation does the tender process based on the estimated requirements. However during the first three years, the KMSCL could not give much concentration and care activities like publication of EDL in booklet form every year and make it available to all health care centers as done by TNMSC. The KMSCL is yet to take up issues like publication of Formulary, STGs etc as done by Delhi and Tamil Nadu⁹. The sixteen year old TNMSC and Delhi policies are presently more effective in the case of publication of hand books, reference materials, Essential Drug Lists, Formularies and other publications aimed at promoting rational and scientific use of medicines. On 25th September 2012 version 1st Essential Drug Handbook was released by KMSCL.

Taking the first anesthetic section, Ether was mentioned in NLEMI but not in KL and TN EML, Ether is nearly obsolete as an anesthetic agent and was deleted from the 14th edition of the WHO Model list (2005). But in 2011, the committee decided to list it in the NLEMI. Currently, ether is not even recommended as an anesthetic for animal experimentation .So it is inappropriate in adding ether in NLEMI¹⁰.

Figure 1: Number of medicines presented in each therapeutic categories of NLEMI, KL-EML and TN-EML



Anti anemic drugs present in TN EML and NLEMI is Cyanocobalamin, where as in KL EML both Cyanocobalamin and Mecobalamin were present. According to Fred Bloem, after injection of Cyanocobalamin it will convert to methylcobalamin and then hydroxocobalamin to be used by the body. Due to the toxins and heavy metals present in the liver of smokers, these people are less able to transform Cyanocobalamin into methocobalamin. Were as, Hydroxocobalamin is the most bioactive form of vitamin B₁₂; it retained longer in the body and can be dosed less frequently. But the cost of hydroxocobalamin and Mecobalamin were very much higher than cyanocobalamin. In WHO EML they have included hydroxocobalamin¹¹.

Selection Criteria

The selection of essential drugs for health care delivery system can be done in a two – step process: *First*: Development of Standard treatment Guidelines for common diseases and complaints, *Second*: Identification of drug and drug products, which provide most cost effective therapy.

WHO recommends the following criteria for consideration on selection of essential drugs or medicines¹²

1. Only medicines for which sound and adequate evidence of efficacy and safety in a variety of settings is available be selected.
2. Relative cost effectiveness is a major consideration for choosing medicines within the same therapeutic category. In comparisons between, the total costs of the treatment not only the unit cost of the medicine must be considered and be compared with its efficacy.
3. The accessibility of facilities for manufacture and storage.
4. Adequate quality, ensured bioavailability and stability preserved medicine must be available.
5. Ideally the essential medicines should be formulated as single compounds. Fixed dose combination products are selected only when the combination has a proven advantage in therapeutic effect, safety and adherence or in decreasing the emergence of drug resistance in malaria, tuberculosis and HIV/AIDS.

The selection of medicines for use within the state or country's public hospitals is a critical process. Ideally the selection of medicines should be linked to evidence based standard clinical guidelines and the list may be divided into levels of care and that both are regularly reviewed and updated¹². The following approach may be useful.

1. Constitution of technical committee consisting of people from different fields such as medicine, nursing pharmacology, pharmacy, public health, consumer affairs and health workers etc. 2. List of common health problems from epidemiological data. 3. Development of standard treatment guidelines. 4. Compiling the list of essential drugs.

From the study it reveals that improper selection of essential medicines from the same category is unnecessary, here in KL EML they included Ranitidine, Omeprazole, Rabeprazole, and Pantaprazole. Considering NLEMI they have selected Ranitidine, Famotidine, Omeprazole and Pantaprazole for Gastrointestinal medicines¹⁰. While TN EML had selected Omeprazole and Ranitidine appropriately.

Zinc Sulphate formulation used for the treatment of pediatric diarrhoea was included in NLEMI, but both TN EML and KL EML fail to include this medicine in list. Zinc tablets were available in TN EML under the vitamins and minerals section. Even though zinc sulphate were supplied to all sub centres through National Rural Health Mission (NRHM)¹⁰.

Child friendly dosage forms were available in TN EML for Anti Infective and Vitamin and mineral Sections. Even though it is not specifically mentioned, Pediatric formulations were available in KL EML. Considering NLEMI many drugs have formulations to go with different adult doses. For example, fluconazole tablets are presented 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 Children¹⁰.

Comparing the three lists, TN EML has less number of medicines compared to other two. TNMSC had the system of distributing 10 percent of the annual budget to hospitals which has helped the Corporation to counter the criticism that the drug list was inadequate¹³.

4. CONCLUSION

The EML can help countries to rationalize the purchasing and distribution of medicines, by this means reducing costs to the health system. The KL-EML have more number of medicines when compared to TN-EML, In KL-EML medicines was not classified according to its therapeutic categories as done by TN-EML and NEMLI. But the recent edition of KL EML, categories medicine and brings it like a booklet form. The common therapeutic categories include most of the drugs in all the 3 lists when compare with WHO model list.

For the publication and popularisation of EML the printed copies of EML was made available at all government level and to individual clinicians and other health care providers to make them aware and adhere to in discharging their duties. Criteria for modifying EML of two states was done through a committee of experts from various disciplines, they gave the reasons or evidence which steer their decision regarding addition/deletion/alteration. There is a need for certain add-on drugs like antidotes, Zinc Sulphate for pediatric diarrhoea in TN EML and KL EML. It was found that the KL EML was not supported by STG and there is redundant exclusion of child friendly dosage forms in NLEMI.

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