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Review Article

Essential Medicines Research in India: Situation Analysis

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ABSTRACT

World Health Organization established the concept of essential medicines with the main aim to improve the availability of most necessary drugs to fulfil basic health care needs of population. Access to essential medicines is one of the crucial components of primary health care. Access to medicines is included in millennium development goals as well as universal health coverage policy. In 2000, India made a policy "Health for All" and one of the main objective of this policy is to ensure availability of quality medicines at reasonable cost to the society. The overall budget on medicines differs widely in different states of India and as a result their access is also highly variable. This review will emphasis on essential medicine concept and report of various research surveys conducted to evaluate availability of essential medicines in different parts of India. An exhaustive literature search was planned to study the availability of essential medicines in India. The search engines used were PubMed and Google Scholar. Relevant keywords were used to make the searches such as essential medicines concept, essential medicines report, essential medicine research in India, availability of essential medicines in India. The articles published in English language between the years 2003 and 2017 were extracted and included. The findings of these studies were summarized into a narrative review.

Key words: Essential medicines, Public health, Government sector, Private sector, Health for All, National policy, Universal health coverage.

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INTRODUCTION

In the International conference on primary health care held in 1978, the Alma-Ata declared Health as fundamental human right. Thereafter provision of best possible health care services for society has gained a lot of important worldwide.[1] Health is an important indicator for developmental status of a country. In India, there are 33 federal states/ union territories which are ruled by different elected government of various political parties. Both the central as well as state governments in India have roles in the management of health.[2] As per World Health Organization (WHO), a strong health care system is one which provides regular access to safe, efficacious and cost effective health care services.[3] Medicines are an important part of health care system and account for major and considerable part of household expenses.[2] The Alma-Ata declaration has stated that there are eight crucial components of primary healthcare and access to essential medicines is one among them.[1] Medicines acts by preventing disease, maintaining and restoring health.[4]

In 2000, India made a policy "Health for All" and one of the main objectives of this policy is to ensure availability of quality medicines at reasonable cost to the society.[5] The Medical Council of India (MCI) has also issued circular that every physician in country should prescribe essential medicines with their generic names as far as possible.[6] There are many medicines and medical products available in market but no health system can afford adequate supply of all medicines at all times. India is a country of many federal states. The overall budget on medicines differs widely in different states of India and as a result their access is also highly variable. The expenditure on medicines is different in different states of India which is as little as less than 2% in Punjab to as much as 17% in Kerala.[2] In resource poor countries, availability of medicines is often irregular especially in public health facilities.[7] Therefore it is necessary to select and ensure the supply of those medicines which are cost effective and used to treat majority of health problems.

METHOD OF LITERATURE SEARCH

An exhaustive literature search was planned to study the availability of essential medicines in India. The search engines used were PubMed and Google Scholar. Relevant keywords were used to make the searches such as essential medicines concept, WHO essential medicines report, essential medicine research in India, availability of essential medicines in India. The articles published in English language between the years 2003 and 2017 were extracted and included in the study. The findings of these studies were synthesized into a narrative review.

ESSENTIAL MEDICINES CONCEPT

WHO established the concept of essential medicine for the first time in 1977.[4] In 1975, In 28th World Health Assembly, The Director General of WHO examined the main drug problems occurring in the developing countries and defined the possible new drug policies.[8] The main aim of new drug policy was to improve the availability of most necessary drugs to fulfil basic health needs of population.[9] Director General called for information on most recommended drugs from all over the world. Based on this information, in October 1977, a consultation of seven participants was conducted in Geneva to prepare a common list of essential drugs to cover primary health care needs of developing countries. The first model list of essential medicines was framed by WHO in 1977. This list was subsequently revised in 1979, 1983, 1985 and 1988.[10] The latest is the 21th list which was published in 2019.[11] The essential medicine concept was one of the eight pillars of WHO's primary health care plan. Primary healthcare is concerned with the important health problems in the community, promoting, preventing and rehabilitating services to people.[2] Essential medicines are defined by WHO as "medicines that satisfy the health care need of majority of population". Essential medicines are medicines to be available at all the times in required amount, required dosage forms, with optimal quality and appropriate information and at

