# Implementation of principles of pharmacoeconomics and pharmacovigilance to achieve optimal financial and therapeutic benefits through WHO - Essential medicine policy and adoption of NLEM-Based hospital formulary policy

# Suresh Saravdekar<sup>1</sup>, Vijay K. Shukla<sup>2</sup>, Omprakash P. Upadhya<sup>3</sup>, Madhukar Rai<sup>4</sup>, Kiran Giri<sup>5</sup>

<sup>1</sup>Honorary Consultant, <sup>2</sup>Medical Education, Institute of Medical Sciences, Banaras Hindu University, <sup>3</sup>Medical Superintendent, Sir Sundar Lal Hospital, <sup>4</sup>Professor and Head of Medicine Department, <sup>5</sup>Department of Pharmacology, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India

#### **ABSTRACT**

Context: WHO in its development of the roadmap on access to medicines and vaccines 2019-2023 has emphasized that the greatest challenge in achieving Universal Health Coverage (UHC) stem from persistent barriers to accessing health services and to accessing affordable and quality assured health products. In this context, WHO introduced the concept of essential medicines in 1977, and since then, this concept, has been revised every 2 years and is accepted by many countries as guideline to develop National Drug Policy. The concept emphasizes that all aspects of drug management, including procurement, storage, distribution, and use, are easier if fewer essential medicines/items must be dealt with. Essential Medicines are those that satisfy the priority healthcare needs of the population. Aims: During 2017-18, based on the principles of Essential Medicines Concept, we decided to develop and implement "Quality Procurement Management Policies' (QPMP) at Sir Sundar Lal Hospital, at Varanasi, The Pharmaco-econmics and Pharmacovigilance tools are also used to further maximize financial and therapeutic benefits. Materials and Methods: This is evidence based, an observational, and retrospective study. Initially, the analysis of current data on sales of antibiotics during November 2017, December 2017, and January 2018, the procurement practices, selection of medicines, and pattern of use was studied and based on these findings reforms were designed and implemented through the Hospital Formulary Committee. Results: This study revealed that- By the application of QPMP, both the Cost and Quality factors of Medication Management can be dealt with very effectively. And it is possible to make available Quality Assured Medicines at most economic prices, resulting in substantial savings. This study has further, shown that the confidence of physicians also improved as quality assured medicines are provided. Conclusion: The study at Sir Sundar Lal Hospital is thus worth emulating and shown that a doable roadmap with signposts at each and every turn can be designed and can be effectively implemented so that the goal of UHC can be achieved.

**Keywords:** Government savings, medicine procurement, pharmacoeconomics, pharmacovigilance, public health, quality-assured medicines

Address for correspondence: Dr. Suresh Saravdekar, Honorary Consultant, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India. E-mail: saravdekarsuresh@gmail.com

Received: 05-04-2019 Revised: 07-04-2019 Accepted: 28-04-2019

# Access this article online Quick Response Code: Website: www.jfmpc.com DOI: 10.4103/jfmpc.jfmpc\_287\_19

#### Introduction

Many people worldwide do not have adequate and regular access to even a limited basket of basic, low-cost essential medicines,

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

**How to cite this article:** Saravdekar S, Shukla VK, Upadhya OP, Rai M, Giri K. Implementation of principles of pharmacoeconomics and pharmacovigilance to achieve optimal financial and therapeutic benefits through WHO - Essential medicine policy and adoption of NLEM-Based hospital formulary policy. J Family Med Prim Care 2019;8:1987-93.

poor selection of medicines and health products, inadequate domestic or government financing and ineffective policy interventions and processes to manage expenditure and out of pocket expenditure, contribute to a lack of access to medicines and health products at unaffordable prices.<sup>[1]</sup>

