Medicine and Society

Essential medicines for cardiovascular diseases in India: Rapid appraisal of policies and processes at the subnational level

ANKUR GARG, ADRIANNA MURPHY, ASHISH KRISHNA, SWAGATA KUMAR SAHOO, MARK D. HUFFMAN, SANDEEP P. KISHORE, ROOPA SHIVASHANKAR

ABSTRACT

Background. The burden of cardiovascular diseases (CVDs) and response to health systems vary widely at the subnational level in India. Our study aimed to assess the variation in state-level access to medicines for CVDs by comparing the essential medicines lists (EMLs) at the national and subnational levels in India and by rapid appraisal of the existing policies and processes of drug procurement.

Methods. We assessed the inclusion of six classes of medicines for CVDs in the recent and publicly available national and subnational EMLs from July to September 2018 in the states of Telangana and Madhya Pradesh. We examined the drug procurement and distribution policies and processes using documentary review and five key informant interviews between March and June 2018.

Results. The WHO's EML, India's national EML, and 21 of 28 publicly available (75%) Indian state and Union Territory EMLs included all six classes of essential medicines for CVDs. However, some medicines were not included in the policy packages of essential medicines meant for primary health centres. Both the states used centralized tendering and decentralized distribution as part of the public sector drug procurement process. The requirement was based on the previous year's consumption. The approximate time between procurement planning and distribution was 7–8 months in both the states.

Conclusion. Substantial variation exists in the selection of drugs for CVDs in EMLs at the subnational level in India. Improving forecasting techniques for requirement of medicines and reducing time lags between forecasting and distribution to health facilities may allow for better access to essential medicines.

Natl Med J India 2022;35:357–63

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[**To cite:** Garg A, Murphy A, Krishna A, Sahoo SK, Huffman MD, Kishore SP, *et al*. Essential medicines for cardiovascular diseases in India: Rapid appraisal of policies and processes at the subnational level. *Natl Med J India* 2022;**35**:357–63.]

INTRODUCTION

WHO's Global Action Plan has set a goal of ensuring the availability and affordability of essential medicines to 80% of people with cardiovascular diseases (CVDs) in both public and private sector facilities by 2025.[1] Achieving this goal requires vital policy elements that ensure the rational selection of medicines, sustainable financing and reliable supply systems to provide safe, effective and available medication.[2] CVDs are the leading cause of mortality worldwide, with 80% of premature deaths due to CVD occurring in low- and middle-income countries.[3] In India, CVDs account for 28% of the country's mortality.[4,5] Yet, only 25% of rural and 38% of urban Indians use blood pressure-lowering medications.[6] Irregular, infrequent or non-availability of essential medicines for CVDs is common in public healthcare facilities of India.[7,8] There is low accessibility to essential medicines for CVDs in public healthcare facilities in the country. Health is a state subject in India; hence drug procurement and policies and processes of distribution vary widely between states.

Public health programmes are financed and implemented at the subnational level in 29 states and 7 Union Territories with assistance from the Central Government.[9,10] While India has a national list for essential medicines, states and Union Territories have their essential medicines list (EML) based on the burden of disease in the region. The subnational EMLs, drug procurement and distribution policies vary widely from each other, eventually influencing access to drugs.[11,12]

We hypothesize that a better understanding of the processes that underlie access to essential medicines, and potential barriers to ensuring affordable access, can inform policy reform for progress towards the goal of WHO's Global Action Plan. This study aims to assess the policy processes of drug procurement of the public sector and selection of medicines for CVDs in the national and subnational EMLs.

Our work is guided by the WHO's framework for Equitable Access to Essential Medicines.[2] This framework outlines the policy elements involved in ensuring that essential medicines

are available and affordable to all the population. It includes rational selection and use of medicines and a reliable supply system.

METHODS

Rapid appraisal of the existing drug procurement and distribution policies of the public sector and processes in Telangana and Madhya Pradesh

We used the rapid appraisal (RA) approach to identify factors affecting variations in state-level access to medicines for CVDs, with a focus on procurement and distribution of essential medicines in two states of India—Madhya Pradesh (low income) and Telangana (high income).