a price that individual can afford.[4] Essential medicines have noticeable health impact and are considered as one of the most effective and vital component of modern healthcare.[7,12] Regular availability of essential medicines will result in improving the performance of health system and also increase public confidence in the health system.[7,13] Access to medicines is included in the millennium development goals as well as universal health coverage policy of WHO. Regular supply of safe, efficacious and affordable medicines to society is the basis to achieve universal health coverage.[9,14] The quality and functioning of health care system is closely related to the access of essential medicines.[15] Access to medicines will be pre-requisite for implementation of "health rights".[10] In 2000, United Nations Millennium Summit established eight international development goals called MDG (Millennium Development Goals). Target 8e of MDG goals also emphasise that there is need to improve availability of affordable medicines especially for low income countries.[2] Globally, nearly 2 billion people do not have access to medicines needed for chronic illness, unnecessary disability and preventable deaths.[16] Availability, affordability, access, acceptability and quality are the five dimensions of access to medicines in health care facility.[17,18] The Access to Medicines Index is another resource that ranks the world's largest pharmaceutical companies based on their efforts to address access to medicines.[19] Studies have shown that selection of limited number of essential medicines resulted in an improved quality of care, reduced medicines wastage and better cost-effective use of available health care resources.[8] Essential medicines can be different for different countries based upon public health relevance, safety evidence, efficacy and comparative cost-effectiveness. National drug policy of any country should include the principle of selection of essential medicines. It is applicable in both public and private sector at different levels of health care system.[20,21] Access has been defined as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk of the population.[22] Surveys conducted in different countries to assess the availability of essential medicines reported poor availability of essential medicines especially in public health care facilities.[19]

India has made a tremendous growth in the pharmaceuticals. The India ranks as third-largest pharmaceutical producer in the world in terms of volume and 14th in terms of value.[23] In the South-East Asia region, India's rank is high in the list of countries with highest out-of pocket (OOP) expenditure on health.[24-26] In both public and private facilities, the largest component of OOP expenditure is that on medicines. About 72% of OOP spending is on medicine.[27] It is expected to shorten the learning curve of those embarking on such programme on improving availability and access to medicines. These lessons are particularly important in view of the National Health Assurance Mission (NHAM) recently announced by the Central government in moving a step towards Universal Health Coverage (UHC). NHAM provides assurance of providing 50 priority Essential medicines available at all times at all levels of health care to the citizens of India below poverty line.[28] In 1994, the supply of medicine in government hospitals and dispensaries was irregular and unsymmetrical. The EML (Essential Medicines List) committee prepared a common list of 250 essential medicines for hospitals and 100 medicines for dispensaries to overcome this problem. Standard Treatment Guidelines were also issued for the most frequent health problems in adults and children at primary health care centres. The use of these medicines by hospitals run by the Delhi government led to a steep drop in procurement prices and a 30% savings in annual drug bills. These savings resulted to over 80% availability of medicines at healthcare facilities.[29,30]

A survey conducted in 36 developing and middle-income countries showed that public sector have poor availability of generics medicines as compared to the private sector. Survey conducted in 40 low-income countries reported that 44% of public sector and 65% of private sector outlets had generic medicines listed in stock. Lack of drugs in public health facilities forces patients to purchase medicines from private sector outlets. In private sector outlets, price of generic medicine is almost 6 times more than its international reference price.[31,32] According to WHO report, one third of the world's population has limited access to essential medicines and the situation is worse in developing countries.[33] A systematic review was carried out to identify drug availability and impact factors in lower, lower and upper-middle countries. Relevant studies between 2007 and 2017 were identified using the electronic database. A total of 33 articles were found, of which only six studies met the review criteria. This review reported that relatively low availability of drugs in some developing countries and the average availability of generic drugs is better than innovator brand drugs, especially in the public sector. Most of the factors that may affect drug availability are related to government policies to improve drug access and lower prices and hence there is a need for national drug policy review in each country. Overall, the method used to measure the availability of drugs use a reference method provided by WHO Health Action International. The availability of drugs in low, lower and upper middle countries still need to be improved by increasing drug access and enhancing prices by using appropriate government policies.[34]

