UNIVERSAL ACCESS TO MEDICINES IN INDIA

A BASELINE EVALUATION OF THE RAJASTHAN FREE MEDICINES SCHEME
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I am pleased to introduce this report of the baseline evaluation of the Mukhyamantri Nishulk Dave Yojana, also called the Chief Minister's Free Medicines Initiative. This initiative was launched by the Government of Rajasthan in October 2011 and was developed in compliance with the state government's commitment to provide essential medicines free of cost to all patients visiting public healthcare facilities in Rajasthan. The scheme initially began with 240 medicines and at present provides more than 600 medicines that are on the essential medicines list.

This initiative also contributes to the vision and direction of WHO's efforts in the South-East Asia Region of improving access to pharmaceuticals, a key component for advancing universal health coverage and robust health systems.

The baseline evaluation was conducted two years after the commencement of the Free Medicines Initiative. It involves an evaluation of the Rajasthan Medical Services Corporation using scientific and robust research methodology, with evidence drawn from facility surveys in addition to available secondary data. The primary objective of the study was to document evidence that could point to improved access to medicines and reduced out-of-pocket expenditure in 150 facilities included in the study. Several crucial aspects of the scheme were analyzed, such as procurement processes and patterns, trends in public investments on medicines, quality assurance processes, supply chain management processes, storage systems and processes, impact on private spending on drugs, availability and stock-out of drugs, procurement price variations and prescription patterns.

The major achievements of the scheme include: significant increase in government expenditure on medicines; establishment of the Rajasthan Medical Services Corporation to procure essential medicines and coordinate supply chain systems; procurements based on a two-bid system involving technical and financial tenders; and setting up of the e-Aushadi platform, an electronic management information system to facilitate smooth functioning of the entire value chain from procurement to distribution and dispensing of medicines.
The study highlighted that during the period 2013-14, ₹ 3200 million was allocated towards the scheme as against ₹ 1020 million in 2011-12. Out-of-pocket payments of households declined from 85% in 2004-05 to nearly 75% in 2011-12. There were less shortages and stock-outs and an increased availability of medicines at the primary health centre and community health centre levels. As much as 97.3% of the medicines were prescribed using their generic names.

Some of the key recommendations generated by the study were: ensuring government commitment to adequately and sustainably fund the national health system for reliable supply of essential medicines; assuring quality control mechanisms for enhanced safety and efficacy of medicines; continuous supply of high quality generic drugs; streamlining the national and state procurement and supply chain management systems; enforcing rational use of medicines, including the use of essential drug lists and standard treatment guidelines; and continued advocacy and engagement with prescribers at state and district levels.

The two-year experience of the scheme points to an overall improvement in utilization of government health services, availability of medicines at facilities, some turnaround in financial risk protection and health system expansion. We welcome and applaud the leadership of the Rajasthan government for investing more in health in the form of the Chief Minister's Free Medicines Initiative. We also trust that Rajasthan will continue to provide this leadership in ensuring the sustainability of the scheme.

We received cooperation for this study at every level and from every government functionary. Special mention should be made of the Government of Rajasthan and the Rajasthan Medical Services Corporation for their support.

The experience and evidence generated from this study clearly suggests that replication and rapid scale up of such a model in other states is both feasible and desirable. This would help progress towards a more efficient medicine procurement and distribution system and thus ensure access to medicines as a pre-condition to universal health coverage in India as well as in neighbouring countries.

Dr Nata Menabde
WHO Representative to India
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This piece owes its origin to the High Level Expert Group (HLEG) on Universal Health Coverage (UHC) (2011) report and is essentially a follow-up on the strategies and recommendations of the HLEG report. This report was expected to serve as a baseline for further evaluation in the coming years to understand the implications of scaling up funds and improving the efficiency of the procurement systems and effectiveness of supply chain systems in Rajasthan. Rajasthan took a bold and innovative step in 2011 to provide its people free medicines in public health facilities. In a sense, this is a first and critical step towards achieving universal health coverage in Rajasthan.

Two main actors and their role deserve mention at the outset, without which this report would not have been possible. The Government of Rajasthan, especially Dr Samit Sharma, the Executive Director of the Rajasthan Medical Services Corporation (RMSC) and the driving force behind the Free Medicine Initiative needs applause for providing us the necessary official clearance in time and for the transparent manner in which RMSC shared data for the analysis. Though we received cooperation at every level and from every government functionary, special mention should be made of ED Finance, ED Logistics Management, ED Procurement, ED Quality Assurance and AGM, IT of RMSC.

