

Original Research

## Evaluating the validity of the national list of essential medicines 2015 for medicines affecting blood in 2022: An observational cost analysis

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Received : 19 June 2022

Accepted : 10 October 2022

Published : 29 October 2022

**DOI**

10.25259/JHAS\_19\_2022

**Quick Response Code:**



### ABSTRACT

**Objectives:** The study aims at evaluating the validity of the national list of essential medicines (NLEM) 2015 for medicines affecting blood in 2022. The study essentially aims at conducting a cost analysis that mainly compares the cost variation between the highest and lowest priced branded variants of the same.

**Material and Methods:** The study takes into account the aforementioned two classes of “Medicines Affecting Blood,” which is 10.1–antianemia medicines and 10.2–medicines affecting coagulation. Data were collected from MedGuideIndia, a database of medicines marketed in India. Both cost ratio and percentage cost variations were calculated.

**Results:** Under 10.1–Antianemia medicines, hydroxycobalamin 2 ml injection (500 mcg/1 ml) has the highest percentage cost variation at 1451.72% and folic acid 5 mg tablets have the lowest percentage cost variation at 20.45%. Under 10.2– medicines affecting coagulation, phytomenadione 1 ml injection (10 mg/1 ml) has the highest percentage cost variation at 3784.46% and heparin 2 ml injection (1000 IU) has the lowest percentage cost variation at 10.4%.

**Conclusion:** This study essentially reasons the need for the central drugs standard control organization and NPPI to intervene and appropriately modify the NLEM 2015 and introduce stricter rules and regulations, while ensuring that the appropriate price caps are both enforced and maintained for essential medicines.

**Keywords:** Hematology, Anemia, Pharmacoeconomics, Coagulation

### INTRODUCTION

The World Health Organization (WHO) introduced the concept of essential medicines in 1977.<sup>[1]</sup> Essential medicines are those that satisfy the priority healthcare needs of the population. They are selected with a specific emphasis on 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.<sup>[2]</sup>

The WHO developed its very first essential medicines list (EML) in 1977 and since then, the list has been revised every 2 years. The current versions, updated in September 2021, are the 22<sup>nd</sup> EML.<sup>[3]</sup> This EML is merely a guide for individual nations, who can implement their national

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lists depending on the endemicity and prevalence of specific diseases in the population.

The Government of India, recognizing the importance of the EML, prepared and published its first national essential drugs list in 1996, which was revised in 2003 as the National List of Essential Medicines (NLEM).<sup>[4]</sup> The most recent NLEM was released in 2015.<sup>[5]</sup> The current list has 376 drugs. The medicines in NLEM should be available at affordable costs and with assured quality. The medicines used in the various national health programs, and emerging, and reemerging infections should be addressed in the list.<sup>[6]</sup> It was decided by the Core Committee that NLEM should be developed through a consultative and transparent process. Considering the healthcare structure of India, the essential medicines are to be classified targeting the levels of healthcare facilities.

Medicines affecting blood are essentially important in the case of several vascular and systemic diseases and pathophysiological states.<sup>[7]</sup> The NLEM 2015 has two classes of drugs in the category of “Medicines Affecting Blood,” which is 10.1–antianemia medicines and 10.2–medicines affecting coagulation. And these are important medications that may be taken by people from all walks of life, be it age, gender, occupation, ethnicity, and other sociodemographic facets.

With a specific emphasis on the COVID-19 pandemic, and the introduction of several newer medicines, and branded products, an evaluation of the NLEM 2015 is necessitated. The present study attempts at analyzing the costs of the different variants of the essential medicines in the category of “Medicines Affecting Blood,” to assess the cost variations of the different branded variants of the same.

## MATERIAL AND METHODS

The study is of an analytical variety and does not use animals and/or human participants. The study takes into account the aforementioned two classes of “Medicines Affecting Blood,” which are 10.1–antianemia medicines and 10.2–medicines affecting coagulation.

In the present study, two sets, 10.1.2 ferrous salts and 10.1.3 ferrous salt (A) + folic acid (B), were excluded due to both ambiguity and the non-specific nature of both the medicine and dosage forms. All other drugs were included other than any drug variant either in the form of dose or formulation which did not have a competing brand with or without a different price which was excluded from the study. On the basis of the above, phytomenadione tablet 10 mg and warfarin tablet 3 mg were excluded from the study.

Data were collected from MedGuideIndia, a non-profit online website that collects up-to-date information on various aspects of healthcare, drugs, and insurance.<sup>[8]</sup>

The cost in Indian Rupee (INR/₹) of the different branded generic drugs of the same formulations and combinations was collected and compared. The study conducted the cost ratio comparison using data from the above-mentioned sources. Cost ratios are defined as the ratio of prices of the highest priced branded generic formulation and lowest priced branded generic formulation of a drug with the same formulation, dose, and dosage forms.<sup>[9]</sup> Cost ratios give us the data on the number of times the most expensive formulation is priced in comparison to the cheapest formulation.

