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Understanding public drug procurement in India – A comparative study of five Indian states

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Title

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Abstract

India is in the midst of metamorphosis of its health policies to achieve universal healthcare and access to essential medicines is one of its critical mandates. Much discussion has risen on the need to strengthen the public drug procurement systems at the state levels in order to ensure good quality and timely supply of essential drugs at all public health facilities. Different states in India follow different public procurement systems ranging from centralized pooled procurement to decentralized procurement. This study aims to compare and contrast the different procurement models and their detailed implications on price of the drugs procured, supply-chain management, cost-effectiveness of the system in order to provide some key points to policy makers. The finer differences between the state models, even though seemingly similar from the outside impact access to medicines for people hugely and this has been captured in the study. The five states for the study- Tamil Nadu, Kerala, Odisha, Punjab and Maharashtra were chosen to ensure heterogeneity in a number of factors: a) Procurement Type; b) Autonomy of the procurement organization; c) State of public health infrastructure and d) Public health care budgets. The methodology adopted for this study is based on both secondary data and primary data collected from state procurement cells and also from 4 facilities- a district hospital, a taluk hospital, Community healthcare center and Primary healthcare center in each state. The procurement processes in each state were compared across 52 process related factors and on price of the drugs procured. Such a detailed analysis revealed that autonomous procurement organizations were more efficient in relation to payments to suppliers, had relatively lower drug procurement prices and managed their inventory more scientifically. The tables showcased in the study reveals some interesting correlations between process parameters and efficiency of the systems; some intuitive as well as counter intuitive observations that need to be further probed into. In a way, this study raises more questions and seeks the need for further research in this arena.

ARTICLE SUMMARY

Article focus

Compare and contrast different procurement models and their impact on prices, cost effectiveness of the system and supply chain management.

Key messages

Autonomous procurement organizations were more efficient in relation to payments to suppliers, had relatively lower drug procurement prices and managed their inventory more scientifically.

Strengths

One of the first studies to compare and contrast public drug procurement systems across different states in India

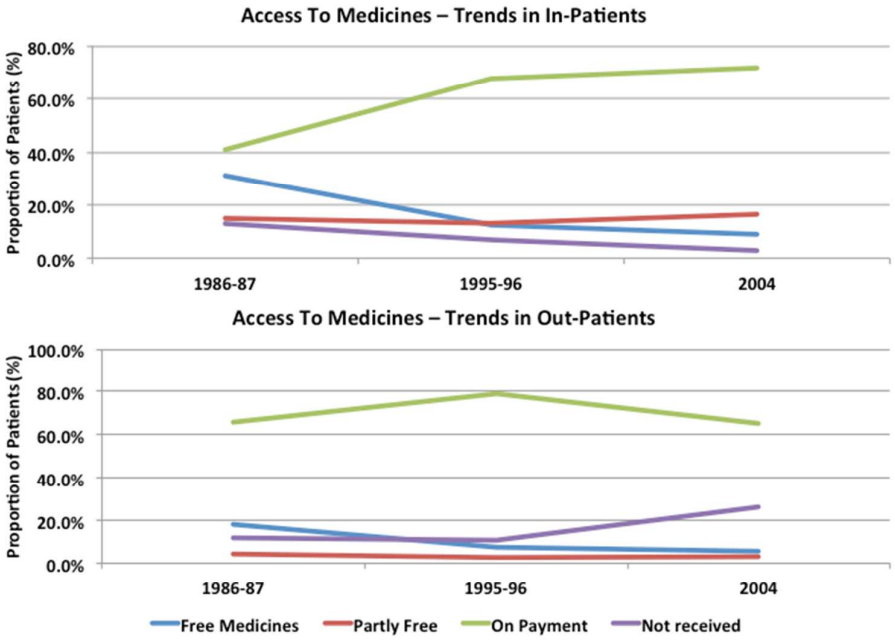
Limitations

• Time and resource constraints have limited our primary data to one or two districts in each State. However, efforts were made to include both urban and rural ones in the study
• Quantifying the 'impact' of each of the procurement systems is rather ambiguous due to the lack of concrete indicators to record aspects like corruption, governance and so on. Thus, this section is qualitatively recorded with the help of a few indicators composed based on existing literature and some aspects specific to public procurement systems

Introduction

Over the years India has seen a tremendous growth in the pharmaceutical sector yet it is grappling with a large population that is denied basic access to healthcare and essential medicines. According to a WHO report on World's medicines situation (WHO, 2004) almost 68% of the people in India have limited or no access to essential medicines. Inadequate medicine access poses a major barrier to the objective of delivering essential healthcare and the more recently talked about universal healthcare. According to United Nations Development Group (UNDG, 2003), medicine access is defined as *"having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour walk from the homes of the people"*. Fulfilment of all these factors is arguably low in developing countries like in India. Exhibit 1 shows the decreasing trend in the supply of free medicines since 1986 and also a corresponding increase in the number of people not receiving any medicines at all for out-patient care.

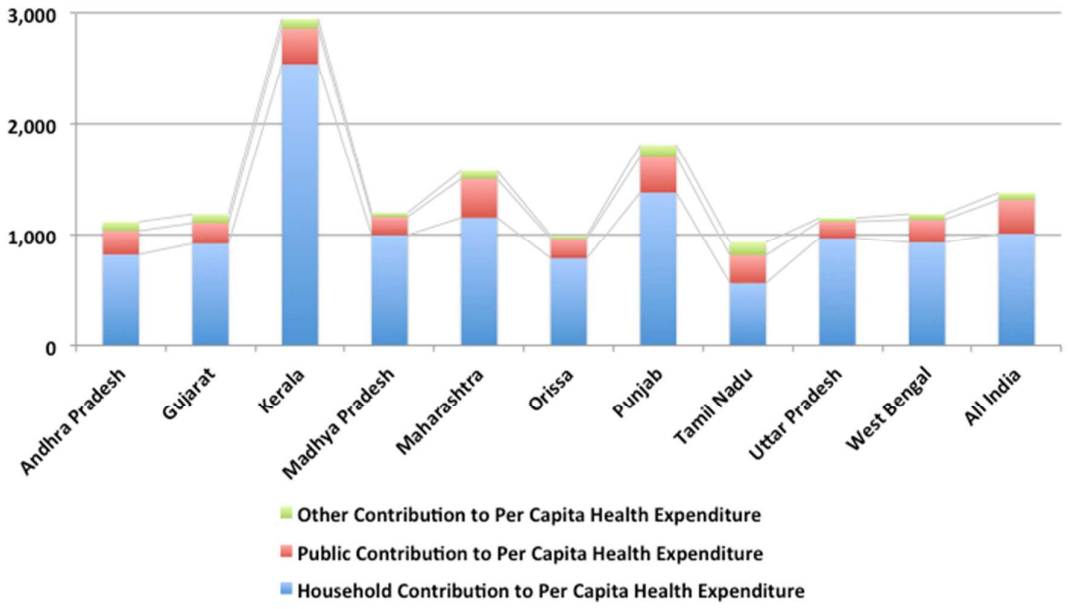
Exhibit 1: Access to medicines in India



Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42

Private health expenditure constitutes almost 70% of the total health expenditure of which drugs form a massive component anywhere between 20-65% in India and other transitional economies compared to 18% in OPEC countries (Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2009). The burden of purchasing medicines is very high in India accounting for the second largest bulk of expenditure after food. The high cost of medicine purchase in India and relatively low public health investment is exacerbating the lack of essential medicines access in India. It is now well known, accepted and documented that out-of-pocket (OOP) payment for health care has pushed many people into poverty. Bearing the costs of a single hospitalization, 35% of people fall below the poverty line and out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year. *(India – Raising the Sights: Better Health Systems for India's Poo*r, World Bank, 2001). Exhibit 2 below gives a glimpse of the health care spending in India for 2004-05 across various states.

Exhibit 2: Healthcare Spending in India 2004-05 (Figures in INR)



Source: Report of National Commission on Macroeconomics and Health, GOI 2005

Strengthening the public sector availability of quality drugs will relieve a large number of people to whom medical expenditure may be catastrophic. This paper, focussing on the public drug procurement models in India, will detail five main factors of the systems – low financial burden, good quality, timely availability, minimal wastage and transparency – that are important to improve access to medicines. Although rational usage of drugs and medical awareness amongst the people is equally important to determine the success of the public procurement systems, this paper only deals with the supply side of the medicines access issue. Accordingly, the objective of the paper is to understand and compare the public drug procurement systems in five Indian states – Kerala, Maharashtra, Odisha, Punjab and Tamil Nadu – on the basis of a set of pre-determined comparison factors. And also explore whether the success of the procurement models depends on some crucial intangible elements beyond the procurement process or price.

Methodology

The study was designed to compare public drug procurement models of a sample of states on a set of 53 pre-determined parameters. These parameters reflect each of the five main objectives of comparison viz. low financial burden, good quality, timely availability, transparency and wastage elimination through efficient supply chain.

The sample states were chosen to ensure heterogeneity in a number of factors: a) Procurement Type (centralized, decentralized or mixed); b) Autonomy of the procurement organization; c) State of public health infrastructure and d) Public health care budgets. Based on these parameters, the sample of states initially chosen were Kerala, Tamil Nadu Maharashtra, Punjab, Uttar Pradesh and West Bengal. Consequently, Right to Information (RTI)[1] applications were sent to the concerned Public Information Officers (PIOs) to seek drug procurement and process data. However, due to lack of data responses despite multiple appeals from Uttar Pradesh and West Bengal, these states were replaced with Orissa (See Exhibit 3)

[1] Right to information act: **Right to Information Act 2005** mandates timely response to citizen requests for government information

Exhibit 3: Sample states for the study

Sampling Attribute	Kerala	Tamil Nadu	Maharashtra	Orissa	Punjab
Procurement Type	Centralized	Mixed	Primarily Decentralized	Mixed	Primarily Decentralized
Autonomy	Fully Autonomous	Fully Autonomous	Government owned	Government owned	Government owned
Health Infrastructure	Good	Good	Poor	Poor	Good
Geography	South	South	Mid-West	Mid-East	North

Procurement type mentioned in the above table is used to refer to the model where in the state drug procurement budget is divided between centralized and decentralized methods of acquiring medicines. Autonomy refers to the extent of government involvement in the decisions of the procurement organization; "fully autonomous" implies minimal involvement while "government owned" indicates a high degree of involvement. The rating of health infrastructure as 'good' and 'poor' has been based upon the perceived condition of the infrastructure such as the drug warehouses, transportation facilities, CHC/ PHC and district hospital conditions.

Brief information about the sample states, for an overview of the context, is presented in Exhibit 4.

Exhibit 4: Overview of Sample States

Parameter	Kerala	Maharashtra	Orissa	Punjab	Tamil Nadu
Total Population	33,387,677	112,372,972	41,947,358	27,704,236	72,138,958
Urban/Rural Population Ratio	91.3%	82.6%	20.0%	60.0%	94.0%
Annual Per capita Income	59,179	83,471	36,923	67,473	72,993
Annual Per capita Exp. - Rural	22,020	13,836	9,816	19,788	13,920
Annual Per capita Exp. - Urban	28,956	29,244	18,576	25,308	23,376
Total Per Capita Health Exp.	2,952	1,576	995	1,813	933
Public Component %	10.8%	22.1%	18.0%	18.0%	26.6%
Private Component %	86.3%	73.3%	79.1%	76.1%	60.7%
Number of Sub-Centers	4,575	10,579	6,688	2,950	8,706
Number of PHCs	697	1816	1279	394	1277
Number of CHCs	226	376	231	129	256
Number of DHs	14	35	32	20	29
Birth Rate (/1000 Population)	14.7	17.9	21.5	17.6	15.8
Death Rate (/1000 Population)	6.8	6.6	9.2	7	7.2
Infant Mortality Rate (/1000 Live Births)	13	33	71	43	35
Maternal Mortality Rate (Per 100,000 Live Births)	110	130	303	192	111
Total Fertility Rate (Children Per Woman)	1.7	2	2.4	2	1.6

Source: Census 2011; Level and Pattern of Consumer Expenditure 2009-10 NSSO 66th round; Bulletin on Rural Health Statistics in India 2008, MoHFW; Sample Registration Survery 2010-11

Primary data for the study was gathered through warehouse audits and semi-structured interviews with executive leadership teams of the drug procurement cells and public health officials in the sample states in March – April 2012. The secondary resources used are the statistical databases, peer reviewed articles and grey literature.

Findings & Discussion

The procurement processes followed in the sample states were evaluated against a pre-determined set of 53 parameters (including price). See Exhibit 5 for the list of pre-determined parameters used for comparison.

Exhibit 5: Overview of Comparison Parameters

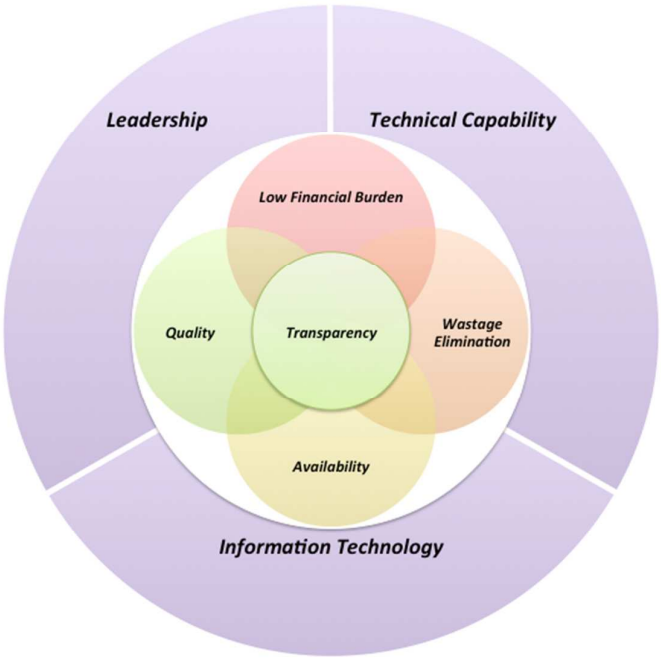
Overall	• *Legal Status of the Procurement Organization; Drug Procurement Budget; Per Capita Drug Procurement Budget;*
Essential Drug List	• *EDL Customization; EDL Committee Composition; Frequency of EDL Revision; Time for EDL Preparation/ Revision; EDL Categorization; Third Party Review of EDL*
Demand Estimation & Forecast	• *Demand Estimation Process; Frequency of Demand Estimation; Methodology for Estimation (Facility Level)*
Procurement Process	• *Procurement mechanism in the state; Financing of Drug Procurement; Emergency Drug Budget Allocation; Bidding Process*
Prequalification Criteria	• *Min. Turnover Criteria; GMP/WHO-GMP/US-FDA; ISI/BIS/ISO/CE; Assurance of avbl. Production Capacity; Market Standing; Exclusion Criteria; Price Relaxation; Product Reservation; EMD (%); Tenders with no bidders; Supply Schedule*
Quality Control	• *External Quality Testing Of Every Consignment; Testing Before Distribution; Testing Before Distribution*
Payment Mechanism	• *Payment Department Status; Lead Time For Payment; Prerequisites For Payment Disbursement*
Inventory Management & Distribution	• *Facilities Per Warehouse; Scientific Warehousing Practices; Supply Chain Management; Inventory Management; Scientific Forecasting; Flexibility to Alter Indent; Tracking dispatched drugs; Scientific inventory Mgmt. at Facility*
Penalties	• *Supply Default; Quality Failure; Blacklisting Criteria*
IT Systems Enablement (of)	• *Demand Estimation & Forecasting; Tendering Process; Quality Control; Payment Disbursement; Inventory Management (Warehouse); Inventory Management (Facility)*

The detailed comparison tablets are presented in annexures (See annexure 1 for procurement process comparison and annexure 2 for price comparison of 32 selected molecules that appear in same dosages commonly across the sample states). In many instances, the process followed is very different from the one given in the manuals. The information captured below relates to the process that are actually followed.

An efficient drug distribution system ensures the ***right medicines*** in ***sufficient quantities*** procured at ***lowest prices*** to secure the ***maximum therapeutic value*** to the ***largest number of beneficiaries*** with the ***available & additional resources***.

Broadly speaking, the two main beneficiaries in this context are the government and the patient. On one hand, rationality dictates that any government in a resource-constrained setting would expect that an effective procurement system would ensure availability of quality medicines while optimizing the finances to ensure best outcomes. It is also in the interest of the government to run this system transparently to promote competition and thus efficiency. On the other hand, a patient expects that good quality medicines are available at all time, free of cost. (See Exhibit 6 for an expectation map of both beneficiaries). Leadership, technical capability and information technology overarching the expectations in the exhibit below are the pre-requisites for running a system efficiently. The capability of each states' procurement system to enhance IT usage and administrative capabilities driven by a strong leader is pre-requisite.

Exhibit 6: Combined Expectation Mapping of Beneficiaries of a Public Procurement System



Low Financial Burden

Low financial burden to the government ex-chequer is an important aspect of the public drug procurement systems because of limited resources. Some of the parameters amongst the 53 comparatives that reflect a procurement system's capacity to reduce financial burden are the extent of capital expenditure for establishing the systems, costs for procurement, storage and transportation, the preciseness of the Essential Drug List (EDL) to suit the state health burden and finally the prices at which drugs are procured.

The procurement process adopted bears some strong repercussions on the budgets, which include both the capital expenditures and operating expenditure to run the system. For completely/ predominantly centralized pooled procurement models like Tamil Nadu, Kerala and Odisha it is imperative to have an optimum number of warehouses to cater to all the public health facilities. Additionally, the system requires adequate transportation facilities to transfer supplies from warehouses to user institutions and IT enablement to manage the entire system necessitating a considerable initial capital expenditure. With a budget of INR 39.8 Million USD and USD 36.3 Million in FY2010 for Tamil Nadu and Kerala respectively, the states have been able to make capital investments – this also includes the cash surplus generated through management fees the autonomous procurement agencies charge. Kerala has about 19 warehouses while Tamil Nadu about 25, most of which comply with scientific standards of inventory management. Odisha, with a budget of INR USD 8.1 Million for FY2011, is unable to make the necessary investments to fully realize the benefits of centralized pooled procurement.

