

SYNOPSIS

Dissertation Topic:

A Comparative Study To Analyse The Compliance Of North-Eastern States EMLs With IPHS 2022 EMLs, With Emphasis On Non-Communicable Medicines

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Abstract

Purpose: Essential medicines are crucial for meeting primary healthcare needs, enhancing wellbeing, reducing suffering, and saving lives. The World Health Organization (WHO) first introduced the concept of essential medicines in 1977 to ensure the availability of affordable, effective, and safe medications. India's Free Drug Service Initiative (FDSI) aims to provide free essential medicines at public health facilities to alleviate the financial burden on patients, particularly in economically disadvantaged regions. A standard for the provision of necessary medications in different healthcare facilities is provided by the Indian Public Health Standards (IPHS) 2022 necessary Medicines List (EML).

Methodology: The study employed a cross-sectional design using secondary data obtained from the latest available EMLs of the North-Eastern states and the IPHS 2022 EML. Medicines were mapped and categorized based on their therapeutic class and indication, focusing on cardiovascular, diabetes, and cancer drugs. The comparative analysis involved quantitative measures of (compliance percentages). Data collection involved official websites, government publications, and communication with state health departments and data analysis was performed using Microsoft Excel to calculate compliance percentages and generate comparative charts and graphs.

Objectives:

- i) To assess the availability of NCD medicines in the EMLs of North-Eastern states compared to the IPHS 2022 EML.
- ii) To evaluate NCD drug availability across different healthcare facility levels (DH), (SDH), (CHC), (PHC), and (SHC-HWC).
- iii) To identify states with the highest and lowest compliance with IPHS standards for NCD medicines.
- iv) To analyze the availability of specific NCD drugs of these categories (cardiovascular, diabetes, cancer).
- v) To propose recommendations for improving compliance with IPHS standards.

Conclusions: The findings highlight substantial disparities in NCD drug availability among North-Eastern states. There is an urgent need for targeted interventions to improve compliance

with IPHS standards, particularly regarding the accessibility of essential cancer medications. Policy measures and resource allocation are crucial to address these gaps and ensure equitable access to essential NCDs medicines across the region.

INTRODUCTION: Essential medications are those that meet the population's top health care demands. They can enhance wellbeing, lessen suffering, and save lives. They are chosen on the basis of comparative costs and cost-effectiveness, evidence regarding clinical efficacy and safety, and prevalence of diseases and public health relevance. Pharmaceuticals systems and budgets across nations are being strained by the rising demand for important medications brought on by the rising number of illnesses.

The concept of essential pharmaceuticals was initially put forth by the World Health Organization (WHO) in 1977. Medications that address the population's primary healthcare needs are considered essential. They are selected taking into account comparative cost-effectiveness, efficacy and safety evidence, and public health significance. Crucial drugs must always be available within the framework of functional health systems, in appropriate dose forms, in adequate amounts, with assured quality and adequate information, and at a price that is affordable for the community as well as the individual. The concept of necessary drugs should be applied flexibly and adaptably to a variety of situations; the particular drugs that are deemed essential remain within national authority.

The original Essential Drugs List, which included 220 medications, was compiled by the World Health Organization in 1977 (the name was later changed). Since then, the Model List has been updated in an open process by the EML Expert Committee, which meets every two years. The list has changed over the years to reflect changing public health issues. Antiretroviral drugs for HIV and formulations to treat noncommunicable diseases are only two examples of the additions. The objective of the Model List is to function as a fundamental resource for nations creating their own national Essential Medicines Lists. By assisting in the identification of priority medications to address their nation's health needs, it can help national decision-makers cut expenditures.

Indian Scenario

Medication is one of the most important aspects of health care, and it accounts for a large amount of family spending. The overall expense of pharmaceuticals differs significantly

throughout Indian states. The State Government's expenditure trend on drugs shows that the states differ significantly from one another, with less than 2% in Punjab and 17% in Kerala in 2001–2002. Medication costs account for more than 15% of the health expenditures in the southern states, such as Kerala and Tamil Nadu. States that rank lowest in terms of health and economic development also tend to spend the least on pharmaceuticals. Medication accounts for five percent or less of the health expenditures in states like Bihar, Orissa, U.P., Assam, and Bihar.

