

Original Article

STUDY ON AVAILABILITY AND AFFORDABILITY OF ANTI HYPERTENSIVE MEDICINES IN THE STATE OF KERALA

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ABSTRACT

**Objective:** Since the 1970s, one of the smallest Indian States, Kerala, has been internationally applauded for its excellent performance in its health indicators. Even if mortality is low, the morbidity (those suffering from chronic/non-communicable diseases) levels in urban and rural is high in Kerala compared to other Indian states. Gradually, the public sector becomes incapable to convene the demands for health care and people have responded to this meagerness by increasing the use of an emerging private sector. To overcome this scenario, Kerala government established KMSCL for promoting access to medicines to the patients approaching the public hospitals in Kerala by making available selected essential medicines at free of cost. The present study was conducted to evaluate the availability, cost and affordability of anti-hypertensive medicines in Kerala.

**Methods:** This prospective, observational study was conducted in Trivandrum district in Kerala, from June 2013 to November 2013. Three types of medication prices were taken into contemplation with the intension for calculation purposes, the highest and the lowest branded medication costs in private pharmacy and Karunya Community Pharmacy (KCP) prices. Affordability was calculated for the different level of skilled workers and through the wages fixed by the government of Kerala for these categories, who were consuming the medications at the time. A comparison was also done between various treatment guidelines of hypertension.

**Results:** There was 15.5% to 230% price variation between the highest and lowest price of branded anti-hypertensive medicines respectively. For treating Stage 3 of hypertension; unskilled and highly skilled workers had to spend a minimum of 1.22 and 0.84 wage days respectively and a maximum of 5.23 and 4.34 wage days respectively in private pharmacies. All the medicines required for the treatments of hypertension were available in both private and KCP.

**Conclusion:** The study revealed that there was an average availability at of antihypertensive medicines in public health facilities. The availability of all medicines at KCP in low price shows the good impact of KMSCL for promoting access of medicines to the poor.

**Keywords:** Hypertension, Medicine Price, Karunya Community Pharmacy, Public sector.

INTRODUCTION

India has a flourishing drug industry and has played a major role to making generics at low prices worldwide [1]. Generate 8 per cent of the medicines available in the global market and ranks 3rd in terms of volume and ranks 13th in world production by value [2]. We are truly proud of this. But medicines situation within India is quite different they are overpriced and unaffordable, a glaring silent violation of human rights [1]. Inequitable access to medicines is a major drawback in the Indian health care system. Nearly sixty per cent (499-649 million) of the population in India does not have reliable access to essential medicines. [3][2]

About 60-90 per cent of healthcare spending by poor people is on medicines. The main focus of the government's drug policies has been on the manufacturing and marketing of drugs to various countries and the private sectors, and not much focused on improving accessibility of essential medicines for the people [2]. A total of 347 essential drugs were brought under price control in the Drug Price Control Order (DPCO) of 1979. Later on the drug companies have succeeded in reducing the basket of price controlled drugs to 142 drugs in 1987. By 1995, it eroded to 76 drugs and only 74 out of about 550 commonly used drugs are under legal price control. So that for the remaining drugs there is no ceiling on drug prices and the companies are free to fix the maximum retail price (MRP) of their own choice, which could be 5 to 10 times or even more the actual production cost [4].

The Department of Pharmaceuticals had notified the Drugs (Prices Control) Order 2013, under which prices of 348 medicines in the National List of Essential Medicines (NLEM) have been brought under price control, thus replacing an earlier order of 1995 that regulated prices of only 74 bulk drugs.

The Government of Kerala constituted Kerala Medical Services Corporation (KMSCL) with the primary objective of making available quality medicines, surgical items and other hospital requisites to all the patients through the public health care networks and for that purpose procure the medicines at most economical rates. The Karunya Community Pharmacy (KCP) under the control of Community Pharmacy Services (CPS) division of KMSCL is a valiant intervention of Govt. of Kerala to reduce the Out-of-Pocket expenditure incurred by the common man, for the huge expenditure on medicines. The KCP scheme helps to provide medicines which are not available in government hospitals for free supply, at reduced/subsidised prices to the patients in a hitherto unknown professional manner.