Maharashtra follows the system of centralized rate contracting and decentralized purchasing where the suppliers directly deliver the medicines to the facilities. While transportation costs are not borne by the state, its cost is built into the drug price. This system also requires significantly large storage facilities at each user institution thereby increasing the overall cost. Punjab was not considered into this analysis because it follows a mixed system with drugs worth about USD 0.4 Million being purchased in a centralized manner while user charges collected by district hospitals accounting for USD 3 Million are utilized to directly purchase drugs from the open market.

A well-formulated and localized EDL is imperative to make optimal use of the limited financial resources. Tamil Nadu, Kerala and Odisha purchase about 260 drugs each year as a part of EDL while in Maharashtra centralized rate contracting (decentralized purchasing) is done for about 1,850 drugs. Though the decentralized purchasing model offers more flexibility for facilities, the administrative costs of finalizing rate contracts for 1,850 drugs and empanelling the suppliers is by no measure insignificant.

Finally – drug price: the largest expenditure component. Theoretically, centralized procurement offers volume discounts thereby reducing the financial burden; however Annexure 2 comparing prices of 32 drugs across the five states reveals that Tamil Nadu may not necessarily have the lowest price despite greater quantities. Despite the bulk discounts, some drugs are cheaper in states with arguably inefficient centralized/ predominantly centralized models like Odisha and Punjab and states with decentralized models like Maharashtra. Due to larger population, public preference towards the government's health system and good health infrastructure, it is safe to assume that the quantities for procurement in Tamil Nadu would be significantly higher than Odisha, Kerala or Punjab. Then the question that remains unanswered is how are the other states able to procure at prices lower than Tamil Nadu? The reasons could be many. For instance, supplier location – more than half of the suppliers to Tamil Nadu are from within the state. The same statistic for Kerala is 14%, Maharashtra 34% and for Odisha, a surprising zero percent! With insufficient data, we are unable to confidently conclude the financial burden of all the variants of the procurement models. But perhaps this is a good lead to think about what is causing unexpected discrepancies in prices?

Wastage Elimination

Eliminating wastage of drugs (through mishandling or expiry) is necessary (but not sufficient) to optimize expenditure and ensure availability. Eliminating wastage is predicated upon effective inventory management, which deals with requirement gathering, analyzing consumption patterns and forecasting demand. Trained pharmacists using weekly, quarterly and annual consumption data are supposed to do the demand estimation each year. However in reality, the previous year's data is inflated by 10 – 15% in most states. In Odisha, however, owing to the lack of trained personnel, clerks/ computer operators perform these tasks.

Kerala was able to mitigate this inaccuracy in estimation by introducing the option of issuing a second purchase order (PO). The initial PO given to the supplier is only for 75% of the tender quantity. The procurement authorities have the privilege of either not issuing the second PO or issuing the second PO for 25% or 50% of the tender quantity thereby building in a flexibility of 25%. All other states have a rather static inventory management.

Furthermore, Kerala and Tamil Nadu use software tools to monitor stock levels and manage inventory and distribution. The warehouses in Punjab, Odisha and Maharashtra manually manage the inventory by recording data into ledgers. These systems are not designed to store all types of drugs in a scientific manner. These practices not only lead to wastage of material but also precious warehouse space (in case of over-supply).

Availability

In the centralized model of pooled procurement, the distribution is managed centrally and the onus of the procurement agency is to ensure availability at the user institutions. The public health centers in Punjab and Maharashtra are at the mercy of the suppliers, owing to their decentralized purchasing model, whose supply is often sporadic due to various reasons like delayed payments, lack of proper planning etc. This impacts availability at the time of need and could potentially lead to wastage.

Quality

A procurement organization has two levers to ensure that only quality drugs enter the system: a) Pre-qualification criteria to filter out unqualified suppliers b) External quality testing protocols. When these levers are used together, quality is ensured while still keeping the prices low. States that have stringent external quality testing protocols can afford to keep the minimum turnover criterion low. For instance, Tamil Nadu has empanelled laboratories to which every sample from each batch is sent for quality testing before distributing to user institutions and the minimum turnover criteria is set at USD 0.7 Million (INR 3 Crores). Kerala too has similar quality testing protocols but has a higher minimum turnover criteria (set at USD 2.1 Million/ INR 10 crores) to enforce faith into the public system. Odisha and Maharashtra do not have any quality testing protocols in place, apart from the supplier's internal quality certificate, and have therefore set the minimum turnover criterion at INR 10 crores, assuming that higher volumes are more likely to be generated by suppliers with high quality products.

Additionally, states that have external quality testing protocols also have policies that provide price relaxation to Small Scale Industries (SSIs) and Public Sector Undertakings (PSUs) to encourage local industry. Such preference treatment doesn't exist in Odisha or Punjab. Maharashtra reserves 20% of quantities to SSIs only if they match the L1 rates and thus do not get any price preferences.

An important aspect of the pre-qualification criteria is also the GMP (good manufacturing practices) certificate. This certificate ensures that the facility follows the stipulated guidelines according to the industrial benchamarks and thus can ascertain a certain level of quality. Maharashtra demands a WHO-GMP certificate which is deemed to be more strict and reviewed every two years.

Transparency

A public procurement system is accountable to various stakeholders and it is important that transparency is maintained in all its activities. Certain conditions need to be established for a more open and efficient functioning. TNMSC and KMSCL are autonomous organisations that are headed by an appointed Director who maybe a civil services officer with a very good technical and administrative background. The idea of having an autonomous organisation in the public sector may enable it to function more transparently by avoiding the plausible procedural delays and also to be able to make decisions of contracting and outsourcing as best suited for the prosperity of the organisation. On the other hand, Odisha, Punjab and Maharashtra have procurement cells that are a part of the Directorate of Health Services (DHS) in the state. A clear difference in the efficiency of the processes can be seen between the autonomous organisations and the state run organisations – In terms of lead times for payments, quality control and in the usage of IT systems and so on. In an autonomous system, most of the staff are contractual based on their technical capabilities which may not be the case in state run procurement organizations.

A multistakeholdership in the organisation may be useful tool for bringing in more transparency and representation provided it is well coordinated. Right from the formation of the essential drugs list (EDL) to the award of the tenders, open and multi-stakeholder decision making may help keep the system become more transparent. All the states under the purview of the study have a multi-stakeholder decision making body.

It is deemed to be a good practice to have a separate payment processing team from the tender award team in order to keep transactions more transparent. All the states issue the payment based on the receipt of stock in the warehouse and a quality certificate (either internal or external). The processing of payments through the public channels like (Auditor General's Office or Directorate of Accounts & Treasury) usually takes much longer, as noted in Maharashtra, Odisha and Punjab compared to the autonomous payment departments of TNMSC and KMSCL.

Conclusion

In conclusion, we opine that the critical success factors of each model need to be carefully analyzed to see if they are valid in the state contexts. It is important for policy makers to understand in detail the tangible and intangible aspects that go into running a successful model before trying to replicate it. Also, in some states the existing structures may be serving the purpose but there maybe a need to do and undo several aspects of the current method of procurement, to make it more efficient. Sometimes, scrapping existing structures for new procedures may be a herculean task, which needs to be well thought out before undertaking.

Despite an effort to draw inferences from various primary and secondary sources, the study has some limitations that are mentioned below:

- Time and resource constraints have limited our primary data to one or two districts in each State. However, efforts were made to include both urban and rural ones in the study
- Quantifying the 'impact' of each of the procurement systems is rather ambiguous due to the lack of concrete indicators to record aspects like corruption, governance and so on. Thus, this section is qualitatively recorded with the help of a few indicators composed based on existing literature and some aspects specific to public procurement systems

Works Cited

Cameron, A., Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R. (2009). Medicines prices, availability and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet* , 240-249.

CDSCO. (2009). *Report on Country-Wide Survey of Spurious Drugs.* New-Delhi: CDSCO, MoHFW.

Khan, A., & Ghilzai, N. (2007). Counterfeit and Substandard Quality of drugs: The need for an effective and stringent regulatory control in India and other developing countries. *Indian J Pharmacol* , 206-207.

Kotwani, A., Ewen, M., Dey, D., Iyer, S., Lakshmi, P., Patel, A., et al. (2007). Prices and availability of common medicines at six sites in India using standard methodology. *Indian Journal of Med Res* , 645-654.

Narayanan, D. (2010 йил 27-July). Tamil Nadu Medical Services Corporation: A Success Story. *Forbes India* .

Patel, V., Vaidya, R., Naik, D., & Borker, P. (2005). Irrational Drug Use in India: A Prescription Survey from Goa. *Journal of Postgraduate medicine* , 9-12.

Russell, S. (2004). The Economic Burden of Illness for Households in Developing Countries: A Review of Studies Focussing on Malaria, Tuberculosis and Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome. *American Journal of Tropical Medicine and Hygiene* , 147-155.

Selveraj, S., & Karan, A. (2009). Deepening Health Insecurity in India: Evidence from National Sample Surveys Since 1980's. *Economic and Political Weekly* , 55-60.

Selveraj, S., & Nabar, V. (2010). Access to medicines in India: Issues, Challenges and Response. In A. Mahal, B. Debroy, & L. Ihandri, *India Health Report 2010.* New Delhi.

TNMSC. (2010 йил 15-July). Retrieved 2012 йил 28-March from TNMSC News Bulletin: http://www.tnmsc.com/tnmsc/publication/July2010.pdf

UNDG. (2003). *Indicators for Monitoring the Millennium Development Goals.* New York: United Nations.

USAID. (2006). *Procurement Strategies for Health Commodities.* Arlington: DELIVER.

WHO. (2004). *The World Medicines Situation.* WHO. WHO.

Yadav, P., Stapleton, O., & Wassenhove, L. N. (2011). *Always Cola, Rarely Essetial Medicines: Comparing Medicine and Consumer Product Supply Chain in the Developing World.* INSEAD.

Authors' Contributions

- Prabal Vikram Singh: Involved in the conceptpualization and study design, and analysis of findings.
- Anand Tatambhotla: Involved in the conceptpualization and study design, field data collection and analysis of findings.
- Rohini Kalvakuntla: Involved in the conceptpualization and study design, field data collection and analysis of findings.
- Maulik Chokshi: Involved in the conceptpualization and study design, and analysis of findings.

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- Funded by Center for Health Market Innovations .

Data Sharing Statement

- There is no additional data set available.

Competing Interests

- There are no competing interests.

Annexure 1

Parameter	Kerala	Orissa	Tamil Nadu	Punjab	Maharashtra
Legal Status Of Procurement Organization	Autonomous (KMSCL)	Government Owned (Part Of DHS)	Autonomous (TNMSC)	Government Owned (PHSC)	Government Owned
Drug Procurement Budget (USD)	36.3 Million (2011 - 12)	8.1Million (2010 - 11)	39.8Million (2010 - 11)	3.4 Million (0.4 mil. State Budget + 3 mil. User Fees)	87.5 Million (2010-11)
Per Capita Drug Procurement Budget	51	8.8	22.5	5.8	35.6
Essential Drug List					
Customized State EDL	Yes	Yes	Yes	Yes	No, But It Has A Drug List Comprising 1850 Drugs
Composition Of EDL Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee
Frequency Of EDL Revision	1 Year	2 Years	1 Year	1 Year	N/A
Time For EDL Preparation/ Revision	2 - 3 Months	7 - 8 Months	2 - 3 Months	4 Months	N/A
EDL Categorization	Yes (8 Product-Based Categories)	Yes (2 Demography-Based Lists)	Yes (Product-Based Categories)	Yes	N/A
Third Party Review Of EDL	No	Yes (By WHO Experts)	No	No	N/A
Demand Estimation& Forecast					
Demand Estimation Process	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Facility Level Indenting
Frequency Of Demand Estimation	1 Year	1 Year	1 Year	1 Year	1 Year
Methodology For Estimation (Facility Level)	10 - 15% Over Previous Year's Indent; Performed By Pharmacist	No Scientific Method; Usually Performed By Computer Operator/ Clerk	10% Of The Previous Year Consumption	N/A	10% Of Previous Year Consumption
Procurement Process					
Procurement Mechanism In The State	Centralized	80% Centralized; 20% Decentralized	90% Centralized; 10% Decentralized	12.5% Centralized;87.5% Decentralized	Centralized Rate Contracting ; Decentralized Purchasing
Financing Of Drug Procurement	State Budget Allocation	State Budget Allocation	State Budget Allocation	State Budget Allocation & User Charges	State Budget Allocation
Emergency Drug Budget Allocation	Yes (Additional Funds Released)	No (Purchased From Existing Budget)	Yes (Additional Funds Released)	No	Yes (Additional Funds Released)
Tendering Process					

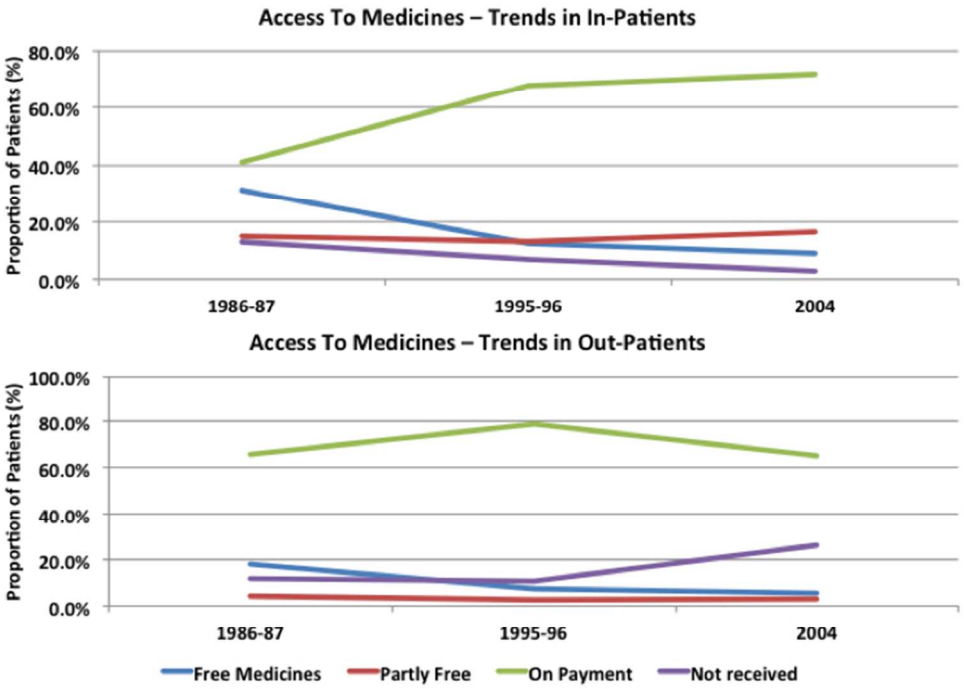
Bidding Process	Two Bid System	Two Bid System	Two Bid System	Two Bid System	Two Bid System
Prequalification Criteria					
Min. Turnover Criteria (INR/USD)	10 Crore/ 2.1 Million	10 Crore/ 2.1 Million	3 Crore/ 0.7 Million	50 Crore/ 10.7 Million	10 Crores/ 2.1 Million
GMP/ WHO-GMP/ US-FDA	Required	Required	Required	Required	WHO-GMP Required
ISI/ BIS/ ISO/ CE	Required	Required	N/A	N/A	N/A
Assurance Of Available Production Capacity	Required (MPMASS)	None	Production Capacity Certificate	N/A	Production Capacity Certificate
Market Standing	2 Years	3 Years	3 Years	3 Years	3 Years
Exclusion Criteria For Factory Inspections	Supply To Premier Institutions	None	None	None	N/A
Price Relaxation For SSIs/ PSUs	Yes (SSI - 10%; PSU - 15%)	Yes (SSI - 10%; Additional 3% For ISO Certification)	Yes (SSI - 15%)	PSU produced Antibiotics	None (20% Quantity Reserved If SSI Matches L1 Rate)
Product Reservation For SSIs/ PSUs	None	31 Items (From SSIs)	None	None	None
EMD	1% Of Tender Value	1 - 5% Of Tender Value	1% of Tender value (maximum upto 50,000 INR), expempted for SSI	Differs For Each Drug	INR 25,000
Process For Tenders With No Bidders (In Order Of Priority)	Re-Tender (Revised Pre-Qualifications); Limited Tender; Short Tender; Direct Purchase	Re-Tender (Same Pre-Qualifications) - Open Until Bids Are Received	Re-tender (Limited and Short tender process is used)	Pharmacy Based Purchasing	Re-Tendering, Limited Tendering Or Direct Purchase
Supply Schedule	60 Days - 40% Of PO Quantity; 90 Days - 70%; 120 Days - 100%	60 Days - 50% Of PO Quantity; Rest Before Specified Date	Starting from 30 days and has to end by 60 days, otherwise specified	30 days to 3 months from the time of issue of PO	Within 3 Months From The Issue Of PO
Quality Control					
External Quality Testing Of Every Consignment	Empanelled Private Labs	No External Quality Testing (Supplier's Internal Quality Certificate)	Empanelled Private and government labs	Empanelled Government Labs	No External Quality Testing (Supplier's Internal Quality Certificate)
Testing Before Distribution	Mandatory	Not Mandatory	Mandatory	Mandatory	Not Mandatory
Lead Time For Quality Testing	~ 15 Days	Within 8 Weeks	15 Days For Tablets And Capsules; 1 Month For Suspensions	1 Month	N/A
Payment Mechanism					
Payment Department Status	Autonomous (Managed By Contractual Staff)	Government (Account General's Office)	Autonomous (Managed By Contractual Staff)-IT	Government	Government (Directorate Of Accounts And Treasuries)

			enabled		
Lead Time For Payment	~ 30 Days	~90 Days	30 Days	Min. 30 Days	~ 90 Days
Prerequisites For Payment Disbursement	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Supplier's Internal Quality Certificate	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Quality Certificates From Labs	Facility Material Receipt, Internal Quality Certificate
Inventory Mgmt.& Distribution					
Facilities (All) Catered To Per Warehouse (Average)	~290	~235	~411	N/A	N/A
Scientific Warehousing Practices	Yes	No	Yes	No	No
In-House/ Outsourced Supply Chain Management	Outsourced	In-House	In-House	In-House	In-House (Facility Level)
Inventory Management	Dynamic (Flexibility Of 2nd PO)	Static (Only Single PO Is Issued)	Dynamic (Flexibility Of 2nd PO)	Static	25% Flexibility For Quantity Maintained
Scientific Consumption/ Inventory Forecasting	Yes (Inventory Management Software)	No	Yes (Inventory Management Software)	No	No
Flexibility For Facilities To Alter Indent	Yes (Just Before Dispatch)	No	Yes	Yes	No
Tracking Dispatched/ Delivered Drugs	Currently Passbook (Volume Based; Online In Future)	No Tracking	Passbook (Value Based)	N/A	No
(Scientific) Inventory Management At Facility	No (Online In Future)	No	Use First in First Out (FIFO) principle	No	No
Penalty					
Penalty For Supply Schedule Default	10% Of The Unexecuted Supply; Unexecuted Supply Purchased At The Cost Of Supplier In Case Of Inability To Supply	N/A	0.5% per day to maximum of 15% of the tender amount	N/A	0.5% Of The Value Of Unsupplied Goods Per Week Up To 5 Weeks, After Which Unexecuted Supply Purchased At The Cost Of Supplier
Penalty For Quality Failure	Supplier Blacklisted With Forfeiture Of Security Deposit	Suppliers Have To Replace The Entire PO Quantity Or Risk Blacklisting	Supplier Blacklisted With Forfeiture Of Security Deposit	Forfeiture Of EMD	Supplier Blacklisted With Forfeiture Of Security Deposit

