CHAPTER 2

METHODOLOGY

2.1 INTRODUCTION

In order to meet the objectives outlined above, the study utilized primary and secondary data sources from different levels in the supply chain. An in depth literature review was conducted of the national as well as international published literature to identify the general level of availability of medicines in public health facilities under different health-care systems. Primary data was collected from various levels of service delivery as well as from state-level policy makers through structured questionnaires and semi-structured interviews, respectively by a team of pharmacists and health system specialists during June–August 2013. A list of 160 medicines was identified from the NLEM for the purpose of this study in technical discussion with subject experts. The list included medicines that were identified by levels of care (primary, secondary and tertiary). A robust sampling methodology was developed during discussion in a technical workshop with clinicians, health economists, statisticians and epidemiologists to derive the adequate sample size and distribution of the same among health facilities.

Three tools were developed to capture the structured interviews at facility level and semi-structured interviews with policy makers. The data captured through the interviews were entered in the data entry interface developed using MS Access 2010 with necessary check points to limit typographical errors. Ten per cent of the total records which were randomly selected and verified for errors were found to contain 1% typographical errors. These were corrected by a review process.

Apart from the above, the team also collected various financial and procurement data from the RMSC information database e-Aushadhi (passbook data). The same was analysed to derive policy implications and outcomes in terms of the health system and policy indicators. Our study adopted scientific techniques and statistical tools to analyse collected data from the facility surveys. Use of statistical software (STATA) and MS Excel 2010 helped analyse the large dataset collected from the RMSC database related to medicine procurement and availability including ABC analysis, which fed into several analyses in our report.
2.2 SAMPLING
The state of Rajasthan is not only large but is also characterized by heterogeneity in the State's profile of its population. In view of its social, economic, demographic and cultural diversity, the selection of the representative number of facilities at the appropriate levels of care is very vital while conducting such a large-scale study. We used statistical software N-Master to determine the minimum sample size required to evaluate availability of medicines and stock-outs at each level of health-care facility. Once a representative number of facilities were chosen, we adopted a two-stage cluster sampling: (i) selection of districts in the state of Rajasthan, and (ii) selection of health facilities (both public and private) within the identified districts. The criteria for selection at each level of facility are outlined in the succeeding paragraphs. The primary objective of the survey of health facilities was to evaluate the availability of essential medicines in health facilities, stock-outs, as well as prescribing and dispensing practices at each level of the health-care delivery system.

2.2.1 FIRST STAGE SAMPLING: SELECTION OF DISTRICTS (30% OF TOTAL NUMBER OF DISTRICTS)
In order to capture the socioeconomic diversity of the state, we selected 30% of the total districts based on economic and geographical indicators. In sum, we selected 10 districts from a total of 33 districts in the State. The economic criteria identified per capita net district domestic product (NDDP)* for ranking the districts and then selected districts using systematic sampling including highest ranked district, lowest ranked district and the districts at equal intervals of economic ranking. We then adjusted this selection to geographical criteria by mapping the districts on the political map to incorporate the maximum geographical representation from the State to essentially take care of the spread of districts (Fig. 2.1).

*Per capita net district domestic product used for the study is estimation for the year 2004–05 at current prices obtained from the Directorate of Economics and Statistics, Rajasthan.
2.2.2 SECOND STAGE SAMPLING: SELECTION OF HEALTH FACILITIES

A health facility is the primary sampling unit for capturing the scenario of availability of medicines, stock-outs and prescription and dispensing pattern in public health facilities. We selected health facilities at each level of care, from the medical college representing the highest level to the primary health centre (PHC) denoting the lowest level of care. Although ideally sub-centres (SCs) could have been the lowest level of care, we restricted our analysis to PHC level due to the low volume and value of medicines dispensed at the SC level.
2.3 SAMPLE SIZE

We selected one specialty tertiary care hospital – a government medical college in the State capital Jaipur which ideally represents one of the largest public sector hospitals in the State. At the district level, we selected one district hospital from each selected district, which works out to a total of 10 district hospitals.