The high cost of medications affects the most prevalent illness of Kerala, which is hypertension. Recent surveys in different categories of subjects in Kerala reveal that one out of three adults in Kerala is a hypertensive. Hypertension leads to heart attacks, stroke and kidney failure. It is a lifetime disease and needs careful and sensible management throughout life.[5] There was a high prevalence of hypertension in Kerala compared to other parts of India. Highest rate of prevalence was observed in Thiruvananthapuram city in Kerala (30.7%). Elderly sample population has a very high prevalence of hypertension (52%) in Kerala.[6]. 40.6% of adult males and 38.5% of adult females of our State are hypertensive compared to the national average of 30.7% and 31.9% respectively[7].

The primary goal of therapy of hypertension should be effective control of BP in order to stop, reverse or holdup the development of complications and thus reduce the overall risk of an individual without adversely affecting the quality of life. According to Indian Hypertension guidelines by The Association of Physicians of India (API) Younger individuals have high renin hypertension, therefore ACE inhibitors/ARBs or beta-blockers are favored; while older

individuals have low renin hypertension and hence diuretics or CCBs are preferred as first line agents[8].

In combination, one out of the two groups A [ACE inhibitor/ ARB] or B [beta-blocker] is combined with C [calcium channel blocker] or D [thiazide diuretic] (step 2) In refractory patients, when 3 agents are to be used, A+C+D is a good choice (step 3) The combined use of diuretics and beta-blockers is discouraged due to a high incidence of new-onset 9 diabetes.

According to the Treatment protocol of hypertension by government of Kerala (Directorate of Health Services) medicines presented are Amlodipine 2.5mg to 5mg, Enalapril/ Lisinopril 2.5mg -10mg, Chlorthalidone 6.25- 25mg /Hydrochlorothiazide 12.5- 50mg, Losartan 25-50mg[9].

### Objectives

The objectives of the present study are to determine the availability of medicines for the treatment of hypertension in the government hospital and community pharmacies in Kerala. To calculate retail pharmacy medicine prices and assess their affordability and to calculate Karunya Community pharmacy medicine prices and assesses their affordability.

### MATERIALS AND METHODS

A prospective, observational study was conducted in Thiruvananthapuram, capital city of Kerala, from June 2013 to November 2013. The methodology was designed from earlier studies of availability and affordability of medicines, after the critical evaluation by all study investigators. Survey sites was urban City Corporation Area of Thiruvananthapuram district in the state of Kerala, with population of 33,07,284(15,84,200 – males, 17,23,084 – females) and literacy rate of 92.66% (94.60% male and 90.89% female) according to the census report of 2011[10]. The selection of the sample population, consisting of both public hospitals and private pharmacies was based as per the WHO manual comprising of indicators for assessing national drug policies. The district was separated into three geographical area, Highlands, Midlands, and Lowlands. Chirayinkeezhu, and Thiruvananthapuram Taluks situated on the midland and lowland regions, while the Nedumangad Taluk situated in the midland and highland regions, and the Neyyattinkara Taluk extended over all the three regions. Thus the study site was divided into four taluks. Out of each unit, a sample of at least 20 pharmacy units is required (in each zone five retail pharmacy and five government hospitals included in the study). The private pharmacies were selected based on the following criteria: first- the proximity of the private pharmacy to a public health facility, second the willingness of the pharmacy owner to allow the survey. Initially ten pharmacies were identified in each zone, then screened to 5 pharmacies which are located in five km radius. Out of which five selected on the basis of stock maintenance, prominence, accessibility and sales turn over were considered while selecting the community pharmacies (private pharmacies). Availability: For one calendar month, i. e., 4<sup>th</sup> January – 4<sup>th</sup> February 2014, data was collected by studying the availability of anti-hypertensive medication stock at the study sites i. e. Government hospitals and community pharmacies. The medication stock was accounted for thrice during the study, on the 1st day, at the end of 2 weeks and at the end of 4 weeks. From the Hypertension treatment protocol by Gov. of Kerala (DHS) identified 6 medicines for the treatment. The medicines used for stage 1 hypertension and stage 2 hypertension were included in the survey they are, Amlodipine, Enalapril/ lisinopril, Combination of Amlodipine and Enalapril or Lisinopril, Combination of Amlodipine, Enalapril/ Lisinopril and Chlorthalidone / Hydrochlorothiazide, Combination of Amlodipine, Enalapril/ lisinopril, Chlorthalidone / Hydrochlorothiazide and Losartan. These medicines list were compared with NRHM Hypertension Guidelines and JNC 8 Hypertension Guidelines.