WHO in its development of the roadmap on access to medicines and vaccines 2019-2023 has emphasized that achieving Universal Health Coverage (UHC) requires a consistent emphasis on building strong and resilient health systems. Some of the greatest challenges in achieving UHC stem from persistent barriers to accessing health services and to accessing affordable and quality-assured health products. The availability, accessibility, acceptability, and affordability of medicines and vaccines of assured quality need to be addressed in order to achieve the Sustainable Development Goals, in particular target. All aspects of drug management, including procurement, storage, distribution, and use, are easier if fewer essential medicines/ items must be dealt with. [2] Essential Medicines are those that satisfy the priority healthcare needs of the population. World Health Organization (WHO) introduced the concept of essential medicines in 1977, [3] and since then, the list has been revised every 2 years. The current list is twentieth model essential medicines list released in March 2017. The updated list contains only 433 essential medicines.<sup>[4]</sup> In this context, its new long-term framework for 2016-2030 aims to provide a broad vision and strategic direction to focus and reinforce WHO's ability to help Member States achieve universal access to safe and quality-assured health products and universal health coverage. [5] Essential medicine is a pharmacoeconomics tool developed to economize on medicine purchase. Pharmacoeconomics is a branch of health economics, which particularly focuses upon the costs and benefits of drug therapy. [6] Drugs account for a significant proportion of the total healthcare cost, and writing of a prescription is the most common therapeutic intervention in medicine. [7] A knowledge of pharmacoeconomics is, therefore, vital for doctors to promote rational prescribing, as the consumption decisions in health care are taken by the doctor and not by the consumer (the patient) who actually use it and pays for it. [8,9]

Status of Essential Drugs in India - In India, based on WHO Essential Medicines List, the National List of Essential Medicines (NLEM) was first introduced in 1996. Three subsequent revisions of this list took place in 2003, 2011, and 2015. Many Indian states, namely, Tamilnadu, Kerala, Andhra Pradesh, Rajasthan, Maharashtra, etc., have prepared their State Lists of Essential medicines, based on NLEM. However, many factors such as lack of preparation of Standard Treatment Guidelines (STGs), lack of trained staff in procurement, lack of market intelligence, insufficient fund allocation, and lack of confidence in the quality of medicines supplied through the public health care system have failed to implement it effectively. Shortages are a particular issue in Indian public health centers, forcing patients to purchase products from open market at exorbitant cost.

With the effect, an estimated 80% of outpatient consultations and 60% of inpatient treatments take place in private facilities

and only 22% of the Indian population has access to public healthcare.

It has been shown in earlier studies by the Maharashtra State that if the principles of pharmacoeconomics and essential drugs concept are implemented effectively the availability, accessibility, and affordability of essential medicines can be improved and substantial amount of government exchequer can also be saved.<sup>[10]</sup>

The Hospital Formulary Process - In order to achieve these goals, the hospital should have Hospital Formulary Committee (HFC), which is also called as Drugs and Therapeutic Committee (DTC) to ensure that patients are provided with the best possible cost effective essential medicines and quality of care through determining what medicines will be available, at what cost, and how they will be used. [11] The formulary process is the cornerstone. It consists of preparing, using, and updating a formulary list (essential medicines list, EML), a formulary manual (providing information on drugs in the formulary list), standard treatment guidelines (STGs), and standard operating procedures for Medication Management. This ready reference book is thus best tool to curtail irrational use of medicines.

Pharmacovigilance - Irrational use of medicines includes use of too many medicines per patient ("polypharmacy"); inappropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections; over-use of injections when oral formulations would be more appropriate; failure to prescribe in accordance with clinical guidelines; inappropriate self-medication, often of prescription-only medicines; non-adherence to dosing regimes.<sup>[12]</sup> Pharmacovigilance aims at mapping the signals of Adverse Drugs Reactions and promotion of Rational Use of Medicines in the health care.

#### Objectives of the Study

The objective of this study was to review and analyze the economic evaluation of adoption of "NLEM based Hospital Formulary Policy" and "Policy of Quality Assured Procurement" measured as

- Extent of financial savings that can be achieved by the patients by providing all purchase of essential medicines at lowest price
- Assurance of quality of medicines by adoption of prequalification conditions in the tenders called for medicines
- Promotion of Rational Use of Medicines by providing only essential medicines
- To assess the financial need if all essential medicines are to be provided free of charge to all indoor patients under category of "Below Poverty Line – status" visiting at Sir Sunder Lal Hospital (SSH - BHU), Varanasi.