Medication costs account for about 12% of the Central Government's total health expenditure. Medication purchases account for about 10 percent of India's health spending budget.

Free Drug Service Initiative

The majority of patients in India seeking treatment for acute or chronic illnesses were coping with a crisis related to access to essential medications. India has some of the highest Out of Pocket Expenses (OOPE) in the world for healthcare; the NSSO 68th round reports that over 67% of OOPE is attributed to prescription drugs. If all patients who visit public health institutions had free access to essential, high-quality pharmaceuticals, they would save a significant amount of money. Thus, giving out free prescriptions is one of the most important things you can do to ease the load of healthcare bills. Achieving universal health care coverage through affordable, safe, high-quality, and acceptable generic Goals pharmaceuticals can contribute to achieving the Sustainable Development.

The Ministry of Health and Family Welfare of the Indian government has recognized the need of having essential pharmaceuticals publicly accessible and readily available at public healthcare facilities. Consequently, the "Free Drugs Service Initiative" (FDSI) was established in 2015 by the National Health Mission (NHM). Operational Guidelines and Model RFPs were sent to the states for the initiative's execution along with the budget release. Finding reasonably priced generic copies of essential drugs is emphasized heavily in the suggestions, which do away with irrational prescriptions and non-scientific set dosing regimens.

National List of Essential Medicines (NLEM)

(NLEM) is a dynamic list of medications that are used to treat illnesses that are significant for a nation's public health. After updating the previous edition, which was released in 2015, In

September 2022, India published the fifth version of the NLEM. The first three editions were published in 1996, 2003, and 2011. Drugs that address public health issues, are competitively priced, have a proven safety profile and efficacy, and comply with national practice recommendations have been included in the most recent edition. Every drug on the list has been approved by India's Drug Controller General and is supported by the relevant government programs. There are 384 medications on the list as of right now, up from 348 in NLEM 2011 and 376 in NLEM 2015. Twenty-six new medications have been added, and thirty-four pharmaceuticals from the prior list have been removed.

Indian Public Health Standards (IPHS)

The Indian government's Ministry of Health & Family Welfare initially introduced the IPHS to establish guidelines for healthcare services and infrastructure at different levels of healthcare facilities. At first, the Primary Health Centers (PHCs), Community Health Centers (CHCs), and District Hospitals were to set criteria for their facilities, staffing, and services. A universal right to comprehensive health security and a comprehensive state obligation to provide enough food and nutrition, appropriate medical care, safe drinking water, proper sanitation, education, health-related information, and other factors that promote good health served as the cornerstones of UHC. Public health facilities now have an obligation to provide high-quality care in order to fulfill all of these domestic and international obligations. The IPHS, which were essentially a set of universal criteria, were introduced to fulfill these goals and provide high-quality services to all residents in a respectful and dignified manner. For this reason, the IPHS for Sub Centers, PHCs, CHCs, Sub-District Hospitals (SDH), and District Hospitals (DH) was released in 2007 and updated in 2012 to serve as a guide for the development and renovation of public health care infrastructure in the States and UTs. In order to deliver health services at these institutions, they offer advice on the infrastructure, human resources for health, medications, diagnostics, equipment, quality, and governance needs.

The initiative's effectiveness depends on the availability of Essential Medicines Lists. Updated IPHS 2022 recommendations with facility-specific Essential Medicines Lists (EMLs) were announced in April 2022 for the Health and Wellness Center - Sub Center, PHC, CHC, SDH, and DH. The National List of Essential Medicines (NLEM-2015), expert group recommendations, MoHFW Program Guidelines, and HWC service packages serve as the foundation for EMLs.