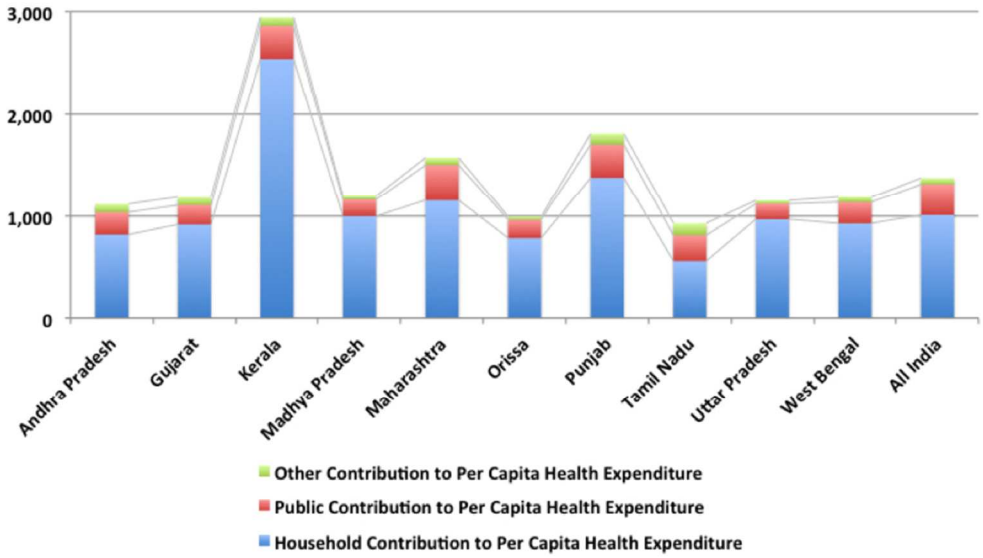
Blacklisting Criteria	Defaulting On 3 POs Or More With Less Than 50% Supply; Blacklisted By Any Other Procurement Agency On Quality Grounds	Quality Failure After Material Supply	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Supply Default After Extension Period; Quality Failure
IT Enablement Processes:					
Demand Estimation & Forecasting	Yes	No	Yes	No	No
Tendering Process	Yes	No	Yes	No	Yes
Quality Control		No	Yes	No	No
Payment Disbursement	Yes	No	Yes	No	No
Inventory Management (Warehouse)	Yes	Yes	Yes	No	No
Inventory Management (Facility)	No	No	Yes	No	No

Annexure 2

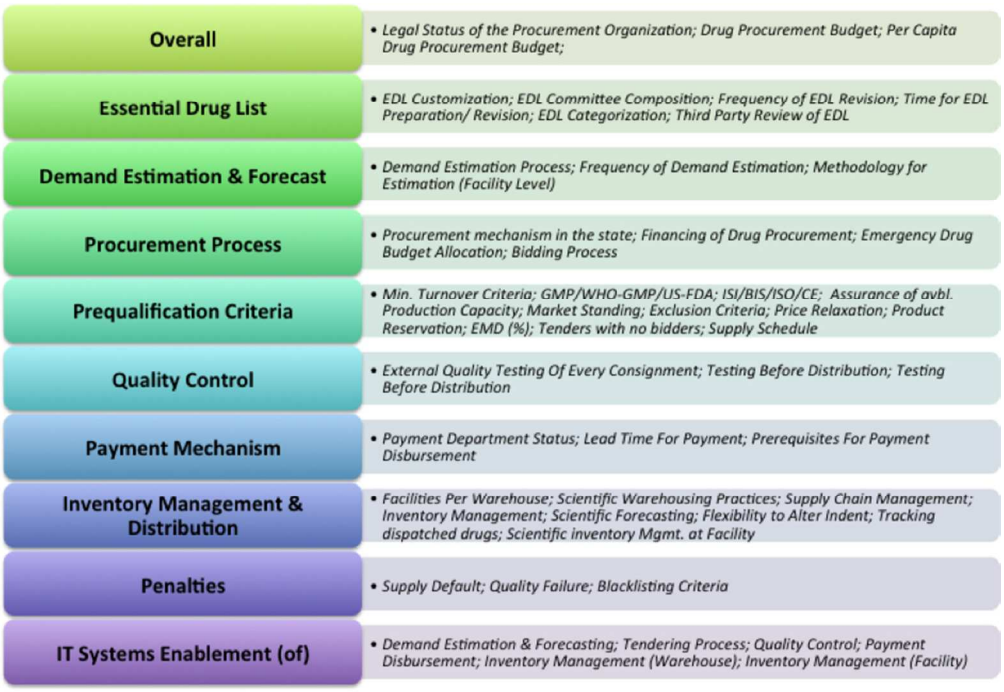
Name of Drug	Dosage	Unit	Price (INR)				
			Kerala 2012	Tamil Nadu 2012	Odisha 2009	Maharashtra 2011	Punjab 2010
Adrenaline	1mg/1 ml	Ampoule	2.89	1.21	1.46	1.80	n/a
Albendazole	400 mg	Tablet	0.81	0.57	0.49	0.61	0.64
Aminophylline	25 mg/ml	Ampoule	n/a	2.60	2.91	4.90	n/a
Amitriptyline	25 mg	Tablet	0.22	0.15	0.15	0.19	n/a
Amlodipine	5 mg	Tablet	0.16	0.06	0.09	0.10	0.13
Atenolol	50 mg	Tablet	0.125	0.11	0.13	0.14	0.14
Benzyl Penicillin	10 Lakh IU	Vial	3.68	3.08	4.20	4.88	n/a
Carbamazepine	200 mg	Tablet	0.59	0.54	0.42	0.53	n/a
Cefotaxime	250 mg	Vial	4.73	3.94	5.40	5.14	n/a
Ciprofloxacin	500 mg	Tablet	1.09	1.04	0.87	1.07	1.86
Co-trimoxazole	40mg+ 200mg per 5ml	Bottle	n/a	5.91	5.90	6.74	n/a

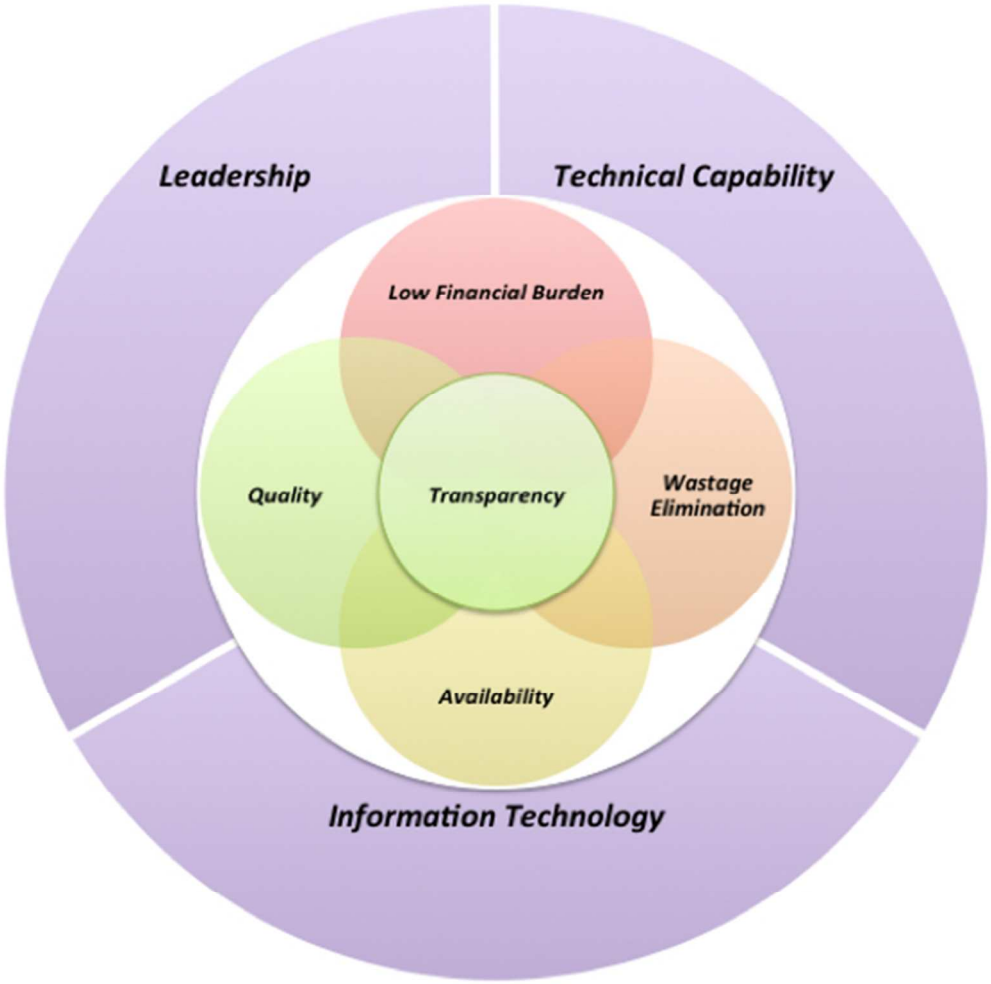


Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42



Source: Report of National Commission on Macroeconomics and Health, GOI 2005


Overall
• Legal Status of the Procurement Organization; Drug Procurement Budget; Per Capita Drug Procurement Budget;
Essential Drug List
• EDL Customization; EDL Committee Composition; Frequency of EDL Revision; Time for EDL Preparation/ Revision; EDL Categorization; Third Party Review of EDL
Demand Estimation & Forecast
• Demand Estimation Process; Frequency of Demand Estimation; Methodology for Estimation (Facility Level)
Procurement Process
• Procurement mechanism in the state; Financing of Drug Procurement; Emergency Drug Budget Allocation; Bidding Process
Prequalification Criteria
• Min. Turnover Criteria; GMP/WHO-GMP/US-FDA; ISI/BIS/ISO/CE; Assurance of avbl. Production Capacity; Market Standing; Exclusion Criteria; Price Relaxation; Product Reservation; EMD (%); Tenders with no bidders; Supply Schedule
Quality Control
• External Quality Testing Of Every Consignment; Testing Before Distribution; Testing Before Distribution
Payment Mechanism
• Payment Department Status; Lead Time For Payment; Prerequisites For Payment Disbursement
Inventory Management & Distribution
• Facilities Per Warehouse; Scientific Warehousing Practices; Supply Chain Management; Inventory Management; Scientific Forecasting; Flexibility to Alter Indent; Tracking dispatched drugs; Scientific inventory Mgmt. at Facility
Penalties
• Supply Default; Quality Failure; Blacklisting Criteria
IT Systems Enablement (of)
• Demand Estimation & Forecasting; Tendering Process; Quality Control; Payment Disbursement; Inventory Management (Warehouse); Inventory Management (Facility)



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Understanding public drug procurement in India – A comparative study of five Indian states

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Title

Understanding public drug procurement in India – A comparative study of five Indian states

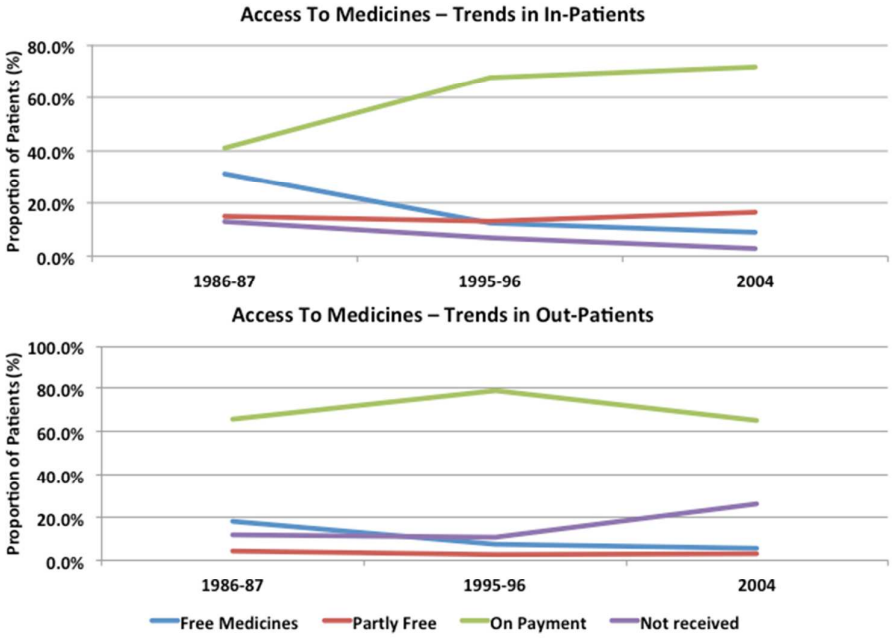
Abstract

India is in the midst of metamorphosis of its health policies to achieve universal healthcare and access to essential medicines is one of its critical mandates. Much discussion has risen on the need to strengthen the public drug procurement systems at the state levels in order to ensure good quality and timely supply of essential drugs at all public health facilities. Different states in India follow different public procurement systems ranging from centralized pooled procurement to decentralized procurement. This study aims perform an initial comparison, predominantly qualitative, between the different procurement models to frame questions for future research in this area. The finer differences between the state models, even though seemingly similar from the outside impact access to medicines for people hugely and this has been captured in the study. The five states included in the study – Tamil Nadu, Kerala, Odisha, Punjab and Maharashtra were chosen to ensure heterogeneity in a number of factors such as procurement type (centralized, decentralized or mixed); autonomy of the procurement organization; state of public health infrastructure; and geography. Data on procurement processes was collected through key informant analysis by way of semi-structured interviews with leadership teams of procuring organizations. This process data was valided through interviews with field staff (stakeholders of district hospitals, taluk hospitals, community health centers, and primary health centers) in each state. Data on procurement price was assimilated by way of RTI responses from state public information officers. The procurement processes in each state were compared across 52 pre-determined parameters. The analysis indicated that autonomous procurement organizations were more efficient in relation to payments to suppliers, had relatively lower drug procurement prices and managed their inventory more scientifically. Furthermore, the authors highlight critical success factors that significantly influence the outcome of any procurement model. In a way, this study raises more questions and seeks the need for further research in this arena.

Introduction

Over the years India has seen a tremendous growth in the pharmaceutical sector yet it is grappling with a large population that is denied basic access to healthcare and essential medicines. According to a WHO report on World's medicines situation (WHO, 2004) almost 68% of the people in India have limited or no access to essential medicines. Inadequate medicine access poses a major barrier to the objective of delivering essential healthcare and the more recently talked about universal healthcare. According to United Nations Development Group (UNDG, 2003), medicine access is defined as *"having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour walk from the homes of the people"*. Fulfilment of all these factors is arguably low in developing countries like in India. Exhibit 1 shows the decreasing trend in the supply of free medicines since 1986 and also a corresponding increase in the number of people not receiving any medicines at all for out-patient care.

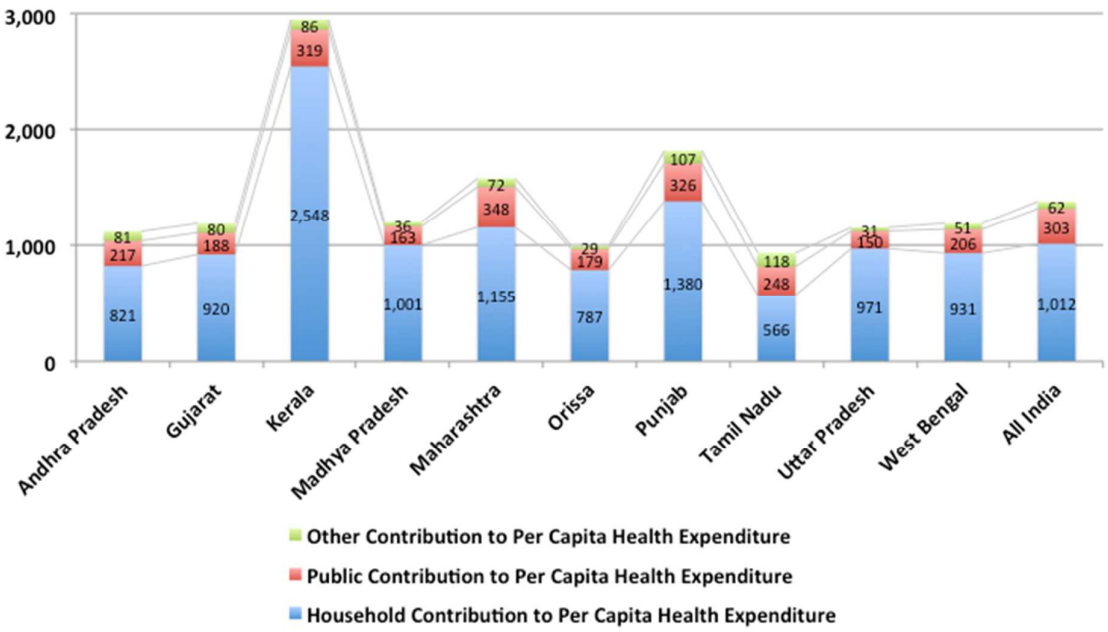
Exhibit 1: Access to medicines in India



Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42

Private health expenditure constitutes almost 70% of the total health expenditure of which drugs form a massive component anywhere between 20-65% in India and other transitional economies compared to 18% in OPEC countries (Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2009). The burden of purchasing medicines is very high in India accounting for the second largest bulk of expenditure after food. The high cost of medicine purchase in India and relatively low public health investment is exacerbating the lack of essential medicines access in India. It is now well known, accepted and documented that out-of-pocket (OOP) payment for health care has pushed many people into poverty. Bearing the costs of a single hospitalization, 35% of people fall below the poverty line and out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year. *(India – Raising the Sights: Better Health Systems for India's Poo*r, World Bank, 2001). Exhibit 2 below gives a glimpse of the health care spending in India for 2004-05 across various states.

