PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Understanding public drug procurement in India – A comparative study of five Indian states
AUTHORS	Singh, Prabal; Tatambhotla, Anand; Kalvakuntla, Rohini; Chokshi, Maulik

VERSION 1 - REVIEW

REVIEWER	Subramanian, S V Harvard School of Public Health, Department of Society, Human Development and No conflicts of interest. However, I am strong believer in double blinded review process.
REVIEW RETURNED	12-Sep-2012

GENERAL COMMENTS	Overall: • The paper is topical and interesting, especially in highlighting how diverse and state-specific the health delivery system in India is, and how much state context matters for health indicators. • The paper needs restructuring overall, and clarity on methods and results. • The authors assume that international audiences are familiar with the Indian health system, and need to reference/footnote any terms that are specific to India. • The authors have defined an ideal drug procurement system as one that is affordable. In other places, they say that drugs need to be free of cost. I think there is a difference in this, and it is unclear what drugs being affordable means. Methodology: Requires more detail and clarity – • Tools used for primary research, • Naming the databases for secondary research • What grey literature was searched and how • What statistical techniques (if any, used for assessment) Comments: • Annexure 1 and 2 seem to be Results. Results and discussion are merged and need separation. Current Results & Discussion section seems like Discussion. • Description of the exhibits provided would be useful. In Exhibit 1, the description focuses on free medicines but trends highlight – free, partly free, on payment and not received. More information on these categories as a footnote would be useful. • Exhibit 2: unclear if the better off states are paying more – can this

	figure be provided in % to highlight the comparison. • Exhibit 3 and 4 may be combined. It is important to note and highlight that the five states chosen have different 1) political systems, 2) are at different points in industrialization (vs agrarian systems) 3) development indicators, demographic and epidemiological transitions. Some of this comes across in the table through % of urban population, birth and death rates (Odisha is far behind the others), but may need highlighting. • Exhibit 4 – full forms of PHCs, CHCs, as footnote at the end of the table. • It is worth thinking about how the development indicators of these states have impacted 1) the drugs needed by the states; – (page 8) discusses how some states consider 260 drugs in their essential drug list and others have considered 1850; 2) the human resource and technical capacity to create and have functional systems in place to run procurement systems. • While the abstract mentions collection of data from hospitals, it is unclear what data was collected and how. It seems that this refers to drug price data in annexure 2, and would be useful to have clarity. • Abstract indicates interesting correlations – but much of this is qualitative, and no indicator to look at correlation or association. • Even though this is the first study on drug procurement (as authors state), it seems that centralized systems work better than decentralized; autonomous systems work better than those entrenched in government bureaucracy, and Kerala and TN are ahead of other states. Useful to state the authors' conclusions clearly. Abstract: • Should be rewritten as Intro, Methods, Findings, Discussion – for greater clarity. • Mentions 1 hospital in each state – unclear how this would be representative of the state context. • Secondary datasets should be named.

REVIEWER	Prashant Yadav Director of Healthcare Research WDI, University of Michigan USA No competing interests
REVIEW RETURNED	17-Oct-2012

GENERAL COMMENTS	**Recommendation: Accept with MAJOR Revision** **Background** The authors study the public drug procurement models of 5 states in India and highlight the commonalities and differences. The problem they study is interesting, relevant and has implications for policy makers. However, the data is not analyzed to generate insights that are rigorous and can be used for large scale policy use. Appropriate modifications and revisions are required before this paper is deemed fit publication in BMJOpen. **Major Comments on the paper** The logical linkages between the categories of parameters measured, the prerequisites (leadership, technical capability, and information technology), and the objectives (transparency, low financial burden, waste elimination, quality, availability) are not

	adequately explained. A logical framework that starts with the prerequisites and then shows how each parameter relates to each objective is crucial to develop. In the absence of that it is hard to understand how each parameter impacts the objectives. The narratives on p7-9 attempt to do that but are not comprehensive for each category of parameters, neither are they concise. I recommend a precise but comprehensive framework to explain this. There needs to be a discussion on tradeoffs between the different objectives i.e. the tradeoff between financial burden and quality, or the tradeoff between waste elimination and availability etc. need to be adequately explained. Examples from the five states on how they manage these tradeoffs are also important to include. Availability: The primary purpose of such models is to make the drugs available upto the lowest level of the health system. The authors have no discussion on availability, neither do they comment on which model performs better on availability. Without that information other performance metrics become moot or secondary. An agency can achieve low financial burden, low wastage, and high quality without making drug sufficiently available. This will also put some more clarity into the distribution models used by the five states studied. Exhibit 6 puts transparency at the center as compared to other objectives. It is hard to understand what drives that. Research shows that transparency, especially pertaining to medicine prices, in some instances hurts the system. See for example Danzon and Towse 2 (2002), Kyle and Ridley (2007) for the unintended negative consequences of price transparency. The article mentions that for predominantly central procurement models it is imperative to have an optimum number of warehouses but does not provide any more details on this. How many tiers of warehousing are needed? State depot>>direct to clinics or state depot>>district depot>>clinics. Currently, it is unclear how many tiers exist in which state and what are the implications of that? P4 Line 26: The authors state that “Strengthening the public sector availability of quality drugs will relieve a large number of people…”. Is strengthening public sector availability the only way? The authors do not mention of any other arrangement that could help this. While their focus is on this particular way, in the problem background it should be described how this fits with other methods. OECD countries generally do not have a public sector model for procuring and distributing drugs and yet the out of pocket catastrophic expenses are low because of public or private insurance. So why can’t there be models like the SUS Farmacia system in Brazil or in Jordan or many other countries where the government pays private retail pharmacies instead of creating a public system. Putting this in the right context instead of phrasing as if this is the only way to address the problem is important in an academic journal article. P8 line 20: In describing prices the authors seem to assume that price and volume are necessarily correlated. Many streams of research show that is not the case. See for example Waning et al (2008) which shows that volume effects on price paid for pharmaceuticals for HIV/AIDS are insignificant. Quality: It is unclear what is tested in the external or internal laboratories? API content? API presence? Using what methods?