The cost ratio was calculated using the following formula;

$$= \frac{\text{Maximum Price (INR)}}{\text{Minimum Price (INR)}}$$

The percentage cost variation was calculated using the formula:

$$= \frac{(\text{Maximum Price} - \text{Minimum Price})}{\text{Minimum Price}} \times 100$$

Both cost ratio and percentage cost variation are taken unto two decimal points.

The data obtained were then analyzed using descriptive statistics.

## RESULTS

The data collected from the previously mentioned sources were analyzed, tabulated, and graphed. A total of 19 variations of the drugs were considered, seven drugs under 10.1–antianemia medicines and 12 drugs under 10.2–medicines affecting coagulation. The cost ratios and percentage cost variations were then further analyzed and compared.

[Table 1] contains the drug generic names, dose, formulation, maximum and minimum branded generic prices, and the percentage cost variation, calculated using the formula mentioned.

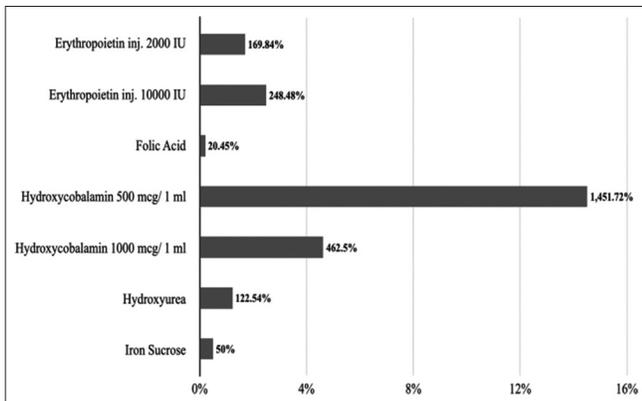
Under 10.1–antianemia medicines, hydroxycobalamin 2 ml injection (500 mcg/1 ml) has the highest percentage cost variation at 1451.72% followed by hydroxycobalamin 1 ml injection (1000 mcg/1 ml) at 122.54%. Folic acid 5 mg tablets have the lowest percentage cost variation at 20.45% followed by iron sucrose 1 ml injection (20 mg/1 ml) at 50%. The average percentage cost variation was 360.79%. [Figure 1] represents the percentage cost variation of 10.1–antianemia medicines.

Along the same lines, hydroxycobalamin 2 ml injection (500 mcg/1 ml) has the highest cost ratio at 15.52 followed by hydroxycobalamin 1 ml injection (1000 mcg/1 ml) at 5.63. Folic acid 5 mg tablets have the lowest cost ratio at 1.2

**Table 1:** Drugs, dose, formulation, highest and variants, and percentage cost variation of medicines affecting blood in national list of essential medicines 2015 lowest priced.

NLEM No. <sup>1</sup>	Drug Name	Dose	Formulation (No. per Unit)	Lowest Priced Brand	Highest Priced Brand	Cost Ratio	Percentage Cost Variation (%)
10.1-antianemia medicines							
10.1.1	Erythropoietin	2000 IU	Injection (1 Vial)	366.88	990	2.70	169.84
		10000 IU	Injection (1 Vial)	1320	4600	3.48	248.48
10.1.4	Folic acid	5 mg	Tablets (10)	13.25	15.96	1.20	20.45
10.1.5	Hydroxycobalamin	500 mcg/1 ml	Injection (2 ml)	5.8	90	15.52	1451.72
		1000 mcg/1 ml	Injection (1 ml)	16	90	5.63	462.50
10.1.6	Hydroxyurea	500 mg	Capsules (10)	70.55	157	2.23	122.54
10.1.7	Iron Sucrose	20 mg/1 ml	Injection (1 ml)	100	150	1.50	50.00
10.2- Medicines Affecting Coagulation							
10.2.1	Enoxaparin	40mg/0.4 ml	Injection (0.4 ml)	224.28	902	4.02	302.18
		60 mg/0.6ml	Injection (0.6 ml)	243.78	1157	4.75	374.61
10.2.2	Heparin	1000 IU	Injection (1 ml)	27	32.5	1.20	20.37
		1000 IU	Injection (2 ml)	6.25	6.9	1.10	10.40
		1000 IU	Injection (5 ml)	35	90	2.57	157.14
10.2.3	Phytomenadione	10 mg/1 ml	Injection (1 ml)	5.02	195	38.84	3784.46
10.2.4	Protamine	10 mg/1 ml	Injection (1 ml)	29	69.5	2.40	139.66
10.2.5	Tranexamic acid	500 mg	Tablets (10)	42.9	178.45	4.16	315.97
		100 mg/1 ml	Injection (5 ml)	18.59	315	16.94	1594.46
10.2.6	Warfarin	1 mg	Tablets (10)	10	26.41	2.64	164.10
		2 mg	Tablets (10)	12	43.84	3.65	265.33
		5 mg	Tablets (10)	5.25	37.3	7.10	610.48

