Assessment of Public Pharmaceutical Supply Management System at Rural Primary Health Centers in Udupi District, Karnataka

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ABSTRACT
In India, Karnataka is more urbanized and is supported with an extensive healthcare system assisted with well-trained qualified personnel. In the year 2002, Karnataka Drugs Logistics and Warehousing Society were launched to supply free drugs to all health facilities under government administration. The existing system has proved advantageous over the previous system that was functioning under Government Medical Stores.

Aim: The objective of this study is to assess the public pharmaceutical procurement and distribution system that is followed at the rural primary health centers in Udupi district, Karnataka; processes followed to achieve accessibility to essential drugs.

Methods: Retrospective data was collected during the period 2012-13 to 2014-15 from a cross-sectional study conducted in Udupi district, Karnataka. The collected data is related to the supply system adopted for public procurement and distribution of essential pharmaceuticals in the district to ensure accessibility and availability of essential medicines. The data was collected from a set of sampled primary health centers located in the rural area across Udupi district.

Results and Discussion: An explosive increase in population, demographic changes, higher incidence, and prevalence of diseases has contributed to a steep growth in health care expenditure and level of complexity. In order to match the increasing demand rate, tremendous developments in the field of public health care have been achieved over the decades to provide “good health” to all. However, the system facades a lot of defies in the pharmaceutical segment dealing with drug selection, usage, regulations, uninterrupted access (physically and financially), availability, affordability, information flow, data standardization and coordination between the main players and activities in the system. A holistic approach in drug management is not addressed effectively in the state and thus leading to incongruous usage of pharmaceuticals in the public healthcare sector.

Conclusion: Overall, it can be observed that there are several areas that can improved within the public pharmaceutical supply system to improve the accessibility to essential drugs at the primary healthcare level. Incorporation of standardized strategic methodology with Information and Communication Technology interventions in processes dealing with pharmaceutical purchasing, selection, quantification, distribution, management of human resource, and inventory management will drive the system towards achieving “Good Health to all.”

Key words: KDLWS, Public rural healthcare, Pharmaceutical procurement in Karnataka, Public drug supply and distribution in Udupi, Primary health centers (rural).

INTRODUCTION
Pharmaceutics comprise a vital place in the healthcare system and contributes a major significant share in the health expenditure. Medicine or therapeutic drugs can be defined as chemical compounds or substances that are administered to living beings as an aid for treatment, diagnosis, prevention of diseases and other abnormal conditions, relief to pain, to improve or control any pathological or physiological state. With the advent of essential drug concepts, essential medicines defined by WHO need to be dispensable and
satisfy the requirements of the majority of the population. Thereby, the drugs need to be available and accessible whenever required, in all appropriate dosage forms at affordable pricing. Improvement of pharmaceutical services and inventory management can ease in more efficient and better quality of healthcare services.

The escalating health care costs and the ever-growing expectations about the health care delivery system by the public, prove a threat to the sustainability of the existing public healthcare service delivery system. A study conducted to analyze the health spending by the state of Karnataka indicates that over a decade, it is less than 1% and there is an alarming dependency on the central government for improving the health expenditure. The per capita expenditure on health in the state is about 225 and the additional spending from other health departments, increases to 390. With NRHM spending on health from the central government, the per capita expenditure shoots up to 468. The analysis also reveals that expenditure for public health and primary care is taken care by the state government, but they are also severely constrained for funds. Hence, the central government plays a vital role in funding public and primary health within the state.¹

Healthcare policy makers are struggling with broader health care reforms to achieve and promote decision-making, guided through real time evidences and to create an environment with inter-professional collaboration, which will lead to quality improvement.² The Public Health care Delivery System is under tremendous pressure to patch up resources with the demands. The status of the pharmacy services at the primary healthcare level is tangled around a routinized complex system, where the personnel are overworked and pharmaceutical resources are overly limited. Lack of computerization in managing the pharmaceutical services is exacerbating the situation.

With time, the system has realized that expenditure associated with the supply chain consumes almost 40% of the total operating budget. This comprises the second largest overhead for the system after labor. Previously, health care executives viewed supply chain management as a back office cost center. Now, it is realized that supply chain is not only the main target for significant reduction of cost, but also the central strategy for overall sustainability of the health delivery system. Increasing demand from the public for reliability, pricing, transparency, visibility in the functionalities, greater efficiency, and accountability throughout the health care system has revolutionized the drive for a new level of discipline in the field of pharmaceutical supply chain management system.³

Traditional supply chain metrics have completely focused on the transactional aspects. Introduction of new metrics that are strategic and provide a better understanding about the supply chain management, patient safety, purchasing based on real time demand and clinical outcomes, inventory optimization and supply chain management would evolve as a key stratagem for evidence based medicine and rational utilization of drugs. This will lead to overcome scarcity amongst the abundance i.e. even though a plethora of medicines is manufactured in the state; there is overproduction of drugs that are affordable by the rich while the medicines required by the poor are neither adequate nor available.³

The analysis was undertaken to perform a situational study in Udupi District, Karnataka. Focusing on the pharmaceutical supply sector in rural primary health centers, to highlight the clusters of bottlenecks persist in the system and the need for a reliable resolution system with Information Communication Technology interventions. The study involves assessment of the structure, functionality, processes involved in procurement and distribution of pharmaceuticals, and outcomes of pharmaceutical use at the primary health centers. The overall findings of this analysis are described below.

The words “medicine” and “drug” are used interchangeably in this report.