Volume 8 : Issue 6 : June 2019

#### Scope of the study

This study is done to review the Impact of Implementation of Principles of Pharmacoeconomics and Pharmacovigilance to achieve optimal financial and therapeutic benefits through WHO - Essential Medicine Policy and adoption of NLEM-Based Hospital Formulary Policy at SSH as advocated by Hospital Formulary Committee (HFC) of the hospital. No such study was done previously at Pharmacy of SSH.

Sir Sundar Lal Hospital is a teaching hospital, established in 1922, affiliated with the Institute of Medical Sciences, Banaras Hindu University (IMS-BHU) in Varanasi, India. It has grown from its initial size of 96 beds to 927 beds, as of 2011 and recently to 1900, and being upgraded to 2,500 beds. It is the largest tertiary referral hospital in eastern Uttar Pradesh that treats >15 lakh patients annually and fulfilling the healthcare needs of about 20 crore population of the Eastern UP, MP, Jharkhand, Bihar, Chhattisgarh and West Bengal and neighboring country.

#### Plan of study and methodology

This is evidence based, an observational, and retrospective study, conducted:

- A. Constitution of "Hospital Formulary Committee" (HFC):

  Based on the WHO guidelines, the committee consisting of heads of departments from Medicine, Surgery and Pharmacology, an Honorary Consultant (Procurement of Medicines) and two Pharmacists is constituted in June 2017. The committee studied the current procurement procedures followed in SSH and suggested policies and strategies for improving and streamlining overall "Medication Management" in terms of
- **B. Selection of only essential medicines** by reducing current total number of medicines around 2–3 lakhs formulations to minimum possible.
- **C.** Procurement of Quality-Assured medicines only from reputed and quality conscious manufacturers, by central e-tendering and rate contracting procedure and
- D. Reforms to improve availability of essential medicines all the time
- E. To study the impact of Strategies and Policies suggested by HFC and its implementation, by analyzing the data of on comparative rates of branded medicines currently available through Umang Pharmacy, and rates of Quality-Assured Generic Medicines received from reputed manufacturers obtained through e-tendering at SSH. The e-tendering procedure is recently carried out under the guidance and supervision of Hospital Formulary Committee.

#### **Observations and Discussion**

#### **Analysis of Current Situation**

**A. Selection Medicines** Currently, at SSH, all the medicines are sold to all treated patients, through the Umang Pharmacy, a

- private pharmacy, located in hospital campus. It is observed by the HFC from the data collected from Umang pharmacy that the clinicians in the hospital are currently prescribing around 2–3 lakhs medicines under various brand names, formulations, and combinations. Moreover, the industry pushes daily new medicines and many Fixed Dose Combinations (FDCs) in the market, having very little benefit. With the effect that today's medicine market is a therapeutic jungle, flooded with many, me too drugs, non-essential medicines and their unethical and irrational combinations. Most of these are currently being sold through Umang Pharmacy.
- B. Cost and Quality of medicines Sale of antibacterial, their cost, and quality) Currently, Umang Pharmacy is selling medicines at a discount of 5%–10% on Maximum Retail Price (MRP). MRM is an inflated price, decided by the manufacturer to earn maximum profit margins, which usually ranges from minimum 100% to 1,000%. This amounts to total medicine purchase cost of around Rs. 3 crores per month, (around Rs. 35–40 crores per annum). This is very unreasonable cost of purchase on medicines by any standards for a 1,900 bed public hospital.
- C. Pattern of Medicine Use To get an overall idea on pattern, quality, and cost of medicines, this study is restricted to analyze the pattern of use of antimicrobials,

The preliminary analysis of these data on sales during November 2017, December 2017, and January 2018 revealed that

- 1. There is overall preference for expensive brands by clinicians, which is seen higher in the month of January 2018 as that in December 2017. Ceftriaxone is the most preferred antibiotic prescribed as a single as well as in combinations. It held nearly 30% of the share of overall antibiotic sales per month. Four of the top 10 brands were Ceftriaxone compositions. Aristo Pharma is leading with almost 10% of the overall sales share,
- 2. The Other unrecognized brands, namely, Pipzo, Sozid, and Rupex, are new entrants to the top 10 list in the months of December 2017 and January 2018.
- 3. Sales for Cefaxone1GM I.V. revealed *interesting finding*. The sales from Lupin, which is reputed MNC, is Rs. 1,72,932.5, while Sales from Starry Healthcare, not much known company, is Rs. 1, 93,223,85. Hospital could have achieved *better assurance of quality* and also *could have saved* Rs. 20,291.35, if Cefaxone, would have been sold from Lupin, instead from manufacturer, Starry Healthcare.
- Similarly, by giving preference for unrecognized brands such as Rupex, and Sozid, which are also ranked among the top 10 brands, hospital has compromised on quality of these medicines.

