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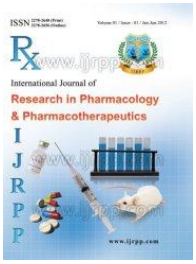

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Comparative analysis of first versus latest version of WHO essential medicine list

Kavyashree AC[1], Laxminarayana Kamath[2]

[1]*Post Graduate Student, Department of Pharmacology, Bangalore Medical College & Research Institute, Bengaluru.*
[2]*Assistant Professor, Department of Pharmacology, Bangalore Medical College & Research Institute, Bengaluru.*

***Corresponding author: Kavyashree AC**
Email: kavyashree.ac@gmail.com

ABSTRACT

Background

The concept of Essential medicines was pioneered by the **WHO** in 1977 to provide safe and effective treatment against the global burden of disease. Latest, 19thEML by WHO and 4th list of NLEM are published in 2015

Aims and Objectives

To study the factors affecting the change in profile of Essential medicine list.

Materials and Methods

The EML was accessed from the official website of WHO and the NLEM from Central Drugs Standard Control Organization website, downloaded and compared. A detailed analysis of 1st and latest EML was done in terms of System wise allocation, addition and deletion of medicines

Results

There is steady increase in number of Essential Medicines from 204 to 414 in latest EML of WHO when compared to first list. Maximum allocation of medicines in WHO first list is for Infectious disease (53/204,26%) followed by Cardiovascular diseases (25/204,12%),Central nervous system disorders (15/204,7%) whereas in latest version of EML by WHO maximum allocation of medicines is to Infectious diseases (135/414,33%) followed by antineoplastic medicines (47/414,11%), cardiovascular disorders (32/414,8%). Maximum increase in medicines is seen with following sub categories of diseases like Antineoplastic (47), Anti viral drugs (27), Anti tubercular drugs (17), Contraceptives (16), antidotes (15). Some of the medicines like Atorvastatin, Telmisartan, Glimepiride, Thiopentone, cetirizine etc are included in NLEM 2015 but not included in WHO-EML 2015

Conclusion

The study gives insight about the change in profile of medicines in essential medicine list over a period of time with respect to change in burden of disease, newer diseases , newer invention of safe and effective medicines

Keywords: WHO, Essential medicine list, NLEM, Allocation

INTRODUCTION

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. 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 [1, 2].

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). It is a dynamic tool, reviewed and revised every 2 years since then. The latest 19th Edition of WHO Essential list was released in April 2015. In India the first National List of Essential Medicines (NLEM) was introduced in 1996 with 3 subsequent revisions in 2003, 2011 and 2015 [3, 4, 5].

The purpose of this study is to analyze the factors affecting the change in profile of Essential medicine list between 1977 to 2015

MATERIALS AND METHODS

The source of data for the study was the World Health Organization 1st and latest; 19th Essential Medicine List which was published in 1977 & 2015 respectively was accessed from the official website of WHO [3, 4]. System wise allocation, factors affecting addition and deletion of medicines was analyzed. The latest National list of Essential medicine was accessed from the official website of the drug regulatory authority of India, the Central Drugs Standard Control Organization [5], downloaded and compared it with the 19th WHO EML. Study Period was from Aug 2016 to Sept 2016. The results were analyzed by descriptive statistics.

RESULTS

Table 1 WHO EML with number of addition and deletion of medicines with each revision

Year	Addition	Deletion	Year	Addition	Deletion
1979	45	17	2000	14	06
1983	20	13	2002	12	00
1985	21	08	2003	04	12
1988	21	13	2005	09	17
1990	15	11	2007	22	03
1992	07	01	2009	16	04
1995	09	04	2011	27	21
1997	11	11	2013	17	01
1998	31	13	2015	42	02