BACKGROUND

Earlier in Karnataka, the state followed a central governance system for pharmaceutical procurement and supply. The essential medicines were procured and distributed to the state public healthcare institutions through the Government Medical Stores (GMS). In 2002, the Karnataka State Drugs Logistics and Warehousing Society (KDLWS) were established with the assistance of the European Union. It was registered in 2003 under the Karnataka Registration Act 2003. KDLWS operates from its headquarters in Bengaluru, comprising of six departments covering administration, procurement, logistics, quality control, accounts and finance and information technology. The system was established analogous to the Tamil Nadu Medical Services Corporation Ltd. This society was initiated to achieve the following objectives—
• Procurement and distribution of drugs and other medical essentials at reasonable economic rate
• Establishment of drug procurement and distribution management system
• Ensuring availability of drugs in the remote locations and to the poorest population
• Implementation of hi-tech system of networking and logistics in drug distribution and management
• Improvisation of overall health care delivery system
• Free Drug Scheme-Provision of drugs to the patients free of cost

KDLWS administers, manages and conceives the following functionalities-

• Identification of drugs and formulation of the state formulary
• Drugs procurement
  • Drug Quantification
  • Call for tenders (supply of medicines)
  • Purchasing of drugs
• Drug supply and distribution management
• Quality assurance for medicines
• Accounting and finances

Even though both organizations were initiated with the same objectives and functionalities, the significant difference is that KDLWS is a typical government set up and TNMSC is autonomous. The governing council comprises of 12 ex-officio members where the chair is the Principal Secretary to the state government Health and Family Welfare. The Society is comprised of various committees for decision making in procurement of drugs and medical equipment. Figure 1\(^1\) represents the composition of the committees existing under KDLWS.

There are about 14 drug ware houses located in the state servicing 30 districts (approximately 1 drug warehouse for every 2 districts) and the state government is initiating to establish one drug warehouse for every district. The district drug warehouse is staffed by one main in-charge, one chief pharmacist, two junior pharmacists, one data operator, and two attendees. Initially, an electronic based Drug Distribution Management System was developed and operated between KDLWS and at the district drug warehouses. The system is initiated to adhere to the modern warehousing techniques to stringent quality control and to provide information technology empowered services. Recently, the system has evolved to extend up to all the health care facilities at various levels of functionality. Its prime task is to receive annual drug indents from all the state owned public health care facilities and it is called the Drug Management Information System. Drugs, chemicals, and other sundry items are procured through society for the usage in government owned hospitals and other healthcare services. The State Sector, District Sector, and the Directorate of Medical Education undertake the procurement in the state. The society also takes care of the drug requirements of various other programs like National Rural Health Mission (NRHM), Karnataka State Aid Prevention Society (KSAPS), and Akshara Dasoha of Education Department.\(^4\)

The state implemented NRHM programs in 2005 but full-fledged activities only came into existence in 2007-08. NRHM shares about 22%-25% of the state health expenditure, ensuing a remarkable hike in the budget allocated for the state.\(^5\)

Only from 2010, e-procurement and electronic Drug Distribution management system came into existence.

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\(^1\)Source: KSDLWS, http://www.kdlws.kar.nic.in/index.html

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Figure 1: Committees of KSDLWS
Hence, the electronic based drug supply-chain system in Karnataka is still in its nascent stage, where still major functionalities and transactions are manually done with cumbersome paper based proceedings.

METHODS

Study design

A cross sectional analysis of the sampled rural primary health centers (PHC) Udupi district, Karnataka was undertaken. The analysis comprehends the accessibility and availability of quality essential drugs, procurement procedures, budgetary allocation for procurement of drugs, drug quantification or forecasting, storage and distribution strategies, and the procedures practiced in maintaining records of drug consumption, and rational utilization at every rural PHC. Retrospective information was collected from the last three years (2012-13, 2013-14, and 2014-15).

Specific foci of the study

- To understand the existing system of drug procurement with an aim to scrutinize the bottlenecks and key gaps existing between the actual demand and supply, the budgetary allocation for procurement of drugs and other medical essentials by the Karnataka state government and to analyze drug distribution strategies.
- To assess the procedures practiced in procuring, quantification, distribution, maintaining, and record-keeping of drug consumption at the sampled rural PHCs in Udupi district.

Data collection

To document the State’s current drug procurement and distribution system, data were gathered from-

1. Desk-based literature review of published work papers, journals, articles, online references etc.
2. Informal interviews and discussions with the medical professionals, and
3. Solicited inputs from health officials and authorities presently working in the public healthcare at both state and district level.

Information related to the budgetary allocation to the rural public health institutions was collected from the District Health and Family Welfare Office, Udupi. Visits and interviews were conducted at every rural PHC to collect the vital information regarding the PHC infrastructure, the demography of the surrounding area, availability, and access to medicines, drug procurement procedure, inventory stock keeping, and rational utilization of the procured drugs. Processes followed for drug quantification, forecasting and usage were evaluated by reviewing the annual indent books, ledgers maintaining the stocks and consumption, passbooks, and other documents that throw light over the actual practices followed in pharmaceutical procurement, distribution, and utilization.

Data collected from these public health institutions were corroborated with the District Health and Family Welfare Office, Udupi through the permission provided by the Directorate of Health & Family Welfare Services, Bangalore.

Sampled area

The Coastal Karnataka region is a composition of three main districts namely, Uttara Kannada, Udupi, and Dakshina Kannada spreads up to 18,997 square kilometers with a total population of 4,709,179. Sampled area under study is Udupi district. The city Udupi is the headquarters of Udupi district. The district comprises of three taluks i.e. Kundapur, Udupi, and Karkala with majority of rural population with an agrarian economy. Table 1 summarizes the demography of Udupi district, Karnataka. Numerous ridges and spurs of the Western Ghats with difficult terrains traverse through the region. The entire belt is covered with a tropical monsoon climate with excessive humidity, strong winds and heavy rainfall during monsoon season.

The health care delivery system in Udupi district includes both private, public health institutions as well as specialized Ayurvedic hospitals. The publicly funded government health institutions provide the basic medical care and other healthcare facilities, but most of the locals

Table 1: Demography of Udupi District, Karnataka

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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kundapur</td>
<td>1561</td>
<td>398471</td>
<td>405494</td>
<td>8403</td>
</tr>
<tr>
<td>Karkala</td>
<td>1076</td>
<td>216091</td>
<td>219352</td>
<td>7289</td>
</tr>
<tr>
<td>Udupi</td>
<td>928</td>
<td>562799</td>
<td>573485</td>
<td>59857</td>
</tr>
<tr>
<td>Total</td>
<td>3565</td>
<td>1177361</td>
<td>1198331</td>
<td>75549</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td></td>
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</tbody>
</table>

and expats prefer to utilize the services provided by the private hospitals and clinics. The health system in the district is categorized as shown in Figure 2.