Exhibit 2: Healthcare Spending in India 2004-05 (Figures in INR)



Source: Report of the National Commission on Macroeconomics and Health, Government of India, 2005

Strengthening the public sector availability of quality drugs is one of the long-term, sustainable ways to relieve a large number of people to whom medical expenditure may be catastrophic. This paper, focussing on the public drug procurement models in India, will detail five main factors of the systems – low financial burden, good quality, timely availability, minimal wastage and transparency – that are important to improve access to medicines. Although rational usage of drugs and medical awareness amongst the people is equally important to determine the success of the public procurement systems, this paper only deals with the supply side of the medicines access issue. Accordingly, the objective of the paper is to understand and compare the public drug procurement systems in five Indian states – Kerala, Maharashtra, Odisha, Punjab and Tamil Nadu – on the basis of a set of pre-determined comparison factors. And also explore whether the success of the procurement models depends on some crucial intangible elements beyond the procurement process or price.

Methodology

The study was designed to compare public drug procurement models of a sample of states on a set of 53 pre-determined parameters. These parameters reflect each of the five main objectives of comparison viz. low financial burden, good quality, timely availability, transparency and wastage elimination through efficient supply chain.

The sample states were chosen to ensure heterogeneity in a number of factors such as procurement type (centralized, decentralized or mixed); autonomy of the procurement organization; state of public health infrastructure; and geography. Based on these parameters, the sample of states initially chosen were Kerala, Tamil Nadu Maharashtra, Punjab, Uttar Pradesh and West Bengal. Consequently, Right to Information (RTI)[1] applications were sent to the concerned Public Information Officers (PIOs) to seek drug procurement and process data. However, due to lack of data responses despite multiple appeals from Uttar Pradesh and West Bengal, these states were replaced with Orissa. Exhibit 3 provides an overview of the sampling methodology. It is also

[1] Right to information act: Right to Information Act 2005 mandates timely response to citizen requests for government information

noteworthy that some of the sample states are primarily agrarian systems while the others are at different points of industrialization.

Exhibit 3: Sample states for the study

Sampling Attribute	Kerala	Tamil Nadu	Maharashtra	Orissa	Punjab
Procurement Type	Centralized	Mixed	Primarily Decentralized	Mixed	Primarily Decentralized
Autonomy	Fully Autonomous	Fully Autonomous	Government owned	Government owned	Government owned
Health Infrastructure	Good	Good	Poor	Poor	Good
Geography	South	South	Mid-West	Mid-East	North

Procurement type mentioned in the above table is used to refer to the model wherein the state drug procurement budget is divided between centralized and decentralized methods of acquiring medicines. Autonomy refers to the extent of government involvement in the decisions of the procurement organization; "fully autonomous" implies minimal involvement while "government owned" indicates a high degree of involvement. The rating of health infrastructure as 'good' and 'poor' has been based upon the perceived condition of the infrastructure such as the drug warehouses, transportation facilities, community health center, primary health center and district hospital conditions.

Brief information about the sample states, for an overview of the context, is presented in Exhibit 4.

Exhibit 4: Overview of Sample States

Parameter	Kerala	Maharashtra	Orissa	Punjab	Tamil Nadu
Total Population	33,387,677	112,372,972	41,947,358	27,704,236	72,138,958
Urban/Rural Population Ratio	91.3%	82.6%	20.0%	60.0%	94.0%
Annual Per capita Income	59,179	83,471	36,923	67,473	72,993
Annual Per capita Exp. - Rural	22,020	13,836	9,816	19,788	13,920
Annual Per capita Exp. - Urban	28,956	29,244	18,576	25,308	23,376
Total Per Capita Health Exp.	2,952	1,576	995	1,813	933
Public Component %	10.8%	22.1%	18.0%	18.0%	26.6%
Private Component %	86.3%	73.3%	79.1%	76.1%	60.7%
Number of Sub-Centers	4,575	10,579	6,688	2,950	8,706
Number of Primary Health Centers	697	1816	1279	394	1277
Number of Community Health Centers	226	376	231	129	256
Number of District Hospitals	14	35	32	20	29
Birth Rate (/1000 Population)	14.7	17.9	21.5	17.6	15.8
Death Rate (/1000 Population)	6.8	6.6	9.2	7	7.2
Infant Mortality Rate (/1000 Live Births)	13	33	71	43	35
Maternal Mortality Rate (Per 100,000 Live Births)	110	130	303	192	111
Total Fertility Rate (Children Per Woman)	1.7	2	2.4	2	1.6

Source: Census 2011; Level and Pattern of Consumer Expenditure 2009-10 NSSO 66th round; Bulletin on Rural Health Statistics in India 2008, MoHFW; Sample Registration Survery 2010-11

Primary data for the study was gathered through key informant analysis, in which semi-structured interviews were conducted with executive leadership teams of the drug procurement cells and public health officials in the sample states in March – April 2012, and RTI responses from sample states. The information gathered from the key informant analysis was corroborated with the field

staff by way of semi-structured interviews with stakeholders of primary health centers, community health centers, and district hospitals, and qualitative observation during the authors' warehouse visits.

Secondary data on expenditures, budgets and indicators was compiled from datasets published by the National Sample Survey Office, Ministry of Health and Family Welfare (Bulletin on Rural Health Statistics in India), and Office of the Registrar General & Census Commissioner of India (Sample Registration Survey). This study is intended to be a qualitative assessment with an objective of framing questions for future research, therefore no statistical techniques were used.

Findings

The procurement processes followed in the sample states were evaluated against a pre-determined set of 53 parameters (including price). See Exhibit 5 for the list of pre-determined parameters used for comparison.

Exhibit 5: Overview of Comparison Parameters

Overall	• *Legal Status of the Procurement Organization; Drug Procurement Budget; Per Capita Drug Procurement Budget;*
Essential Drug List	• *EDL Customization; EDL Committee Composition; Frequency of EDL Revision; Time for EDL Preparation/ Revision; EDL Categorization; Third Party Review of EDL*
Demand Estimation & Forecast	• *Demand Estimation Process; Frequency of Demand Estimation; Methodology for Estimation (Facility Level)*
Procurement Process	• *Procurement mechanism in the state; Financing of Drug Procurement; Emergency Drug Budget Allocation; Bidding Process*
Prequalification Criteria	• *Min. Turnover Criteria; GMP/WHO-GMP/US-FDA; ISI/BIS/ISO/CE; Assurance of avbl. Production Capacity; Market Standing; Exclusion Criteria; Price Relaxation; Product Reservation; EMD (%); Tenders with no bidders; Supply Schedule*
Quality Control	• *External Quality Testing Of Every Consignment; Testing Before Distribution; Testing Before Distribution*
Payment Mechanism	• *Payment Department Status; Lead Time For Payment; Prerequisites For Payment Disbursement*
Inventory Management & Distribution	• *Facilities Per Warehouse; Scientific Warehousing Practices; Supply Chain Management; Inventory Management; Scientific Forecasting; Flexibility to Alter Indent; Tracking dispatched drugs; Scientific inventory Mgmt. at Facility*
Penalties	• *Supply Default; Quality Failure; Blacklisting Criteria*
IT Systems Enablement (of)	• *Demand Estimation & Forecasting; Tendering Process; Quality Control; Payment Disbursement; Inventory Management (Warehouse); Inventory Management (Facility)*

The detailed comparison tablets on procurement process and prices are presented in Exhibits 6 and 7. In many instances, the process followed is very different from the one given in the manuals. The information captured below relates to the process that are actually followed.

Exhibit 6: Procurement Process Comparison Across the Sample States

Parameter	Kerala	Orissa	Tamil Nadu	Punjab	Maharashtra
Legal Status Of Procurement Organization	Autonomous (KMSCL)	Government Owned (Part Of DHS)	Autonomous (TNMSC)	Government Owned (PHSC)	Government Owned
Drug Procurement Budget (USD)	36.3 Million (2011 - 12)	8.1Million (2010 - 11)	39.8Million (2010 - 11)	3.4 Million (0.4 mil. State Budget + 3 mil. User Fees)	87.5 Million (2010-11)
Per Capita Drug Procurement Budget	51	8.8	22.5	5.8	35.6
Essential Drug List					
Customized State EDL	Yes	Yes	Yes	Yes	No, But It Has A Drug List Comprising 1850 Drugs
Composition Of EDL Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee
Frequency Of EDL Revision	1 Year	2 Years	1 Year	1 Year	N/A
Time For EDL Preparation/ Revision	2 - 3 Months	7 - 8 Months	2 - 3 Months	4 Months	N/A
EDL Categorization	Yes (8 Product-Based Categories)	Yes (2 Demography-Based Lists)	Yes (Product-Based Categories)	Yes	N/A
Third Party Review Of EDL	No	Yes (By WHO Experts)	No	No	N/A
Demand Estimation& Forecast					
Demand Estimation Process	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Facility Level Indenting
Frequency Of Demand Estimation	1 Year	1 Year	1 Year	1 Year	1 Year
Methodology For Estimation (Facility Level)	10 - 15% Over Previous Year's Indent; Performed By Pharmacist	No Scientific Method; Usually Performed By Computer Operator/ Clerk	10% Of The Previous Year Consumption	N/A	10% Of Previous Year Consumption
Procurement Process					
Procurement Mechanism In The State	Centralized	80% Centralized; 20% Decentralized	90% Centralized; 10% Decentralized	12.5% Centralized;87.5% Decentralized	Centralized Rate Contracting ; Decentralized Purchasing
Financing Of Drug Procurement	State Budget Allocation	State Budget Allocation	State Budget Allocation	State Budget Allocation & User Charges	State Budget Allocation
Emergency Drug Budget Allocation	Yes (Additional Funds Released)	No (Purchased From Existing Budget)	Yes (Additional Funds Released)	No	Yes (Additional Funds Released)
Tendering Process					
Bidding Process	Two Bid System	Two Bid System	Two Bid System	Two Bid System	Two Bid System

Prequalification Criteria					
Min. Turnover Criteria (INR/USD)	10 Crore/ 2.1 Million	10 Crore/ 2.1 Million	3 Crore/ 0.7 Million	50 Crore/ 10.7 Million	10 Crores/ 2.1 Million
GMP/ WHO-GMP/ US-FDA	Required	Required	Required	Required	WHO-GMP Required
ISI/ BIS/ ISO/ CE	Required	Required	N/A	N/A	N/A
Assurance Of Available Production Capacity	Required (MPMASS)	None	Production Capacity Certificate	N/A	Production Capacity Certificate
Market Standing	2 Years	3 Years	3 Years	3 Years	3 Years
Exclusion Criteria For Factory Inspections	Supply To Premier Institutions	None	None	None	N/A
Price Relaxation For SSIs/ PSUs	Yes (SSI - 10%; PSU - 15%)	Yes (SSI - 10%; Additional 3% For ISO Certification)	Yes (SSI - 15%)	PSU produced Antibiotics	None (20% Quantity Reserved If SSI Matches L1 Rate)
Product Reservation For SSIs/ PSUs	None	31 Items (From SSIs)	None	None	None
EMD	1% Of Tender Value	1 - 5% Of Tender Value	1% of Tender value (maximum upto 50,000 INR), expempted for SSI	Differs For Each Drug	INR 25,000
Process For Tenders With No Bidders (In Order Of Priority)	Re-Tender (Revised Pre-Qualifications); Limited Tender; Short Tender; Direct Purchase	Re-Tender (Same Pre-Qualifications) - Open Until Bids Are Received	Re-tender (Limited and Short tender process is used)	Pharmacy Based Purchasing	Re-Tendering, Limited Tendering Or Direct Purchase
Supply Schedule	60 Days - 40% Of PO Quantity; 90 Days - 70%; 120 Days - 100%	60 Days - 50% Of PO Quantity; Rest Before Specified Date	Starting from 30 days and has to end by 60 days, otherwise specified	30 days to 3 months from the time of issue of PO	Within 3 Months From The Issue Of PO
Quality Control					
External Quality Testing Of Every Consignment	Empanelled Private Labs	No External Quality Testing (Supplier's Internal Quality Certificate)	Empanelled Private and government labs	Empanelled Government Labs	No External Quality Testing (Supplier's Internal Quality Certificate)
Testing Before Distribution	Mandatory	Not Mandatory	Mandatory	Mandatory	Not Mandatory
Lead Time For Quality Testing	~ 15 Days	Within 8 Weeks	15 Days For Tablets And Capsules; 1 Month For Suspensions	1 Month	N/A
Payment Mechanism					
Payment Department Status	Autonomous (Managed By Contractual Staff)	Government (Account General's Office)	Autonomous (Managed By Contractual Staff)-IT enabled	Government	Government (Directorate Of Accounts And Treasuries)

Lead Time For Payment	~ 30 Days	~90 Days	30 Days	Min. 30 Days	~ 90 Days
Prerequisites For Payment Disbursement	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Supplier's Internal Quality Certificate	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Quality Certificates From Labs	Facility Material Receipt, Internal Quality Certificate
Inventory Mgmt.& Distribution					
Facilities (All) Catered To Per Warehouse (Average)	~290	~235	~411	N/A	N/A
Scientific Warehousing Practices	Yes	No	Yes	No	No
In-House/ Outsourced Supply Chain Management	Outsourced	In-House	In-House	In-House	In-House (Facility Level)
Inventory Management	Dynamic (Flexibility Of 2nd PO)	Static (Only Single PO Is Issued)	Dynamic (Flexibility Of 2nd PO)	Static	25% Flexibility For Quantity Maintained
Scientific Consumption/ Inventory Forecasting	Yes (Inventory Management Software)	No	Yes (Inventory Management Software)	No	No
Flexibility For Facilities To Alter Indent	Yes (Just Before Dispatch)	No	Yes	Yes	No
Tracking Dispatched/ Delivered Drugs	Currently Passbook (Volume Based; Online In Future)	No Tracking	Passbook (Value Based)	N/A	No
(Scientific) Inventory Management At Facility	No (Online In Future)	No	Use First in First Out (FIFO) principle	No	No
Penalty					
Penalty For Supply Schedule Default	10% Of The Unexecuted Supply; Unexecuted Supply Purchased At The Cost Of Supplier In Case Of Inability To Supply	N/A	0.5% per day to maximum of 15% of the tender amount	N/A	0.5% Of The Value Of Unsupplied Goods Per Week Up To 5 Weeks, After Which Unexecuted Supply Purchased At The Cost Of Supplier
Penalty For Quality Failure	Supplier Blacklisted With Forfeiture Of Security Deposit	Suppliers Have To Replace The Entire PO Quantity Or Risk Blacklisting	Supplier Blacklisted With Forfeiture Of Security Deposit	Forfeiture Of EMD	Supplier Blacklisted With Forfeiture Of Security Deposit

Blacklisting Criteria	Defaulting On 3 POs Or More With Less Than 50% Supply; Blacklisted By Any Other Procurement Agency On Quality Grounds	Quality Failure After Material Supply	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Supply Default After Extension Period; Quality Failure
IT Enablement Processes:					
Demand Estimation & Forecasting	Yes	No	Yes	No	No
Tendering Process	Yes	No	Yes	No	Yes
Quality Control		No	Yes	No	No
Payment Disbursement	Yes	No	Yes	No	No
Inventory Management (Warehouse)	Yes	Yes	Yes	No	No
Inventory Management (Facility)	No	No	Yes	No	No

Exhibit 7: Price Comparison of 32 Randomly Selected Drugs Across the Sample States

Name of Drug	Dosage	Unit	Price (INR)				
			Kerala 2012	Tamil Nadu 2012	Odisha 2009	Maharashtra 2011	Punjab 2010
Adrenaline	1mg/1 ml	Ampoule	2.89	1.21	1.46	1.80	n/a
Albendazole	400 mg	Tablet	0.81	0.57	0.49	0.61	0.64
Aminophylline	25 mg/ml	Ampoule	n/a	2.60	2.91	4.90	n/a
Amitriptyline	25 mg	Tablet	0.22	0.15	0.15	0.19	n/a
Amlodipine	5 mg	Tablet	0.16	0.06	0.09	0.10	0.13
Atenolol	50 mg	Tablet	0.125	0.11	0.13	0.14	0.14
Benzyl Penicillin	10 Lakh IU	Vial	3.68	3.08	4.20	4.88	n/a
Carbamazepine	200 mg	Tablet	0.59	0.54	0.42	0.53	n/a
Cefotaxime	250 mg	Vial	4.73	3.94	5.40	5.14	n/a
Ciprofloxacin	500 mg	Tablet	1.09	1.04	0.87	1.07	1.86
Co-trimoxazole	40mg+ 200mg per 5ml	Bottle	n/a	5.91	5.90	6.74	n/a
Diclofenac	25 mg/ml	Ampoule	1.33	1.08	1.04	1.40	2.70
Dicyclomine	10 mg/ml	Ampoule	1.34	0.88	1.17	1.37	n/a

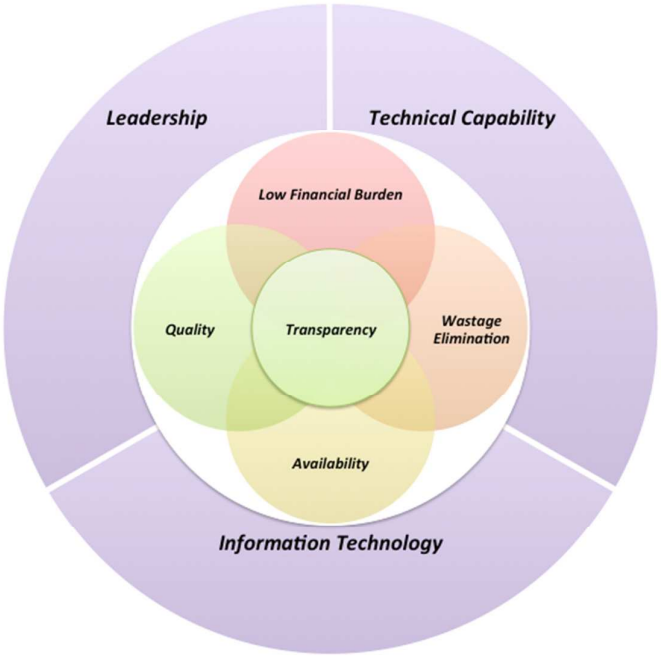
Dopamine	40 mg/ml	Vial	6.4	5.40	5.53	7.87	n/a
Erythromycin	250 mg	Tablet	1.27	1.23	0.81	1.03	n/a
Folic Acid	5 mg	Tablet	0.06	0.06	0.06	0.08	0.05
Gamma Benzene Hexachloride	1% w/v	Bottle	12.5	9.63	12.77	10.18	n/a
Glibenclamide	5 mg	Tablet	0.12	0.07	0.08	0.08	n/a
Glycopyrrolate	0.2 mg/ml	Ampoule	5.22	1.65	3.25	3.51	n/a
Hydrocortisone	100 mg	Vial	11	10.50	7.45	11.38	7.39
Ketamine	50 mg/ml	Vial	n/a	16.27	14.60	17.10	n/a
Lignocaine	2% w/v	Vial	7.75	4.54	3.80	6.30	4.40
Metformin	500 mg	Tablet	0.24	0.19	0.18	0.19	n/a
Methyl Ergometrine	0.2 mg/ml	Ampoule	1.85	1.33	1.71	2.75	n/a
Norfloxacin	400 mg	Tablet	0.78	0.79	0.57	0.76	n/a
Oxytocin	5 IU/ml	Ampoule	n/a	1.16	1.65	1.51	n/a
Pentazocine	30 mg/ml	Ampoule	3.05	2.41	2.58	3.51	3.60
Phenobarbitone	30 mg	Tablet	0.28	0.09	0.12	1.43	0.11
Phenytoin	100 mg	Tablet	0.36	0.16	0.11	1.60	n/a
Promethazine	25 mg	Ampoule	1.68	1.19	1.10	1.60	n/a
Ranitidine	50 mg	Ampoule	1.31	0.81	0.98	1.40	2.20
Thiopentone	500 mg	Ampoule	21.5	16.60	17.20	11.85	n/a

Discussion

An efficient drug distribution system ensures the ***right medicines*** in ***sufficient quantities*** procured at ***lowest prices*** to secure the ***maximum therapeutic value*** to the ***largest number of beneficiaries*** with the ***available & additional resources***.