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The study was done in partnership with Prayas, who have shown exceptional efficiency in taking up the field work at a short time and analyzing the data. From the very beginning this partnership has evolved through mutual learning and we treasure this partnership immensely. We would like to place on record our special appreciation for Dr Narendra Gupta, not only for his guidance for the study but also for the important contribution he and his team at Prayas is making to ensure access to medicines among one of the poorest settings of the country. The survey team from Prayas including Dhruv, Sandeep and others deserve special appreciation for their meticulous efforts to collect data and information in a systematic manner.

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ABBREVIATIONS

ANM auxiliary nurse midwife
ATC (Classification System) Anatomical Therapeutic Chemical (Classification System)
BIMARU Bihar, Madhya Pradesh, Rajasthan and Uttar Pradesh
CES consumer expenditure survey
CHC community health centre
DDC drug dispensing centre
DDD defined daily dose
DDW district drug warehouse
DSPRUD Delhi Society for the Promotion of Rational Use of Drugs
EDL essential drugs list
EMD earnest money deposit
EML essential medicines list
FDC fixed drug combination
FEFO first expiry first out
FIFO first-in, first-out
GDP gross domestic product
GMP good manufacturing practices
GoI Government of India
HLEG high level expert group
HR human resources
ICT information and communications technology
IEC institute ethics committee
IMS information management system
IPHS Indian Public Health Standards
EXECUTIVE SUMMARY

The issue of access to medicines assumes critical importance in low- and middle-income countries, as it has larger implications for health outcomes and financial risk protection in such countries. Despite India being referred to as the “pharmacy of the global south”, access to essential medicines is still elusive to a large segment of its population. Some of the key barriers that act as impediments to access include gross inadequacy of government spending on health care in general and on medicines and vaccines in particular, resulting in high out-of-pocket (OOP) payments by households; inefficient procurement systems and ineffective medicine distribution mechanisms; unaffordable market prices; and irrational prescription, dispensing and use of medicines.

Realizing the importance of access to medicines, the Rajasthan government initiated the Mukhyamantri Nishulk Dava Yojana (MNDY) (Chief Minister's Free Medicines Initiative) in October 2011. Some of the key features of the scheme are: significant scaling up in public spending on medicines; setting up of the Rajasthan Medical Services Corporation to procure essential medicines and coordinate supply chain systems; establishing medicine storage and transparent distribution warehouses in each of the districts; procurement based on a two-bid system involving technical and financial tenders; distribution of medicines based on a two-passbook system to ensure uninterrupted supply of medicines and supplies to the frontline health facilities from district medicine warehouses; setting up an ‘e-Aushadi’ platform, an advanced electronic inventory management information system, to facilitate smooth functioning of the entire value chain from procurement to distribution of medicines; and multiple layers of quality control mechanisms to promote efficacy and safety of medicines dispensed in the system.
Since the MNDY scheme is expected to have significant implications on several outcome measures, a robust evaluation of the scheme was considered necessary. Utilizing both primary and secondary data and information, the scheme was evaluated by examining the process and outcome indicators. Adopting a two-stage stratified sampling method, a survey of a large sample of 112 public health facilities in Rajasthan was carried out. Besides, the passbook database was used to understand several facets of the scheme. The Rajasthan Government's commitment is already visible with a substantial step up in allocation of funds. During 2013–14, a sum of 3200 million Indian rupees was allocated towards the scheme as against a much lower 760 million Indian rupees in 2011–12. The per capita health expenditure before the MNDY scheme was estimated to be ₹5.70 which now stands close to ₹50.50. This has had a salutary effect on OOP reduction in the State. Early trends suggest that households' OOP payments have declined from 85% in 2004–05 to nearly 75% in 2011–12. Impoverishment caused due to high households' OOP expenditure on medicines have reduced from 3.2% to 2.1%, even though given that these results are at an early stage, we may not be able to conclusively attribute these solely to the MNDY. Allocation of funds to districts has improved dramatically, while inequality in distribution of funds across different levels of care has reduced considerably.

One of the immediate and positive spin-offs from this initiative is the rapid increase in outpatient visits and considerable increase in inpatient admissions. The combined outpatient and inpatient care visits rose quickly from 3.5 million in July 2010 to 7.8 million in July 2013. This unprecedented upsurge in patient visits could be partly due to an 'explosion' in the pent-up demand. As medicines are now available free of cost, absenteeism appears to have reduced considerably, putting pressure on the health system infrastructure to improve further. As a result, frontline public health facilities are experiencing exuberance. Acute shortages and chronic stock-outs, the hallmark of the pre-MNDY regime, have given way to far greater availability and accessibility of medicines. The survey found that the average availability of essential medicines has improved significantly, with an average of 100 essential medicines being available at the primary health centre on the survey day. The numbers for community health centres and district hospitals are around 180 and over 300, respectively.
The MNDY is also expected to influence prescription and dispensing patterns. The survey finds that on an average, 3.34 medicines are prescribed across different facilities. Of all prescribed medicines, 97.3% of the medicines were prescribed using generic names, while 86.3% of the medicines that were prescribed were of single formulations medicine as against fixed-dose medicine combinations. Antibiotics formed 30% of all the prescribed medicines. Injectables constituted 6%, liquid preparations including syrups constituted 8% and vitamins constituted 3.6% of the total preparations dispensed in public health facilities.