The public health care infrastructure in the district is controlled and administered by the District Health and Family Welfare Office located in Udupi city. The District Surveillance Officer heads the organization. The infrastructure of the public healthcare sector in Udupi is as illustrated in Table 2.

### Sampling frame

Purposive sampling was considered to conduct the qualitative study. Out of the health referral pyramid shown in Figure 3, the analysis concentrates on the study unit comprising the primary health centers (rural division) and sub centers under its control. Following framework was used for sampling the primary health centers under study-

- Geographical location and accessibility
- Availability of records
- History of the preceding illness
- Distance from the district drug warehouse
- The population covered under each PHC
- Varying range of patient attendance in each PHC (OPD/IPD)
- Availability of personnel with computer knowledge

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**Table 2: Public Health Infrastructure in Udupi District as on March-2013**

<table>
<thead>
<tr>
<th>Taluk</th>
<th>Taluk Hospitals</th>
<th>District Hospitals</th>
<th>Indian System of Medicines Hospitals</th>
<th>Community Health Centers</th>
<th>Primary Health Centers</th>
<th>Sub-centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kundapur</td>
<td>1</td>
<td>100</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Karkala</td>
<td>1</td>
<td>100</td>
<td>-</td>
<td>-</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Udupi</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>320</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

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Sample size

The study sample includes 20 PHCs in Udupi district, Karnataka. The PHCs are located across the three taluks Karkala, Udupi, and Kundapur under Udupi district jurisdiction. The list of PHCs under study is as listed in Table 3.

Limitations of the study

The analysis conducted in government run rural primary health centers is restricted to Udupi district, Karnataka. The assessment covers the following pharmaceutical management issues:

- Availability of Computer infrastructure with internet connectivity
- Adherence to the Essential Drug List
- Availability of medicines as per the requirement
- Allocated budget and finance
- Pharmaceutical procurements and distribution
- Medicine utilization
- Quality Assurance
- Management and monitoring information
- Existence of drug information system
- Procurement of drugs, chemicals and other essentials
- Quality Assurance
- Forecasting and Drug quantification
- Monitoring of drug distribution, storage and stock maintenance at the PHC level

Infrastructure of PHC (rural division) in Udupi district, Karnataka

For every 30,000 population in plains and 20,000 population in tribal and hilly areas, one primary health center is established. Out of which for a population of 5000 people in the plains and 3000 in tribal and hilly areas, a sub-center is established. Because of inconsistent distribution of population density, implementing the same norms all over is not feasible. Totally, there are 59 primary health centers and 328 sub-centers in Udupi district. The sub-centers are classified into two categories type A and B. In both the categories, they provide all the required and recommended services expect for...
delivery facilities in the former type. The primary health centers are also divided into two types depending on the caseload i.e. 24×7 PHC or regular PHC. A few function round the clock for 24×7, especially those located further from the nearest community health center or district hospital and the others function for a fixed number of hours in a day.

The services delivered by the sub-center are minimal assured services that include preventive, promotive, referral and a few curative services and all the national health programs declared by the central government. Functionality and administration of the sub-center is monitored by the primary health center heading that area. The sub-center acts a linkage between the communities at the grass root level and the most primitive health care services. It occupies the lowest rung of the referral pyramid of health facilities. On the other hand, PHCs are the cornerstone in the public healthcare system. It is a first port of call for a qualified doctor (under public health sector) in rural areas for the sick and those who directly report or referred from Sub-Centers for curative, preventive, and primitive health care. PHC acts as a referral unit for every six sub-centers.

PHCs are allocated with individual buildings with clean surroundings. The premise is located in an easily accessible location with adequate supply of electricity and water, connecting roadways, and communication networks. The building comprises of a separate waiting area, outpatient department, labor room, wards to accommodate 4-6 beds, minor operation theatre, laboratory, and general (main) store for storing medicines, chemicals and other consumable materials. The dispensary is attached with dispensing counters that is accessible to the public. All PHC are supplied with refrigerators, cold storage, and fire handling equipment.

Compared to the set-up of the primary health centers located at the urban areas, the condition is compromised in the rural regions. Only in the recent past, PHCs with the help of government aids are improvising the infrastructure, work force, medical aids and health services. Among the visited PHCs, the conditions and standards describing the level of quality that a health facility are expected to meet or aspire to, is achieved in most parts of Udupi and Karkala taluk. However, the PHCs in the Kundapur taluk, is still struggling to meet the standards, especially the once in remote location (far from the urban inhabitants). In PHCs with heavy caseload, the infrastructure and facilities are inadequate.

Pharmacies in recently developed institutes are well ventilated and furnished with wooden shelves and cupboards for stacking drugs in an orderly manner. On the contradictory, in older premises the storage area is small, unordered stacking of drugs, no control over humidity and temperature, poorly illuminated and not ventilated adequately.

Every primary health center needs to staff with the following list of personnel depending on the type of PHC (type A when the delivery load is less than 20 per month and type B if the load is greater than 20) as shown in Table 4. It is necessary for every facility to possess a

<table>
<thead>
<tr>
<th>Staff</th>
<th>Type A</th>
<th>Type B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Officer- MBBS</td>
<td>1</td>
<td>1#</td>
</tr>
<tr>
<td>Accountant cum Data–Entry Operator</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Nurse-mid Wife (Staff Nurse)</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Health Worker (Female)</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td>Health Assistant (Male)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Health Assistant (Female)/Lady Health Visitor</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Laboratory Technician</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Group-D Worker</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sanitation Worker cum Watchman</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*For Sub-Center area of PHC.
# if the delivery caseload is greater than 30, it is ideal to have 2 medical officers (MBBS) on of them being female.
formal organizational structure document that show the numbers of staffs recruited, positions, levels of authority, job description and the responsibility entrusted upon them.