This market study on the pattern of medicines prescribed and sold through Umang Pharmacy reveled that a) there is overall preference for very expensive brands by the clinicians and b) in site of spending high price, in certain cases, public is forced to buy medicines from unrecognized companies through Umang Pharmacy. This has harmful effect, on the hard earned money.

Because of poor people, visiting SSH, sacrifice their essential needs to bear the cost of the drugs.

#### Observations and data analysis

A) Selection and Preparation of List of Essential Medicines for SSH - It is observed by the HFC from the data collected from Umang pharmacy that the clinicians in the hospital are currently prescribing around 2–3 lakhs medicines under various brand names, formulations, and combinations. It was a herculean task before HFC to reduce this number to minimum and could not have been possible without taking the prescribers in confidence. To do that, the current NLEM was circulated to all clinicians and clinicians were asked to select medicines only from NLEM. However, they were allowed to add medicines, but only if they feel those are also most essential.

This resulted in preparation of two lists:

- 1) Essential Medicines List of SSH based on NLEM containing 1,000 medicines.
- 2) Desirable Medicines List of SSH containing list of additional 1,000 medicines not available under NLEM but suggested by clinicians as essential.
- Deletion of irrational and unsafe FDC of medicines.

The study of current list of medicines sold at Umang Pharmacy also revealed that there is rampant use of various unethical combinations of medicines. Currently, around 200 irrational FDCs containing combinations of vitamins with minerals for treating cough and cold; antibiotics, antibiotics with lactobacillus; analgesics; proton pump inhibitors; and unapproved irrational combinations of antihypertensive medicines and antidiabetic medicines (are being sold). All these FDCs were removed from the list by HFC. This list is was also circulated and specific time was given to all clinicians during which they were asked offer their opinion if they feel some FDCs are essential. All these FDCs are removed as no requests were received from any clinician during this period, and subsequently, they were informed about this decision.

#### B) Quality Assurance for Generic Medicines -

The next task before HFC was to study current market dynamics of medication management and design strategies and policies, so that low-cost generics of assured quality are selected.

Economic Evaluation for Generic Substitution - Generic substitution is the dispensing of a product that is chemically equivalent to the prescribed patented or original branded product, with the same active ingredients in the same dosage form, and identical in strength. Currently, in Indian market, there are numerous generic products available for such substitution, often at much lower prices than branded products. Generic drugs can reduce the healthcare expenditure significantly since their prices are substantially lower than branded drugs.<sup>[10]</sup>

Quality Evaluation of Generic Substitution - However, physicians are usually apprehensive regarding the quality of

generic drugs.<sup>[13,14]</sup> It is observed that poor-quality generic medicines are moving in international market.<sup>[15]</sup> Poor quality may result in lack of therapeutic effect and cause adverse or toxic reactions; antimicrobial resistance; these, in turn, may result in harm to patients (through prolonged or drug-induced illness), as well as waste of limited resources and loss of faith.

In market-dominated procurement, prescribers and procurement departments cannot distinguish between good-quality and poor-quality generic products, and therefore, some prescribers believe that all the generic products are cheap hence, to be of poor quality whereas some clinicians believe that branded generics are of high quality hence are costly. However, they are hardly aware that many regulations are involved in drug quality assurance, namely, quality regulations for domestic and for export market, regulations called as Good Manufacturing Practices (GMP) for raw materials and for final products, control on use by drug licensing authorities and enforcement authorities, etc., and product quality is usually ensured only if the adherence to GMP is in place at manufacturing premises. Although the generic medicines are bioequivalents of their innovator branded counterparts, these are widely believed as inferior in their therapeutic efficacy and quality to branded products.[16-19]

### Various Global and Domestic Standards of Quality of Generic Medicines –

One Generic with Three Quality Standards - Currently, the Indian manufacturer is allowed for manufacturing a particular generic medicine having three standards. Namely, cGMP, WHO/GMP, and Domestic GMP and marketing as per the need of the customer. cGMP (highest and most updated) standards are needed for export to developed countries, WHO/GMP (Medium and Updated every 2 years) standards for export to developing countries, and GMP (lowest and irregularly updated standards) for domestic marketing.