These states were chosen based on convenience to the researchers. The RA approach involves collection and triangulation of multiple data sources to provide an understanding of a situation in a more timely and cost-effective manner than standard social research methods, and to seek a diverse range of perspectives, without aiming for statistical precision.[13] Triangulation provides internal validity and reliability of the data collected,[14] and these data can then be used to develop specific healthcare interventions.[13,14] RAs have previously been used for understanding health system performance for non-communicable diseases (NCDs) such as diabetes[14–16] and hypertension.[16,17]

From March to June 2018, we reviewed publicly available documents related to drug policies, procurement guidelines, EMLs and evaluation reports of the two states. The list of the documents reviewed is given in Supplementary Table I. The documents were obtained from the web portals of drug procurement cells of Telangana and Madhya Pradesh (MP) and peer-reviewed literature databases (including studies regarding the procurement of medication and distribution system at the national and subnational levels) to assess the variations in drug procurement systems in the country. We defined 'forecasting' as the process of estimating drug requirements at the facility level for a given period of time (usually one year). Data on

TABLE I. Medicines for cardiovascular diseases made available at different levels of healthcare facilities in Telangana and Madhya Pradesh as mentioned in the essential medicines lists

| Class | Drugs | Medicines provided at health centres | | | | | | | | |
| | | Primary care* | | | Secondary care† | | | Tertiary care§ | | |
		National	Telangana	Madhya Pradesh	National	Telangana	Madhya Pradesh	National	Telangana	Madhya Pradesh
ACE-inhibitors/ ARBs	Enalapril	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
	Ramipril	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes
	Losartan	No	No	No	No	Yes	No	No	Yes	No
	Telmisartan	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Any ACE-inhibitor or ARB		Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Beta blockers	Atenolol	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Esmolol	No	No	No	No	No	No	Yes	Yes	No
	Labetalol	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes
	Metoprolol	Yes	No	No	Yes	Yes	No	Yes	Yes	Yes
	Propranolol	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes
	Timolol	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
	Betaxolol hydrochloride	No	No	No	No	Yes	No	No	Yes	No
Any beta blocker	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Statins	Atorvastatin	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Rosuvastatin	No	No	No	No	No	No	No	Yes	No
	Simvastatin	No	No	No	No	No	No	No	No	No
Any statin	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Aspirin	Acetylsalicylic acid	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Thiazide or thiazide-like diuretics	Chlorthalidone	No	No	No	No	No	No	No	Yes	No
	Hydrochlorothiazide	Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Any thiazide or thiazide-like diuretic		Yes	No	No	Yes	Yes	Yes	Yes	Yes	Yes
Loop or	Spironolactone	Yes	No	No	Yes	Yes	No	Yes	Yes	No
potassium- sparing diuretics	Furosemide	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Any loop or a potassium- sparing diuretic		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

* Primary healthcare facilities include subcentres, primary health centres and urban health centres   † Secondary healthcare facilities include community health centres, area hospitals and urban dispensaries   § Tertiary healthcare facilities include district hospitals, civil hospitals, teaching hospitals, and advanced and super-specialty hospitals[19,20]   ACE angiotensin-converting enzyme   ARB angiotensin receptor blocker

indicators for procurement and distribution mechanisms, payment mechanisms and quality control were collected by AG and transferred into a Microsoft Excel spread sheet, and the data were double checked by RS. The template for the document review was based on a previously published study which compared procurement policies of five Indian states.[12] These indicators reflected the procurement cycle: policies, forecasting mechanisms, tendering process, supply chain management, quality control, distribution systems and payment mechanisms.

From April to May 2018, we performed five key informant interviews (three in Telangana and two in MP who were approached through existing networks) of the officers at procurement cells and the staff at the drug warehouses to understand processes that were not in the documents. Our sample includes both the officials from the procurement cells, managing the process from indenting to distribution, and drug warehouse officials, responsible for maintaining stocks and supply of medicines to the clinics. We provided the study information sheet and received verbal consent from officers to carry out the interviews.

The indicators set in the document review and preliminary results from the documents were used to inform the topics for the interview guide in Telangana. The preliminary results from interviews and document review from Telangana informed the interviews in MP. The guide had three sections—general information about EML, current procurement and distribution process and details on essential medicines for CVDs.

The interviews were conducted in English by RS at Hyderabad (Telangana, $n=3$) and in Hindi by AG at Bhopal (MP, $n=2$) at the workplaces of participants. RS is a trained qualitative researcher, and AG received training in qualitative interviewing techniques. The interviews in Telangana were audio-recorded, and AG took notes and transcribed the audio recordings. In MP, the interviewees did not give consent for recording. Therefore, AK took notes during the interview. The interview notes in Hindi from Bhopal were translated to English and then back-translated to Hindi by AG.

The ethics committee of the Centre for Chronic Disease Control (Delhi) approved the study.

