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INDIA'S NATIONAL LIST OF ESSENTIAL MEDICINES 2022: A DESCRIPTIVE ANALYSIS

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ABSTRACT: Objectives: The Indian government has revised the National List of Essential Medicines (NLEM) of India after seven long years in 2022. The objective of this study was to compare and analyse changes in the essential medicines listed in 2015 and 2022. We have also compared the listing of antibiotics in NLEM 2022 to those in the 23rd World Health Organization (WHO) Model list 2023. **Materials and Methods:** NLEM of 2015 and 2022 were accessed from the official website of Central Drugs Standard Control Organization (CDSCO). Parameters assessed were number of medicines in NLEMs 2015 and 2022, therapeutic category-wise additions and deletions in 2022, Fixed dose combinations (FDCs) included in NLEM 2022, Antibiotics in NLEM 2022 as per the WHO Access, Watch and Reserve (AWaRe) classification. **Results:** 384 medicines have been included in NLEM 2022. Major changes were done in the anti-infective therapeutic category in which 18 out of 34 (53%) medicines were added and 9 out of 26 (34%) medicines were deleted. Only 22 FDCs are included in the current list, majority of which are anti-HIV medicines (9 FDCs). 16 out of 20, all 11 and 1 out of 9 antibiotics belonging to the Access, Watch and Reserve categories respectively of 23rd WHO Model list are included in NLEM 2022. **Conclusion:** The medicines which had limited availability and not commonly used by the physicians have been deleted after considering their essentiality. The antibiotics in NLEM 2022 are not categorized as Access, Watch and Reserve as per WHO AWaRe classification.

INTRODUCTION: The concept of selecting fewer drugs from the numerous that are available in the world market leads to – Higher quality of care, better management of medicines and more cost-effective use of available health resources¹. World Health Organization (WHO) defines essential medicines as ‘those drugs that satisfy the priority health care needs of the population’.

The first model list of Essential Medicines (EML) was published by WHO in 1977 containing 208 drugs with revisions every 2 years. Current is the 23rd list of essential medicines by WHO released in July 2023 which contains 502 drugs. More than 150 countries have established their own EML till now using WHO EML as a template.

These lists are available to the member countries to help them create and update national essential medicines lists to guide procurement and supply of essential medicines at the national and local levels². The first national list of essential medicines (NLEM) was released by the Ministry of Health and Family Welfare, Government of India (MoHFW, GoI) in the year 1996 comprising of 279

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drugs. Thereafter, it has been revised four times in 2003, 2011, 2015 and 2022. The latest NLEM released in September 2022 comprises of 384 drugs. This is another step towards affordable healthcare with reduced Out-Of-Pocket-Expenditure (OOPE) under the vision of 'Sabko Dawai, Sasti Dawai' ³.

The primary purpose of NLEM is to promote rational use of medicines based on safety, efficacy and relative cost-effectiveness of the medicines. It also helps in optimization of the available health resources, drug procurement and reimbursement, development of state-level essential medicines list, standard treatment guidelines and hospital formularies, medical education and training of healthcare professionals ⁴.

For the medicines to be included in the NLEM, some criterias need to be fulfilled such as the drug should be licensed in India with proven efficacy and safety and useful in a disease which is a public health problem. Fixed dose combinations (FDCs) are generally not included unless they have proven benefit over the individual medicines. All medicines enlisted in National Health Programmes/ National Disease Control Programmes are as such essential and hence included in the NLEM 2022.

Finally the medicines should be readily accessible and affordable at P-Primary, S-Secondary and T-Tertiary healthcare levels. On the other hand, a medicine can be deleted from the NLEM if a) it is banned in India, b) there are reports of safety concerns, c) Another medicine with better safety, efficacy profiles and cost- effectiveness is now available, d) the disease for which a medicine is indicated is no longer a public health problem and e) in case of antimicrobials, the resistance pattern has rendered the medicine ineffective ⁵.