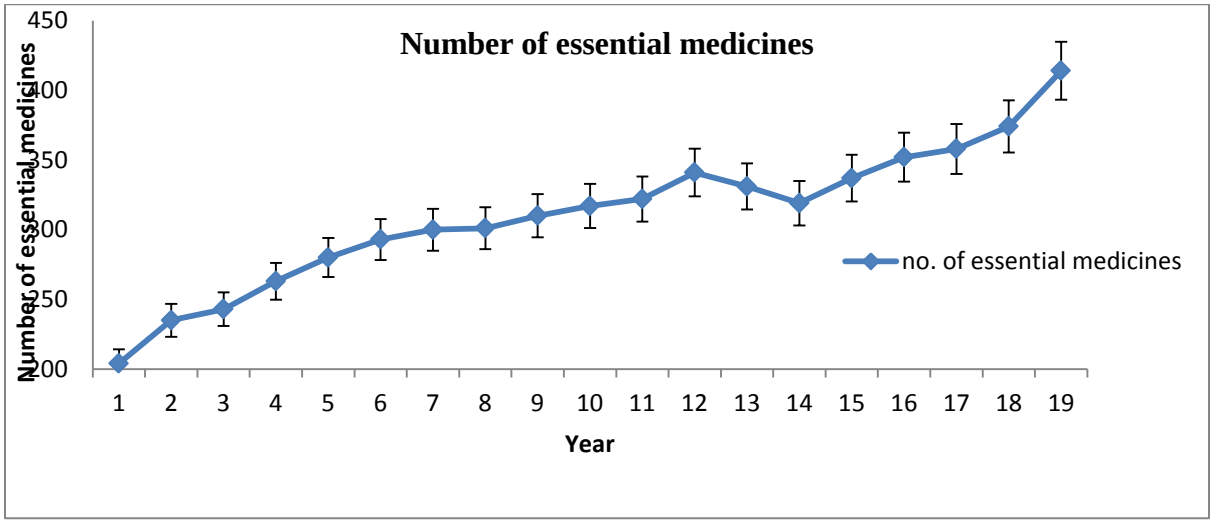

Fig 1 Evolution of the WHO EML

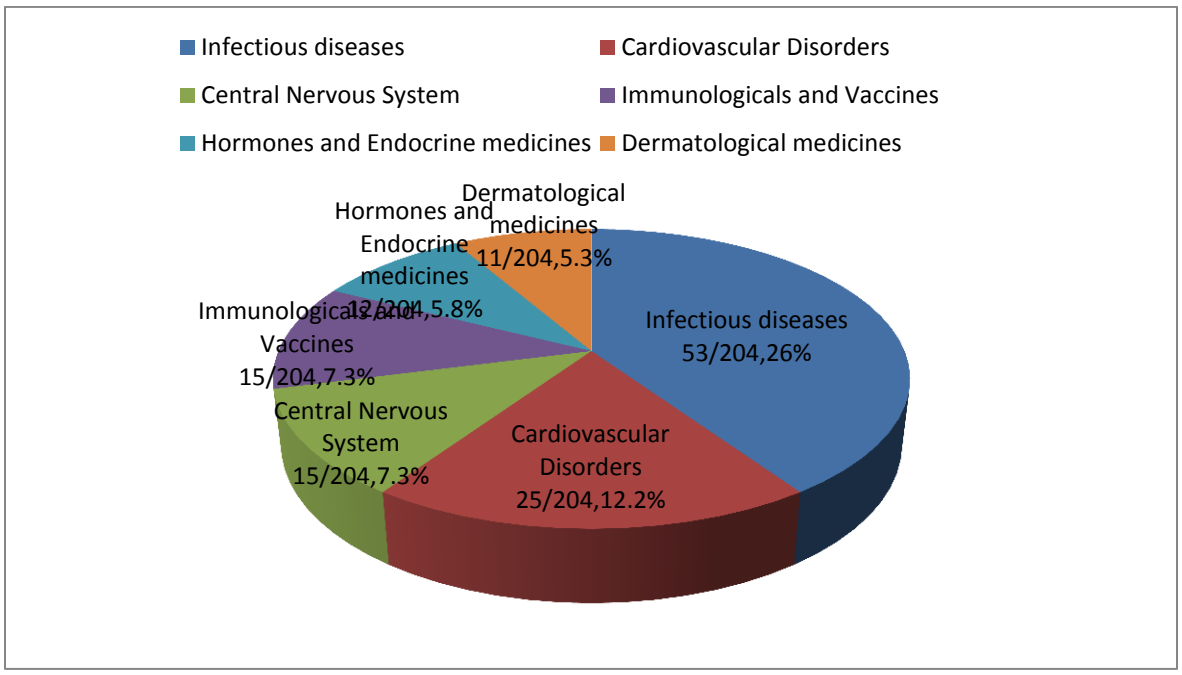

Fig 2 Top six systems with highest allocation of medicines in WHO EML 1977