In most of the PHCs in Kundapur taluk, it was observed that personnel are understaffed and existing ones are overworked. For instances, in the absence of medical officers, pharmacy staff dispenses medicines without the prescription of the medical officer violating the norms and professional responsibility of a pharmacist. Staff nurse is given the privilege of maintaining drug-dispensing records and maintenance of stock-books (both main stock and sub-stock) in the absence of a designated pharmacist. Due to under staffing, a single pharmacist manages around three-four PHCs, in their absence the staff nurse takes over the part of dispensing drugs and maintains the sub-stock records. The organizational structure documents are not maintained most of the PHC. Pharmacy keys are kept under the main pharmacist control and cabinet keys for controlled drugs. Normally, pharmacies are operated by the main pharmacist but inreality in few instances, because of under staffing, it is operated by the staff nurse or medical officer. The pharmacist is accountable for maintaining safety stock, drug expiry, inventory control, medicine availability, and drug supply records.

Financial resources in the rural public health institutions

It is an established truth that NRHM plays a vital role in the total health expenditures of the state. It takes a keen interest in improvising the public and primary health conditions concentrating more on the rural areas. It contributes almost one-fifth of the total expenditures in state health sector. Out of which large amounts of funds are regionalized to the rural areas for construction and modernization of the health facilities. Under the guidelines of Government of India, 70% of the funds are allocated to all districts and 30% more to districts with high priority.

The funds are assigned as plan (new investments) or non-plan (continuing existent expense). It follows a fixed expenditure regime for each kind of activity or type of health center. Generally depends on the level of the health center at the health referral pyramid and remains uniform across the health facilities irrespective of the real evidence based requirements. During the time of emergency, no discretion is given to reallocate funds to meet the needs. In case of persistent need of deviation, permission from the Department of State Finance is required. There by the existing financial approach does not leave any scope for unforeseen expenditures and innovations.

The state government allocates a drug budget for each kind of the public health care facilities based on the type of health facility and the number of beds. Apart from which NRHM, presently known as National Health Mission (NHM) provides three distinct types of funds, namely:

- ArogyaRakshaSamiti (ARS) (RogiKalyanSamithi (RKS) in Karnataka) corpus grant –
- This grant mainly comprises of grant-in-aid from the state government or state level societies in the health sector, and grants or donations from trade, industries, or individuals.
- The fund is mainly utilized for upgradation, expansion, or modernization of the health facilities, provision of ambulance services and can be used for purchasing drugs and equipment whenever required.
- Annual Maintenance Grant (AMG)–The grant is utilized for regular management and maintenance of the facility building and infrastructure.
- Untied Fund–This fund comes with no strict conditions and guidelines for spending of funds. These are facilitated to meet the urgent discrete events, which involve unforeseen expenditures.

The funds allocation for different types of health facilities at various levels can be summarized as shown in the Table 5. The irony is that, in most of the visited primary health centers are handicapped from shortage

<table>
<thead>
<tr>
<th>Grant (in Lakh)</th>
<th>District Hospital</th>
<th>Community Health Center</th>
<th>Primary Health Center</th>
<th>Sub-Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>RKS (Corpus Grant)</td>
<td>5,00,000</td>
<td>1,00,000</td>
<td>1,00,000</td>
<td>-</td>
</tr>
<tr>
<td>AMG</td>
<td>-</td>
<td>1,00,000</td>
<td>50,000</td>
<td></td>
</tr>
<tr>
<td>Untied Grants</td>
<td>-</td>
<td>50,000</td>
<td>25,000</td>
<td>10,000</td>
</tr>
<tr>
<td>Total</td>
<td>5,00,000</td>
<td>2,50,000</td>
<td>1,75,000</td>
<td>10,000</td>
</tr>
</tbody>
</table>

*Funds expended only if the sub-center is facilitated with a building.

Source: Pharmaceuticals in Health Care Delivery; Mission Report 16-26 July 2013.
or blockage of funds. The administrator of these health facilities fail to utilize these funds to an optimum level. Even though these grants come with well-defined guidelines, utilization is not encouraged. This is mainly due to low awareness level and lack of skilled human resources to plan and execute strategies for better welfare of the patients and the institution itself. A constant criticize from the medical officials is that the allocated budget does not compile with the evidence-based requirement especially in the PHC that covers a population exceeding its actual coverage, caseload and those functioning on a 24×7 basis. For an instance, PHCs that used to function on 24×7 basis and converted into regular PHC, funds allocated are not changed. Thereby, in a few situations they have, excess of budget allocated which goes a waste or they have a constrained budget to face the daily activities and functionalities of the PHC.

Each of the visited PHC has an average of 5-6 beds in the in-patient section. Apart from the maintenance of infrastructure, the health institutions need to maintain an inventory of tens to thousands of supplies i.e. medicines, chemicals, surgical instruments and other devices. Procurement of essential medicines accounts a major part of the allocated state funds, even though a part of the medicine is supplied through the federal government programs. The allocated state budget for drugs is transferred directly to KDLWS, to embark on the procurement and distribution of essential medicines. The Table 6 discloses the budget allocated (for the year 2014) to different public health institutions depending on the norms.

In Karnataka, health sector reforms are incremental and piecemeal but it has given rise to extensive changes in the financial aspect. Despite the introduction of various health welfare schemes by the government, the impact of these schemes on the rural population is questionable. Even with the existence of such schemes, the Out-of-Pocket (OOP) expenditure of individuals or households has always been on the higher side. It has become the primary source for financing health care as only a small percentage of the population is covered under health insurance. This is mainly due to the financial status of the people who cannot afford the medical expenses and unavailability of drugs and medical professionals at the public health facilities add to the existing misery. The patients are forced to purchase the medication from local private pharmacies and receive services from private health sectors.

