QUALITY AND AVAILABILITY OF MEDICINES IN PUBLIC HEALTH FACILITIES OF KERALA, INDIAN STATE – AN ANALYSIS!

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Abstract- In spite of Kerala being known for its developmental indicators, there are reports of poor quality and non-availability of medicines in the public health facilities affecting the quality of healthcare. In order to redress these issues, Kerala government strengthened the pharmaceutical management system through establishing a centralized drug procurement and distribution agency known as Kerala Medical Services Corporation Ltd. (KMSCL). The present study is done to analyze the availability of the medicines and its quality. An exploratory research is accomplished using health systems perspective and utilizing the Rapid Pharmaceutical Management Assessment: An Indicator Based Approach. Methods involved key informant interviews with officials of drug quality control department and collect data regarding substandard medicines and to check patient access and drug utilization we reviewed prescriptions (n = 400) in health facilities to calculate standard indicators of appropriate medicines use. There has been gradual decrease of percentage of substandard drugs: 7.79% (2011), 4.07 % (2012) and 3.60% (2013). Only one case of counterfeit drug was reported. On the other hand, the percentage of dispensed medications (about 60%) clearly shows the non-availability of medicines in health facilities. These results should inform health policy makers to improve affordable access to essential medicines under the current health care reform. Though the incidences of NSQ report raises concern, gradual decrease in their incidences over the study period is a promising sign.

I. INTRODUCTION

The pharmaceutical management indicates the complete set of actions intended to make sure the timely accessibility and suitable usage of effective, safe, quality medicines and associated services and products in any of the health care setting[1]. Poor-quality medicines represent a serious threat to individual and public health, irrespectively of whether they are sub-standard or counterfeit[2]. Access to essential medicine is over 78 % in the state of Kerala, against the national average of 33% and the global average of 66 %[3]. In 2007 November, the Government of Kerala introduced the new public supply chain system, through the establishment of the Kerala Medical Services Corporation (KMSCL) as a Govt. Company for the selection, procurement, warehousing and distribution of medicines and other hospital requisites. KMSCL is promoting access to quality medicines to the patients approaching the public hospitals in Kerala by making available carefully selected essential medicines free of cost. Drug consumption in the state of Kerala is higher when compared to the other states in India. Recently, the health ministry announced that of the 48,000 drug samples tested by all state drug controllers across India between 2011 and 2012, nearly 5% failed the quality test, while almost one in three drugs (36%) were found to be "not of standard quality" in the country. States like Maharashtra (23%), Tamil Nadu (13%) and Kerala (9.2%) have a huge issue of sub-standard drugs Semi – urban and rural areas are more prevalent for this issue in all states[4]. The present study is done to analyze the availability the patient access and drug utilization in public health facilities and to know the prevalence of substandard medicine in Kerala state.

II. METHODOLOGY

An exploratory research, was carried out in the state of Kerala during the year 2011-2014, The data collection form was designed to collect the data for the study. The study was conducted in nine district of Kerala. The study site included a total of nine public healthcare facilities comprise of one government medical colleges at Thiruvananthapuram and three general hospitals at Alappuzha, Ernakulam and Kozhikode and five district hospital at Kottayam, Kollam, Palakkad, Malappuram and Thrishur were selected representing the entire state of Kerala. For developing the data collection form relevant points were collected from "Rapid Pharmaceutical Management Assessment: an Indicator based approach" and modified to suit our requirements. The developed form is validated using a pilot study. To check the patient access and drug utilization following indicators were added in data collection form: Average number of drugs prescribed per curative patients encounter in public health facilities. Percentage of drugs prescribed by generic names in public health facilities.Percentage of drugs prescribed by brand names in public health facilities. Percentage of prescribed drugs that are actually dispensed in public health facilities. Retrospective data from 2010 January to December 2013 pertaining to the number of NSQ drugs and number of officials involve in sampling were collected from official website as well

as through key informant interview with the officials of Drug Control Department. Different methods were used to collect data including a survey, visual observations of processes, examination of records and interaction with respondents. Additionally, the survey was also analytical because it was meant to assess the effect of the quality of medicines and its impact on public health and safety.

III. RESULTS

Patient Access and Drug Utilization

A total of 400 prescriptions was taken from eight secondary care and one tertiary care hospital, and found that patients received an average of 4.6 drugs per encounter. The range among health facilities was 4.6 to 6.2 drugs per facility. From the 400 prescription taken 58.94% of drugs was prescribed by generic name . Figure 1, depicted the patient access and drug utilization at various public health facilities. The rate among facilities varied from 48.34 % to 66.34%. An average of 58.43 % of prescribed drugs presented for dispensing were actually dispensed, with a range from 47.84% to 70.02% among facilities.

IV. PREVALENCE OF SUBSTANDARD DRUGS

A total of 6090 sample drugs were collected from the public and private healthcare facilities and pharmacies by the drug inspectors, Out of that 430 (6.25%) drugs were declared as NSQ, Highest percentage of NSQ medicines were found in the year 2010 with 14.37%, results shows the number of NSQ drugs were decreasing from 14.37% to 3.60 % in 2013. Table 1 illustrates the number of NSQ drugs and manufactures.