The process of revision of NLEM 2015 involved more than 130 meetings with subject experts, various stakeholders, patient groups, pharmaceutical associations and concerned government organizations. In order to revise NLEM 2015, MoHFW, GoI constituted Standing National Committee on Medicines (SNCM) in July 2018. The mandate of the SNCM was to revise the NLEM 2015 as well as to include essential medical devices, medical disposables, medical con-

sumables, and other products used for Health and Hygiene used for general public in the next NLEM ⁴.

There have been significant additions to NLEM 2022 including four drugs which are under patent protection. The government has also stressed on enhancing awareness regarding Antimicrobial Resistance (AMR) in NLEM 2022.

Our study was done to compare and analyse the changes in the essential medicines listed in NLEM 2015 and 2022. We have also compared the antibiotics listed in NLEM 2022 to those in the 2023 WHO Model list using the WHO Access, Watch, Reserve (AWaRe) classification to determine up to what extent the NLEM is in alignment with the AWaRe classification framework recommended by WHO.

MATERIALS AND METHODS: The national lists of essential medicines of 2015 and 2022 were accessed from the official website of CDSCO and compared to look for changes or developments. We also went through the report of standing national committee on medicines (SNCM) to better understand the process of revision of NLEM. We have also compared the lists of antibiotics in NLEM 2022 with those in 23rd WHO EML 2023 using the AWaRe classification. This evaluation is based upon the report of SNCM and our own understanding and knowledge of essential medicines. Data was assessed as –

1. Number of medicines added and deleted in NLEMs 2015 and 2022.
2. Therapeutic category-wise additions and deletions in 2022 list.
3. List of FDCs included in NLEM 2022.
4. List of antibiotics in NLEM 2022 as per the WHO AWaRe classification.

Data was entered into Microsoft Excel 365 and analysed using descriptive statistics.

RESULTS: Total 384 medicines have been included in the NLEM 2022 while NLEM 2015 contained 376 medicines. Number of additions and deletions are given in **Fig. 1**.

There are 22 FDCs included in NLEM 2022 out of the total 384 drugs. Majority are anti-HIV medicines (9 FDCs) followed by anti-bacterial

group (3 FDCs) and anti-malarial group of medicines (2 FDCs). Other FDCs included in NLEM 2022 are shown in **Table 2**.

TABLE 2: LIST OF FDCS INCLUDED IN NLEM 2022

Therapeutic group	FDC name	Number & Percentage of FDCs
Anti - HIV	Abacavir + Lamivudine, Atazanavir + Ritonavir, Darunavir + Ritonavir, Lopinavir + Ritonavir, Tenofovir + Lamivudine, Tenofovir + Lamivudine + Dolutegravir, Tenofovir + Lamivudine + Efavirenz, Zidovudine + Lamivudine, Zidovudine + Lamivudine + Nevirapine	9 (41%)
Anti - bacterial	Amoxicillin + Clavulanic acid, Cotrimoxazole (Sulfamethoxazole + Trimethoprim), Piperacillin + Tazobactam	3 (14%)
Anti - malarial	Artemether + Lumefantrine, Artesunate + Sulfadoxine - Pyrimethamine	2 (9%)
Anti - asthmatic	Budesonide + Formoterol	1 (4.5%)
Psychoactive substance abuse	Buprenorphine + Naloxone	1 (4.5%)
Keratolytic agents	Coal tar + Salicylic acid	1 (4.5%)
OCP	Ethinylestradiol + Levonorgestrel	1 (4.5%)
Anti - anaemia	Ferrous salts + Folic acid	1 (4.5%)
For Electrolyte & Acid-base disturbances	Glucose + Sodium chloride	1 (4.5%)
Anti - parkinsonian	Levodopa + Carbidopa	1 (4.5%)
Local Anaesthetic	Lignocaine + Adrenaline	1 (4.5%)

Out of 20 antibiotics listed in the Access category of WHO EML 2023, 16 are included in NLEM 2022. Similarly, all 11 and 1 out of 9 antibiotics belonging to the Watch and Reserve category

respectively are included in the NLEM 2022 **Fig. 3**. The list of antibiotics included in NLEM 2022 are categorized as per WHO AWaRe in **Table 3**.