Funding plays a relevant role in maintenance and upkeep of the health institutes, lack of steady flow of funds effects infrastructure and availability of basic facilities. Absence of ample insurance coverage and increase in cost of drugs, diagnostics and other investigations, expenditure to treat illness among the rural population can eventually led to financial catastrophe, drastically pushing into poverty or deepening their existing poverty.

Outline of the pharmaceutical management in Udupi district, Karnataka

The foundation for a real time accessibility to drugs and other essential medicines involves selection of drugs based on the evidence or diagnosis, rational utilization, price affordability, optimal resources (monetary and personnel) and a reliable, robust and self-sustaining supply system. The pharmaceutical management is undertaken in four major inter-linked phases as illustrated in Figure 4.¹⁰

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¹⁰Source: Managing Drug Supply; Management Sciences for Health in Collaboration with the World Health Organization
The current system is an independent demand system that operates with the management of purchasing and distribution of finished pharmaceutical products. It works based on the forecast from the history of patient consumption rate and with the knowledge of expected changes in the consumption, the order level, and quantities to be ordered. The pre-determined inventory levels are set to provide a distinct level of services to the patients at an acceptable cost. The distribution infrastructure is established on pull-push system. Pharmaceutical requirements are quantified for an annual based purchasing and requirements are forecasted depending on the prior indenting and rate of drug consumption. The required pharmaceutical supplies are distributed by the district drug warehouse to the health facilities directly. With the analysis of data collected from PHCs visits, interviews and questionnaires, the schematic mapping of the procedure followed in procuring of drugs and other essentials can be illustrated as shown in Figure 5.\textsuperscript{11}

\textbf{Selection of Essential Drugs}

KDLWS is accountable for coordinating the development of Essential Medicine/Drug List with State Therapeutic Committee (STC). This committee identifies and decides the drug requirements of the state run healthcare institutions and prepares a formulary called the Essential Medicines List (EML). This list ensures that financial resources are released wisely to provide the type of drugs that are appropriate to the health problems in the state.

\textsuperscript{11}Source: Analytical observation during visits to district drug warehouse and primary health centers

The rationale for selection of limited list of essential drugs is to improvise the supply of drugs, intriguing
balanced usage, and lowering cost associated with the supply of drugs. Essential drugs are those that are deemed to placate the healthcare needs of the population and available at appropriate dosage forms and strength. Selection of vital drugs has a considerable impact on the quality of healthcare services provided and cost related to the treatment provided. The essential drug lists are composed in such a way that it indicates the level of healthcare facility where each medicine can be used.

In the year 2011, Essential Drug List was published into booklets containing 361 pharmaceutical items excluding disinfectants. It was revamped in 2013, with addition of two more drugs resulting in 363 items. The generated list was printed into booklets and copies were circulated to different health facilities for quantification of drugs in form of indents. There were no categorizations of pharmaceutical items based on the health facility level until 2013. Currently, the new list covers about 677 items including drugs, suture materials, and surgical items. Different versions are created and categorized to cater the needs of District hospitals, Taluk level Hospitals, Community Health Centers, and Primary Health Centers. The EDL for PHC alone covers about 287 drugs. These lists are available online on the website managed by KDLWS and health facilities can indent the annual requirement over the online support with in a stipulated time.

Criteria for Selection of Essential Drugs –

The norms for selecting drugs and their dosage forms are as follows:

- Affordability of drugs by keeping a check on the pricing, rendering a cost effective procurement to optimize the utilization of limited financial resources;
- Availability of drugs for treatment of most prevailing diseases, ailments and sicknesses at various levels of the health facilities;
- Accessibility to safe, effective, good quality medicines, and services

Generic Names –

Generic names or International Nonproprietary Names (INN) is used to refer the drugs listed in the state essential drug list. It is used for writing prescriptions and procurement of drugs. The main advantages of using generic names over brand names for medicines are –

- Easy recognition of the type of drugs
- Enables procurement of drugs from multiple sources, ensuring purchasing at a competitive price
- Substitution of drugs where availability is a problem
- Avoidance of confusions related to the usage of brand names

From KDLWS, only the drugs listed in the EDL are distributed to the district health facilities as per their requirements. In reality, most of the PHCs are unable to provide the required drugs and health services free of cost. This is mainly due to chronic shortage of drugs and unscientific stocking of EML drugs at the required moment. This is mainly occurs because, the drug requirements are not submitted on time, inaccurate quantification of drugs, and mismatch between the budget cycle and funding cycle leading to failure in timely supply of essential requirements. The drug supplies are erratic and the stored formulation includes both black listed and expired drugs. Due to non-availability of drugs, patients are compelled to buy part of the prescription from private pharmacies and switch to sub-standard alternatives promoted by the drugs shops due to escalation in prices. In order to cope up shortage of medicines at the time of requirement, medical professionals are compelled to prescribe non-EML items. Majority of non-EML items included antibiotics, analgesics, oral diabetics’ medications, ophthalmic products. Observing the stock lists in the visited PHCs, almost all drugs stocked belonged to EML drugs. Thus, it can be stated that purchasing of non-EML drugs by hospitals is low and purchasing of the same by the patients is higher. Separate prescriptions are used for purchasing of non-EML items due to which the extent of the problem is unknown. Another source for non-EML items are those that are introduced by the private pharmaceutical companies, unethical advertising and promotion of their drugs with unproven claims of effectiveness.

Apart from limited supply of drugs, irrational methods of prescription of drugs by the medical professionals also add to plethora of drug shortage problems. Medicines have become a mark of the new medical culture, where treatment is completely drug-oriented where all other aspects of nursing and caring are neglected to the background. Doctors prefer prescription of symptomatic drugs and thus increasing the drug consumption on an irrational stretch.

Despite the efforts of covering 287 drugs for PHCs under EDL, most of the medical professionals are unaware of the modern pharmaceutical technology and the others argue that the EDL does not cover enough number of drugs to treat patients with complicated conditions. Hence, they are compelled to prescribe non-EML items to the patience and purchase the same from outside.
private pharmacies. Doctors regard EDL as a list of basic set of drugs that could be afforded by the government rather than those actually required curing majority of the healthcare conditions.