**Affordability and Cost of Medicines:** The cost of the medicine was calculated based on the specific condition of the patient and the dosage of the medication proposed the Hypertension treatment protocol by the government of Kerala. The prices of medicines were sorted as highest price, lowest price and Karunya community

pharmacy price. The highest and lowest prices of the brands were taken from CIMS (Oct 2013- Jan 2014). Karunya Pharmacy medicine price was obtained from karunya pharmacy situated in Thiruvananthapuram. The total prices of medications were calculated for ten days of treatment as hypertension was chronic disease and lifelong medications were required. The affordability of medicines in the private sector was evaluated by considering the cost of treatment of hypertension and the minimum wages earned per day by different categories of workers; as specified by the gazette notification of Labour Ministry, Government of Kerala, 2011 [11]. The number of days a daily wage earns would have to work to procure the cost of treatment of hypertension been accessed, lowest, highest and Karunya community pharmacy costs of medications was obtained in the survey. The percentage difference between the maximum and minimum cost of treatment of hypertension was calculated as

$$\frac{\text{Maximum cost} - \text{Minimum cost}}{\text{Minimum cost}} * 100$$

### RESULTS

Table 1 indicates the recommended drug of choice to treat hypertension, according to the condition of the patients. According to the Hypertension Treatment Protocol, three stages have been proposed and each stage requires different treatment. The minimum and maximum prices of the branded and their percentage difference and Karunya community pharmacy prices are summarized in table 1.

The total minimum and maximum cost required for one month treatment of hypertension for stage one is Rs. 16.47 to Rs. 132. In KCP, were they sell both branded and generic and the minimum and maximum cost required for the same treatment is 17.1 to 103.5. In KCP even the branded medicines are available to patients for a low cost. In private medical shops the percentage of price difference between minimum and maximum ranges from 113 to 1040. All the medicines which required for the treatment for hypertension were available at KCP.

Table 2 illustrates a comparison of the guidelines such as NRHM, JNC 8, and Treatment Protocol for hypertension by Kerala government. In which, Beta Blockers which was mentioned in both NRHM guidelines and JNC 8, were not included in the treatment protocol of Hypertension by Kerala Gov., some of the medicines listed in those were not available in Kerala Essential Drug List, such as Lisinopril which cost around a minimum of 2.51 Rs and a maximum of 5.5 Rs in private sector, Chlorthalidone which cost around 1.28 Rs.

Similarly, wage days were calculated for treatment using anti hypertensive drugs for each stage. Table 3 represents the affordability of antihypertensive agents for different categories of workers in the year 2011 in the state of Kerala. For one month of treatment with antihypertensive drugs for an initial stage; unskilled, semiskilled, skilled and highly skilled workers required minimum and maximum of 0.149 and 1.19, 0.144 and 1.15, 0.13 and 1.08, 0.12 and 0.99 wage days respectively in private pharmacies. Similarly, wage days were calculated for treating step two hypertension which required 0.88 and 3.83, 0.85 and 3.70, 0.80 and 3.46, 0.73 and 3.17 respectively. For Step three hypertension treatments required 0.78 and 3.68, 0.75 and 3.56, 0.71 and 3.33, 0.65 and 3.05 wage days. For step four required 1.22 and 5.23, 1.17 and 5.05, 1.10 and 4.73, 0.84 and 3.65wage days respectively.

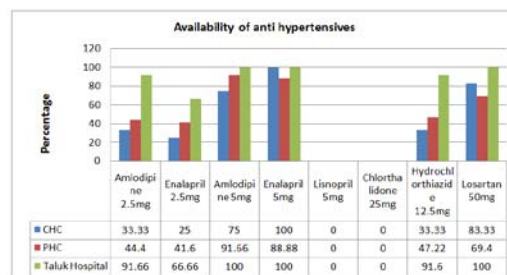


Fig. 1: Availability of selected antihypertensive medicines at public healthcare facility

Figure one, Contains the detail of availability of selected antihypertensive drugs by Gov. of Kerala (Treatment Protocol) at one CHC, three primary health care facility and one Taluk Hospital of four survey area. All the drugs listed were available in private pharmacies.