SITUATIONS IN INDIA

In India, 50-80% of the population has limited access to essential medicine.[35] Several studies have been conducted on the price and availability of medicines in India over the last two decades (Table 1). Surveys has been conducted in public, private and other sectors like non-profit organizations using varying number of medicines ranging from one to 50. Most of the surveys have been conducted in central, west and south Indian states while very few reports were found in north states of India. Most of the studies have been conducted to check the availability of commonly used essential medicines while some studies conducted to access the availability of medicine of specific category such as antibiotics, magnesium sulphate, antiasthma medicines and medicines for smoking cessation. One study conducted to assess the availability of six essential medicines i.e. artemisinin (malaria), lamivudine (HIV/AIDS), rifampicin (tuberculosis), oxytocin (obstetrics), fluoxetine (mental health) and metformin (diabetes) in 124 private retail outlets in Maharashtra found that metformin was the only medicine with high availability (91%) rifampicin had lower availability (64.5%) and the other four medicines had the least (<50%).[36] Another study was conducted in the National Capital i.e. Delhi for 50 essential medicine, found availability of 41.3% in public and private health facilities, 49.3 % in tertiary care health facilities operated by federal government and even lower (23.2%) in health facilities operated by municipal corporations of Delhi.[37] Survey on availability of 34 essential medicine in six randomly selected district of Odisha revealed availability of 17% and 21.8% in public and private sector respectively.[38] One study was undertaken at one primary health centre of Andhra Pradesh found that all the drugs included in the PHC-EML were available at the time of visit (i.e., 100% availability).[39] Another survey regarding availability of 30 core essential medicine in five Indian states reported median availability of zero to 30 per cent in public sector.[40] One study conducted to assess the availability of medicines in 80 public health facilities across 12 districts in two Indian states i.e. Haryana and Punjab. Overall availability of medicines was 45.2 % and 51.1 % in Punjab and Haryana respectively.[41] Study conducted in Chhattisgarh state to check availability of generic medicines in one public health facility, found that around 68.89% of medicines were prescribed by their generic name and around 58.28% of prescribed medicine were available in surveyed health facility.[42] A survey regarding availability of essential medicines which are included in National Rural Health Mission

Table 1: Studies conducted in different parts of India to access the availability of essential medicines.

Author	Year in which study conducted	Number and name of essential medicines included in study	Place where availability was studied	Percentage availability
Anita Kotwani	2003-2004	Two Asthma medicine i.e. Beclomethasone and Salbutamol Inhaler	5 States	In public sector: 0-30% In private sector: 10-65%
Anita Kotwani *et al.*	2004 –2005	30 essential medicines	Five states (Chennai, Haryana, West Bengal, Karnataka and Maharashtra)	0-30%
Gitanjali B *et al.*	2010	5 essential children's medicine	129 public health facilities of 17 states, two union territories and Delhi	80 % (range 0- 100%)
Trupti Rekha Swain *et al.*	2010-2011	34 essential medicines	Public and private health facilities of 6 district of Odisha state	Public sector: 17% Private sector: 21.8%
Anita Kotwani *et al.*	2011	50	Public and private health facilities of Delhi	State government: 41.3% and Municipal corporation of Delhi: 23.2% respectively
Kotwani and Holloway	2011	24 essential antibiotics and eight high-end antibiotics	83 public facilities, 68 primary care, 10 secondary care and 5 tertiary care facilities of Delhi	Suboptimal
Rohit Dixit *et al.*	2011	All Essential medicines listed in hospital formulary	One PHC Andhra Pradesh	100 %
Colin Millard *et al.*	2012	6 (Artemisinin, Lamivudine, Rifampicin, Oxytocin, Fluoxetine and Metformin	124 private retail pharmacies of Maharashtra	Metformin: 91% Rifampicin: 64.5% and remaining four: <50%
Katageri *et al.*	2013	Magnesium sulphate	28 public and 60 private health facilities of two district of north Karnataka	Public sector: 75% Private sector: 92 %
Shankar Prinja	2013	92 at Primary Health Centre level, 132 at Community Health Centre level and 160 at tertiary care level	1 MC, 6 DHs, 11 CHCs and 22 PHCs from each district across 12 district of Haryana and Punjab	Punjab: 45.2% Haryana: 51.1%
Tripathi N *et al.*	2013 –2014	All prescribed generic medicines	1 district hospital, 3 community health centres and 3 primary health centres were selected from 15 district of Chhattisgarh	58.28%
Smitha sarma *et al.*	2016 –2017	Nicotine replacement therapy, Bupropion and Varenicline	199 public, semi public and private pharmacies across five district in Kerala	NRT: 96% Bupropion: 28% Vareniciline: 1%