**Procurement of Drugs, Chemicals and Other Essentials**

Good purchasing practice is prerequisite for efficient accessibility to appropriate and good quality drugs. The main objectives of the procurement system followed in the state are as follows—

- Purchasing of right quantities of drugs in a cost-effective way
- Selection of reliable suppliers of higher quality goods
- Assuring timely delivery and distribution of drugs and other requirements
- Achieving the lowest possible total cost associated with the transaction in the procurement system

Procurement of drugs is based on three aspects—selection of drugs, type of dosage forms and the availability of monetary resources. Procedures followed during the process of procurement are—

- Quantification of each drug product for a given period
- Listing of prices of the required drug in various dosage forms
- Allocation of funds depending on:
  - Requirement priority of the drug and dosage form
  - Available funds

The state follows a centralized drug procurement system through e-tendering process (based on rigid written protocol). The drug requirement of all levels of the public health care delivery system is purchased through a single registered society i.e. Karnataka State Drugs Logistics and Warehousing Society (KDLWS). The society is promulgated under the Karnataka Transparency in Public Procurement (KTPP) Act of 1999 and Rules 2000, which gives it the liberty to advertise, receive, evaluate, and award successful bidders. Tendering is done once a year for most of the products based on recent years rate of consumption and estimation needed by each health care facility. Factors like rate and quality of products are given equal consideration while deciding the tenders.

Once firm wise supply orders are placed, the firms must assure to supply the drugs as per the KDLWS norms. Distribution of drugs to the consignee (district drug warehouse) must adhere to the schedule of the distribution chart enclosed with the supply order. On submission of bids on-line before a specified date, the Tender Scrutiny Committee conducts technical evaluation for all the potential bidders and presents the results to the Tender Accepting Committee. Upon the recommendation made by the Tender Accepting Committee, it provides permission to open an on-line financial bidding only for those suppliers and products that qualify the technical evaluation. The product that passes with the lowest price (L1 price) is selected, provided their prices are equivalent or lower to the prices in the open market. In case the quoted price is greater than that of the market survey, the suppliers are invited to negotiate with the procurement committee. In case, the supplier quoting the lowest price fails to supply the product, suppliers with the next closest bidding price (L2 price and L3 price) are approached. Certain pharmaceutical companies or products are ostracized for supplying inferior quality services or products. This companies or products are blacklisted and are denied the privilege to take part in bidding process or being supplied to the health facilities.

The criteria to qualify technical evaluation are as follows:

- The supplier must be an importer or manufacturer
- Annual turnover of the supplier must be greater than five crore
- The supplier must not be blacklisted by any state/central government purchasing agencies in India and by the Medical Services Corporation
- GMP certified products
- The supplier must have manufactured the product for more than 3 years
- The supplier must make an agreement to supply goods with 80% of the shelf life remaining at time of delivery. Labeling and packaging, should include the KDLWS logo and words “not for sale”
- An agreement will be signed to supply half product stock within the first 60 days and the remaining
All the accepted bidders make an Earnest Money Deposit of Rs.1,00,000, in addition to which a bank guarantee against default at 5% of the value of the amount to be supplied must be made by the successful supplier at the time of contract.

There are many bottlenecks that limit the smooth processing of procurement that result in limiting the performance of the entire system. Bottlenecks frequently appear as delays, which may vary in length at different steps of procurement depending on the complexity. Sluggish contract planning and procurement scheduling, ambiguity over dates and available funds, flawed decision making, delayed processing by the financier and supervisors, slow preparation of bidding document and payments, impeded approval, irregularity in security performance, delay in pre-shipping inspection and testing are a few constraints that can be highlighted in the present system. Even though the entire process is based on e-governance, the efficiency of the system is yet to be exacerbated.

**Quality assurance**

For quality assurance and regular monitoring of drugs supplied by the rate-contracted firms, KDLWS has initiated a strict central quality control cell in its premises. When the drugs consignment arrives at the drug warehouse from the suppliers, in addition to the quality certification provided by the manufacturer, the entire consignment is quarantined. A random sample from each batch of the drugs received is sent to the quality control cell. Each sample is provided with a code, the details and all other traces of the manufacturer is erased and subjected to testing in government empaneled private laboratories. Upon receiving the test results and the certification of quality, the corresponding consignment is taken out of quarantine, decoded to match the lab results with the product name, and distributed for usage. In case if any product fails the laboratory quality test, the sample is again sent to drug testing government laboratory. Even after the retest the sample fails to meet the quality requirements, the KDLWS rejects the entire supply and the suppliers are asked to replace the complete batch of the product.

The quality control cell is headed by a graduated pharmacist and an assistant staff. They regularly receive randomly selected batches of each drug type that is supplied to the district warehouse. The sampled drugs are subjected to various tests to qualify their quality as per the Indian, US or British pharmacopoeias and label claim. Upon testing the drugs, if any substandard drugs results are received, the KDLWS will take appropriate action to penalize the pharmaceutical company in accordance to D & C Act 1948. Drugs, which fail the test, are stopped from distribution, the drug warehouse is immediately intimated, and the subsequent health care centers are restricted from utilizing the same.

**Forecasting and drug quantification**

Quantification is a primary and vital stage of purchasing process. It is embarked to avoid shortage of drugs, assure credible healthcare services, to evade excessive stocking and wastage of limited drug resources and incorporate better financial management. In general terms, it can be defined as a process to integrate the idea of how much of a product is needed for purchasing and exercise the financial means required for procuring the same. Normally, the term forecasting and quantification are used interchangeably.

Currently, the system proposes to follow a consumption-based methodology for quantification of drugs at the primary level of health facilities. An indent for drugs and other medical requirements is raised annually, and the drugs are supplied every quarterly. Past records of consumption pattern of individual drugs are analyzed to project the future needs. On a larger perspective, forecasting pharmaceutical requirements based on consumption is more accurate when the records are up-to-date, complete, properly adjusted taking days-of stock out into consideration and the predictable changes in demand and usage.