Chloroquine and Lisinopril were not listed in EDL so those drugs were not available at Public health facilities. The availability of enalapril and amlodipine 2.5 mg was low as the doctors prescribing those medicines were not frequent now days. All the medicines surveyed were available at KCP.

**Table 1: Recommended drug of choice and prices of antihypertensive medications in private retail pharmacy and Karunya Community Pharmacy Prices.**

S. No.	Treatment of hypertension stages	Medicines	For 30 days of treatment					
			Private Retail Pharmacy			Karunya Community Pharmacy		
			Min MRP Rs	Max MRP Rs	Difference %	Min MRP Rs	Max MRP Rs	Difference %
1	Step 1	Amlodipine 2.5mg or Enalapril 2.5 mg	16.47	132	701	17.1	103.5	505.26
		Or	26.4	67.8	156.81	24.6	54	119.51
2	Step 2	Amlodipine 5mg or Enalapril 10mg	22.62	258	1040	21	201.6	860
		Or	83.25	178.08	113.90	111	135	21.62
3	Step 3	Amlodipine 5mg + Enalapril 5mg	48.12	368.52	665.83	60	296.1	393
		Or	97.92	423	331.98	154.5	282.9	83.10
4	Step 4	Amlodipine 5mg + Lisinopril 5mg	86.64	406.92	369.66	94.5	330.6	249
		Or	63	315.42	400.66	73.5	192	161
3	Step 3	Amlodipine 5mg + Enalapril 5mg + Chlorthalidone 25mg	136.44	461.52	238.25	189	317.4	67.93
		Or	112.8	369.9	227.92	168	245.4	46.07
4	Step 4	Amlodipine 5mg + Lisinopril 5mg+ Hydrochlorothiazide 25mg	134.64	578.07	329.34	112.2	425.1	278
		Or	111	486.45	338.24	91.2	286.5	214

**Table 2: Comparison of Hypertension treatment Guidelines and availability in Kerala EDL**

NRHM Guidelines	JNC 8 guidelines	Gov. of Kerala Treatment Protocol	Kerala EDL
<b>ACE inhibitors</b> Enalapril 5 mg Perindopril 4mg Ramipril 5mg	<b>ACE inhibitors</b> Captopril 50mg Enalapril 5mg Lisinopril 10mg	<b>ACE inhibitors</b> Enalapril 2.5mg Enalapril 5mg Lisinopril 5mg	<b>ACE inhibitors</b> Enalapril 2.5mg Enalapril 5mg
<b>Angiotensin receptor blockers</b> Losartan 50 mg Valsartan 40 mg	<b>Angiotensin receptor blockers</b> Eprosartan 400mg Candesartan 4mg losartan 50mg valsartan 40mg Irbesartan 75mg	<b>Thiazide-type diuretics</b> Chlorthalidone 25mg Hydrochlorothiazide 25mg	<b>Angiotensin receptor blockers</b> Losartan 25mg
<b>β-Blockers</b> Atenolol 25 mg Propranolol 40mg Metoprolol 50 mg	<b>β-Blockers</b> Atenolol 25mg Metoprolol 50mg	<b>Angiotensin receptor blockers</b> Losartan 50mg	<b>β-Blockers</b> Atenolol 50mg Metoprolol 25mg Metoprolol 50mg
<b>Calcium channel blockers</b> Amlodipine 2.5 mg Diltiazem extended release 120 mg Nifedipine 30MG (long acting)	<b>Calcium channel blockers</b> Amlodipine 2.5 mg Diltiazem extended release 120 mg Nitrendipine 10mg	<b>Calcium channel blockers</b> Amlodipine 5mg Amlodipine 2.5mg	<b>Calcium channel blockers</b> Amlodipine 2.5 mg Amlodipine 5mg Nifedipine 5mg Nifedipine 10mg Diltiazem 30mg
<b>Thiazide-type diuretics</b> Hydrochlorothiazide 12.5mg Indapamide 2.5mg	<b>Thiazide-type diuretics</b> Bendroflumethiazide 5		<b>Diuretics</b> Frusemide 10mg Frusemide 40mg Hydrochlorothiazide 25mg
<b>Central α 2 agonists and other centrally acting drug</b> Clonidine 0.15MG Methyl dopa 250 MG	Chlorthalidone 12.5 Hydrochlorothiazide 12.5 Indapamide 1.25		Spirolactone 25mg
<b>Alpha blockers</b> Prazosin 2.5 MG			