Broadly speaking, the two main beneficiaries in this context are the government and the patient. On one hand, rationality dictates that any government in a resource-constrained setting would expect that an effective procurement system would ensure availability of quality medicines while optimizing the finances to ensure best outcomes. It is also in the interest of the government to run this system transparently to promote competition and thus efficiency. On the other hand, a patient expects that good quality medicines are available at all time, free of cost. (See Exhibit 8 for an expectation map of both beneficiaries). Leadership, technical capability and information technology overarching the expectations in the exhibit below are the pre-requisites for running a system efficiently. The capability of each states' procurement system to enhance IT usage and administrative capabilities driven by a strong leader is pre-requisite.

Exhibit 8: Combined Expectation Mapping of Beneficiaries of a Public Procurement System



Low Financial Burden

Low financial burden to the government ex-chequer is an important aspect of the public drug procurement systems because of limited resources. Some of the parameters amongst the 53 comparatives that reflect a procurement system's capacity to reduce financial burden are the extent of capital expenditure for establishing the systems, costs for procurement, storage and transportation, the preciseness of the Essential Drug List (EDL) to suit the state health burden and finally the prices at which drugs are procured.

The procurement process adopted bears some strong repercussions on the budgets, which include both the capital expenditures and operating expenditure to run the system. For completely/ predominantly centralized pooled procurement models like Tamil Nadu, Kerala and Odisha it is imperative to have an optimum number of warehouses to cater to all the public health facilities.

Additionally, the system requires adequate transportation facilities to transfer supplies from warehouses to user institutions and IT enablement to manage the entire system necessitating a considerable initial capital expenditure. With a budget of INR 39.8 Million USD and USD 36.3 Million in FY2010 for Tamil Nadu and Kerala respectively, the states have been able to make capital investments – this also includes the cash surplus generated through management fees the autonomous procurement agencies charge. Kerala has about 19 warehouses while Tamil Nadu about 25, most of which comply with scientific standards of inventory management. Odisha, with a budget of INR USD 8.1 Million for FY2011, is unable to make the necessary investments to fully realize the benefits of centralized pooled procurement.

Maharashtra follows the system of centralized rate contracting and decentralized purchasing where the suppliers directly deliver the medicines to the facilities. While transportation costs are not borne by the state, its cost is built into the drug price. This system also requires significantly large storage facilities at each user institution thereby increasing the overall cost. Punjab was not considered into this analysis because it follows a mixed system with drugs worth about USD 0.4 Million being purchased in a centralized manner while user charges collected by district hospitals accounting for USD 3 Million are utilized to directly purchase drugs from the open market.

A well-formulated and localized EDL is imperative to make optimal use of the limited financial resources. Tamil Nadu, Kerala and Odisha purchase about 260 drugs each year as a part of EDL while in Maharashtra centralized rate contracting (decentralized purchasing) is done for about 1,850 drugs. Though the decentralized purchasing model offers more flexibility for facilities, the administrative costs of finalizing rate contracts for 1,850 drugs and empanelling the suppliers is by no measure insignificant.

Finally – drug price: the largest expenditure component. Theoretically, centralized procurement offers volume discounts thereby reducing the financial burden; however Annexure 2 comparing prices of 32 drugs across the five states reveals that Tamil Nadu may not necessarily have the lowest price despite greater quantities. Despite the bulk discounts, some drugs are cheaper in states with arguably inefficient centralized/ predominantly centralized models like Odisha and Punjab and states with decentralized models like Maharashtra. Due to larger population, public preference towards the government's health system and good health infrastructure, it is safe to assume that the quantities for procurement in Tamil Nadu would be significantly higher than Odisha, Kerala or Punjab. Then the question that remains unanswered is how are the other states able to procure at prices lower than Tamil Nadu? The reasons could be many. For instance, supplier location – more than half of the suppliers to Tamil Nadu are from within the state. The same statistic for Kerala is 14%, Maharashtra 34% and for Odisha, a surprising zero percent! With insufficient data, we are unable to confidently conclude the financial burden of all the variants of the procurement models. But perhaps this is a good lead to think about what is causing unexpected discrepancies in prices?

Wastage Elimination

Eliminating wastage of drugs (through mishandling or expiry) is necessary (but not sufficient) to optimize expenditure and ensure availability. Eliminating wastage is predicated upon effective inventory management, which deals with requirement gathering, analyzing consumption patterns and forecasting demand. Trained pharmacists using weekly, quarterly and annual consumption data are supposed to do the demand estimation each year. However in reality, the previous year's data is inflated by 10 – 15% in most states. In Odisha, however, owing to the lack of trained personnel, clerks/ computer operators perform these tasks.

Kerala was able to mitigate this inaccuracy in estimation by introducing the option of issuing a second purchase order (PO). The initial PO given to the supplier is only for 75% of the tender quantity. The procurement authorities have the privilege of either not issuing the second PO or

issuing the second PO for 25% or 50% of the tender quantity thereby building in a flexibility of 25%. All other states have a rather static inventory management.

Furthermore, Kerala and Tamil Nadu use software tools to monitor stock levels and manage inventory and distribution. The warehouses in Punjab, Odisha and Maharashtra manually manage the inventory by recording data into ledgers. These systems are not designed to store all types of drugs in a scientific manner. These practices not only lead to wastage of material but also precious warehouse space (in case of over-supply).

Availability

In the centralized model of pooled procurement, the distribution is managed centrally and the onus of the procurement agency is to ensure availability at the user institutions. The public health centers in Punjab and Maharashtra are at the mercy of the suppliers, owing to their decentralized purchasing model, whose supply is often sporadic due to various reasons like delayed payments, lack of proper planning etc. This impacts availability at the time of need and could potentially lead to wastage.

Quality

A procurement organization has two levers to ensure that only quality drugs enter the system: a) Pre-qualification criteria to filter out unqualified suppliers b) External quality testing protocols. When these levers are used together, quality is ensured while still keeping the prices low. States that have stringent external quality testing protocols can afford to keep the minimum turnover criterion low. For instance, Tamil Nadu has empanelled laboratories to which every sample from each batch is sent for quality testing before distributing to user institutions and the minimum turnover criteria is set at USD 0.7 Million (INR 3 Crores). Kerala too has similar quality testing protocols but has a higher minimum turnover criteria (set at USD 2.1 Million/ INR 10 crores) to enforce faith into the public system. Odisha and Maharashtra do not have any quality testing protocols in place, apart from the supplier's internal quality certificate, and have therefore set the minimum turnover criterion at INR 10 crores, assuming that higher volumes are more likely to be generated by suppliers with high quality products.

Additionally, states that have external quality testing protocols also have policies that provide price relaxation to Small Scale Industries (SSIs) and Public Sector Undertakings (PSUs) to encourage local industry. Such preference treatment doesn't exist in Odisha or Punjab. Maharashtra reserves 20% of quantities to SSIs only if they match the L1 rates and thus do not get any price preferences.

An important aspect of the pre-qualification criteria is also the GMP (good manufacturing practices) certificate. This certificate ensures that the facility follows the stipulated guidelines according to the industrial benchamarks and thus can ascertain a certain level of quality. Maharashtra demands a WHO-GMP certificate which is deemed to be more strict and reviewed every two years.

Transparency

A public procurement system is accountable to various stakeholders and it is important that transparency is maintained in all its activities. Certain conditions need to be established for a more open and efficient functioning. TNMSC and KMSCL are autonomous organisations that are headed by an appointed Director who maybe a civil services officer with a very good technical and administrative background. The idea of having an autonomous organisation in the public sector may enable it to function more transparently by avoiding the plausible procedural delays and also to be able to make decisions of contracting and outsourcing as best suited for the prosperity of the organisation. On the other hand, Odisha, Punjab and Maharashtra have procurement cells that are a part of the Directorate of Health Services (DHS) in the state. A clear difference in the efficiency of the processes can be seen between the autonomous organisations and the state run organisations –

In terms of lead times for payments, quality control and in the usage of IT systems and so on. In an autonomous system, most of the staff are contractual based on their technical capabilities which may not be the case in state run procurement organizations.

A multistakeholdership in the organisation may be useful tool for bringing in more transparency and representation provided it is well coordinated. Right from the formation of the essential drugs list (EDL) to the award of the tenders, open and multi-stakeholder decision making may help keep the system become more transparent. All the states under the purview of the study have a multi-stakeholder decision making body.

It is deemed to be a good practice to have a separate payment processing team from the tender award team in order to keep transactions more transparent. All the states issue the payment based on the receipt of stock in the warehouse and a quality certificate (either internal or external). The processing of payments through the public channels like (Auditor General's Office or Directorate of Accounts & Treasury) usually takes much longer, as noted in Maharashtra, Odisha and Punjab compared to the autonomous payment departments of TNMSC and KMSCL.

Conclusion

In conclusion, we opine that the critical success factors of each model need to be carefully analyzed to see if they are valid in the state contexts. It is important for policy makers to understand in detail the tangible and intangible aspects that go into running a successful model before trying to replicate it. Also, in some states the existing structures may be serving the purpose but there maybe a need to do and undo several aspects of the current method of procurement, to make it more efficient. Sometimes, scrapping existing structures for new procedures may be a herculean task, which needs to be well thought out before undertaking. Based on the qualitative observations made, the authors assert that some of the critical success factors that define the success of any procurement system are: effective leadership and political support; multi-stakeholder participation for political buy-in; sufficient budget allocation to meet drug demand and administrative costs; outsourcing of non-core services like IT, quality testing, supply chain management etc.; autonomy procurement agency, well defined & localized EDL; scientific demand estimation and forecasting; effective pre-qualification criteria to promote competition and enforce quality; protocols for regular inspection of supplier premises; mandatory external quality testing; prompt payment to suppliers; autonomous payment body; scientific warehousing & inventory management; real time stock monitory (both at warehouse and facility level); and robust IT systems.

Limitations of the study

Despite an effort to draw inferences from various primary and secondary sources, the study has some limitations that are mentioned below:

- Availability of essential medicines at the public health facilities was not assessed a a part of this study. It is the primary indicator of efficacy of a procurement system so all the qualitative findings mentioned in the paper will have to recognize the lack of this data and interpret the findings appropriately
- Time and resource constraints have limited our primary data to two districts in each State. However, efforts were made to include both urban and rural ones in the study
- Quantifying the 'impact' of each of the procurement systems is rather ambiguous due to the lack of concrete indicators to record aspects like corruption, governance and so on. Thus, this section is qualitatively recorded with the help of a few indicators composed based on existing literature and some aspects specific to public procurement systems

Works Cited

Cameron, A., Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R. (2009). Medicines prices, availability and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet* , 240-249.

CDSCO. (2009). *Report on Country-Wide Survey of Spurious Drugs.* New-Delhi: CDSCO, MoHFW.

Khan, A., & Ghilzai, N. (2007). Counterfeit and Substandard Quality of drugs: The need for an effective and stringent regulatory control in India and other developing countries. *Indian J Pharmacol* , 206-207.

Kotwani, A., Ewen, M., Dey, D., Iyer, S., Lakshmi, P., Patel, A., et al. (2007). Prices and availability of common medicines at six sites in India using standard methodology. *Indian Journal of Med Res* , 645-654.

Narayanan, D. (2010 йил 27-July). Tamil Nadu Medical Services Corporation: A Success Story. *Forbes India* .

Patel, V., Vaidya, R., Naik, D., & Borker, P. (2005). Irrational Drug Use in India: A Prescription Survey from Goa. *Journal of Postgraduate medicine* , 9-12.

Russell, S. (2004). The Economic Burden of Illness for Households in Developing Countries: A Review of Studies Focussing on Malaria, Tuberculosis and Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome. *American Journal of Tropical Medicine and Hygiene* , 147-155.

Selveraj, S., & Karan, A. (2009). Deepening Health Insecurity in India: Evidence from National Sample Surveys Since 1980's. *Economic and Political Weekly* , 55-60.

Selveraj, S., & Nabar, V. (2010). Access to medicines in India: Issues, Challenges and Response. In A. Mahal, B. Debroy, & L. Ihandri, *India Health Report 2010.* New Delhi.

TNMSC. (2010 йил 15-July). Retrieved 2012 йил 28-March from TNMSC News Bulletin: http://www.tnmsc.com/tnmsc/publication/July2010.pdf

UNDG. (2003). *Indicators for Monitoring the Millennium Development Goals.* New York: United Nations.

USAID. (2006). *Procurement Strategies for Health Commodities.* Arlington: DELIVER.

WHO. (2004). *The World Medicines Situation.* WHO. WHO.

Yadav, P., Stapleton, O., & Wassenhove, L. N. (2011). *Always Cola, Rarely Essetial Medicines: Comparing Medicine and Consumer Product Supply Chain in the Developing World.* INSEAD.

Authors' Contributions

- Prabal Vikram Singh: Involved in the conceptpualization and study design, and analysis of findings.
- Anand Tatambhotla: Involved in the conceptpualization and study design, field data collection and analysis of findings.

- Rohini Kalvakuntla: Involved in the conceptpualization and study design, field data collection and analysis of findings.
- Maulik Chokshi: Involved in the conceptpualization and study design, and analysis of findings.

Title

Understanding public drug procurement in India – A comparative study of five Indian states

Abstract

India is in the midst of metamorphosis of its health policies to achieve universal healthcare and access to essential medicines is one of its critical mandates. Much discussion has risen on the need to strengthen the public drug procurement systems at the state levels in order to ensure good quality and timely supply of essential drugs at all public health facilities. Different states in India follow different public procurement systems ranging from centralized pooled procurement to decentralized procurement. This study aims ~~to compare and contrast~~perform an initial comparison, predominantly qualitative, between the different procurement models ~~and their detailed implications on price of the drugs procured, supply chain management, cost-effectiveness of the system~~to frame questions for future research in ~~order to provide some key points to policy makers~~this area. The finer differences between the state models, even though seemingly similar from the outside impact access to medicines for people hugely and this has been captured in the study. The five states ~~for~~included in the study~~-~~ – Tamil Nadu, Kerala, Odisha, Punjab and Maharashtra were chosen to ensure heterogeneity in a number of factors~~: a) Procurement Type; b) Autonomy~~ such as procurement type (centralized, decentralized or mixed); autonomy of the procurement organization; ~~c) State~~state of public health infrastructure; and ~~d) Public health care budgets. The methodology adopted for this study is based~~geography. Data on ~~both secondary data and primary data~~procurement processes was collected ~~from state procurement cells and also from 4 facilities a~~through key informant analysis by way of semi-structured interviews with leadership teams of procuring organizations. This process data was valided through interviews with field staff (stakeholders of district ~~hospital, a~~hospitals, taluk ~~hospital, Community healthcare center and Primary healthcare center~~hospitals, community health centers, and primary health centers) in each state. Data on procurement price was assimilated by way of RTI responses from state public information officers. The procurement processes in each state were compared across 52 ~~process related factors and on price of the drugs procured. Such a detailed analysis revealed~~pre-determined parameters. The analysis indicated that autonomous procurement organizations were more efficient in relation to payments to suppliers, had relatively lower drug procurement prices and managed their inventory more scientifically. ~~The tables showcased in the study reveals some interesting correlations between process parameters and efficiency of the systems; some intuitive as well as counter intuitive observations that need to be further probed into.~~ Furthermore, the authors highlight critical success factors that significantly influence the outcome of any procurement model. In a way, this study raises more questions and seeks the need for further research in this arena.