EML - FACILITY WISE	
Health Facilities	Total number of Drugs
Health & Wellness centre - SHC	106
Primary Health Care (PHC)	172
Community Health Centre (CHC)	300
Sub District Hospital (SDH)	318
District Hospital (DH)	381

(Table 1. IPHS, Essential Medicines List facility wise)

The District Hospitals (DH) and Sub-District Hospitals (SDH) have established the 2022 IPHS guidelines. Rural and urban Community Health Centers (CHC). Both rural and urban Primary Health Centers (PHCs) and Health and Wellness Centers are available, with multispecialty UPHCs (Polyclinics) located in metropolitan areas. Rural and urban areas' Sub-Health Center—Health and Wellness Center (SHC-HWC).

India's North-East Region is defined by diversity in its social systems, topography, and ethnic composition (NER). Over time, the region has witnessed an increase in socioeconomic and healthcare development, but non-communicable and communicable diseases (NCDs) have had a significant negative impact, particularly with regard to treatment. It is impossible for chronic diseases (NCDs) to spread from one person to another. They typically take a long time to manifest and evolve slowly. Although it affects people of various ages, those over thirty are most frequently associated with it. Studies show that diseases that affect people under the age of seventy-nine account for 16 million deaths globally. Cancer, diabetes mellitus, ischemic heart disease, cerebrovascular accidents, rheumatic heart disease (RHD), chronic obstructive pulmonary disease, and asthma are the main non-communicable diseases. Due to a combination of social, cultural, and environmental variables, high tobacco use, alcohol consumption, obesity, physical inactivity, stress, and a high-fat diet, the prevalence of cardio-metabolic illnesses such as diabetes mellitus and hypertension has rapidly grown. An epidemiologic transition has resulted from the observation that non-communicable diseases (NCDs) are now the leading cause of disease burden in the majority of low- and middle-income countries (LMICs), surpassing infectious diseases. It is anticipated that by 2020, the number of deaths in India from Non-Communicable Diseases will nearly double, from around 4.5 million in 1998

to 8 million. India is home to about 20% of the world's diabetic population. According to estimates, cardiovascular disease accounts for around 2.4 million fatalities in India each year.

The north-eastern states of India, which includes -

- 1) Assam,
- 2) Arunachal Pradesh,
- 3) Manipur,
- 4) Meghalaya,
- 5) Mizoram,
- 6) Nagaland,
- 7) Sikkim, and
- 8) Tripura



RESEARCH QUESTION: How compliant are the Essential Medicines Lists (EMLs) of the North-Eastern states of India with the Indian Public Health Standards (IPHS) 2022 EMLs, particularly concerning the availability of medicines for non-communicable diseases (NCDs) at various healthcare facility levels?

OBJECTIVES: To compare the availability of non-communicable disease (NCD) medicines in the EMLs of the North-Eastern states with the IPHS 2022 EMLs.

- Assess the overall percentage of NCD drugs available in each state.
 - Identify the specific categories of NCD drugs that are underrepresented in the state EMLs.
1. To evaluate the availability of NCD medicines at different levels of healthcare facilities (DH, SDH, CHC, PHC, SHC-HWC) in each North-Eastern state.
 - Determine the percentage of NCD drugs available at each facility level within each state.
 - Highlight the differences in drug availability between higher-level (DH, SDH) and lower-level (CHC, PHC, SHC-HWC) healthcare facilities.
 2. To identify the states with the highest and lowest compliance with the IPHS 2022 EMLs regarding NCD medicines.
 - Rank the North-Eastern states based on their compliance percentage.
 - Highlight the key strengths and weaknesses of each state's EML in relation to IPHS standards.
 3. To analyze the availability of specific categories of NCD drugs (e.g., cardiovascular, diabetes, cancer) across the North-Eastern states.
 - Compare the availability of drugs for different NCD categories across states.
 - Identify the categories with the highest and lowest availability in each state.
 4. To provide recommendations for improving the compliance of North-Eastern states' EMLs with IPHS 2022 standards, focusing on NCD medicines.
 - Suggest strategies for enhancing drug availability in states with low compliance.
 5. To conduct a secondary analysis of existing data on the availability of NCD medicines in the North-Eastern states.
 - Review existing literature and reports on NCD drug availability in the region.
 - Utilize secondary data sources to corroborate the findings from the primary analysis.