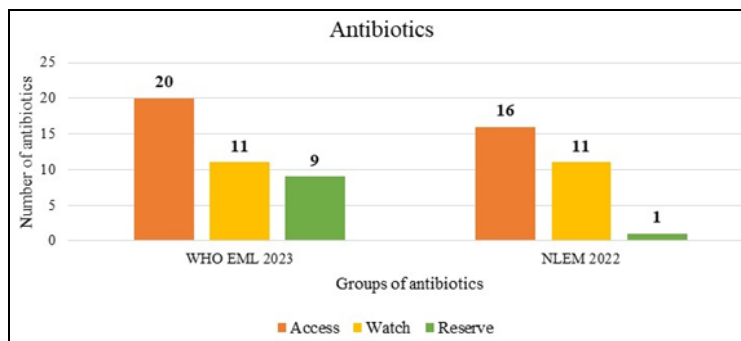


FIG. 3: ANTIBIOTICS IN NLEM 2022

TABLE 3: LIST OF ANTIBIOTICS INCLUDED IN NLEM 2022 AS PER WHO AWARE

Access	Watch	Reserve
Amikacin, Amoxicillin, Amoxicillin + Clavulanic acid, Ampicillin, Benzathine, benzylpenicillin, Benzylpenicillin, Cefazolin, Clindamycin, Cloxacillin, Doxycycline, Gentamicin, Metronidazole, Nitrofurantoin, Phenoxymethylpenicillin, Procaine benzylpenicillin, Sulfamethoxazole + trimethoprim	Azithromycin, Cefixime, Cefotaxime, Ceftriaxone, Cefuroxime, Ciprofloxacin, Clarithromycin, Meropenem, Piperacillin + Tazobactam, Vancomycin, Ceftazidime	Linezolid

DISCUSSION: In our study, we have compared the national list of essential medicines released in

September 2022 with the previous list of 2015 and analysed the changes. NLEM 2022 contains 384

medicines while NLEM 2015 contained 376 medicines. In NLEM 2015, 106 medicines were added and 70 were deleted. 34 medicines have been added and 26 deleted in NLEM 2022. Thus, it was observed that relatively less number of medicines were added and deleted in NLEM 2022. In NLEM 2022, maximum additions and deletions were in the therapeutic category of anti-infective medicines. 18 medicines are added and 9 have been deleted. We have mentioned some of the medicines added. Phoxymethyl penicillin and Procaine benzylpenicillin which were not included in NLEM 2015 have been added in NLEM 2022. The probable reasons for their addition can be better oral absorption and acid stable property of phoxymethyl penicillin and longer duration of action of procaine benzylpenicillin⁶. Examples of some significant additions to the NLEM 2022 include anti-cancer medicines like Bendamustine hydrochloride used for treating chronic lymphocytic leukemia & non-Hodgkin lymphoma, Irinotecan HCL Trihydrate for colorectal and pancreatic cancers and Lenalidomide for multiple myeloma and myelodysplastic syndrome⁷.