One Generic Three Equivalents - Consequently, in Indian Generic market, for a particular generic substitution, three generic equivalents are available - 1) chemically equivalent generics (CEG), 2) bioequivalent generics (BEG), and 3) therapeutic equivalent generics (TEG). However, what is needed clinically is therapeutically equivalent or at least bioequivalent generic. Merely having chemical equivalence will provide a generic with "assumed quality" but not necessarily "assured quality generic." Therefore, in United States, which is the largest generic market, there is a website run by US FDA, called "Orange Book," where generics having all three equivalents CEG, BEG, and TEG are displayed on this website, since 1980s, so that a clinician or pharmacist can substitute the particular generic medicine as per the clinical needs. However, due to lack of availability of this data on the website of Indian drugs regulator's websites, it becomes responsibility of hospital procurement department to provide these choices to clinicians as per their needs.

Volume 8 : Issue 6 : June 2019

One Generic Three Licenses - In India, generics are allowed to be manufactured under three different licenses: OWN license, LOAN License, and third-party license. Under the category of last two licenses, the license holder is not actual manufacturer but gets the branded and generics medicines manufactured from other manufacturer. He only markets the medicine but not manufacturers it. Under this typical licensing system, the quality liability of the medicines is 100% with owner of the license only if it is manufactured on Own License. In case of rest two loan and third-party licenses, the quality liability is not shouldered by the license holder owner but by the loan or third-party licensee. Most big pharmaceutical companies get their most branded and generic products manufactured on either loan license or on third party licenses from small- and medium-scale firms, at very low rates, and add huge profit on it and sell their brands, as most trusted expensive branded products. However, this facility of outsourcing the manufacturing is a big flaw in the Indian drug regulatory system, because, for any type of quality lapses during manufacturing of medicines, these big firms can easily escape the legal nets and push this Quality Burden on third party and loan licensee as they themselves do not manufacture medicines but get it manufactured on outsource basis.

## Model Quality Assurance System - Procurement of Quality-Assured Essential Medicines

Therefore, it should be clear from above discussion that Indian generic market is very typically based on market needs and dynamics and not on health needs of population, where

- First, the small- and medium-scale firms that offer the cheapest prices
  and do so by getting licenses, wherein diluted version of manufacturing
  processes (domestic GMP, CEG, and Third Party manufacturing) are
  allowed and cutting corners in formulation.
- Second, because of this peculiar lax system of regulation, the big firms
  get their medicines manufactured by outsourcing their manufacturing
  to small firms at lowest cost and earn 1000 times profit by simply
  marketing it by giving only brand names. And at the same time can
  escape the regulatory quality net easily.

Good procurement, therefore, dictates that the cheapest as well, costliest tenders are not accepted if they are of dubious quality, even though it is difficult not to be swayed by price and illusionary quality of brand names.

Based on these studies, and experiences by State of Maharashtra, The Hospital Formulary Committee came out with a following policy of Prequalification Criteria for participation in the tenders called for medicines, so as to get Quality-Assured Generics by selecting only quality conscious manufacturer.

- 1. Only manufacturers and not their agents or distributors
- 2. Only those who manufacture the generic medicine on *Own licensing* and not on Loan or Third Party License
- Only those who manufacturers holding WHO GMP certification and
- 4. Only those manufacturers having Annual Minimum Turnover above Rs. 500 crores during preceding 3 year.

This policy of prequalification, really helped in *screening/filtering out* all frivolous and unfaithful manufacturers. By this screening process, only 35–40 quality conscious and reputed manufactures (out of around total 11,000 Indian manufacturers) became qualified.