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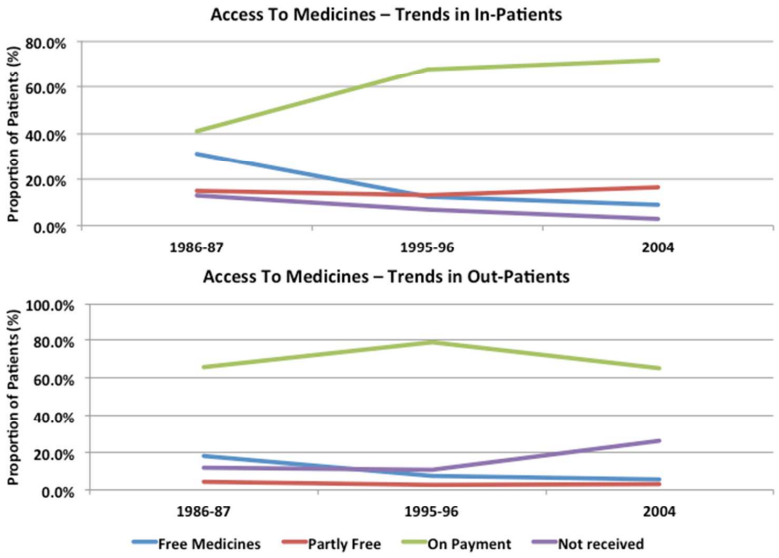
Introduction

Over the years India has seen a tremendous growth in the pharmaceutical sector yet it is grappling with a large population that is denied basic access to healthcare and essential medicines. According to a WHO report on World's medicines situation (WHO, 2004) almost 68% of the people in India have limited or no access to essential medicines. Inadequate medicine access poses a major barrier to the objective of delivering essential healthcare and the more recently talked about universal healthcare. According to United Nations Development Group (UNDG, 2003), medicine access is defined as *"having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour walk from the homes of the people"*. Fulfilment of all these factors is arguably low in developing countries like in India. Exhibit 1 shows the decreasing trend in the supply of free medicines since 1986 and also a corresponding increase in the number of people not receiving any medicines at all for out-patient care.

Exhibit 1: Access to medicines in India



Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42

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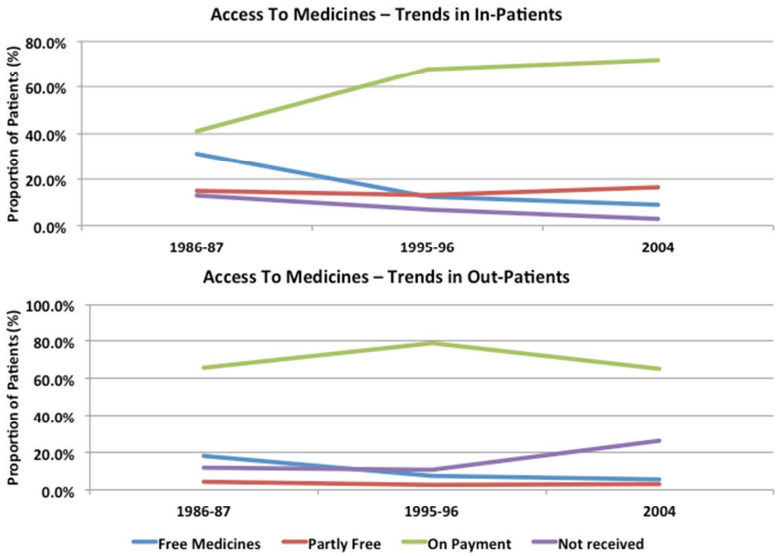

Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42

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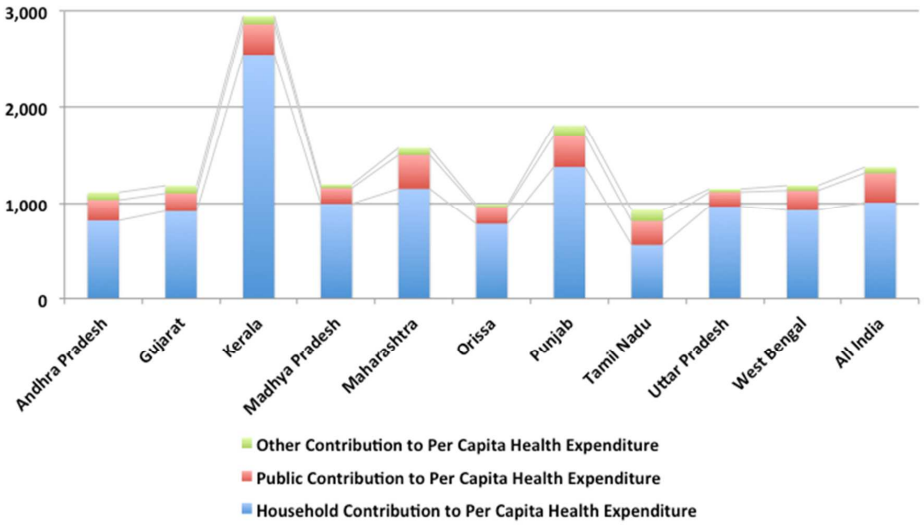
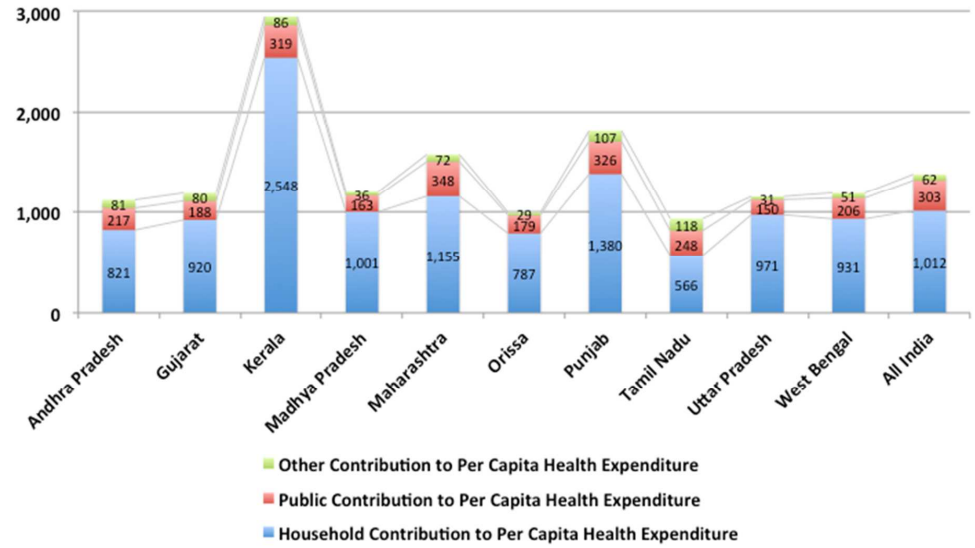
Private health expenditure constitutes almost 70% of the total health expenditure of which drugs form a massive component anywhere between 20-65% in India and other transitional economies compared to 18% in OPEC countries (Cameron, Ewen, Ross-Degnan, Ball, & Laing, 2009). The burden of purchasing medicines is very high in India accounting for the second largest bulk of expenditure after food. The high cost of medicine purchase in India and relatively low public health investment is exacerbating the lack of essential medicines access in India. It is now well known, accepted and documented that out-of-pocket (OOP) payment for health care has pushed many people into poverty. Bearing the costs of a single hospitalization, 35% of people fall below the poverty line and out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year. *(India – Raising the Sights: Better Health Systems for India's Poo*r, World Bank, 2001). Exhibit 2 below gives a glimpse of the health care spending in India for 2004-05 across various states.

Exhibit 2: Healthcare Spending in India 2004-05 (Figures in INR)



Source: Report of National Commission on Macroeconomics and Health, GOI 2005



Source: Report of the National Commission on Macroeconomics and Health, Government of India, 2005

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Strengthening the public sector availability of quality drugs ~~will~~is one of the long-term, sustainable ways to relieve a large number of people to whom medical expenditure may be catastrophic. This paper, focussing on the public drug procurement models in India, will detail five main factors of the systems – low financial burden, good quality, timely availability, minimal wastage and transparency – that are important to improve access to medicines. Although rational usage of drugs and medical awareness amongst the people is equally important to determine the success of the public procurement systems, this paper only deals with the supply side of the medicines access issue. Accordingly, the objective of the paper is to understand and compare the public drug procurement systems in five Indian states – Kerala, Maharashtra, Odisha, Punjab and Tamil Nadu – on the basis of

a set of pre-determined comparison factors. And also explore whether the success of the procurement models depends on some crucial intangible elements beyond the procurement process or price.

Methodology

The study was designed to compare public drug procurement models of a sample of states on a set of 53 pre-determined parameters. These parameters reflect each of the five main objectives of comparison viz. low financial burden, good quality, timely availability, transparency and wastage elimination through efficient supply chain.

The sample states were chosen to ensure heterogeneity in a number of factors~~: a) Procurement Type~~ such as procurement type (centralized, decentralized or mixed); ~~b) Autonomy~~autonomy of the procurement organization; ~~c) State~~state of public health infrastructure; and ~~d) Public health care budgets~~geography. Based on these parameters, the sample of states initially chosen were Kerala, Tamil Nadu Maharashtra, Punjab, Uttar Pradesh and West Bengal. Consequently, Right to Information (RTI)[1] applications were sent to the concerned Public Information Officers (PIOs) to seek drug procurement and process data. However, due to lack of data responses despite multiple appeals from Uttar Pradesh and West Bengal, these states were replaced with Orissa ~~(See Exhibit 3).~~ Exhibit 3 provides an overview of the sampling methodology. It is also noteworthy that some of the sample states are primarily agrarian systems while the others are at different points of industrialization.

Exhibit 3: Sample states for the study

Sampling Attribute	Kerala	Tamil Nadu	Maharashtra	Orissa	Punjab
Procurement Type	Centralized	Mixed	Primarily Decentralized	Mixed	Primarily Decentralized
Autonomy	Fully Autonomous	Fully Autonomous	Government owned	Government owned	Government owned
Health Infrastructure	Good	Good	Poor	Poor	Good
Geography	South	South	Mid-West	Mid-East	North

Procurement type mentioned in the above table is used to refer to the model ~~where in~~wherein the state drug procurement budget is divided between centralized and decentralized methods of acquiring medicines. Autonomy refers to the extent of government involvement in the decisions of the procurement organization; "fully autonomous" implies minimal involvement while "government owned" indicates a high degree of involvement. The rating of health infrastructure as 'good' and 'poor' has been based upon the perceived condition of the infrastructure such as the drug warehouses, transportation facilities, ~~CHC/ PHC~~community health center, primary health center and district hospital conditions.

Brief information about the sample states, for an overview of the context, is presented in Exhibit 4.

Exhibit 4: Overview of Sample States

Parameter	Kerala	Maharashtra	Orissa	Punjab	Tamil Nadu
Total Population	33,387,677	112,372,972	41,947,358	27,704,236	72,138,958
Urban/Rural Population Ratio	91.3%	82.6%	20.0%	60.0%	94.0%
Annual Per capita Income	59,179	83,471	36,923	67,473	72,993

[1] Right to information act: Right to Information Act 2005 mandates timely response to citizen requests for government information

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Annual Per capita Exp. - Rural	22,020	13,836	9,816	19,788	13,920
Annual Per capita Exp. - Urban	28,956	29,244	18,576	25,308	23,376
Total Per Capita Health Exp.	2,952	1,576	995	1,813	933
Public Component %	10.8%	22.1%	18.0%	18.0%	26.6%
Private Component %	86.3%	73.3%	79.1%	76.1%	60.7%
Number of Sub-Centers	4,575	10,579	6,688	2,950	8,706
Number of ~~PHCs~~Primary Health Centers	697	1816	1279	394	1277
Number of ~~CHCs~~Community Health Centers	226	376	231	129	256
Number of ~~DHs~~District Hospitals	14	35	32	20	29
Birth Rate (/1000 Population)	14.7	17.9	21.5	17.6	15.8
Death Rate (/1000 Population)	6.8	6.6	9.2	7	7.2
Infant Mortality Rate (/1000 Live Births)	13	33	71	43	35
Maternal Mortality Rate (Per 100,000 Live Births)	110	130	303	192	111
Total Fertility Rate (Children Per Woman)	1.7	2	2.4	2	1.6

Source: Census 2011; Level and Pattern of Consumer Expenditure 2009-10 NSSO 66th round; Bulletin on Rural Health Statistics in India 2008, MoHFW; Sample Registration Survery 2010-11

Primary data for the study was gathered through ~~warehouse audits and~~key informant analysis, in which semi-structured interviews were conducted with executive leadership teams of the drug procurement cells and public health officials in the sample states in March – April 2012~~. The secondary resources used are the statistical databases, peer-reviewed articles and grey literature~~, and RTI responses from sample states. The information gathered from the key informant analysis was corroborated with the field staff by way of semi-structured interviews with stakeholders of primary health centers, community health centers, and district hospitals, and qualitative observation during the authors' warehouse visits.

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Secondary data on expenditures, budgets and indicators was compiled from datasets published by the National Sample Survey Office, Ministry of Health and Family Welfare (Bulletin on Rural Health Statistics in India), and Office of the Registrar General & Census Commissioner of India (Sample Registration Survey). This study is intended to be a qualitative assessment with an objective of framing questions for future research, therefore no statistical techniques were used.

Findings ~~& Discussion~~

The procurement processes followed in the sample states were evaluated against a pre-determined set of 53 parameters (including price). See Exhibit 5 for the list of pre-determined parameters used for comparison.

Exhibit 5: Overview of Comparison Parameters

Overall	• *Legal Status of the Procurement Organization; Drug Procurement Budget; Per Capita Drug Procurement Budget;*
Essential Drug List	• *EDL Customization; EDL Committee Composition; Frequency of EDL Revision; Time for EDL Preparation/ Revision; EDL Categorization; Third Party Review of EDL*
Demand Estimation & Forecast	• *Demand Estimation Process; Frequency of Demand Estimation; Methodology for Estimation (Facility Level)*
Procurement Process	• *Procurement mechanism in the state; Financing of Drug Procurement; Emergency Drug Budget Allocation; Bidding Process*
Prequalification Criteria	• *Min. Turnover Criteria; GMP/WHO-GMP/US-FDA; ISI/BIS/ISO/CE; Assurance of avbl. Production Capacity; Market Standing; Exclusion Criteria; Price Relaxation; Product Reservation; EMD (%); Tenders with no bidders; Supply Schedule*
Quality Control	• *External Quality Testing Of Every Consignment; Testing Before Distribution; Testing Before Distribution*
Payment Mechanism	• *Payment Department Status; Lead Time For Payment; Prerequisites For Payment Disbursement*
Inventory Management & Distribution	• *Facilities Per Warehouse; Scientific Warehousing Practices; Supply Chain Management; Inventory Management; Scientific Forecasting; Flexibility to Alter Indent; Tracking dispatched drugs; Scientific inventory Mgmt. at Facility*
Penalties	• *Supply Default; Quality Failure; Blacklisting Criteria*
IT Systems Enablement (of)	• *Demand Estimation & Forecasting; Tendering Process; Quality Control; Payment Disbursement; Inventory Management (Warehouse); Inventory Management (Facility)*

The detailed comparison tablets ~~are presented in annexures (See annexure 1 for procurement process comparison and annexure 2 for price comparison of 32 selected molecules that appear in same dosages commonly across the sample states).~~on procurement process and prices are presented in Exhibits 6 and 7. In many instances, the process followed is very different from the one given in the manuals. The information captured below relates to the process that are actually followed.

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Exhibit 6: Procurement Process Comparison Across the Sample States

Parameter	Kerala	Orissa	Tamil Nadu	Punjab	Maharashtra
Legal Status Of Procurement Organization	Autonomous (KMSCL)	Government Owned (Part Of DHS)	Autonomous (TNMSC)	Government Owned (PHSC)	Government Owned
Drug Procurement Budget (USD)	36.3 Million (2011 - 12)	8.1Million (2010 - 11)	39.8Million (2010 - 11)	3.4 Million (0.4 mil. State Budget + 3 mil. User Fees)	87.5 Million (2010-11)
Per Capita Drug Procurement Budget	51	8.8	22.5	5.8	35.6
Essential Drug List					
Customized State EDL	Yes	Yes	Yes	Yes	No, But It Has A Drug List Comprising 1850 Drugs
Composition Of EDL Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee	Multistakeholder Committee
Frequency Of EDL Revision	1 Year	2 Years	1 Year	1 Year	N/A
Time For EDL Preparation/ Revision	2 - 3 Months	7 - 8 Months	2 - 3 Months	4 Months	N/A
EDL Categorization	Yes (8 Product-Based Categories)	Yes (2 Demography-Based Lists)	Yes (Product-Based Categories)	Yes	N/A
Third Party Review Of EDL	No	Yes (By WHO Experts)	No	No	N/A
Demand Estimation& Forecast					
Demand Estimation Process	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Facility Level Indenting
Frequency Of Demand Estimation	1 Year	1 Year	1 Year	1 Year	1 Year
Methodology For Estimation (Facility Level)	10 - 15% Over Previous Year's Indent; Performed By Pharmacist	No Scientific Method; Usually Performed By Computer Operator/ Clerk	10% Of The Previous Year Consumption	N/A	10% Of Previous Year Consumption
Procurement Process					
Procurement Mechanism In The State	Centralized	80% Centralized; 20% Decentralized	90% Centralized; 10% Decentralized	12.5% Centralized;87.5% Decentralized	Centralized Rate Contracting ; Decentralized Purchasing
Financing Of Drug Procurement	State Budget Allocation	State Budget Allocation	State Budget Allocation	State Budget Allocation & User Charges	State Budget Allocation
Emergency Drug Budget Allocation	Yes (Additional Funds Released)	No (Purchased From Existing Budget)	Yes (Additional Funds Released)	No	Yes (Additional Funds Released)
Tendering Process					
Bidding Process	Two Bid System	Two Bid System	Two Bid System	Two Bid System	Two Bid System