Comparison of national/subnational essential medicines lists with WHO's essential medicines list

We searched for national, state ($n=29$) and Union Territory ($n=7$) medical services corporation's online portals of individual states/Union Territories for EMLs between July and September 2018. From the most national and subnational EMLs, we extracted information on the total number of all and essential medicines for CVDs and compared them with WHO's EML for 2017.[18] We checked whether the EMLs included the following six classes of medicines for CVDs: (i) angiotensin-converting enzyme inhibitors (ACE-I)/angiotensin receptor blockers (ARB); (ii) aspirin; (iii) beta-blockers; (iv) loop or potassium-sparing diuretics; (v) statins; and (vi) thiazide or thiazide-like diuretics as these are the most common medicines for CVDs used in India and globally.[19]

We assessed whether the number of classes of essential medicines for CVDs varied by the Empowered Action Group (EAG) status. EAG states are high-focus states for social development, as defined by the Government of India.[20] We used Chi-square test at 5% significance to evaluate whether the presence of these six classes of medicines in the EML of the states varied by EAG status using Stata SE 12 software.

Data analysis

We used the framework analysis[21] to summarize and triangulate data from documentary review and key informant interviews. The study was informed by the WHO framework for access to medicines,[2] which helped in deriving codes *a priori*. Broad themes (e.g. general structure and functions of EML and EML committees, procurement, forecasting, supply chain and distribution processes, quality control and assurance procedures and budget) were generated from the framework and further refined using themes identified from the interviews. The themes and the data obtained were written in a descriptive manner and triangulated with the data obtained from document analysis. The qualitative data are not presented as quotes, but the findings have been incorporated within the RA descriptions. Interview recordings and notes were coded using qualitative data software, Open Code v4.02, University of Umeå, Sweden.

RESULTS

Rapid appraisal of existing public sector drug procurement and distribution policies and processes in Telangana and Madhya Pradesh

Telangana, which separated from Andhra Pradesh in June 2014, is a non-EAG state with 31 districts and a population of 35 million.[22] The State Health and Family Welfare Department provides health services at the health facilities under the Department of Public Health, Vaidya Vidhana Parishad and Medical Education Department.[23] Telangana State Medical Services Infrastructure and Development Corporation (TSMSIDC), an autonomous organization, is responsible for the procurement and distribution of essential medicines and equipment to the public healthcare facilities.[24]

MP was formed in 1950 and is an EAG state with 52 districts and a population of 73 million.[25] The Directorate of Health Services under the State Health and Family Welfare Department is responsible for all health policies and health services, including drug distribution in the state.[26] The MP Public Health Services Corporation Limited (MPPHSCL) procures essential drugs and equipment.[27]

Essential medicines lists

In both Telangana and MP, the EML is expected to be updated every 2 years (document review).[28,29] The state officials informed during the interview that a new EML committee is formed every 2 years under the leadership of the state health department and consists of experts in various medical specialties. However, EML updates may be delayed due to practical difficulties in convening multiple medical experts (key person interviews). The latest EMLs in Telangana (2015)[28] and MP (2018)[27] included 557 and 361 medicines, respectively (document review).

EMLs of both states included all six classes of drugs for CVDs. During interviews, we learnt that the EMLs were further stratified as per the level of healthcare facilities to which any particular drug was supplied. Using this unit of analysis, only a subset of drugs for CVDs on both EMLs was available at the primary healthcare level (Table I).

Forecasting, procurement and distribution of essential medicines for CVDs

The information on forecasting, procurement and distribution was obtained during the key person interviews and supplemented or confirmed by documentary reviews.

In both states, essential medicines for CVDs are procured in the general drug procurement system. The funds for medicines from the National Programme for Control of Diabetes, CVDs, Cancers and Stroke (NPCDCS) are pooled along with the state pool of general medicines. The autonomous corporations, TSMSIDC and MPPHSCL, have employed an IT-enabled platform since 2015 for the entire procurement process—from indenting to placing orders—which is known as e-Aushadhi in Telangana[24] and MP-Aushadhi in MP.[27]

Table II compares the pattern of forecasting, procurement and distribution of essential medicines for CVDs in Telangana and MP. The data on the variables are provided by both review of existing state-level documents and key informant interviews. In both the states, the forecasting of annual drug requirements is undertaken before the beginning of the financial year and is based on the consumption from the previous year. In Telangana, each health facility estimates annual requirements, while in MP, forecasting is done at the state level.