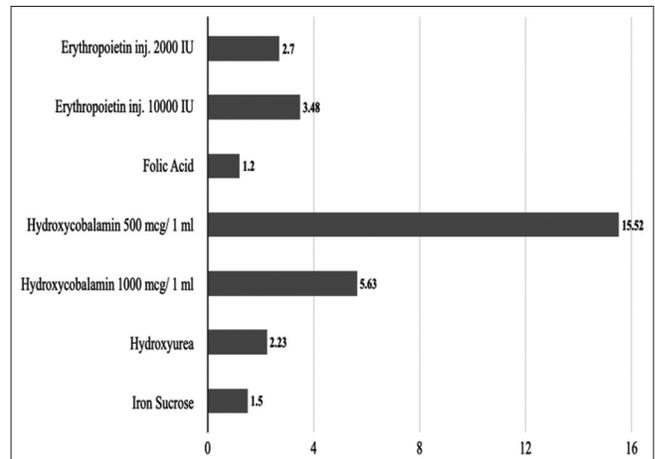
<sup>1</sup>Drug Number as Assigned in National List of Essential Medicines (NLEM) 2015 Drug 10.1.2 and 10.2.3 were excluded due to ambiguous nature of the classification according to NLEM 2015 mcg: Micrograms ml: Milliliters IU: International units



**Figure 1:** Percentage cost variations of 10.1-antianemia medicines.

followed by iron sucrose 1 ml injection (20 mg/1 ml) at 1.5. The average cost ratio was 4.6. [Figure 2] represents cost ratios of 10.1-antianemia medicines.

Under 10.2-medicines affecting coagulation, phytomenadione 1 ml injection (10 mg/1ml) has the highest percentage cost variation at 3784.46% followed by tranexamic acid 5 ml injection (100 mg/1ml) at 1594.46%. Heparin 2 ml injection (1000 IU) has the lowest percentage cost variation at 10.4% followed by heparin 1 ml injection (1000 IU) at 20.37%. The average percentage cost variation was 644.92%.



**Figure 2:** Cost ratios of 10.1-antianemia medicines.

[Figure 3] represents a percentage cost variation of 10.2-medicines affecting coagulation.

Similarly, phytomenadione 1 ml injection (10 mg/1 ml) has the highest cost ratio at 38.84 followed by tranexamic acid 5 ml injection (100 mg/1 ml) at 16.94. Heparin 2 ml injection (1000 IU) has the lowest cost ratio at 1.1 followed by heparin 1 ml injection (1000 IU) at 1.2. The average cost ratio was 7.44. [Figure 4] represents cost ratios of 10.2-medicines affecting coagulation.

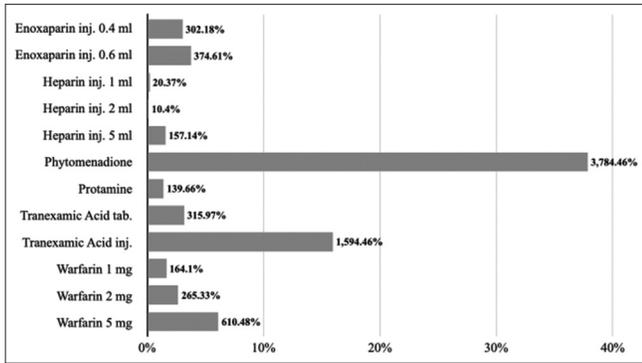


Figure 3: Percentage cost variations of 10.2-medicines affecting coagulation.

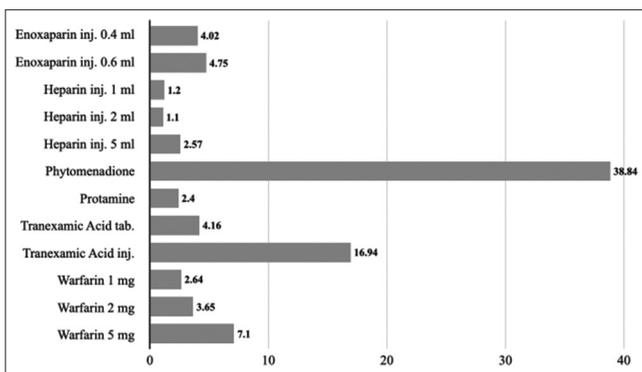


Figure 4: Cost ratios of 10.2-medicines affecting coagulation.