Projection of future needs and choice of drug types and quantities are based on –

- Availability of funds
- Human resources capacity
- Population coverage
- Disease pattern
- Seasonal variation in the disease pattern
- Rate of monthly drug consumption
- Lead time taken for delivery of drugs from the nearest drug warehouse
- Time delay between the placing an indent and receiving the orders
- Stock keeping—the knowledge of quantity of drugs of each form that is consumed regularly

Apart from the above mentioned criteria, distance between the primary healthcare facility and the regional drug warehouse, the size or capacity of the drug store...
rooms and the number of patients visiting the primary health facility plays a vital role in determining the maximum quantity of the drugs to be stocked.

In reality, most of the records available in the PHCs are not systematically maintained and number of days of drug stock-outs is not gauged accurately. There are no such standard formulas used to identify stock-out periods or estimate the demand. Quantification is based on previous year’s consumption pattern, adjustments, and addition put forth by the senior staffs of the facility. Normally, the quantification is done in the presence of Medical Officer, main Pharmacist and the senior staff nurse. In a few instances, it was found that the pharmacist itself lists out the requirements without the concern of the Medical Officer. Another reason adding to the existing misery is that the government supplies drugs as per the allocated fixed drug budget for each facility as per the number of beds and not corresponding to the actual needs. According to the guidelines put forth by the government, minimum of three months buffer stock need to be maintained, in practice, this is not followed in any health facility. Since in actuality the forecasting is completely based on individual perception and lack of systematic method, it leads to inappropriateness of the past records of medicine consumption. Finally, perpetuation of irrational usage of drugs that is under stocking or over stocking of drugs due to under estimating and over-estimating respectively of the requirements. Capturing of real and actual demand poses a vital move for executing consumption based drug quantification.

**Drug distribution, storage and stock maintenance at the PHC level**

Distribution takes place from the supplier who possesses the procurement contract for the product directly to the district drug warehouse. Upon receiving a request from the warehouse that is processed by KDLWS, the manufacturer or the suppliers deliver the product. An electronic based Drug Distribution Management System (DDMS), maintained by KDLWS that extends up to the district warehouse level that helps in monitoring and tracking the stock level in the warehouse. It also helps in checking the quantity of the budget allocation utilized by each of the health facilities that fall under its jurisdiction. However, the DDMS does not penetrate until the public health facility level like the district hospitals, CHCs or the PHCs. They still rely on traditional paper system.

After the submission of the annual indent book to the District Health office, approximately within a span of 3 months upon the availability of drugs, the District Health Officer fixes a date for supplying the required drugs to the respective PHC. Depending on the route map, at a time around 4 to 5 neighboring PHCs are intimated. The PHC pharmacist accompanied by a Group D worker is sent to the district warehouse to collect the drug consignment. Based on the availability, the medicines are supplied. For every supply, the entries of each transaction is entered in a book called the passbook, it contains the details of
the date of supply, drugs issued, price and balance. The passbook comprises the history of every transaction (value based) and, as and when the drugs are issued, the corresponding amount is deducted from the yearly budget that is allocated and the balance amount is entered. By the end of the financial year, if any amount is remaining, it is nullified. Drugs requirement of sub-centers are intended along with the requirements of the PHC (under its management) and later distributed to the sub-center by the managing PHC as per their day-to-day requirements. The drugs consignment is received with an invoice from the district drug warehouse. The distribution of drugs to the primary healthcare level can be pictorially represented as soon in the Figure 6.\(^\text{12}\)

On the arrival of drugs at the PHC, the stock is stored in the Main drug store with an optimum environment suitable for storage. The pharmacist maintains the main stock book where the stock level is maintained with respect to drug names. Entries like the name of the store supplied, the name of the drug manufacturer, invoice number, quantity supplied, batch no, date of manufacturing and date of expiry is entered for each drug. Along with the stock book entry, a Batch Index Number (BIN) card is maintained for each drug. As and when the drugs are retrieved for consumption, entries are made in the BIN card, and later the required drugs are stored in the Sub-store. In the sub-store, a separate sub-stock book is maintained to keep a track of medicines in the sub-store. The drugs required for the day’s consumption are stored in the dispensary, where the drugs are dispensed to the patients and respective entries are made in the daily issue book. Since the drug requirement for a sub-center is indented along with PHC drugs, when the drugs are received from the district drug warehouse, entries are made in the main stock book and the medicines are dispatched to the sub-center Auxiliary Nurse Mid-wife or Health workers. Figure 7\(^\text{13}\) highlights the methodology followed in maintaining the stock records at the PHC level.\(^\text{14}\)

In case of distribution of sub-standard drugs, only upon information intimated by the District health office regarding the counterfeited drugs, they are removed from the main store; stock entry is nullified and stored separately. Even in case of excessive drugs closing to expiry date, around 3 to 6 months from expiring, neighboring PHCs are intimated, if there is any immediate requirement for drugs. If so, the drugs are supplied to the other PHCs that require them and related entries are made in the main stock book of the PHCs (issued and received).

During emergency or intermittent requirement of drugs during the year, local purchases are made from medical stores or pharmacies, and related entries are made in the stock books i.e. the drug name, quantity, amount, store purchased from, manufacturer’s details, and the bill details.ARS funds are used to procure drugs from local pharmacies. Even though the procurement and distribution guidelines state that supply of drugs is on quarterly bases (once in every three/four months), some facilities do not know when the supplies will come as there is no agenda for the staggered distribution. The health facilities complain that they are not always supplied

\(^{12}\)Source: KDLWS- District Drug Warehouse, Mangalore, Karnataka

\(^{13}\)Source: Analytical observation at the visited primary health centers

\(^{14}\)Source: Analytical Observation on Visits to Primary Health Center, Udupi District, Karnataka
with pharmaceutical items that are required. Despite the declaration that the warehouse need to replace 5% of the expired drugs or those nearing to expiry; this never takes place. Additional requirement of drugs that are not part of the indent is not supplied. In case of such situations, permission from KDLWS is required.