Subsequently, 30% of community health centres (CHCs) were selected from each selected district using the following formula:

\[ N = A \times D \times 30\% \]

where \( N \) is the number of CHCs selected; \( A \) is the average number of CHCs per district; \( D \) is the total number of districts chosen.

In all, 34 CHCs were selected from 10 sample districts. Four CHCs were chosen from larger districts such as Udaipur, Barmer, Bharatpur and Jhalawar, whereas three CHCs were considered from Karauli, Chittorgarh, Jaipur, Churu, Bikaner and Baran. The CHC selection was done on the basis of accessibility, distance from district headquarters and geographical location of the CHC, to make it best representative of the district population.

Finally, we chose 64 PHCs on the basis of two PHCs reporting to each selected CHC using random sampling (Table 2.1). An equally proportionate number (in the ratio of 1:1) of private sector retail outlets near the medical colleges, district hospitals and CHCs in each of the selected districts were also surveyed to obtain data on availability and stock-outs along with market conditions and procurement practices in the private sector (for a detailed list of sample facilities selected, see Annex 1).
Table 2. Summary of samples selected

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample size</th>
<th>Total districts/facilities</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample districts @ 30%</td>
<td>10</td>
<td>34</td>
<td>30.30</td>
</tr>
<tr>
<td>Sample district hospitals @ 1 each</td>
<td>10</td>
<td>34</td>
<td>29.41</td>
</tr>
<tr>
<td>Sample CHCs @ 30%</td>
<td>34</td>
<td>376</td>
<td>9.04</td>
</tr>
<tr>
<td>Sample PHCs (CHCs x 2)</td>
<td>68</td>
<td>1517</td>
<td>4.48</td>
</tr>
<tr>
<td>Sample medical college</td>
<td>1</td>
<td>7</td>
<td>14.29</td>
</tr>
<tr>
<td>Total public facilities sampled</td>
<td>112</td>
<td>1935</td>
<td>5.79</td>
</tr>
<tr>
<td>Total private facilities sampled</td>
<td>45</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Total sample size</td>
<td>157</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**PHC** – primary health centre; **NA** – not available

*Source: Rural Health Statistics 2011, Ministry of Health and Family Welfare, Government of India (GoI), accessed 15 January 2013*

### 2.4 DESCRIPTION OF SURVEY INSTRUMENTS

For the purpose of this study, we developed three study tools to capture various dimensions of access to medicine in Rajasthan. Form 1 was designed to capture policy-level evidence on health system preparedness in the State (Annex 2). Forms 2 and 3 (Annexes 3 and 4) were designed to capture facility-level information on various issues relating to infrastructure, human resources (HR), prescription and dispensing practices, workload at facility level, availability of essential medicines and stock-out of the same in both public and private facilities.

A team of three researchers visited each sample facility with survey tools in order to capture as much information as available through structured interviews with the medical officer/store in charge/pharmacist/any other person handling medicine procurement and dispensing at facility level. The availability of medicines on the day of the survey and stock-out scenario for the previous six months were captured from stock registers and passbooks available in each facility. This was corroborated by manually checking randomly for the presence of essential medicines in the dispensing counters.
2.4.1 ASSESSMENT OF MEDICINE POLICIES
A case-study approach was adopted for the state level policy analysis through semi-structured interviews with various stakeholders including the MD RMSC, Principal Secretary Health and Family Welfare, state programme managers of the Department of Health And Family Welfare, procurement officers such as procurement officials from the National Rural Health Mission (NRHM) and other officials involved in procurement and distribution of medicines in Rajasthan.

The Medicine Policy Assessment Tool (Annex 2) was used to collect data on all aspects of the medicine supply system including State medicine policies, supply chain management, selection of essential medicines, contracting, inventory management and distribution.