Table 3: Affordability of hypertension treatment for ten days Treatment (in Year 2011)

S. No.	Treatment of hypertension stages	Medicines	Unskilled	Semiskilled	Skilled	Highly Skilled
1	Step 1	Amlodipine 2.5mg or Enalapril 2.5 mg	0.149/1.19	0.144/1.15	0.13/1.08	0.12/0.99
		Or	0.23/0.61	0.23/0.59	0.21/0.55	0.06/0.17
2	Step 2	Amlodipine 5mg or Enalapril 10mg	0.20/2.33	0.19/2.25	0.18/2.11	0.16/1.93
		Or	0.75/1.61	0.72/1.55	0.68/1.45	0.62/1.33
3	Step 3	Amlodipine 5mg + Enalapril 5mg	0.43/3.33	0.42/3.22	0.39/3.02	0.36/2.76
		Or	0.88/3.83	0.85/3.70	0.80/3.46	0.73/3.17
3	Step 3	Amlodipine 5mg + Enalapril 5mg + Chlorthalidone 25mg	0.78/3.68	0.75/3.56	0.71/3.33	0.65/3.05
		Or	0.57/2.85	0.55/2.75	0.51/2.58	0.47/2.36
3	Step 3	Amlodipine 5mg + Enalapril 5mg + Hydrochlorothiazide 25mg	1.23/4.18	1.19/4.03	1.11/3.78	1.02/3.46
		Or	1.02/3.35	0.98/3.23	0.92/3.03	0.84/2.77
4	Step 4	Amlodipine 5mg + Lisinopril 5mg+ Hydrochlorothiazide 25mg	1.22/5.23	1.17/5.05	1.10/4.73	0.84/4.34
		Or	1.00/4.40	0.97/4.25	0.90/3.98	0.83/3.65
		Amlodipine 5mg + Chlorthalidone 25mg+ Losartan 50mg				
		Or				
		Amlodipine 5mg + Hydrochlorothiazide 25mg+ Losartan 50mg				

## DISCUSSION

The state of Kerala, with just over 3 % of the national population has attained the status of number one position in per capita medicine consumption. It is estimated that 9- 11 % of Indian domestic medicine market share is consumed in the state. Access to essential medicine is over 78 % in the state against the national average of 33% and the global average of 66 %. [12] The State has reported the highest proportion of hospitalized persons both in rural and urban areas. Share of public providers in non-hospitalized medical treatment of ailments in Kerala is higher than that of all India percentages (Kerala Rural- 37%; Kerala urban- 22%; India rural-2%; India urban- 19%)[5]. Also, there is a decreasing trend in the hospitalized treatment from public sources in Kerala. The cost of treatment is the lowest in Kerala even now, both in rural and urban areas, compared to other states though it has increased significantly over the years. According to NSSO 60th round conducted in 2004, the average medical and other related non-medical expenditure per treated person during 15 days preceding the survey was Rs. 182 in rural areas and Rs. 193 in urban areas of Kerala while the national averages were Rs. 257 in rural areas and Rs. 306 in urban areas. The position of Kerala is the reverse, where only 37 percent secured treatment from public hospitals, while 63 percent secured treatment from private and corporate.[13] In India, more than 68 % (Census 2011) populations live in rural area and they work on farms or perform other menial jobs which pay on a day to day basis. The poor people mostly depend on the government hospitals for healthcare. Our study also point out that the price of anti hypertensive medicines in the private sector is very high compared to the Govt. Owned Community Pharmacy. Even though, public health facilities providing free or subsidized care, 81% of outpatient and 45% of inpatient care in India were assessing private healthcare. This may be due to the unused / under used potentials of many institutions such as a) Lack of periodic or annual maintenance of buildings resulting to dilapidated conditions. b) Non- availability of building / lack of proper electrification/ lack of water and sanitation facilities. c) Lack of manpower: Often building and equipment was constructed and established but the lack of man power results in idling of a facility. d) Lack of sufficient equipment and furniture.(rusty and unrepaired cots, spoilt mattress and torn dirty bed sheets or their absence is a common sight in many of the government healthcare institutions. e) Majority of them may not even have basic clinical investigation facilities and may even lack life supporting facilities like round the clock availability of oxygen etc. f)

shortage of medicine due to the irregular supply of medicines and other materials, so patients seeking medical care from the government hospitals are forced to buy them from outside, curt attitudes of doctors and other staff members, corruption, deficiency of hygiene.