In times of drug shortage, theoretically every drug warehouse should maintain buffer stocks of drugs or perform inter-warehouse movement of drugs to overcome the needs. This can be carried out only with prior approval from KDLWS. Movement of drugs can also take place between health facilities where the neighboring health care centers are intimated for checking the availability of drugs. If the required drug is in excess in the neighboring health care center, the amount required is requested and received. Local adjustment is done in the stocks through inventory certificates, which have the details of the present stock, requested stock and the amount of stock received, and on the other hand, the corresponding stock levels are entered in the health care center that supplied the excessive stock.

The storage facilities and records (patient records, pharmacy records, vouchers, prescriptions, invoice copies, data sheets etc.) maintained by the PHCs are less systematized and arranged in unordered manner. The details are written in local languages and do not maintain any uniformity and clarity. The certain PHCs in Kundapur district, the drugs are stored in loose unnamed boxes. The common thing observed in most of the PHC pharmacy is that, expired and black listed drugs are not disposed appropriately. These drugs are stored separately in the main store and have accumulated over the years. The institutions do not follow a hygiene method of disposing bio-chemical wastes. Dearth of skilled and qualified workforce, lack of modern scientific knowledge (i.e. in the field of medicine, logistics and stock management, public health and pharmacology), irrational usage of limited resources, insufficient utilization of modern technology like computers and internet, and deficiency in real-time based planning and purchasing activity makes the system a slow, complex and a cumbersome process.

**POSSIBLE RECOMMENDATIONS**

In reviewing the case study conducted, procurement bottlenecks and gaps are identified around several subjects; which includes access to the allocated funds, technical capacity, cumbersome processes, lack of adequate qualified personnel & staffing, compromised infrastructure, dearth of transparency, quality concerns etc. The main challenge in the present procurement system is the cumbersome manual processes where every procurement transaction is totally paper based. As medicines are procured by different health facilities/institutes, by different departments in the state as well as district level, recordkeeping of each of this transaction is a laborious task. Multiple sources of procurement cause delays and make it difficult to monitor the procurement process and thereby hamper the accessibility, affordability, and rational utilization of drugs. This directly affects the objective of providing “health to all.” Some of the possible recommendations that can amend the bottlenecks in the present system are-

- The society KDLWS can evolve into an autonomous corporation with multi-stake holders to govern the government purchasing and decision-making.
- Allocation of optimum budget, avoidance of delay in payment, and removing blockades of funds can help in meeting the demand rates of drugs and cover the management and administrative costs.
- KDLWS should extend the electronic drug distribution management system up to the lower level of the health facilities located at the base of the referral pyramid so that the system introduces a possibility of tracking and tracing to improve operational efficiencies.
- Services like quality testing, payment mechanism, automation with IT infrastructure and other drug supply chain activities can be outsourced as this reduces the overhead costs, optimized utilization of resources, inculcates more operational control, consistent and reasonable costing, staffing flexibility and better risk management.
- Annual reviewing of the essential drug list with grouping of medicines and other pharmaceutical needs based on the health facility level and real-time based requirements. Web based procedures need to be integrated to add new medications in the EML under strict criteria and super vision.
- Impart training to the health facility staffs regarding the utility and usage of drugs listed in the EML, financial management of allocated budgets, improving administrative skills and warehouse, and storage management.
- Generate annual reports to document the procurement, distribution, consumption pattern from every district health facilities. Along with these reports, documenting the patients statistics can help in analyzing the disease trends and evidence based requirements of drugs, which tend to vary from one region to another.
• Review the system of drug quantification and stock control. Standard methods or formulas can be incorporated to exercise scientific methods in forecasting the future requirements considering the stock-out periods, buffer stocks and the stock on hand.

• Systematize the drug storage system and imparting pharmacy and medical education to the staffs to focus on management of drugs.

• Hiring adequate number of skilled workforce in order to avoid over workloads.

• Motivating rational usage of drugs by monitoring adherence to the drugs in EML, entering prescription information into an electronic system, and conducting regular prescription audits need to be incorporated. Standard treatment guidelines need to be disseminated to every medical professional emphasizing usage of minimal medicines.

• Computerization of all process involved in the drug procurement management system helps in creating a robust, reliable scheme that acts as a strong foundation for a better-automated drug supply chain.

CONCLUSION

In Karnataka, the existing model for procurement and distribution of drugs run by KDLWS does serve the purpose of its integration and has improved the availability of medicines largely when compared to the timespan before its commencement. However, there are still certain major factors and features that need to be revised and reviewed in order to make it more efficient and self-sustaining.

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• Primary Health Centers, Udupi District, Karnataka
• Karnataka Drugs Logistics and Warehousing Society, Bangalore, Karnataka
• District Health Office, Udupi, Karnataka
• NRHM Office, Udupi, Karnataka
• District Drug Warehouse, Mangalore, Karnataka

CONFLICT OF INTEREST

The terms and conditions of this research has been reviewed and approved by all the authors and Manipal University at Manipal, Karnataka in accordance with its policy on objectivity in research.

ABBREVIATION USED

KDLWS: Karnataka Drugs Logistics and Warehousing Society
WHO: World Health Organization
NRHM: National Rural Health Mission
GMS: Government Medical Stores
TNMSC: Tamil Nadu Medical Services Corporation
KSAPS: Medical Services Corporation
PHC(s): Primary Health Centers
CHC(s): Community Health Centers
OPD: Out Patient Department
IPD: In-Patient Department
NHM: National Health Mission
ARS: ArogyaRakshaSamiti
RKS: RogiKalyanSamiti
AMG: Annual Maintenance Grant
OOP: Out-Of-Pocket
STC: State Therapeutic Committee
EML/EDL: Essential Drug/Medicine List
INN: International Non-proprietary Names
KTPP: Karnataka Transparency in Public Procurement
GMP: Good Manufacturing Practice
D & C Act: Drugs and Cosmetic Act
DDMS: Drug Distribution Management System
BIN: Batch Index Number
REFERENCES