MC: Medical College; PHC; Primary Health Centres; DH: District Hospitals; CHC; Community Health Centres; NRT; Nicotine Replacement Therapy

(NRHM) for children conducted in 129 health facilities spanning over 17 states, 2 union territory and National Capital region of Delhi reported an overall availability of 80% (range 0% to 100%) with Punjab, Tamil Nadu and Jharkhand having 100% (range 0-100%) medicine available.[43]

Antimicrobial resistance is rapidly increasing globally and required suitable policy and actions. The first step in combating inappropriate use of antibiotics is to measure access to antibiotics. One survey conducted to access the availability of 24 essential antibiotics and eight high end antibiotics in public and private health facilities of Delhi, found good availability of antibiotics in private sector as compared to public sector. In public sector, antibiotics were not available at optimal level and none of the surveyed health facilities were having all the surveyed antibiotic.[44] Asthma is a major chronic disease affecting both adults and children. Approximately 50 million asthma patients reside in India. Asthma medicines have been included in Indian national list of essential medicines therefore essential inhalation medicines for asthma should be available in the public sector where low-income populations receive treatment. A study conducted to assess the availability, price and affordability of beclomethasone and salbutamol inhalers in five Indian states reported that beclomethasone and salbutamol inhalers were available in only 25% of public health facilities. Apart from Rajasthan, inhalers were not available at any public health facilities in other state surveyed. The availability of generic beclomethasone inhalers was 10% in Haryana, 20% in Karnataka, 35% in Maharashtra, 65% in Rajasthan and 90% in Chennai. Salbutamol inhalers were available in all the surveyed states, although the availability ranged from 20% to 95%.[45] Pre-eclampsia

and eclampsia are major causes of maternal morbidity and mortality worldwide. Magnesium sulphate is the drug of choice for the prevention and treatment for the seizures of eclampsia and included in both WHO essential medicines list and the Indian National List of Essential Medicines (NLEM), 2015. One study regarding availability of magnesium sulphate at public and private health care facilities of North Karnataka shown that availability in different types of public health facilities range from 60% - 100% and 92% in private sector.[46] India is the world's second largest consumer of tobacco, but tobacco cessation remains uncommon due to underutilization of cessation pharmacotherapy. In 2004, India became a party to the World Health Organization's Framework Convention for Tobacco Control (FCTC). Article 14 of the FCTC recommends that countries improve access to pharmaceutical treatment of tobacco dependence in an effort to improve quit rates. A cross-sectional survey to evaluate the availability different smoking cessation medicines i.e. nicotine replacement therapy, bupropion and varenicline in public, semi-private, and private pharmacies across five districts in Kerala reported non availability of cessation medications in public hospitals and in public specialty centres while at least one cessation medicine was available at 63% of private pharmacies and 27% of semi-private pharmacies.[47]

Above conducted studies in India found that availability of medicines is not adequate especially in public health facilities. In private health facilities availability is better than the government sector.

CONCLUSION

Public health facilities are primary source of free medicines for a majority of India's low income population. In India, access of essential medicines in public health facilities is poor Studies revealed that availability of medicines is better in private retail pharmacies but affordability remains a big challenge for a majority of the population. Indian health system need to be strengthened by making essential medicine available for patients. Availability of essential medicines can be improved by financial allocation for generic medicines and by improving supply chain and logistics.

ABBREVIATIONS

WHO: World Health Organization; **MCI:** Medical Council of India; **MDG:** Millennium Development Goals; **OOP:** Out-of-Pocket; **NHAM:** National Health Assurance Mission; **UHC:** Universal Health Coverage; **EML:** Essential Medicines List; **NRHM:** National Rural Health Mission; **NLEM:** National List of Essential Medicines; **FCTC:** Framework Convention for Tobacco Control.

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