	Similarly, it is not clear what type of GMP standard is used? c-GMP, ICH Q7?, or Indian Schedule M. Delhi Drug Procurement model also should be compared with the ones in the paper. Chaudhary et al 2005 (Health Policy and Planning Mar 2005) provide a good overview. Conclusions: There are no clear conclusions in the paper. The authors say critical success factors need to be carefully evaluated before replicating. At the very least the authors should provide detail on what type of factors should be examined? The learnings are very rich to draw inferences on the factors that are more important. **Minor comments** Exhibit 2: the units should be included on the Y axis too, currently they are only in the figure title. P8 line 11: "Finally drug price:.." The writing style here is informal 3 P8 line 25: "..But perhaps.." The sentence ends with a question mark and again reflects informal writing style. Literature review on TNMSC is not comprehensive. There are other publications examining the Tamil Nadu model.

VERSION 1 – AUTHOR RESPONSE

Methodology:

Requires more detail and clarity –
• Tools used for primary research,
• Naming the databases for secondary research
• What grey literature was searched and how
• What statistical techniques (if any, used for assessment)

All the above comments have been addressed.

Comments:
• Annexure 1 and 2 seem to be Results. Results and discussion are merged and need separation. Current Results & Discussion section seems like Discussion. -
Addressed
• Description of the exhibits provided would be useful. In Exhibit 1, the description focuses on free medicines but trends highlight – free, partly free, on payment and not received. More information on these categories as a footnote would be useful. -

Irrelevant to the discussion

• Exhibit 2: unclear if the better off states are paying more – can this figure be provided in % to highlight the comparison. -

Addressed

• Exhibit 3 and 4 may be combined. It is important to note and highlight that the five states chosen have different 1) political systems, 2) are at different points in industrialization (vs agrarian systems) 3) development indicators, demographic and epidemiological transitions. Some of this comes across

in the table through % of urban population, birth and death rates (Odisha is far behind the others), but may need highlighting. -

Authors do not think that some of the parameters will have an impact but have written a line to highlight the point on industrialization.

• Exhibit 4 – full forms of PHCs, CHCs, as footnote at the end of the table. -
Addressed

• It is worth thinking about how the development indicators of these states have impacted 1) the drugs needed by the states; – (page 8) discusses how some states consider 260 drugs in their essential drug list and others have considered 1850; 2) the human resource and technical capacity to create and have functional systems in place to run procurement systems.

- irrelevant because authors state that decentralized systems have 1850 without giving thought to local disease burden/ patterns

• While the abstract mentions collection of data from hospitals, it is unclear what data was collected and how. It seems that this refers to drug price data in annexure 2, and would be useful to have clarity.

- Addressed

• Abstract indicates interesting correlations – but much of this is qualitative, and no indicator to look at correlation or association.

- Addressed

• Even though this is the first study on drug procurement (as authors state), it seems that centralized systems work better than decentralized; autonomous systems work better than those entrenched in government bureaucracy, and Kerala and TN are ahead of other states. Useful to state the authors' conclusions clearly.

- Addressed

Abstract:
• Should be rewritten as Intro, Methods, Findings, Discussion – for greater clarity.

- Addressed

• Mentions 1 hospital in each state – unclear how this would be representative of the state context.

- Addressed

• Secondary datasets should be named.

- Addressed

Prashant Yadav's comments:

Background
The authors study the public drug procurement models of 5 states in India and highlight the commonalities and differences. The problem they study is interesting, relevant and has implications for policy makers. However, the data is not analyzed to generate insights that are rigorous and can be used for large scale policy use. Appropriate modifications and revisions are required before this paper is deemed fit publication in BMJOpen.

Response

- The authors agree that there has been a misrepresentation of the intention behind the paper. It is not intended to be a policy piece but an initial/ rapid qualitative assessment to identify/ frame key research questions. So many of the comments made below would be invalid. The authors have addressed some of them but would like the reviewer to view it again in the light of this new revision.

VERSION 2 – REVIEW

REVIEWER	S V Subramanian HSPH
REVIEW RETURNED	25-Nov-2012

- The reviewer completed the checklist but made no further comments.