The SNCM considered that medicines having a cure rate of >90% for certain cancers should be included in the NLEM despite low incidence of such cancers. The list also includes 4 medicines which are still under patent – such as Bedaquiline and Delamanid for TB, Dolutegravir for HIV, and Daclatasvir for the treatment of Hepatitis C – all of which are part of the government's national health programmes⁴. The rotavirus vaccine, now a part of the government's universal immunisation programme and Ivermectin, which was launched in combination with Diethylcarbamazine and Albendazole as Triple drug therapy for elimination of lymphatic filariasis has also been added in NLEM 2022^{8,9}. Examples of some major deletions are anti-tubercular medicines like Capreomycin, Kanamycin which are substituted by novel drugs like Bedaquiline and Delamanid. These two novel drugs were approved for treatment of multidrug resistance tuberculosis (MDR TB) under conditional access through the Revised National Tuberculosis Control Programme (RNTCP) [currently known as National Tuberculosis Elimination Programme (NTEP)]. Capreomycin and Kanamycin were removed probably due to their dose and duration dependent toxicities like

ototoxicity and nephrotoxicity^{10, 11}. Amongst anti-HIV drugs, Stavudine is no longer commonly used because of high rates of hepatotoxicity and hence all formulations containing stavudine were deleted¹². One of the most commonly used antacid Ranitidine has been removed in NLEM 2022 since unacceptable levels of a contaminant known as N-nitrosodimethylamine (NDMA) which is a probable carcinogen was found in many of the samples tested by the U.S. Food and Drug Administration¹³. An FDC is included only if the combination is rational and has a proven advantage in terms of improved therapeutic efficacy, safety and compliance or in decreasing the emergence of drug resistance⁴. 22 FDCs are included in NLEM 2022 out of which majority FDCs (9, 41%) are anti-HIV medicines. NLEM 2015 also contained 22 FDCs. In NLEM 2022 only 4 FDCs have been changed as compared to the previous list while rest of the FDCs remain the same. The FDCs deleted from NLEM 2015 are ethinylestradiol with norethisterone, combination of lamivudine, nevirapine and stavudine, stavudine with lamivudine and prilocaine with lignocaine.

Examples of FDCs added in NLEM 2022 are Anti-HIV FDCs like darunavir with ritonavir and tenofovir with lamivudine and dolutegravir. Other FDCs added were buprenorphine with naloxone for opioid dependence treatment and coal tar with salicylic acid as keratolytic agents. Antimicrobial resistance is a major problem faced by physicians in treating infections. Antimicrobial stewardship programme is helping to tackle this problem through antibiotic use surveillance jointly with WHO essential medicine list AWaRe classification¹⁴. As per the WHO, antibiotics are classified into three groups – Access, Watch and Reserve – based on the potential of antibiotics to induce and propagate resistance. On comparison with the AWaRe classification of WHO EML 2023 we observed that out of 20, 16 antibiotics from Access category, all 11 from Watch category and only 1 out of 9 Reserve category (Linezolid) was listed in the NLEM 2022. Amongst the list of antibiotics mentioned in **Table 3**, amikacin, phoxymethyl penicillin, procaine benzylpenicillin, cefuroxime and meropenem were included in NLEM 2022. However, this categorization of antibiotics into Access, Watch and Reserve was not done in NLEM 2022. WHO AWaRe classification should be

followed in making of NLEM. This should be incorporated in the future NLEMs so that antimicrobial stewardship programme can be implemented more easily and effectively in India. In addition to the above findings, we also noticed an error in NLEM 2022. Section 6 is anti-infective medicines in which section 6.2.1 is 'Beta-lactam medicines' and section 6.2.2 is 'Other Antibacterials'. Cefuroxime, phenoxymethyl penicillin and procaine benzylpenicillin are beta-lactam antibacterials and have been put under section 6.2.2 instead of section 6.2.1.

Limitation: We could not elaborate on the addition of new sections like medicines for COVID-19 management, inclusion of coronary stents and give reasoning for other drugs included or deleted due to the word constraints of the article.

CONCLUSION: Our study indicate that the medicines and their formulations (dosage form and strength) which had limited availability and not fulfilling the criteria of NLEM have been deleted after considering their essentiality. The antibiotics in NLEM 2022 are not in alignment with WHO AWaRe classification. Also there is an error in section 6 of NLEM 2022. These changes should be considered while drafting the next NLEM which should be revised more frequently.

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