#### **Results and Conclusions**

This study, thus, revealed that

- The proper selection based on NLEM resulted in substantial reduction in number of essential medicines, from current number of 2–3 lakhs medicines prescribed and sold through Umang Pharmacy to only 2,000 essential medicines.
- The selection of minimum and limited number of essential medicines will now further improve Rational Use of Medicines
- There will be reduction in the overall expenditure on purchase of medicines and expenditure on inventory carrying costs.
- 4. The implementation of prequalification conditions effectively helped in screening out "both" profit earning big marketing firms and quality unconscious small firms.
- 5. The expenditure on procurement of antibiotics being large and major (up to 30%–40% of total annual expenditure) the expenditure on top selling antibiotics is analyzed in current study. For that, the data on expenditure of these antibiotics during November and December 2017 and January 2018, are studied. The expenditure data during month of January 2018 are then further analyzed to get an insight into extent of savings that could be achieved through these policies. The extent of savings that can be achieved is vast, which evident from the analysis of comparative data of rates obtained in tender and rates offered by Umang Pharmacy. This is as shown in Tables 1, 2, and 3, below.
- 6. It is evident from the above analysis that many quality conscious reputed manufacturers such as, Cipla, Hetero, Unichem, IPCA, Wokhardt, etc., offered very competitive and most economic rates in the tender, resulting further in substantial amount of savings on Government exchequer.
- 7. This can help in taking decision of providing all essential medicines "free of charge to patients below poverty line" as very less funds will be needed due to very low rates obtained in tenders.
- 8. To improve availability of essential medicines through multiple suppliers per item for all medicines— The second problem usually faced in public healthcare procurement procedure is because of bulk requirements and because of inability to withstand the long outstanding payments, few firms even though on contractual liability, stop supplies of medicines. To tackle this problem of nonsupply, a totally new policy has been advocated by HFC. Under this policy, instead one, multiple suppliers are selected for each medicine so that at a particular time if one supplier fails to execute the purchase order the "standby supplier" can supply. For this, the bidders at the rank of L2 and L3 are called and asked to match the lowest rates offered by bidder at L1 level and only at this lowest rate, the quantity of supply is divided into three suppliers, as 50% quantity to L1, 30% quantity to L2, and 20%

Table 1: Comparative rates of Umang Pharmacy and rates obtained in tender called by Sir Sundar Lal Hospital for top selling antibiotic during January, 2018

Brand names of the Products currently sold	Composition by Generic name	MRP rates offered by Umang Pharmacy	Manufacturer (in UMANG Pharmacy)	Approx. Monthly Sales quantity	Monthly Sales by Umang Pharmacy Value (Rs.)	Tender rate Rs.	Monthly Cost By Tender price -Rs	Monthly Expected approximate Saving -Rs	Manufacturer (in BHU TENDER)
TAZAR	Piperacillin,	183.06	LUPIN HE	371	59,765.43	65.00	24,115.00	35,650.43	Unichem
2.25MG INJ 1s	tazobactum								
RUPEX 250	CEFUROXIME	199.00	ARTEFACT	736	128,888.32	76.60	56,377.60	72,510.72	Hetero
TAB 10s	AXETIL IP		FORMULATIONS						
TAZOJET	ANHYDROUS	210.00	STARRY HEALTH	322	59,505.60	87.75	28,255.50	31,250.10	Wockhardt
4.5GM INJ 1s	PIPERACILLIN		CARE PVT. LTD.						
	TAZOBACTAM								
TAZAR	Piperacillin,	229.48	LUPIN LTD.	445	89,864.37	87.75	39,048.75	50,815.62	Wockhardt
4.5GM INJ 1s	Tazobactum								
PIPZO 4.5GM	Piperacillin,	249.31	ALKEM HEALTH	2100	460,724.88	87.75	184,275.00	276,449.88	Wockhardt
INJ 1s	Tazobactum		SCIENCE						
PIPTAZ	Piperacillin,	427.00	VHB	207	77,782.32	87.75	18,164.25	59,618.07	Wockhardt
4.5GM INJ 1s	Tazobactum								
Approximate Sa	ving per month				8,76,530.32		3,50,236.10	5,26,294.82	