In general, RMSC prices did not differ by large margins from Tamil Nadu Medical Services Corporation Ltd. (TNMSC) rates; the majority of RMSC rates were within a 25% range of TNMSC rates. In fact, TNMSC rates were higher than RMSC rates for 19 medicines. As far as RMSC prices are concerned, weighted mean market prices are on average 300% higher than RMSC prices. In a few cases, RMSC rates are higher than the market price such as for anti-snake venom, factor fraction VIII, sodium chloride and dextrose injection. However, the relatively small number of suppliers for these formulations in the open market may be indicative of less competition in the specific medicine markets and somewhat limited scope for improving the public procurement rate.

The two-year experience of MNDY points to an overall improvement in utilization of government health services, availability of medicines at facilities, some turnaround in financial risk protection and health system expansion. The efficiency of the procurement process has significantly improved, while delivery of medicines and supplies has been made very effective. While the underlying reforms associated with accelerated investment are a bold and innovative step, there is need to emphasize its sustenance. Rather than treating it as a one-off project-based initiative, the Government of Rajasthan must endeavour to institutionalize these reforms. The experience and evidence generated from this study clearly suggests a replication and rapid scale up of such a model in other states, aimed at progressing towards more efficient medicine procurement and distribution.
CHAPTER 1

CONTEXTUALIZING

1.1 INTRODUCTION

The issue of medicines and vaccines is of critical importance as they are an important building block of the health system. They assume an extremely vital role in low- and middle-income countries (LMICs), as lack of access to essential medicines and vaccines leads to poor financial risk protection and substantial impoverishment. Firstly, health care financing and provision is largely a private affair in many LMICs. India perhaps leads the chart with nearly 70% of all health-care financing derived from households.\(^1\) Due to persistent underinvestment in public sector units, the private medicine market has flourished. The result is catastrophic payments on medicines being incurred by households, leaving them vulnerable to impoverishment. Expenditure on medicines accounts for a large share of the households' OOP expenditure and is a dominant reason for impoverishment. Of 100 million globally impoverished due to OOP expenditure of households,\(^3\) over 40 million reside in India.\(^4\) Thus, in the context of developing countries like India, ensuring availability and distribution of medicines becomes a crucial starting point to attract people towards government health services.

Poor financial risk protection of households in India due to gross underinvestment in the health sector, especially on medicines, has led to a scenario where access to essential medicines has become extremely difficult. According to several national household surveys, during the mid-1980s, approximately a third of the medicines prescribed during hospitalization in public facilities were supplied free of cost. However, during 2004, the mean availability declined sharply to roughly 9%.\(^5\) As far as outpatient care is concerned, free medicine supply declined from 18% to about 5% over the same period. During the same period, the number of hospitalization episodes in which the ailing population paid OOP rose dramatically from about 41% to 72%. Since essential medicines supplies had started dwindling, in over one fourth of outpatient episodes in 2004, patients did not receive medicines because they could not afford them.
While the evidence is limited, available data from several Indian states demonstrates significant variations in the availability and stock-outs of essential medicines. For example, a recent survey in Tamil Nadu and Bihar showed that the mean availability of the selected basket of essential medicines for Bihar was about 43% as compared to 88% for Tamil Nadu,\textsuperscript{6} while a study by Cameron et al. (2008) noted that the median availability of critical medicines in the public health system was about 10% in Haryana, 12.5% in Karnataka, 3.3% in 12 districts of Maharashtra and 0% in West Bengal. In the city of Chennai, the figure was 30%.\textsuperscript{7}

Several factors can influence the provision and use of essential medicines via the public health system such as poor and incomplete stocking of essential medicines due to inadequate budgetary support; poor supply chain management leading to frequent stock-outs; prevailing prescription practices leading to inessential and costlier prescriptions for medicines from outside the public health system and a lack of confidence in the quality of medicines supplied through the public system.

Health systems in several LMICs are in disarray due to persistent underinvestment. Procurement and supply chain systems involving public health-care institutions are weak and poorly governed. On the one hand, an inefficient medicine procurement system leads to sub optimal use of resources with poor value for money. A decentralised procurement system fails to optimise monopsony power, thereby leading to a bloated government budget for procuring medicines. On the other hand, an unreliable distribution system results in chronic shortages and acute stock-outs of essential medicines. However, pooled procurement models in some states of India (Tamil Nadu and Kerala) have demonstrated the effectiveness of such models in ensuring timely availability of free essential medicines and avoiding stock-outs (Sakthivel et al. 2011).\textsuperscript{5} To revamp the entire medicine procurement and distribution systems, the Indian Government has envisaged channelling additional funds to states to replicate the success of these pooled procurement models. Despite commitments from the Prime Minister in this regard, things have hardly progressed meaningfully.