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Prequalification Criteria					
Min. Turnover Criteria (INR/USD)	~~10 Crore/ 2.1 Million~~	~~10 Crore/ 2.1 Million~~	~~3 Crore/ 0.7 Million~~	~~50 Crore/ 10.7 Million~~	~~10 Crores/ 2.1 Million~~
GMP/ WHO-GMP/ US-FDA	Required	Required	Required	Required	WHO-GMP Required
ISI/ BIS/ ISO/ CE	Required	Required	N/A	N/A	N/A
Assurance Of Available Production Capacity	Required (MPMASS)	None	Production Capacity Certificate	N/A	Production Capacity Certificate
Market Standing	2 Years	3 Years	3 Years	3 Years	3 Years
Exclusion Criteria For Factory Inspections	Supply To Premier Institutions	None	None	None	N/A
Price Relaxation For SSIs/ PSUs	Yes (SSI - 10%; PSU - 15%)	Yes (SSI - 10%; Additional 3% For ISO Certification)	Yes (SSI - 15%)	PSU produced Antibiotics	None (20% Quantity Reserved If SSI Matches L1 Rate)
Product Reservation For SSIs/ PSUs	None	31 Items (From SSIs)	None	None	None
EMD	1% Of Tender Value	1 - 5% Of Tender Value	1% of Tender value (maximum upto 50,000 INR), expempted for SSI	Differs For Each Drug	INR 25,000
Process For Tenders With No Bidders (In Order Of Priority)	Re-Tender (Revised Pre-Qualifications); Limited Tender; Short Tender; Direct Purchase	Re-Tender (Same Pre-Qualifications) - Open Until Bids Are Received	Re-tender (Limited and Short tender process is used)	Pharmacy Based Purchasing	Re-Tendering, Limited Tendering Or Direct Purchase
Supply Schedule	60 Days - 40% Of PO Quantity; 90 Days - 70%; 120 Days - 100%	60 Days - 50% Of PO Quantity; Rest Before Specified Date	Starting from 30 days and has to end by 60 days, otherwise specified	30 days to 3 months from the time of issue of PO	Within 3 Months From The Issue Of PO
Quality Control					
External Quality Testing Of Every Consignment	Empanelled Private Labs	~~No External Quality Testing~~ (Supplier's Internal Quality Certificate)	Empanelled Private and government labs	Empanelled Government Labs	~~No External Quality Testing~~ (Supplier's Internal Quality Certificate)
Testing Before Distribution	Mandatory	Not Mandatory	Mandatory	Mandatory	Not Mandatory
Lead Time For Quality Testing	~ 15 Days	Within 8 Weeks	15 Days For Tablets And Capsules; 1 Month For Suspensions	1 Month	N/A
Payment Mechanism					
Payment Department Status	Autonomous (Managed By Contractual Staff)	Government (Account General's Office)	Autonomous (Managed By Contractual Staff)-IT enabled	Government	Government (Directorate Of Accounts And Treasuries)

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Lead Time For Payment	~ 30 Days	~90 Days	30 Days	Min. 30 Days	~ 90 Days
Prerequisites For Payment Disbursement	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Supplier's Internal Quality Certificate	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Quality Certificates From Labs	Facility Material Receipt, Internal Quality Certificate
Inventory Mgmt.& Distribution					
Facilities (All) Catered To Per Warehouse (Average)	~290	~235	~411	N/A	N/A
Scientific Warehousing Practices	Yes	No	Yes	No	No
In-House/ Outsourced Supply Chain Management	Outsourced	In-House	In-House	In-House	In-House (Facility Level)
Inventory Management	Dynamic (Flexibility Of 2nd PO)	Static (Only Single PO Is Issued)	Dynamic (Flexibility Of 2nd PO)	Static	25% Flexibility For Quantity Maintained
Scientific Consumption/ Inventory Forecasting	Yes (Inventory Management Software)	No	Yes (Inventory Management Software)	No	No
Flexibility For Facilities To Alter Indent	Yes (Just Before Dispatch)	No	Yes	Yes	No
Tracking Dispatched/ Delivered Drugs	Currently Passbook (Volume Based; Online In Future)	No Tracking	Passbook (Value Based)	N/A	No
(Scientific) Inventory Management At Facility	No (Online In Future)	No	Use First in First Out (FIFO) principle	No	No
Penalty					
Penalty For Supply Schedule Default	10% Of The Unexecuted Supply; Unexecuted Supply Purchased At The Cost Of Supplier In Case Of Inability To Supply	N/A	0.5% per day to maximum of 15% of the tender amount	N/A	0.5% Of The Value Of Unsupplied Goods Per Week Up To 5 Weeks, After Which Unexecuted Supply Purchased At The Cost Of Supplier
Penalty For Quality Failure	Supplier Blacklisted With Forfeiture Of Security Deposit	Suppliers Have To Replace The Entire PO Quantity Or Risk Blacklisting	Supplier Blacklisted With Forfeiture Of Security Deposit	Forfeiture Of EMD	Supplier Blacklisted With Forfeiture Of Security Deposit

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Blacklisting Criteria	Defaulting On 3 POs Or More With Less Than 50% Supply; Blacklisted By Any Other Procurement Agency On Quality Grounds	Quality Failure After Material Supply	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Supply Default After Extension Period; Quality Failure
IT Enablement Processes:					
Demand Estimation & Forecasting	Yes	No	Yes	No	No
Tendering Process	Yes	No	Yes	No	Yes
Quality Control		No	Yes	No	No
Payment Disbursement	Yes	No	Yes	No	No
Inventory Management (Warehouse)	Yes	Yes	Yes	No	No
Inventory Management (Facility)	No	No	Yes	No	No

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Exhibit 7: Price Comparison of 32 Randomly Selected Drugs Across the Sample States

Name of Drug	Dosage	Unit	Price (INR) Kerala 2012	Tamil Nadu 2012	Odisha 2009	Maharashtra 2011	Punjab 2010
Adrenaline	1mg/1 ml	Ampoule	2.89	1.21	1.46	1.80	n/a
Albendazole	400 mg	Tablet	0.81	0.57	0.49	0.61	0.64
Aminophylline	25 mg/ml	Ampoule	n/a	2.60	2.91	4.90	n/a
Amitriptyline	25 mg	Tablet	0.22	0.15	0.15	0.19	n/a
Amlodipine	5 mg	Tablet	0.16	0.06	0.09	0.10	0.13
Atenolol	50 mg	Tablet	0.125	0.11	0.13	0.14	0.14
Benzyl Penicillin	10 Lakh IU	Vial	3.68	3.08	4.20	4.88	n/a
Carbamazepine	200 mg	Tablet	0.59	0.54	0.42	0.53	n/a
Cefotaxime	250 mg	Vial	4.73	3.94	5.40	5.14	n/a
Ciprofloxacin	500 mg	Tablet	1.09	1.04	0.87	1.07	1.86
Co-trimoxazole	40mg+ 200mg per 5ml	Bottle	n/a	5.91	5.90	6.74	n/a
Diclofenac	25 mg/ml	Ampoule	1.33	1.08	1.04	1.40	2.70
Dicyclomine	10 mg/ml	Ampoule	1.34	0.88	1.17	1.37	n/a

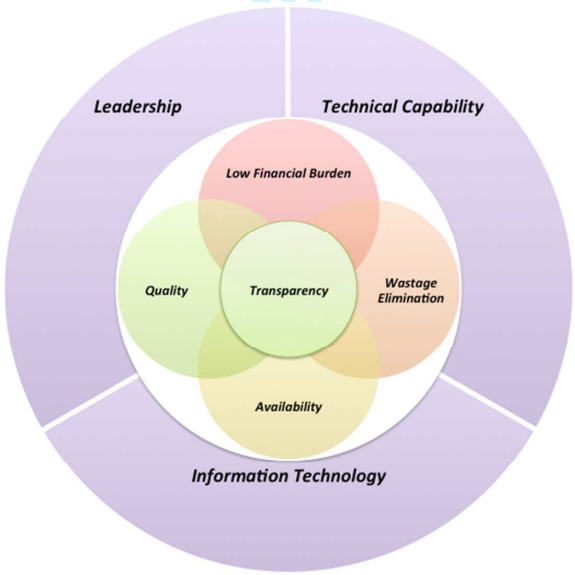
Dopamine	40 mg/ml	Vial	6.4	5.40	5.53	7.87	n/a
Erythromycin	250 mg	Tablet	1.27	1.23	0.81	1.03	n/a
Folic Acid	5 mg	Tablet	0.06	0.06	0.06	0.08	0.05
Gamma Benzene Hexachloride	1% w/v	Bottle	12.5	9.63	12.77	10.18	n/a
Glibenclamide	5 mg	Tablet	0.12	0.07	0.08	0.08	n/a
Glycopyrrolate	0.2 mg/ml	Ampoule	5.22	1.65	3.25	3.51	n/a
Hydrocortisone	100 mg	Vial	11	10.50	7.45	11.38	7.39
Ketamine	50 mg/ml	Vial	n/a	16.27	14.60	17.10	n/a
Lignocaine	2% w/v	Vial	7.75	4.54	3.80	6.30	4.40
Metformin	500 mg	Tablet	0.24	0.19	0.18	0.19	n/a
Methyl Ergometrine	0.2 mg/ml	Ampoule	1.85	1.33	1.71	2.75	n/a
Norfloxacin	400 mg	Tablet	0.78	0.79	0.57	0.76	n/a
Oxytocin	5 IU/ml	Ampoule	n/a	1.16	1.65	1.51	n/a
Pentazocine	30 mg/ml	Ampoule	3.05	2.41	2.58	3.51	3.60
Phenobarbitone	30 mg	Tablet	0.28	0.09	0.12	1.43	0.11
Phenytoin	100 mg	Tablet	0.36	0.16	0.11	1.60	n/a
Promethazine	25 mg	Ampoule	1.68	1.19	1.10	1.60	n/a
Ranitidine	50 mg	Ampoule	1.31	0.81	0.98	1.40	2.20
Thiopentone	500 mg	Ampoule	21.5	16.60	17.20	11.85	n/a

Discussion

An efficient drug distribution system ensures the ***right medicines*** in ***sufficient quantities*** procured at ***lowest prices*** to secure the ***maximum therapeutic value*** to the ***largest number of beneficiaries*** with the ***available & additional resources***.

Broadly speaking, the two main beneficiaries in this context are the government and the patient. On one hand, rationality dictates that any government in a resource-constrained setting would expect that an effective procurement system would ensure availability of quality medicines while optimizing the finances to ensure best outcomes. It is also in the interest of the government to run this system transparently to promote competition and thus efficiency. On the other hand, a patient expects that good quality medicines are available at all time, free of cost. (See Exhibit ~~6~~8 for an expectation map of both beneficiaries). Leadership, technical capability and information technology overarching the expectations in the exhibit below are the pre-requisites for running a system efficiently. The capability of each states' procurement system to enhance IT usage and administrative capabilities driven by a strong leader is pre-requisite.

Exhibit ~~6~~8: Combined Expectation Mapping of Beneficiaries of a Public Procurement System



Low Financial Burden

Low financial burden to the government ex-chequer is an important aspect of the public drug procurement systems because of limited resources. Some of the parameters amongst the 53 comparatives that reflect a procurement system's capacity to reduce financial burden are the extent of capital expenditure for establishing the systems, costs for procurement, storage and transportation, the preciseness of the Essential Drug List (EDL) to suit the state health burden and finally the prices at which drugs are procured.

The procurement process adopted bears some strong repercussions on the budgets, which include both the capital expenditures and operating expenditure to run the system. For completely/ predominantly centralized pooled procurement models like Tamil Nadu, Kerala and Odisha it is imperative to have an optimum number of warehouses to cater to all the public health facilities.

Additionally, the system requires adequate transportation facilities to transfer supplies from warehouses to user institutions and IT enablement to manage the entire system necessitating a considerable initial capital expenditure. With a budget of INR 39.8 Million USD and USD 36.3 Million in FY2010 for Tamil Nadu and Kerala respectively, the states have been able to make capital investments – this also includes the cash surplus generated through management fees the autonomous procurement agencies charge. Kerala has about 19 warehouses while Tamil Nadu about 25, most of which comply with scientific standards of inventory management. Odisha, with a budget of INR USD 8.1 Million for FY2011, is unable to make the necessary investments to fully realize the benefits of centralized pooled procurement.

Maharashtra follows the system of centralized rate contracting and decentralized purchasing where the suppliers directly deliver the medicines to the facilities. While transportation costs are not borne by the state, its cost is built into the drug price. This system also requires significantly large storage facilities at each user institution thereby increasing the overall cost. Punjab was not considered into this analysis because it follows a mixed system with drugs worth about USD 0.4 Million being purchased in a centralized manner while user charges collected by district hospitals accounting for USD 3 Million are utilized to directly purchase drugs from the open market.

A well-formulated and localized EDL is imperative to make optimal use of the limited financial resources. Tamil Nadu, Kerala and Odisha purchase about 260 drugs each year as a part of EDL while in Maharashtra centralized rate contracting (decentralized purchasing) is done for about 1,850 drugs. Though the decentralized purchasing model offers more flexibility for facilities, the administrative costs of finalizing rate contracts for 1,850 drugs and empanelling the suppliers is by no measure insignificant.

Finally – drug price: the largest expenditure component. Theoretically, centralized procurement offers volume discounts thereby reducing the financial burden; however Annexure 2 comparing prices of 32 drugs across the five states reveals that Tamil Nadu may not necessarily have the lowest price despite greater quantities. Despite the bulk discounts, some drugs are cheaper in states with arguably inefficient centralized/ predominantly centralized models like Odisha and Punjab and states with decentralized models like Maharashtra. Due to larger population, public preference towards the government's health system and good health infrastructure, it is safe to assume that the quantities for procurement in Tamil Nadu would be significantly higher than Odisha, Kerala or Punjab. Then the question that remains unanswered is how are the other states able to procure at prices lower than Tamil Nadu? The reasons could be many. For instance, supplier location – more than half of the suppliers to Tamil Nadu are from within the state. The same statistic for Kerala is 14%, Maharashtra 34% and for Odisha, a surprising zero percent! With insufficient data, we are unable to confidently conclude the financial burden of all the variants of the procurement models. But perhaps this is a good lead to think about what is causing unexpected discrepancies in prices?

Wastage Elimination

Eliminating wastage of drugs (through mishandling or expiry) is necessary (but not sufficient) to optimize expenditure and ensure availability. Eliminating wastage is predicated upon effective inventory management, which deals with requirement gathering, analyzing consumption patterns and forecasting demand. Trained pharmacists using weekly, quarterly and annual consumption data are supposed to do the demand estimation each year. However in reality, the previous year's data is inflated by 10 – 15% in most states. In Odisha, however, owing to the lack of trained personnel, clerks/ computer operators perform these tasks.

Kerala was able to mitigate this inaccuracy in estimation by introducing the option of issuing a second purchase order (PO). The initial PO given to the supplier is only for 75% of the tender

quantity. The procurement authorities have the privilege of either not issuing the second PO or issuing the second PO for 25% or 50% of the tender quantity thereby building in a flexibility of 25%. All other states have a rather static inventory management.

Furthermore, Kerala and Tamil Nadu use software tools to monitor stock levels and manage inventory and distribution. The warehouses in Punjab, Odisha and Maharashtra manually manage the inventory by recording data into ledgers. These systems are not designed to store all types of drugs in a scientific manner. These practices not only lead to wastage of material but also precious warehouse space (in case of over-supply).

Availability

In the centralized model of pooled procurement, the distribution is managed centrally and the onus of the procurement agency is to ensure availability at the user institutions. The public health centers in Punjab and Maharashtra are at the mercy of the suppliers, owing to their decentralized purchasing model, whose supply is often sporadic due to various reasons like delayed payments, lack of proper planning etc. This impacts availability at the time of need and could potentially lead to wastage.

Quality

A procurement organization has two levers to ensure that only quality drugs enter the system: a) Pre-qualification criteria to filter out unqualified suppliers b) External quality testing protocols. When these levers are used together, quality is ensured while still keeping the prices low. States that have stringent external quality testing protocols can afford to keep the minimum turnover criterion low. For instance, Tamil Nadu has empanelled laboratories to which every sample from each batch is sent for quality testing before distributing to user institutions and the minimum turnover criteria is set at USD 0.7 Million (INR 3 Crores). Kerala too has similar quality testing protocols but has a higher minimum turnover criteria (set at USD 2.1 Million/ INR 10 crores) to enforce faith into the public system. Odisha and Maharashtra do not have any quality testing protocols in place, apart from the supplier's internal quality certificate, and have therefore set the minimum turnover criterion at INR 10 crores, assuming that higher volumes are more likely to be generated by suppliers with high quality products.

Additionally, states that have external quality testing protocols also have policies that provide price relaxation to Small Scale Industries (SSIs) and Public Sector Undertakings (PSUs) to encourage local industry. Such preference treatment doesn't exist in Odisha or Punjab. Maharashtra reserves 20% of quantities to SSIs only if they match the L1 rates and thus do not get any price preferences.

An important aspect of the pre-qualification criteria is also the GMP (good manufacturing practices) certificate. This certificate ensures that the facility follows the stipulated guidelines according to the industrial benchamarks and thus can ascertain a certain level of quality. Maharashtra demands a WHO-GMP certificate which is deemed to be more strict and reviewed every two years.

Transparency

A public procurement system is accountable to various stakeholders and it is important that transparency is maintained in all its activities. Certain conditions need to be established for a more open and efficient functioning. TNMSC and KMSCL are autonomous organisations that are headed by an appointed Director who maybe a civil services officer with a very good technical and administrative background. The idea of having an autonomous organisation in the public sector may enable it to function more transparently by avoiding the plausible procedural delays and also to be able to make decisions of contracting and outsourcing as best suited for the prosperity of the organisation. On the other hand, Odisha, Punjab and Maharashtra have procurement cells that are a part of the Directorate of Health Services (DHS) in the state. A clear difference in the efficiency of

the processes can be seen between the autonomous organisations and the state run organisations – In terms of lead times for payments, quality control and in the usage of IT systems and so on. In an autonomous system, most of the staff are contractual based on their technical capabilities which may not be the case in state run procurement organizations.

A multistakeholdership in the organisation may be useful tool for bringing in more transparency and representation provided it is well coordinated. Right from the formation of the essential drugs list (EDL) to the award of the tenders, open and multi-stakeholder decision making may help keep the system become more transparent. All the states under the purview of the study have a multi-stakeholder decision making body.

It is deemed to be a good practice to have a separate payment processing team from the tender award team in order to keep transactions more transparent. All the states issue the payment based on the receipt of stock in the warehouse and a quality certificate (either internal or external). The processing of payments through the public channels like (Auditor General's Office or Directorate of Accounts & Treasury) usually takes much longer, as noted in Maharashtra, Odisha and Punjab compared to the autonomous payment departments of TNMSC and KMSCL.