When purchase orders are placed by the state corporation (Telangana) or district health officers (MP) for procurement, suppliers send medicines to district warehouses in both states (10 in Telangana and 27 in MP[30]). Both the states send random samples to the National Accreditation Board for Testing and Calibration Laboratories for external quality testing. The medicines received at the drug stores in both states are quarantined until quality testing is completed before being added to the usable stock.

Healthcare facilities in both states are expected to maintain a 3-month buffer stock of medicines to prevent stock-outs. Healthcare facilities in need of medicines submit their requests to the medical services. A system of diversion of medicines also exists in both states, facilitated by their e-Aushadhi portals, where the medicines from one facility, having unused or excess medicines, can be shifted to another facility in need of those medicines.

In both the states, the total time required from forecasting to drug distribution is estimated to be between 7 and 8 months.

Comparison of Indian national/subnational EMLs with WHO's EML

The Indian national EML was updated in 2015 (Fig. 1). Among 29 Indian states and 7 Union Territories, we could not identify publicly available EMLs from three states (Goa, Jharkhand and West Bengal) and five Union Territories (Andaman and Nicobar Islands, Chandigarh, Dadra and Nagar Haveli, Daman and Diu and Lakshadweep). The publicly available subnational EMLs were updated between 2012 and 2018. For the states of Arunachal Pradesh, Jammu and Kashmir, Meghalaya and Uttar Pradesh, we could not obtain information on the date of the EML's latest update.

The WHO and Indian national EML had 433 and 376 medicines, respectively. The number of medications on state- and Union Territory-level EMLs varied from as low as 153 medicines in Manipur to as high as 1390 medicines in Delhi (Fig. 1).

All six classes of medicines for CVDs were present on the WHO, India's national and 21 (75%) available EMLs at the subnational level (58% of total states/Union Territories). ACE-I/ARBs, beta-blockers and loop or potassium-sparing diuretics were present in all the EMLs at the subnational level. Aspirin was present in 27 (96%) available EMLs, and statins were included in 23 (82%) of the available EMLs (Fig. 2). The selection of essential medicines for CVDs into the EML did not differ significantly by EAG status (p=0.45). Many northeastern states (e.g. Arunachal Pradesh, Bihar, Mizoram, Nagaland and Sikkim)

TABLE II. Comparison of the public sector drug procurement and distribution system in Telangana and Madhya Pradesh

| Indicator	Telangana	Madhya Pradesh
Essential medicines list (EML)		
Number of drugs in EML	557	361
All six classes of drugs for secondary prevention of cardiovascular diseases (CVDs) present	Yes	Yes
Target frequency of updating EML (years)	2	2
Year of last EML update	2015	2018
Drug procurement mechanism		
Procurement type	80% centralized (state level) 20% decentralized (facility level)	100% decentralized (facility level)
Rate contracts	At the state level	At the state level
Rate contract—duration of validity (years)	2	2
Forecasting and procurement		
Point of procurement	State: one procurement unit	Districts: 136 procuring units
Annual indenting process	Fresh indents from individual facilities	Based on previous years' consumption data at the state level
Medicine forecasting process	All drugs estimation is received from health facilities through e-portal	Current drugs: estimated using previous years' data at the state level. New drugs: estimates provided by health facilities
Information technology (IT) enablement of the tendering process	Yes	Yes
Monitoring the process of stock position	Tracked in management information system by state authority	By authorities at the district level through the management information system (MIS)
Supply		
Supply schedule	45–90 days from the date of order	Within 60 days from the date of order
Distribution		
Distribution mechanism	Decentralized: from district warehouses to health facilities	Decentralized: from district warehouses to health facilities
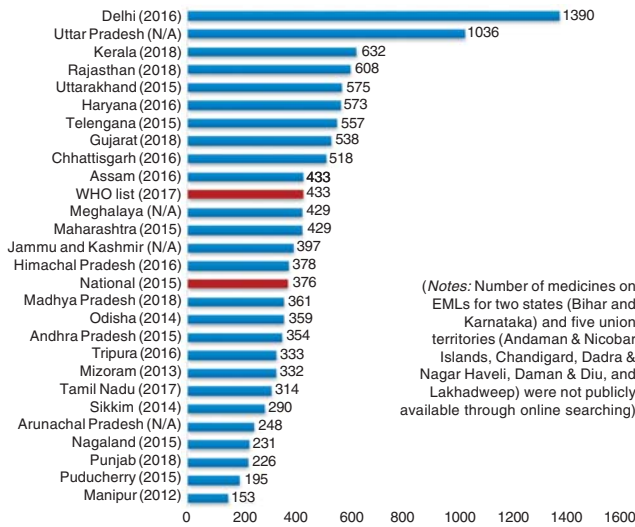
FIG 1. Comparison of number of medicines in the publicly available latest essential medicines list of Indian states and Union Territories to Indian national and WHO's essential medicines list
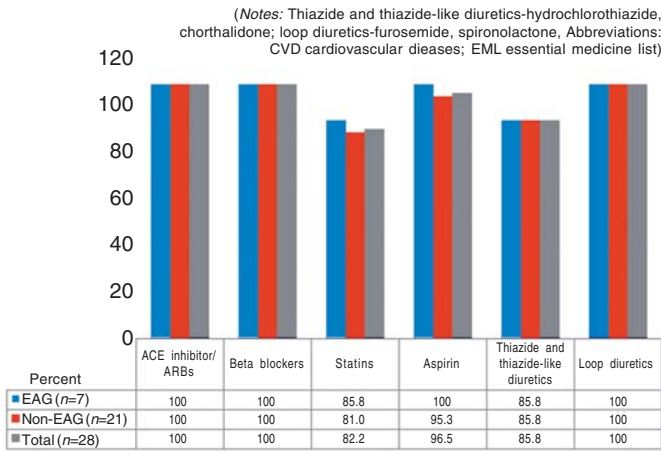