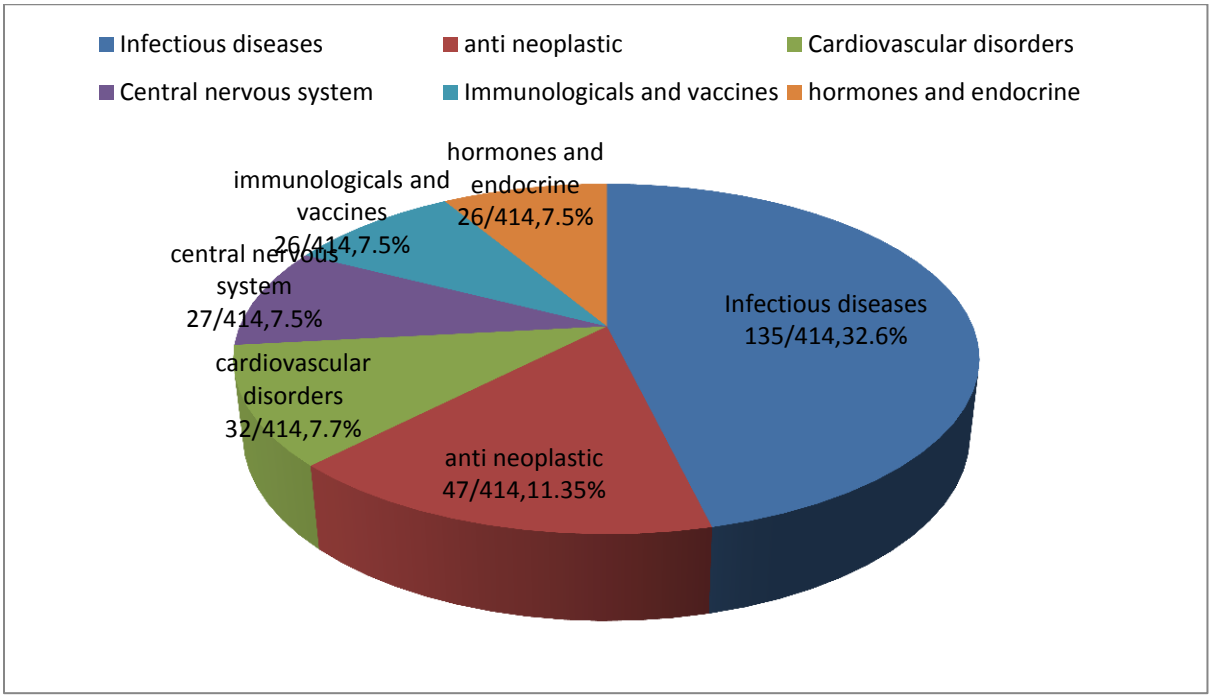

Fig 3 Top six systems with highest allocation of medicines in WHO EML 2015

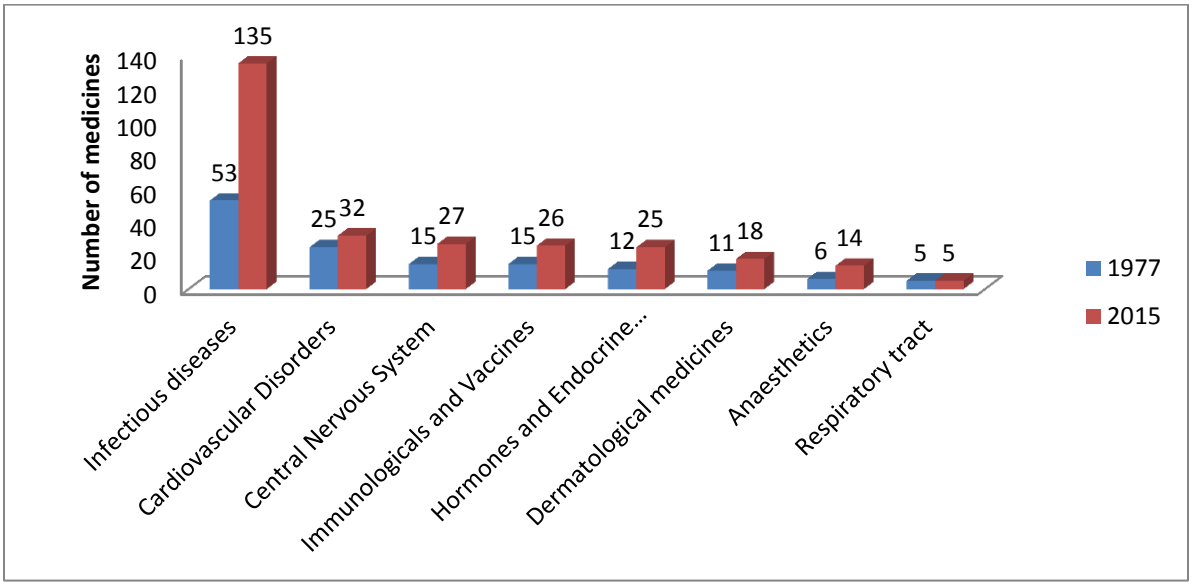