## DISCUSSION

The NLEM 2015 has not been revised in almost 7 years, since its introduction. The last revision was done after 2011 in 2015, based on an order issued by the Supreme Court of India.<sup>[6]</sup> Several modifications have been made to the same, but the validity of the NLEM 2015 is what is brought into question in the present study.

As we have shown in [Table 1], the cost ratios range from 1.2 to 38.84. This entails that in the case of some drugs in NLEM 2015, the higher priced variant is more than 38 times more expensive than the cheapest variant. This is a cause for concern, as “comparative cost-effectiveness” is one of the core principles of EMs since 1977, and 45 years since, we are still unable to satisfy this requirement.

In India, studies that compare the cost of the same drug sold under different brand names by different pharmaceutical companies are few. For this reason, this study was undertaken to compare the cost of different brands of drugs under Section 10 of NLEM 2015. Moreover, several of the drugs under Section 10 are given for prolonged periods, which may even be a lifetime, and may affect the mortality and morbidity in patients with several vascular and hematological diseases.

This study, further, necessitates the intervention by the appropriate authorities, the Central Drugs Standard Control Organization (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA). The main goal of the NPPA is to be a “Regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.”<sup>[10]</sup> As can be seen from this study, some drugs such as phytomenadione 1 ml injection (10 mg/1 ml) and tranexamic acid 5 ml injection (100 mg/1 ml), have percentage cost variations at 3784.46% and 1594.46%, respectively, urgent action is required.

The drug price control order (DPCO) is an order issued by the Government of India, to fix the prices of the drug. Drugs that come under the DPCO cannot be sold at a price higher than that fixed by the government. In India, in 1979, 80–85% of the drugs in the market were under price control, and in recent years, this number has slowly decreased, and by 2002, only 15–20% of drugs were under price control.<sup>[11]</sup>

As can be seen from a randomized controlled trial by Jose *et al.*,<sup>[12]</sup> these medications are used in pregnant women as well, leading toward the conclusion that the at-risk groups are also concerned concerning the aforementioned medications. Anemia is widespread in India with 58.6% of children, 53.2% of non-pregnant women, and 50.4% of pregnant women who were found to be anemic in 2016, as per the National Family Health Survey.<sup>[13]</sup> This high prevalence is also associated with high requirements for iron supplements, especially in the pregnant population.

Another limitation of NLEM 2015 is that several formulations, doses, and dosage forms available in the market were excluded from the list.<sup>[5]</sup> This is further worrying and needs appropriate rectification by the core committee responsible for drafting the NLEM.

With the economic impact of the COVID-19 pandemic lasting more than 2 years, the financial issues attributed to patients have, further, increased.<sup>[14]</sup> For this reason, the urgency of the situation needs to be noted by the NPPA and the CDSCO.

Higher medication costs are a reason for medication non-adherence and are related to an increase in adverse health outcomes.<sup>[15]</sup> Medication non-compliance can be one of the single most common reasons for treatment failure. Non-compliance with the drug therapy results in the progression of the disease which increases the overall medical care costs dramatically. The treatment with generic drugs has been found to have fewer adverse clinical outcomes and improved treatment adherence than treatment with more expensive brand name versions. Das *et al.*<sup>[16]</sup> and Gallelli *et al.*<sup>[17]</sup> identified that generics and branded variants are equally effective in chronic conditions and other conditions, respectively.

One of the advantages of this study is that it uses a relevant government document, the NLEM 2015 as a reference for cost analysis, and also uses MedGuideIndia instead of the current index of medical specialties as the database, which has more up-to-date information than the latter.

The limitation of the study is the exclusion of 10.1.2 ferrous salts and 10.1.3 ferrous salt (A) + folic acid (B). We have not compared the iron supplements and molecules due to the diverse nature of their combinations which would saturate the current paper.

## CONCLUSION

The study mainly discusses the large price variations between the lower and higher branded variants of “Medicines Affecting Blood.” Increased treatment adherence can be ensured by maintaining appropriate costs ensuring both affordability and accessibility. This study essentially reasons the need for the CDSCO and NPPI to intervene and appropriately modify the NLEM 2015 and introduces stricter rules and regulations while ensuring that the appropriate price caps are both enforced and maintained for essential medicines.

## Declaration of patient consent

Patient's consent not required as there are no patients in this study.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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**How to cite this article:** Ahmed HS. Evaluating the validity of the national list of essential medicines 2015 for medicines affecting blood in 2022: An observational cost analysis. *J Hematol Allied Sci* 2022;2:91-5.