Consequently affordability of medicines was a major issue. For one month of hypertension treatment an unskilled worker has to spend 0.149-5.23 days wage require from minimum price brand to maximum price in private pharmacies similarly for other class of workers. (Table 2)

Large variation in costs of medicines was viewed. In India, the pricing policy for medicines was disoriented which was a major reason for the price variation. The prices of all medicines were not under price control and have been left to the market forces. The maximum allowable post manufacturing expense (MAPE) permitted for medicines under price control is 100 percent and ceiling prices have been fixed for these For the other medicines, there is no restriction on the MAPE, resulting in large and variable prices. The variation in prices of the same medicine but sold under different brands is large and may range from 25-3400 percent [14].

The results of this study emphasize the need to improve medication availability and increase affordability of medicine for hypertension, particularly in the public sector. Although many medicines for hypertension as well as for other diseases were theoretically provided for free cost in the public sector, but all the medicines were not available in the public institutions, leading to patients purchasing them from private community pharmacies at higher costs [15]. Branded medications are more costly than their generic equivalents, but in India many branded medications are not available, as a result of which their generic counterparts are overtly pricey. In our study the price difference comparison was minimum for enalapril 113% and maximum for Amlodipine 1040 %. Generic medications are cheaper compared to brand medications but they are not much available in the government facilities. As a result, the same cheap generic medications are sold in the market at a high price and which make poor patient to spend out of pocket.

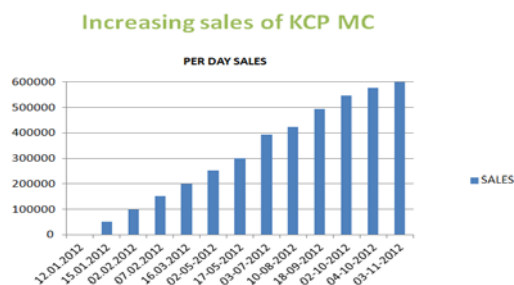
The Karunya Community Pharmacy under the control of Community Pharmacy Services (CPS) division of KMSCL was a courageous intervention of Govt. of Kerala to reduce the Out-of-Pocket expenditure of the society, mostly because of the great expenditure on medicines. The first outlet at Medical college, Trivandrum opened

on 12<sup>th</sup> January 2012. Main features of Karunya Community Pharmacy are: 20-90% discount from MRP for all medicines, Operational 24 X 7 Advanced inventory supply management system,

State of art scientific warehousing (Karunya Medicine Depots) and Patient counseling. Specialty drugs are mostly given in purchase rate itself without taking any margin.

**Table 4: Below shows the price difference which Karunya community pharmacy offers to the public.**

S. No.	Medicine name	MRP	KCP rate(Rs)	%difference
1	Zoledronic Acid(ALZIC Inj)	2,450.00	<b>176.75</b>	92.78
2	Dobutamine(DOBUSTAT Inj 5 ml)	259.00	<b>28.75</b>	88.89
3	Human Albumin(ALBUREL)	5000.00	<b>2100.00</b>	58
4	Peginterferon alpha 2a (PEGASYS PFS 135 MCG)	12415.00	<b>6842.00</b>	44.88
5	Liposomal Amphotericin (AMPHOCEL 50 MG vial)	7990.00	<b>2950.00</b>	63.07



**Fig. 2: Sales analysis during the period from 12.01.12 to 03.11.12**

This drastic increase in sales of KCP shows that the poor patients are getting the branded medicines in much a reduced cost than the private pharmacy price. The number of people resorting to the public healthcare system increased during last 15 years. A study by Kerala Sasthra Sahitya Parishath(KSSP) comparing the scenario in 1996 to that of 2004 showed that 28% of the population was dependent on the government sector in 1996 and it increased to 32% in 2004. Kerala is the first state to implement the union government's initiative to supply free generic medicine to patients through government hospitals from November 1<sup>st</sup>, 2012. A significant increase in the number of outpatients has been reported from the General Hospitals in Thiruvananthapuram, Ernakulam and Kozhikode following the launch of the free generic medicines scheme. Officials of the Kerala medical services corporation (KMSCL) declared that many patients from private hospitals are returning to government hospitals for free generic medicines and they said that there is a 50 to 100 percentage increase in the number of outpatients at these hospitals [16]. In order to make the availability of quality essential medicines in the public health care facilities of the state and to ensure their rational and prudent use, the following problems deserve special attention.