Fig 4 System wise comparison of WHO EML 1977 versus 2015

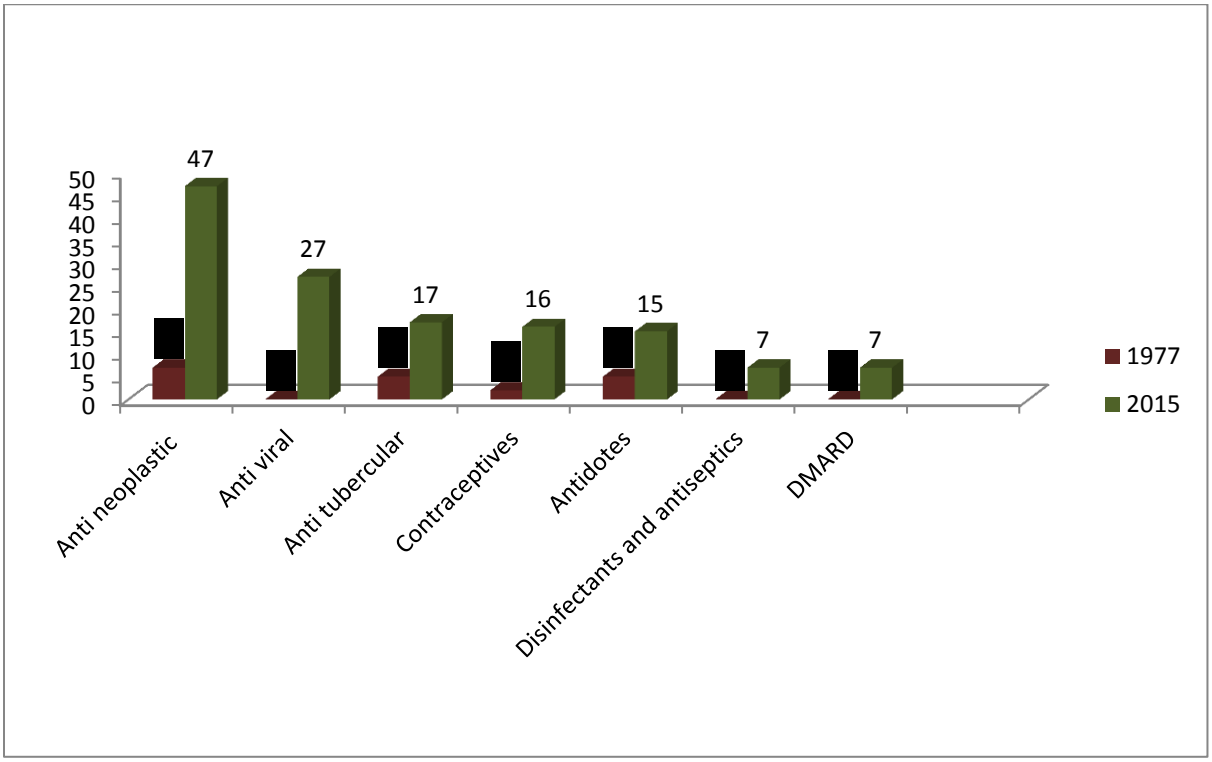

Fig 5 Subset of disorders with drastic increase in allocation of essential medicines