MATERIAL AND METHODS:

STUDY DESIGN: The study undergone for this research is cross-sectional study as the data used here is secondary in nature as extracted from North eastern states of India, which was collected from respective states official sites, and the observations were recorded and analysed.

STUDY TOOLS: Data was analyzed using Microsoft Excel. It was used for data entry, standardization, and initial mapping, statistical analysis, including the calculation of compliance percentages and the generation of comparative charts and graphs.

DURATION OF STUDY: The duration of the study was 2 months.

SAMPLE SIZE: Sample size for this study depends on the North-eastern states of India selected after studying relevance and the increase in NCD.

DATA COLLECTION PROCEDURE: The primary data for this study consists of the latest available Essential Medicine Lists from the north-eastern states of India, which includes -

- i. Arunachal Pradesh,
- ii. Manipur,
- iii. Assam,
- iv. Meghalaya,
- v. Mizoram,
- vi. Nagaland,
- vii. Sikkim, and
- viii. Tripura.

These lists were obtained from the respective state health department websites, official government publications, and communication with state health officials when necessary. The IPHS 2022 EML was sourced from the Ministry of Health and Family Welfare, Government of India.

DATA ANALYSIS PLAN: Molecules/ Medicine Mapping

To facilitate a structured comparison, the medicines listed in each state's EML were mapped against the IPHS 2022 EML. This process involved the following steps:

- i. **Categorization:** Medicines were categorized based on their therapeutic class and indication, with a specific focus on those used for non-communicable diseases. Under three main categories which are medicines for cardiovascular diseases and stroke, diabetes, and cancer, only these 3 were finalised based on NPCPCDS guideline and IPHS drugs categories and final list was prepared based on that.
- ii. **Standardization:** Drug names were standardized to their International Non-proprietary Names (INNs) to ensure consistency and accuracy in comparison. Variations in brand names, dosage forms, and strengths were noted.
- iii. **Mapping:** Each medicine in the state EMLs at all facility level (DH, SDH, CHC, PHC, SHC-HWC) was cross-referenced with the IPHS 2022 EML. The presence or absence of each medicine was recorded, and discrepancies were highlighted as **(YES/NO)**.

ETHICAL CONSIDERATIONS: This study utilized publicly available data from state and national health departments. As such, it did not require ethical approval. However, care was taken to ensure that data was handled responsibly and that the findings were presented objectively and transparently.

IMPLICATIONS OF RESEARCH: One important factor in determining health outcomes is having access to essential drugs, which are also a vital and frequently necessary part of medical care. "Essential drug policy" is a strategy that has been promoted to guarantee access to medications. Based on the current demographic profile and disease prevalence rate, the states must prioritize which medications should be made available. Out-of-pocket costs result from spending money on needless or illogical medications and diagnostic tests. When compared to the cost of a branded medication purchased by an individual customer, the government's bulk generic drug procurement significantly reduces costs. Patients would save a great deal of money if all visitors to public health facilities received high-quality essential medications at no cost. In light of the aforementioned and in accordance with the Government of India's "Free Drug Service Initiative," all essential medications ought to be provided at no cost in all public health institutions.

Free drug medicines under the Essential Medicines List (EML) are highly relevant in the North Eastern states of India for several reasons:

- The region faces a high burden of both communicable (like malaria, tuberculosis) and non-communicable diseases (like hypertension, diabetes).
- Many residents in the North Eastern states face economic challenges. Free medicines under the EML significantly reduce out-of-pocket expenses, making essential healthcare more accessible.
- North Eastern states might have fewer healthcare facilities and pharmacies compared to other parts of India. The EML ensures essential medicines are available in public health settings, even in remote areas.
- Compared to other regions of India, the North Eastern states may have a higher rate of certain diseases. By adding pertinent drugs, the EML can be modified to meet these local needs.
- The rugged topography and isolated locations of the north-eastern states make it difficult to reach medical facilities.
- Because of higher rates of poverty than in other parts of India, a sizable section of the populace cannot pay for their own medical bills.

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