Conclusion

In conclusion, we opine that the critical success factors of each model need to be carefully analyzed to see if they are valid in the state contexts. It is important for policy makers to understand in detail the tangible and intangible aspects that go into running a successful model before trying to replicate it. Also, in some states the existing structures may be serving the purpose but there maybe a need to do and undo several aspects of the current method of procurement, to make it more efficient. Sometimes, scrapping existing structures for new procedures may be a herculean task, which needs to be well thought out before undertaking. Based on the qualitative observations made, the authors assert that some of the critical success factors that define the success of any procurement system are: effective leadership and political support; multi-stakeholder participation for political buy-in; sufficient budget allocation to meet drug demand and administrative costs; outsourcing of non-core services like IT, quality testing, supply chain management etc.; autonomy procurement agency, well defined & localized EDL; scientific demand estimation and forecasting; effective pre-qualification criteria to promote competition and enforce quality; protocols for regular inspection of supplier premises; mandatory external quality testing; prompt payment to suppliers; autonomous payment body; scientific warehousing & inventory management; real time stock monitory (both at warehouse and facility level); and robust IT systems.

Limitations of the study

Despite an effort to draw inferences from various primary and secondary sources, the study has some limitations that are mentioned below:

- Availability of essential medicines at the public health facilities was not assessed a a part of this study. It is the primary indicator of efficacy of a procurement system so all the qualitative findings mentioned in the paper will have to recognize the lack of this data and interpret the findings appropriately
- Time and resource constraints have limited our primary data to ~~one or~~ two districts in each State. However, efforts were made to include both urban and rural ones in the study
- Quantifying the 'impact' of each of the procurement systems is rather ambiguous due to the lack of concrete indicators to record aspects like corruption, governance and so on. Thus,

this section is qualitatively recorded with the help of a few indicators composed based on existing literature and some aspects specific to public procurement systems

Works Cited

Cameron, A., Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R. (2009). Medicines prices, availability and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet* , 240-249.

CDSCO. (2009). *Report on Country-Wide Survey of Spurious Drugs.* New-Delhi: CDSCO, MoHFW.

Khan, A., & Ghilzai, N. (2007). Counterfeit and Substandard Quality of drugs: The need for an effective and stringent regulatory control in India and other developing countries. *Indian J Pharmacol* , 206-207.

Kotwani, A., Ewen, M., Dey, D., Iyer, S., Lakshmi, P., Patel, A., et al. (2007). Prices and availability of common medicines at six sites in India using standard methodology. *Indian Journal of Med Res* , 645-654.

Narayanan, D. (2010 йил 27-July). Tamil Nadu Medical Services Corporation: A Success Story. *Forbes India* .

Patel, V., Vaidya, R., Naik, D., & Borker, P. (2005). Irrational Drug Use in India: A Prescription Survey from Goa. *Journal of Postgraduate medicine* , 9-12.

Russell, S. (2004). The Economic Burden of Illness for Households in Developing Countries: A Review of Studies Focussing on Malaria, Tuberculosis and Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome. *American Journal of Tropical Medicine and Hygiene* , 147-155.

Selveraj, S., & Karan, A. (2009). Deepening Health Insecurity in India: Evidence from National Sample Surveys Since 1980's. *Economic and Political Weekly* , 55-60.

Selveraj, S., & Nabar, V. (2010). Access to medicines in India: Issues, Challenges and Response. In A. Mahal, B. Debroy, & L. Ihandri, *India Health Report 2010.* New Delhi.

TNMSC. (2010 йил 15-July). Retrieved 2012 йил 28-March from TNMSC News Bulletin: http://www.tnmsc.com/tnmsc/publication/July2010.pdf

UNDG. (2003). *Indicators for Monitoring the Millennium Development Goals.* New York: United Nations.

USAID. (2006). *Procurement Strategies for Health Commodities.* Arlington: DELIVER.

WHO. (2004). *The World Medicines Situation.* WHO. WHO.

Yadav, P., Stapleton, O., & Wassenhove, L. N. (2011). *Always Cola, Rarely Essetial Medicines: Comparing Medicine and Consumer Product Supply Chain in the Developing World.* INSEAD.

Authors' Contributions

- Prabal Vikram Singh: Involved in the conceptpualization and study design, and analysis of findings.

- Anand Tatambhotla: Involved in the conceptpualization and study design, field data collection and analysis of findings.
- Rohini Kalvakuntla: Involved in the conceptpualization and study design, field data collection and analysis of findings.
- Maulik Chokshi: Involved in the conceptpualization and study design, and analysis of findings.

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Annexure 1

Parameter	Kerala	Orissa	Tamil Nadu		
Legal Status Of Procurement Organization	Autonomous (KMSCL)	Government Owned (Part Of DHS)	Autonomous (TNMSC)	Government Owned (PHSC)	Government Owned
Drug Procurement Budget (USD)	36.3 Million (2011 - 12)	8.1Million (2010 - 11)	39.8Million (2010 - 11)	3.4 Million (0.4 mil. State Budget + 3 mil. User Fees)	87.5 Million (2010
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Third Party Review Of EDL	No	Yes (By WHO Experts)	No	No	N/A
Demand Estimation& Forecast					
Demand Estimation Process	Aggregation Of Facility Indents	Aggregation Of Facility Indents	Aggregation Of Facility Indents		
Frequency Of Demand Estimation	1 Year	1 Year	1 Year	1 Year	1 Year
Methodology For Estimation (Facility Level)	10 - 15% Over Previous Year's Indent; Performed By Pharmacist	No Scientific Method; Usually Performed By Computer Operator/ Clerk	10% Of The Previous Year Consumption	N/A	10% Of Previous Consumption
Procurement Process					
Procurement Mechanism In The State	Centralized	80% Centralized; 20% Decentralized	90% Centralized; 10% Decentralized		
Financing Of Drug Procurement	State Budget Allocation	State Budget Allocation	State Budget Allocation	State Budget Allocation & User Charges	State Budget Alloca
Emergency Drug Budget Allocation	Yes (Additional Funds Released)	No (Purchased From Existing Budget)	Yes (Additional Funds Released)	No	Yes (Additional Fu Released)
Tendering Process					
Bidding Process	Two Bid System	Two Bid System	Two Bid System		
Prequalification Criteria					
Min. Turnover Criteria (INR/USD)	10 Crore/ 2.1 Million	10 Crore/ 2.1 Million	3 Crore/ 0.7 Million		
GMP/ WHO-GMP/ US-FDA	Required	Required	Required		
ISI/ BIS/ ISO/ CE	Required	Required	N/A		
Assurance Of Available Production Capacity	Required (MPMASS)	None	Production Capacity Certificate	N/A	Production Capac Certificate
Market Standing	3 Years	3 Years	3 Years	3 Years	3 Years
Exclusion Criteria For Factory Inspections	Supply To Premier Institutions	None	None	None	N/A
Price Relaxation For SSIs/ PSUs	Yes (SSI - 10%; PSU - 15%)	Yes (SSI - 10%; Additional 3% For ISO Certification)	Yes (SSI - 15%)	PSU produced Antibiotics	None (20% Quan Reserved If SSI Mate Rate)
Product Reservation For SSIs/ PSUs	None	31 Items (From SSIs)	None	None	None
EMD	1% Of Tender Value	1 - 5% Of Tender Value	1% of Tender value (maximum upto 50,000 INR), exempted for SSI	Differs For Each Drug	INR 25,000
Process For Tenders With No Bidders (In Order Of Priority)	Re-Tender (Revised Pre-Qualifications); Limited Tender; Short Tender; Direct Purchase	Re-Tender (Same Pre-Qualifications) - Open Until Bids Are Received	Re-tender (Limited and Short tender process is used)	Pharmacy Based Purchasing	Re-Tendering, Lim Tendering Or Dir Purchase

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Supply Schedule	60 Days - 40% Of PO Quantity; 90 Days - 70%; 120 Days - 100%	60 Days - 50% Of PO Quantity; Rest Before Specified Date	Starting from 30 days and has to end by 60 days, otherwise specified	30 days to 3 months from the time of issue of PO	Within 3 Months Fro Issue Of PO
Quality Control					
External Quality Testing Of Every Consignment	Empanelled Private Labs	No External Quality Testing (Supplier's Internal Quality Certificate)	Empanelled Private and government labs	Es	
Testing Before Distribution	Mandatory	Not Mandatory	Mandatory	Mandatory	Not Mandatory
Lead Time For Quality Testing	~ 15 Days	Within 8 Weeks	15 Days For Tablets And Capsules; 1 Month For Suspensions	1 Month	N/A
Payment Mechanism					
Payment Department Status	Autonomous (Managed By Contractual Staff)	Government (Account General's Office)	Autonomous (Managed By Contractual Staff) -IT enabled		
Lead Time For Payment	~ 30 Days	~90 Days	30 Days	Min. 30 Days	~ 90 Days
Prerequisites For Payment Disbursement	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Supplier's Internal Quality Certificate	Warehouse Material Receipt, External Quality Certificate	Warehouse Material Receipt, Quality Certificates From Labs	Facility Material Re Internal Quality Cert
Inventory Mgmt & Distribution					
Facilities (All) Catered To Per Warehouse (Average)	~200	~235	~411		
Scientific Warehousing Practices	Yes	No	Yes	No	No
In-House/ Outsourced Supply Chain Management	Outsourced	In-House	In-House	In-House	In-House (Facility L
Inventory Management	Dynamic (Flexibility Of 2nd PO)	Static (Only Single PO Is Issued)	Dynamic (Flexibility Of 2nd PO)	Static	25% Flexibility For Q Maintained
Scientific Consumption/ Inventory Forecasting	Yes (Inventory Management Software)	No	Yes (Inventory Management Software)	No	No
Flexibility For Facilities To Alter Indent	Yes (Just Before Dispatch)	No	Yes	Yes	No
Tracking Dispatched/ Delivered Drugs	Currently Passbook (Volume Based; Online In Future)	No Tracking	Passbook (Value Based)	N/A	No
(Scientific) Inventory Management At Facility	No (Online In Future)	No	Use First in First Out (FIFO) principle	No	No
Penalty					
Penalty For Supply Schedule Default	10% Of The Unexecuted Supply; Unexecuted Supply Purchased At The Cost Of Supplier In Case Of Inability To Supply	N/A	0.5% per day to maximum of 15% of the tender amount		Which Unexecuted S Purchased At The C Supplier
Penalty For Quality Failure	Supplier Blacklisted With Forfeiture Of Security Deposit	Suppliers Have To Replace The Entire PO Quantity Or Risk Blacklisting	Supplier Blacklisted With Forfeiture Of Security Deposit	Forfeiture Of EMD	Supplier Blacklisted Forfeiture Of Secu Deposit
Blacklisting Criteria	Defaulting On 3 POs Or More With Less Than 50% Supply, Blacklisted By Any Other Procurement Agency On Quality Grounds	Quality Failure After Material Supply	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Defaulting Continuously on 3 POs With Less Than 50% Supply, Quality Failure, Blacklisted By National Or Other State Level Agencies	Supply Default Af Extension Period, Q Failure
IT Enablement Processes:					
Demand Estimation & Forecasting	Yes	No	Yes		

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Tendering Process	Yes	No	Yes	No	Yes
Quality Control		No	Yes		
Payment Disbursement	Yes	No	Yes		
Inventory Management (Warehouse)	Yes	Yes	Yes	No	No
Inventory Management (Facility)	No	No	Yes	No	No

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Annexure 2

Name of Drug	Dosage	Unit	Price (INR)				
			Kerala 2012	Tamil Nadu 2012	Odisha 2009	Maharashtra 2011	Punjab 2010
Adrenaline	1mg/1 ml	Ampoule	2.89	1.21	1.46	1.80	n/a
Albendazole	400 mg	Tablet	0.81	0.57	0.49	0.61	0.64
Aminophylline	25 mg/ml	Ampoule	n/a	2.60	2.91	4.90	n/a
Amitriptyline	25 mg	Tablet	0.22	0.15	0.15	0.19	n/a
Amlodipine	5 mg	Tablet	0.16	0.06	0.09	0.10	0.13
Atenolol	50 mg	Tablet	0.125	0.11	0.13	0.14	0.14
Benzyl Penicillin	10 Lakh IU	Vial	3.68	3.08	4.20	4.88	n/a
Carbamazepine	200 mg	Tablet	0.59	0.54	0.42	0.53	n/a
Cefotaxime	250 mg	Vial	4.73	3.94	5.40	5.14	n/a
Ciprofloxacin	500 mg	Tablet	1.09	1.04	0.87	1.07	1.86
Co-trimoxazole	40mg+ 200mg per 5ml	Bottle	n/a	5.91	5.90	6.74	n/a

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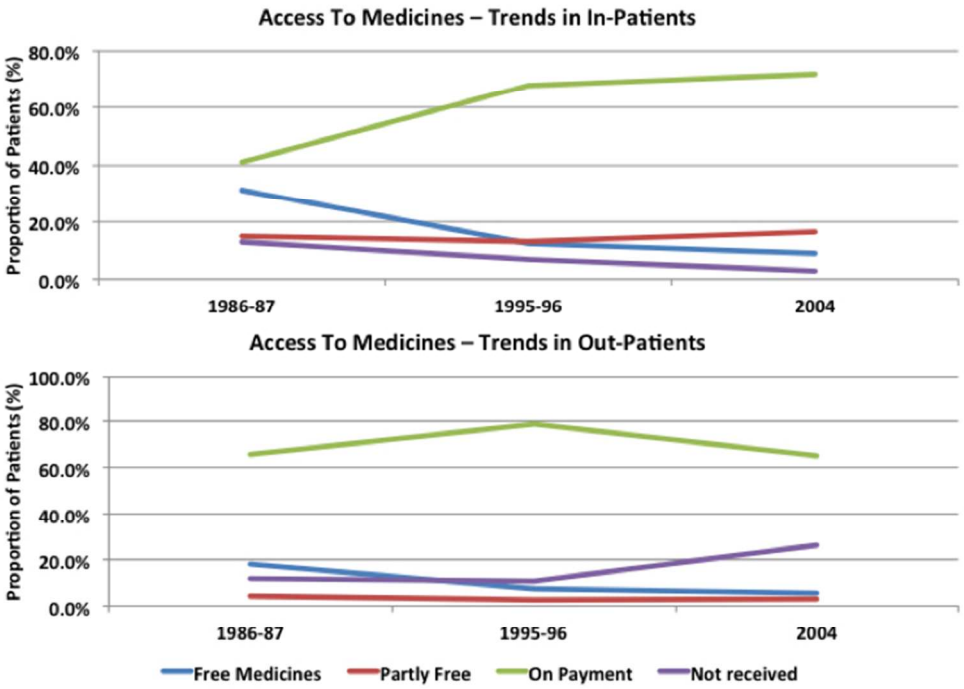
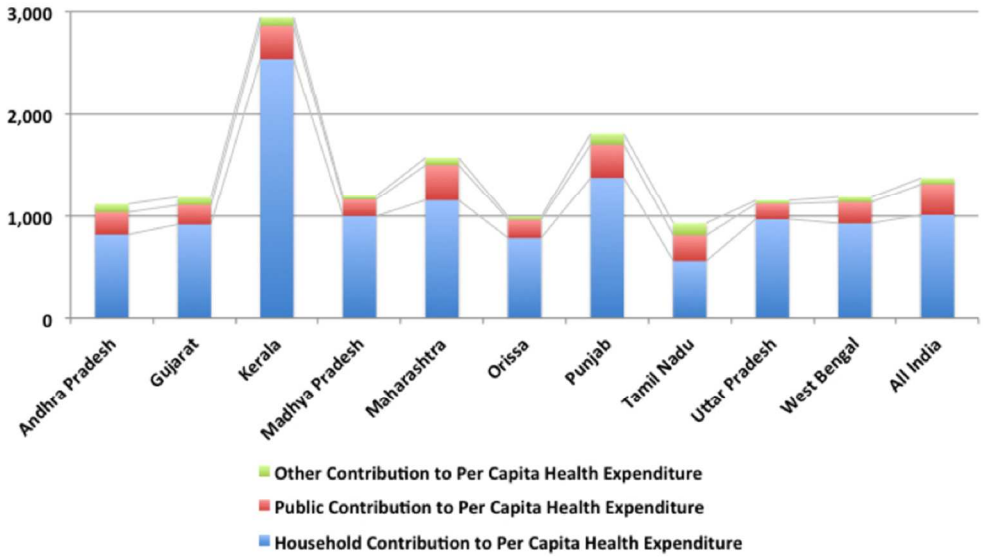


Source: Health data extracted from National Sample Survey Rounds 60, 52, and 42



Source: Report of National Commission on Macroeconomics and Health, GOI 2005

Overall	• *Legal Status of the Procurement Organization; Drug Procurement Budget; Per Capita Drug Procurement Budget;*
Essential Drug List	• *EDL Customization; EDL Committee Composition; Frequency of EDL Revision; Time for EDL Preparation/ Revision; EDL Categorization; Third Party Review of EDL*
Demand Estimation & Forecast	• *Demand Estimation Process; Frequency of Demand Estimation; Methodology for Estimation (Facility Level)*
Procurement Process	• *Procurement mechanism in the state; Financing of Drug Procurement; Emergency Drug Budget Allocation; Bidding Process*
Prequalification Criteria	• *Min. Turnover Criteria; GMP/WHO-GMP/US-FDA; ISI/BIS/ISO/CE; Assurance of avbl. Production Capacity; Market Standing; Exclusion Criteria; Price Relaxation; Product Reservation; EMD (%); Tenders with no bidders; Supply Schedule*
Quality Control	• *External Quality Testing Of Every Consignment; Testing Before Distribution; Testing Before Distribution*
Payment Mechanism	• *Payment Department Status; Lead Time For Payment; Prerequisites For Payment Disbursement*
Inventory Management & Distribution	• *Facilities Per Warehouse; Scientific Warehousing Practices; Supply Chain Management; Inventory Management; Scientific Forecasting; Flexibility to Alter Indent; Tracking dispatched drugs; Scientific inventory Mgmt. at Facility*
Penalties	• *Supply Default; Quality Failure; Blacklisting Criteria*
IT Systems Enablement (of)	• *Demand Estimation & Forecasting; Tendering Process; Quality Control; Payment Disbursement; Inventory Management (Warehouse); Inventory Management (Facility)*