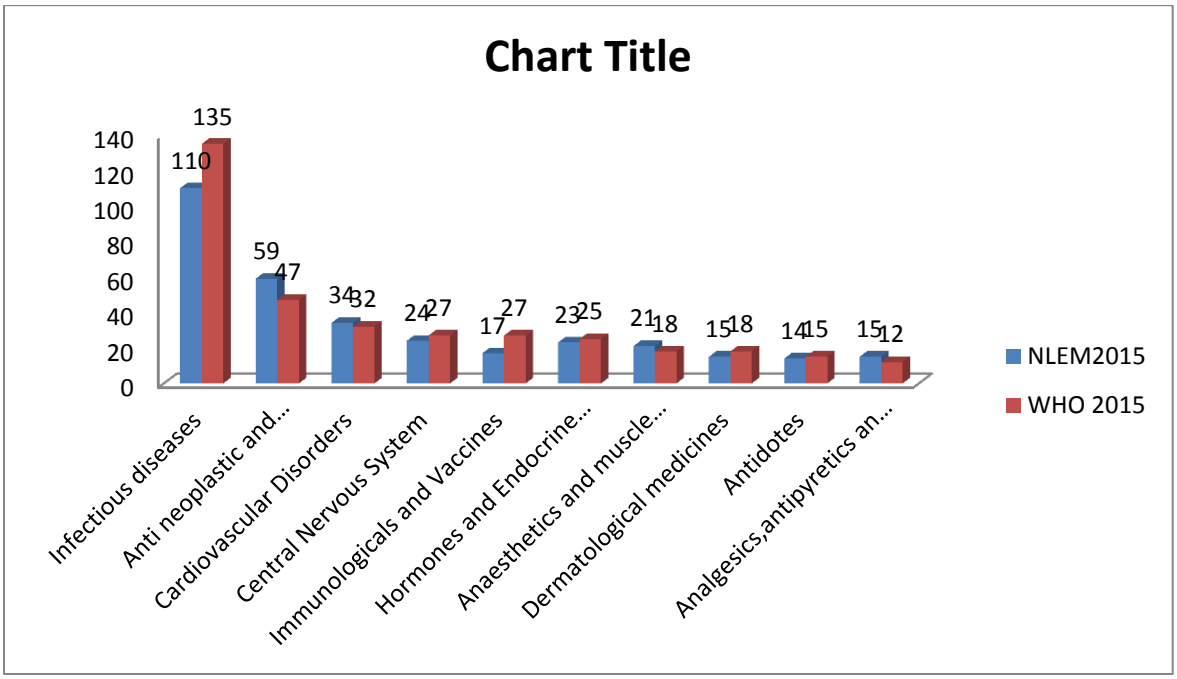

Fig 6 Comparison of NLEM 2015 with WHO 2015

After analysing WHO and NLEM Essential Medicine lists the following results were obtained. Initially in 1977, the WHO EML had 204 essential medicines and the latest list of 2015 includes 414

essential medicines The Evolution of number of essential medicines from 1977 to 2015 was shown in Fig 1

A Majority of medicines added to Essential medicine list over a period of time include Anti Neoplastic, Antiviral, Anti Tubercular and Antidotes. The addition and deletion of Essential medicines with each revision of EML by WHO was depicted in Table1

Infectious diseases (53/204, 26%) followed by Cardiovascular disorders (25/204, 12%), Central Nervous system disorders (15/204, 7%), Immunologics and Vaccines (15/204,7%) allocated with highest proportion of Essential medicines in 1st WHO EML (1977)which is graphically shown in Fig 2

Infectious diseases (135/414, 33%) followed by Anti Neoplastic drugs (47/414, 11%) Cardiovascular disorders (32/414,8%), Central Nervous system disorders (27/414,7.5%), Immunologics and Vaccines (26/414,7.5%) allocated with essential medicines in a descending order in latest WHO EML (2015) which was shown in Fig 3

After comparing the number of medicines system wise in 1st WHO EML with latest WHO EML more clarity regarding steady growth of EML over a period of 40 years is obtained. Which revealed the rise in number of Essential medicines allocated to Infectious diseases (53 vs 135), Cardiovascular disorders (25 vs 32), Central Nervous system disorders (15 vs 27), Immunologics and Vaccines (15 vs 26), and the same is shown in Fig 4

On further analysis a drastic increase in number of essential medicines is seen with the special subset of disorders such as Anti Neoplastic (7 to 47), Antiviral (0 to 27), Anti tubercular (5 to 17), Antidotes (5 to 15) is further analysed for drastic increase in Essential medicine which is shown in Fig 5

Finally a comparision between latest WHO EML and NLEM was carried out and results were Infectious diseases (135 vs 110), Anti Neoplastic (47 to 59) Cardiovascular disorders (32 to 35), Central Nervous system disorders (27 to 24), Immunologics and Vaccines (26 to 17) as shown in Fig 6

DISCUSSION

The WHO EML has steadily grown in terms of the number of drugs included in the list with each revision. Initially in 1977, the WHO EML had 204 essential medicines and the latest list of 2015 includes 414 essential medicines [6]. This steady increase in number of essential medicines is because of various reasons such as change in burden of diseases, change in disease prevalence, emergence of newer infections, emergence of drug resistance , availability of newer and better medicines, incremental innovations in drug delivery systems and formulations, emergence of innovative therapy options, continuing advances with change in disease treatment guidelines. So the list of essential medicines cannot be static but has to be ever dynamic with each revision.