Moreover, with the provision of free medicines, utilization of public health services is predicted to rise as a major proportion of the population will be able to access public health care when the financial barriers are removed. Success will be predicated on reforms to the drug supply systems and by regulation of the prescribing and dispensing practices. The current study is a comprehensive effort to assess the situation of access to medicines in the state of Rajasthan using standard processes and outcome measures.
1.2 RAJASTHAN CHIEF MINISTER'S FREE MEDICINE SCHEME

In an effort to address the issues outlined above, the Government of Rajasthan established the Rajasthan Medical Services Corporation (RMSC) in May 2011. The Free Medicine Initiative was launched on 02 October 2011 with the primary objective of procurement and distribution of generic medicines, surgical and diagnostic equipment for the Department of Health and Family Welfare, Department of Medical Education, Department of Ayurveda and other medical relief societies to cater for all patients visiting public health-care facilities. RMSC is a public endeavour owned by the Government of Rajasthan and was constituted in compliance with the Government’s commitment to provide the most commonly used essential medicines free of cost to all patients visiting public health-care facilities. Essential medicines were initially identified by aligning with the National List of Essential Medicines (NLEM) but modified and expanded subsequently to add more medicines as per the need of the population. While the RMSC began with about 240 medicines initially, at present there are more than 600 medicines on the essential medicines list (EML) of RMSC. RMSC procures medicines and surgical items through an open tender (two-bid) system and also procures high-end medicines for cancer and other complex diseases directly from importers. RMSC procures medicines only from manufacturers or importers, which assure them of getting the best prices by eliminating intermediaries and the associated profit margins from the supply chain. Supply chain management is carried out through e-Aushadhi, a web based software developed for continuous monitoring and smooth functioning of the organization (medicine management system) and by establishing one medicine warehouse in each district, which is linked to public health facilities.

1.3 OBJECTIVES OF THE STUDY

As the MNDY completes two years of its existence, this study primarily intends to examine various aspects of the scheme and their implications on outcome measures. This exercise can also be considered as a mid-line evaluation of the RMSC involving scientific and robust research methodology, with evidence drawn from facility surveys in addition to available secondary data. The specific goals of the study are:
- to examine budgetary allocation for medicines at the Central and state government levels, especially in the state of Rajasthan;
- to study the availability and stock-outs of essential medicines at frontline service providers in both public facilities and private pharmacies;
- to examine the current procurement and distribution practices/systems of essential medicines in public health facilities;
- to analyse prescription and dispensing practices in public health facilities;
- to identify and document gaps and challenges in policies and institutional structures that impede access to medicines;
- to analyse procurement prices obtained by RMSC vis-à-vis market prices and the effectiveness of purchasing;
- to identify and provide policy-level inputs that could address the current challenges, and solutions to mitigate them.

1.4 SCHEME OF THE REPORT
The report is broadly classified into nine chapters outlining different dimensions of access to medicines in the context of the MNDY.

The first chapter presents the contextualization of the problem and the rationale behind the study. The second chapter focuses on the detailed scientific methodology adopted in the evaluation process along with the sampling strategy. It also discusses the study tools used to evaluate the health system at the state level and at the facility level. The third chapter highlights the health system in the State involving the aspects of public health infrastructure, health workforce and governance in a broader perspective.

The fourth chapter discusses financing for medicines in India through a detailed analysis of public expenditure on health at state and national levels, with special focus on expenditure on medicines in the state of Rajasthan. The chapter also highlights inter-district and inter-facility allocation of budget for procuring medicines. The fifth chapter gives out various procurement and distribution models adopted by several states in India. In addition, this chapter also analyses governance issues involving procurement, tendering process, quality control, procurement cycle and supply chain management in the state of Rajasthan.

The sixth chapter analyses the scenario of availability and stock-outs of essential medicines at different levels of care and across Anatomical Therapeutic Categories (ATCs) through primary data collected from 157 sample facilities and secondary data collected from e-Aushadhi.
The seventh chapter deals with rational use of medicine in public health facilities, based on prescription analysis of more than 2000 prescriptions collected from sampled public health facilities. The eighth chapter analyses medicine procurement prices in various public procurement systems in India. The prices of public procurement in Rajasthan were compared with market prices along with capturing variation in pricing within the public tendering processes. The ninth chapter summarizes the report with key recommendations. These are intended as inputs for addressing current challenges in Rajasthan and other states aspiring to replicate the centralized procurement model for medicines.