Table 2: Comparative rates of Umang Pharmacy and rates obtained in tender called by Sir Sundar Lal Hospital for top selling antibiotic during January, 2018

Brand names of the Products currently sold	Composition by Generic name	MRP rates offered by Umang Pharmacy	Manufacturer (in UMANG Pharmacy)	Approx. Monthly Sales Quantity	Monthly Sales by Umang Pharmacy Value (Rs.)	Tender rate Rs.	Monthly Cost By Tender price -Rs	Monthly Expected approximate Saving Rs	Manufacturer (in BHU TENDER)
VANCOGRAM 1GM INJ 1s	VANCOMYCIN	444.60	BIOCHEM	107	41,863.54	149.36	15,981.52	25,882.02	Hetero
DALACIN C 600 INJ 1s	Clindamycin	310.20	PFIZER	411	117,292.82	150.00	61,650.00	55,642.82	Cipla
MEROSTAR 1000MG 1s	MEROPENEM	799.00	STARRY HEALTH CARE PVT. LTD.	110	80,858.80	190.00	20,900.00	59,958.80	Unicem
AZOPEN 1GM 1s	MEROPENEM IP & SODIUM CARBONATE IP	1000.00	RPG LIFE SCIENCES	304	3,04,000.00	190.00	57,760.00	2, 46, 240	Unicem
Approximate amount of saving per month				5,44,015.16		1,56,291.52	3,87,723.64		
VANLID 250MG 5ML INJ 1s	VANCOMYCIN	211.26	CIPLA	220	46,477.20	190.00	41,800.00	4,677.20	Cipla

to the L3 level bidder. With this arrangement, each medicine will have three suppliers, at the same lowest rate, the latter two L2 and L3 suppliers are "back up suppliers" and called for supply only in the event of nonsupply by the L1 supplier.

#### **Summary**

It can be seen from above results that the overall impact and benefits of adopting pharmacoeconomics and pharmacovigilance principles through NLEM-based Hospital Formulary Policy are manifold. These policies are worth emulating in all public healthcare systems. To put these findings succinctly -

 These policies have been based on three basic principles: 1) selection of essential medicines based on NLEM. 2) selection of Quality Assured Essential Medicines, and 3) selection of multiple *suppliers per medicine* to improve all time availability of essential medicines

- This policy of essential medicines can further improve the healthcare services, through following two pharmacovigilance benefits, namely, 1) promoting ethical use of essential medicines only and 2) protecting the health of patients from harmful effects of unethical FDCs; and following two pharmacoeconomics benefits: 1) curtailing wastage of funds on procurement of nonessential medicines and 2) reducing workload of procurement, storage, and inventory of medicines.
- By procuring the Assured Quality Medicines at economic prices, it not only improves confidence of physicians but also reduces hospital stay of the patients because of fast recovery and all these benefits together help in improving the image of the hospital in the society.

Table 3: Comparative rates of Umang Pharmacy and rates obtained in tender called by Sir Sundar Lal Hospital for top selling antibiotic during January, 2018

				0.	, -				
Brand of Product	Composition-by generic	MRP Rs.	Manufacturer by - UMANG PHARMACY	Approx. Sales	Appx Sales	Tender rate-Rs	Approx. Amt. by	Appx. Monthly	Manufacturer In BHU
				Qty/M	Amt.by		Tender	Saving Rs	TENDER)
					UMAMG		rate		
LVC 500 TAB 5s	LEVOFLOXACIN	40.5	FLORA & PHARMA	1278	47,618.28	14.35	18,339.30	29,278.98	KAPL
ALSEF 1GM	Ceftriaxone	52.35	STARRY HEALTH	1329	64,007.30	18.9	25,118.10	38,889.20	Wockhardt
10ML INJ 1s			CARE PVT. LTD.						
GRAMOCEF	CEFTRIAXONE	124.84	MICRO LABS LIMITED	1360	1,56,1699	35.5	48,280.00	107,919.81	Cipla
2GM INJ 1s	SULBACTAM								
	(1000 + 500)  mg								
CEFTUM	CEFUROXIME	379.25	GLAXO SMITH KLINE	163	56,872.33	36.8	5,998.40	50,873.93	Akums
500MG TAB 4s									
3 G 1GM INJ 1s	Cefoperazone,	179	ENTRUST	346	56,979.28	41.67	14,417.82	42,561.46	Hetero
	Sulbactam		HEALTHCARE PVT.						
			LTD.						
AUGMENTIN	Amoxicillin +	121.95	GLAXO SMITH KLINE	469	52,618.99	45.5	21,339.50	31,279.49	Cipla
1.2GM VAIL 1s	Clavulanic acid								
SOZID	Ceftazidime	499	S V PHARMA	778	3,41, 635	55.98	43,552.44	298,082.92	KAPL
1.125GM INJ 1s									
Approximate amount of saving per month 5.98,885.92									