Since its inception in 1977 with each revision there was addition and deletion of drugs. [7, 8] Addition of new drugs is based on documented scientific evidence of efficacy, safety and comparative cost-effectiveness. A Majority of medicines added to Essential medicine list over a period of time include Anti Neoplastic, Antiviral, Anti Tubercular and Antidotes. While reasons for deletions include lack of proof of effectiveness, unacceptable side effects, availability of safer or more effective alternatives, the disease burden for which a medicine is indicated is no longer a health concern. In case of antimicrobials, if the resistance pattern has rendered a medicine ineffective. Some noted examples for deleted drugs were Ether, Digitoxin, Reserpine, Emetine, Alcuronium, Thioacetazone, Pentolamine and Sulphadiazine.

There is a drastic increase in drugs added to Cancer Chemotherapy. Some of the drugs added to this category are Rituximab, Transtuzumab, Tacrolimus and Bortezomib etc. Anti-infectives appear to be the another area with the highest increase, presumably driven by the addition of therapies for evolving health concerns such as tuberculosis, malaria, and HIV some of the medicines added to this are Refabutin, Amikacin, Capreomycin, Bedaquilline, Acyclovir, Sulfomethaxazol+Trimethoprim , Nevirapine, Zidovudine, Ritonavir ,Ribavirin etc. Hormones and vaccines are the other therapy areas with significant number of drugs added to the original list such as Tamoxifene , methylprednisolone, levonorgesterol, gliclazide, pneumococcal vaccine, rotavaccine, MMR vaccine etc. It is also worth mentioning here that drugs for the treatment of Rheumatic disorders, Antidotes, Disinfectants and Antiseptics, Blood

products which have least contribution in the first WHO EML added nearly 40 medicines to latest WHO EML

The Model list of the WHO is a template and serves as a guide for countries to prepare their own lists. The country wise final list is decided based on regional factors such as patterns of prevalent diseases, availability of medicines, treatment facilities and personnel, affordability, genetic, demographic, and environmental factors [9, 10].

The Indian EML (NLEM) has fewer unique molecules compared to the WHO EML (376 vs. 414).However with the increasing burden of infectious disease NLEM has included a higher share of anti infective medicines when compared to WHO EML (135 vs 110).On the contrary the number of drugs included for cancer therapy are higher in WHO EML compared to NLEM (59vs47). While the number of drugs under various systems such as CVS, CNS, Hormones, Dermatological medicines etc. are similar between the lists of the WHO and India. As in the WHO EML, most drugs in the Indian EML are generic agents. Both NLEM and WHO EML provides fixed dose combination drugs for Tuberculosis, HIV, Malaria etc.. Fixed Dose Combinations (FDCs)are included if there is advantage over individual ingredients administered separately, in terms of increasing efficacy, reducing adverse effects and/or improving compliance.

The clear cut distinction of NLEM when compared to WHO EML is that the listing of medicine in NLEM is based according to the level of health care, i.e. Primary (P), Secondary (S) and Tertiary (T). This is because the treatment facilities, training, experience and availability of health care personnel differ at these levels. Out of 376 essential drugs included in NLEM, 209 medicines are listed for all levels of health care (P, S, T), 115 medicines for secondary and tertiary levels (S, T) and 79 medicine formulations for the tertiary level (T).

Some of the important medicines like Amikacin, Bedaquiline, Flucytosine, Gliclazide, Hydralazine, Ivermectin, Levamisole, Oseltamivir, Propyl thiouracil, Rifapentine etc are included in WHO EML 2015 which are not in NLEM. However ,some of the important medicines like Atenolol, Telmisartan, Ramipril, Atorvastatin, Chlorphenaramine, Cetrizine, Diclofenac, Cyclosporine, Mycophenolate Mofetile, Thiopentone, Sevoflurane, Glycopyrolate, Dobutamine, Glimepiride etc are included in NLEM 2015 which are not included in WHO EML.

CONCLUSIONS

To conclude, study gives insight about the the change in profile of medicines in essential medicine list with each revision is because of change in burden of disease, newer diseases, newer invention of safe and effective medicines.

Declarations

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

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