#### **Periodic updating and adherence to Essential Medicines List (EML) of the state**

The list of items in the EML has to be updated at regular intervals with the support of an effective addition/ deletion policy norms. It has to be made known to all those involved in the prescription writing and handling, indenting and dispensing of medicines. The KMSCL has to take the TNMSC model in popularising the EML hand books in an easy to refer format (pocket book for over coat) throughout the state health care facilities.

#### **Updating the Hospital Formulary system**

The Hospital Formulary system working in the state has to be strengthened, particularly in the specialty and tertiary care hospitals with the support of some mechanism ensuring continuous and persistent efforts in that regard till the objective is achieved.

#### **Accreditation of Pharmacy services in Hospitals and Communities**

There shall be a set up for accreditation of hospital and community pharmacies in the state with the objective of promoting good

dispensing practices and good storage practices. It will also help to ensure the presence of the sufficient number of qualified pharmacists with identifiable uniform/ dress code in the pharmacies as initiated by the Kerala State Pharmacy Council. Accreditation will help to make pharmacy services more professional, ethical and scientific.

#### **Publication of standard treatment guidelines**

The absence of STG can lead to many difficulties in implementing a state policy on medicines. It is difficult to make available the required / needy medicines in the health care facilities without interruption without EDL and STGs. Lack of STG leads to duplication and multiplication of certain medicines in the KMSCL warehouses and the hospital pharmacies causing much difficulties and hardships to the inventory management. It also promotes different prescription pattern even for mild conditions. Publication of STG/STP is essential to promote rational drug use.

#### **Effective quality assurance process and timely testing facilities for medicines**

Being a consumer state without much pharmaceutical manufacturing units, the state has to take extra care in ensuring quality control and quality assurance aspects of medicines marketed and/ used in the state. Unethical marketing strategies adopted by certain corners and the delay in withdrawing drugs found 'not of standard quality' (NSQ) are examples of serious issues faced by the state. The quality control mechanism is in doldrums and about less than one% of the batches of medicines used in the state are tested in the drug testing laboratory of the drugs control department. The proposal for establishing four regional laboratories of the department is not moving in the expected speed/ manner.

#### **Computerized medicine registry for the state.**

The state is facing many threats in the case of medicines, their storage, distribution and usage both in public and private set ups. The drug safety has to be ensured with respect to their quality, authenticity, availability and affordability. Unapproved combination drugs, formulations and dosage forms; drugs with similar/ identical or same names, marketing of defective and manipulated pharmaceutical products, clandestine marketing network, clinical trials etc. are issues to be attended seriously. Currently the state is not having any set-up to have a data base on medicines used/ marketed in the state. Drugs with same and similar trade/brand names are available in the hospitals and community pharmacies with entirely different active ingredients. Some agencies supply medicines to the state and vanish from the scene. It is difficult to trace them out as they don't have any office or premises anywhere. The drugs control department is helpless in this regard. In order to solve such issues and establish a system in the state, a computerized medicine registry has to be established.

#### **CONCLUSION**

Access to quality essential medicines at the government health facilities and at affordable prices at private pharmacies and hospitals is essential. The availability of antihypertensive medications is average in public sector, when compared with KCP and private pharmacies were all the antihypertensive medicines available. The high cost of the medicines in India makes treatment less affordable

for the poor sections of the population. The KCP prices are not the lowest as per the common beliefs, but they are significantly lower than the highest priced branded medication available in the market. The Government should consider in expanding the KCP services to other districts at the earliest, which will be benefit for the society. Even though the rule is there, make sure that doctors should prescribe generic medications and government should generate awareness among the people about the availability and quality of generic medications. Modifications and monitoring of pharmaceutical policy at the national and state level are necessary to improve affordability and hence access to medicines for the people.

#### CONFLICT OF INTEREST

No conflict of interest declared by authors.

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