#### Financial support and sponsorship

Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

#### References

- World Health Organisation, Drug and therapeutics Committees-A practical guide, 2004, WHO/EDM/ PAR/2004.13. 82.
- WHO, Development of the roadmap on access to medicines and vaccines. 2017;2019-2023. http://www.who.int/ medicines/organization/par/edl/trs/trs914.shtml.
- 3. WHO, *The selection of essential drugs. Report of a WHO Expert Committee.* Geneva, World Health Organization, 1977, WHO Technical Report Series, No. 615.
- WHO Expert Committee on the Selection and Use of Essential Medicines, 27 to 31 March 2017:- WHO Technical Report Series, No. 1006-.
- WHO, TOWARDS ACCESS 2030-WHO Medicines and Health Products Programme Strategic Framework 2016 - 2030, 2017:WHO reference number: WHO/EMP/2017.01.
- Walley, Haycox A. Pharmacoeconomics: Basic concepts and terminology. Br J Clin. Pharmacol 1997;43:343-8.
- Kulkarni U, Dalvi K, Moghe VV, Deshmukh YA. Pharmacoeconomics: An emerging branch in health sciences for decision making. Afr J Pharm Pharmacology 2009;3:362-7.
- Ramesh L. Economic evaluation of antibiotic prescriptions: A cost minimization analysis. J App Pharm Sci, 2013;3:160-3.
- 9. Tilyard MW, Dovey SM, Rosentstreich D. General

- practitioners' views on generic medication and substitution. N Z Med J 1990;103:318-20.
- 10. Saravdekar. Implementation of principles of pharmaco-economics and pharmacovigilance to achieve optimal financial and therapeutic benefits through W.H.O.- Essential medicine policy. International Journal of Bioassays 2018;8.1:5684-91.
- 11. WHO-Developing and Maintaining a Formulary- Session 2, 2007;...https://www.who.int/medicines/technical\_briefing/tbs/02-PG\_Formulary-Management\_final-08.pdf?ua=1) 1-26.
- 12. W.H.O.-The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experiences, WHO reference number:, 2012, WHO/EMP/MAR/2012.3.
- Biswas R, Chatterjee P, Mundle M. Prescribing habits of physicians in medical college, Calcutta. Indian J Community Med 2000;25:161-5.
- 14. Shrank WH, Cox ER, Fischer MA, Mehta J, Choudhry NK. Patients' perceptions of generic medications. Health Aff (Millwood) 2009;28:546-56.
- 15. JAMA Essential medicines for universal health coverage, 2016; *Veronika J Wirtz\**, *Hans V Hogerzeil\* et al.* http://dx.doi.org/10.1016/S0140-6736(16)31599-9. Published online November 7, 2016.
- 16. Hassali A, Stewart K. Quality use of generic medicines. Aust Prescr 2004;27:80-1.
- 17. Shafie AA, Hassali MA. Price comparison between innovator and generic medicines sold by community pharmacies in the state of Penang, Malaysia. J Gen Med 2008;6:35-42.
- 18. Figueiras MJ, Marcelino D, Cortes MA. People's views on the level of agreement of generic medicines for different illnesses. Pharm World Sci 2008;30:590-4.
- 19. Kjoenniksen I, Morten Lindbaek M, Granas AG. Patients' attitudes towards and experiences of generic drug substitution in Norway. Pharm World Sci 2006;28:284-9.

Volume 8 : Issue 6 : June 2019