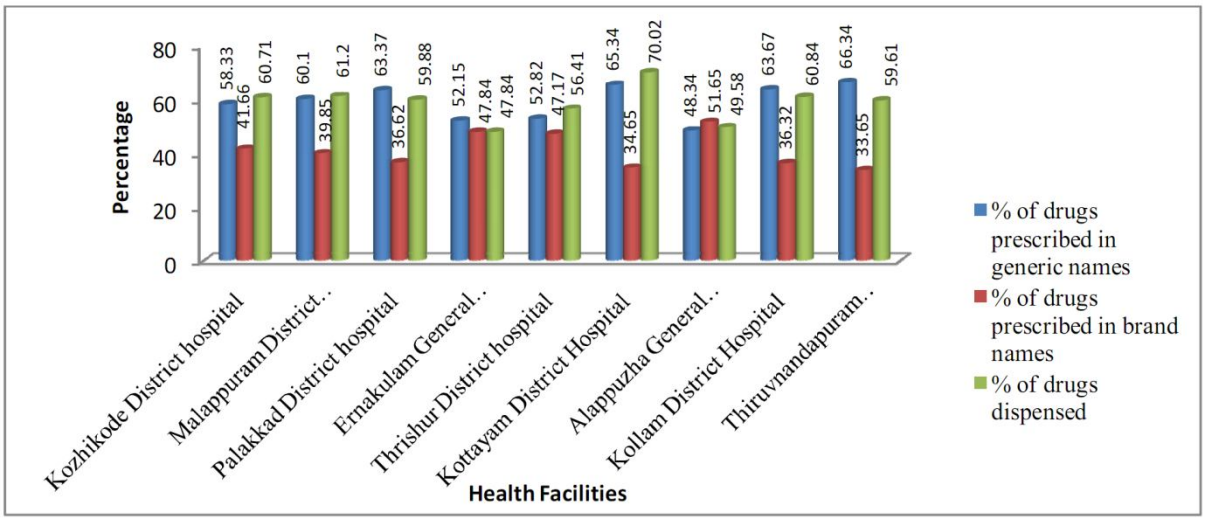


Figure 1: Patient Access and Drug Utilization pattern

Table 1: Number of NSQ drugs and manufactures in each year.

Year	No of drug samples collected	No of NSQ Drugs	%	No of Manufactures
2011	1680	131	7.79	81
2012	2700	110	4.07	78
2013	1710	74	3.60	49
Total	6090	315	5.17%	208*

*Manufacture who supplied in one year will be supplying in next year also, so without repeating the number of manufactures in three years

On the analysis of the three year substandard medicine list we recognized that the NSAID's, such as paracetamol, diclofenac, ibuprofen were spotted to be the most frequent substandard medicines (23.80%), abide by Gastro-Intestinal medicines such as rabeprazole, omeprazole, pantaprazole (17.46%), and Cardiovascular drugs particularly anti-hypertensives such as enalapril, atenolol, amolodipine and statins (15.87%) followed by antibiotics such as amoxycillin and ciprofloxacin (10.46%).

V. DISCUSSION

Substandard medicine will cause disgraceful impact in the society such as increased mortality and morbidity rate, drug resistance and failure of

medicine efficacy and adverse effects from the inaccurate drug ingredients. Patients will lose their trust in the health system and health workers, and also causing financial loss for the patient, their families and the health facilities. Great human effort on carrying out clinical trials, manufacturing quality medicines and economic outlay for it are become meaningless. And finally all this has led to increased burden for the government and its regulatory authorities as well as police officers[5] .Considering the government supply of medicines to the public, an appreciating factor is the decrease in the percentage of substandard medicines. This was possible through the strict regulations by the KMSCL. The results of the patient access and drug utilization emphasize the need to improve medication availability in the public sector. Although medicines were theoretically provided for free cost in the public sector, but all the medicines were not available in the public institutions, leading to out of pocket expenditure to patients while, purchasing them from private community pharmacies at higher costs[6]. 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 revision and compliance to Essential Medicines List (EML) of the state, Accreditation of Pharmacy services in Hospitals and Communities, Publication of Standard Treatment Guidelines, Effective Quality Assurance Process and well-timed testing facilities for medicines, Computerized medicine registry for the state. The drug safety has to be guaranteed 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 flawed and manipulated pharmaceutical products, surreptitious marketing network, clinical trials etc. are issues to be focused seriously .At present the state is not having any system to have a data base on medicines used/ marketed in the state. Drugs with similar trade/brand names are obtainable in the hospitals and community pharmacies with completely different active ingredients. Various agencies supply medicines to the state and disappear from the panorama. It is intricate to trace them out as they don't have any office or location 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

Through this study we have found that drug regulation by the Drug Control department in Kerala were effective and transparent. But the regulations omit certain area such as lack of official data regarding the presence of all kinds of medicines available in the market, product registration and limited availability of drug inspectors in drug control department. It also reveals that the services offered by KMSCL such as through increasing the availability of free and quality medicines and there by reducing the out of pocket expenditure of medicine to patient is not satisfactory. Modifications and monitoring of pharmaceutical policy at the national and state level are necessary to improve quality of medicines and hence access to essential medicines for the people.

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