2.4.2 BASKET OF ESSENTIAL MEDICINES
For the purpose of this study, a basket of medicines was identified from the NLEM and the State EML. A total of 160 medicines under different therapeutic categories were identified and segregated based on availability of such medicines at different levels of care as suggested by national public health guidelines. We identified 92 medicines at PHC level, 132 medicines at CHC level and 160 medicines at tertiary care level, i.e. super specialty hospital attached with a medical college. However, not all of these medicines were procured by RMSC. RMSC allocates 10% of its facility budget for local purchases. In order to capture availability of medicines that have been procured by RMSC, we excluded medicines which were not procured by the RMSC from the list. This left 55 medicines which were relevant for the PHCs, 99 medicines for CHCs and 123 medicines for district hospitals. The tool was designed to include only generic names of essential medicines to maintain uniformity in information. The medicines were also further segregated based on dosage and type (injectable, tablets/capsules, suspension). The essential generic medicines were then segregated based on the Anatomical Therapeutic Chemical (ATC) Classification System as per WHO guidelines.

2.4.3 ASSESSING AVAILABILITY AND STOCK-OUTS
For assessing availability and stock-outs of essential medicines at the facility level, the Facility Availability and Stock-out Tool (Forms 2 and 3 given in Annexes 3 and 4) was sought to be completed directly from the facilities, to record data on the medicine availability on the day of the survey, medicine stock-out position for the previous six months from the date of the survey and the duration of stock-outs
Additional data on dispensing and other relevant information was also collected. In the case of private sector retail outlets, the highest and lowest prices for each medicine and brand name were recorded, wherever possible.

The key outcome indicators of the analysis were:
- availability of essential medicines across survey districts
- availability of essential medicines across levels of care
- availability of essential medicines across therapeutic categories and levels of care.

2.4.4 PRESCRIPTION AUDITS
In order to study prescription practices in public health facilities, a prescription audit was undertaken at the public facility sites. Data from a random sample of prescription slips was captured on the day of the facility visit (roughly 20 – 30 slips per facility). Prior consent of the respective medical heads of the facilities as well as oral consent of the patients was sought. Analysis of prescription slips was carried out using WHO guidelines for prescription analysis. Data collected were tabulated and presented in a summarized format to analyse and comment on rational use of medicines. District level analysis was also performed by levels of care, i.e. PHC, CHC and district hospital for various indicators of prescription audit.

The key outcome indicators used in this analysis based on the WHO methodology were:
- average number of medicines per counter
- percentage of medicines prescribed by generic name
- percentage of antibiotics prescribed
- percentage of injections prescribed
- percentage of encounters with syrup prescribed
- percentage of encounters with vitamins prescribed
- percentage of single medicines prescribed as against combination medicines.

2.5 SECONDARY DATA
In addition to primary data obtained from facility surveys, data from various secondary data sources were also collected. Specifically, this study uses budget documents of Rajasthan and other comparable states to analyse the government financing mechanism of the Rajasthan health system. State-specific information on health facilities and facility-level information to compliment primary survey information was drawn from Rural Health Statistics, Ministry of Health and Family
Welfare for 2011 and 2012. State-specific demographic and socioeconomic figures were drawn from the Economic Review, Government of Rajasthan (2011–12, 2012–13). Information was also obtained from published tender documents of RMSC since 2011. Comparative statements of technical bids provided by RMSC and office orders and rate contracts announced from time to time were studied to understand the procurement price system and associated mechanism. The RMSC also shared relevant facility-wise, medicine-wise issue details and pass-book related data for all the public facilities, which was used for ABC analysis of medicines disbursed at different levels of health care. A parallel analysis on the private sector (private medicines market) was also undertaken using Information Management System (IMS) database. For OOP expenditure-related analysis on health financing we have used various rounds (fiftieth, sixty-first and sixty-eighth rounds) of consumer expenditure surveys of the National Sample Survey Office (NSSO). Other than these key secondary data sources, we obtained information from the Directorate of Economics and Statistics, Government of Rajasthan website.

Additionally, the other secondary data used in this study include documents related to medicines provision under national health programmes, procurement documents such as tenders, contracts, guidelines and manuals and other policy documents.

2.6 ETHICAL CLEARANCE

Before the study was initiated, clearance was obtained from the Institute Ethics Committee (IEC) of the Public Health Foundation of India (PHFI). Due ethical protocol was followed to maintain the confidentiality of respondents. The identity of persons interviewed was kept anonymous and our study does not directly identify them in records or during reporting of the data.