FIG 2. Proportion of Indian states and Union Territories having cardiovascular disease medicine classes in essential medicines list; Comparison across Empowered Action Groups versus Non-Empowered Action Groups

TABLE III. List of states or Union Territories missing any of the selected six classes of medicines for cardiovascular diseases in their essential medicines list (*n*=28)

Medicine category	States missing the medicines
Angiotensin-converting enzyme inhibitors/angiotensin receptor blockers	None
Aspirin	Arunachal Pradesh
Beta-blockers	None
Loop or potassium-sparing diuretics*	None
Statins	Arunachal Pradesh, Bihar, Mizoram, Nagaland and Sikkim
Thiazide and thiazide-like diuretics†	Arunachal Pradesh, Bihar, Puducherry and Tamil Nadu

* These include exemplars such as furosemide, spironolactone † For example, hydrochlorothiazide and chlorthalidone. The essential medicines lists for Goa, Jharkhand and West Bengal were not publicly available, thus are not included in the study.

did not have statins on their EML (Table III). Statins, thiazide and thiazide-like diuretics were absent in Bihar and Arunachal Pradesh. At the same time, Arunachal Pradesh also did not include aspirin in addition to statins and thiazide and thiazide-like diuretics.

DISCUSSION

A large amount of work has been done at the global level to study the status of availability and accessibility of essential medicines.[31,32] The selection of medications in the EML has been generally looked at the global and national levels.[33,34] However, this is one of the few studies to document the variability in the selection of medicines for CVDs in EMLs and describe the drug procurement processes at the subnational level in India.[31,34] This study highlights several crucial issues related to EML and drug procurement in two states of India.

First, the presence of a drug in the national EML does not ensure their inclusion in the EMLs at the subnational level. For example, high serum cholesterol is a leading risk factor for CVDs,[4] yet 18% of EMLs at the subnational level did not include statins. Further, due to the sub-stratification of EMLs based on the levels of health facilities, availability of essential medicines for CVDs at different levels of health facilities was variable. Thus, the presence of medicine in the state EML does not ensure its availability at the primary care level as seen in the in-depth analysis of two states in this study.

Second, the current method of forecasting of medicines in Telangana and MP is based on the pattern of previous consumption. While the consumption data method might be considered one of the simplest in forecasting, it largely depends on a reliable source of data from health facilities.[35] The clinics may not be empowered with appropriate equipment for accurate estimations, which contributes to the stock-outs or shortages. Stock-out or shortage of one drug influences prescribing patterns where less preferred drugs may be prescribed. Further, the consumption method does not consider the changes in protocols and guidelines or the increasing burden of the disease in the population. Sole reliance on this method may perpetuate insufficient access or even irrational use of medicines, and irrational and ineffective prescriptions.[35,36] This problem is particularly of concern for medicines for CVDs. Population-based screening for NCDs is being carried out in India under the NPCDCS, and thus, the number of patients to be treated for CVDs is expected to increase rapidly.[37] Further, healthcare providers are being trained for appropriate management of CVDs,[38] and thus, the prescription pattern is likely to change and therefore would need better forecasting of required drugs.

Third, our findings also suggest that resource allocation within state-level healthcare facilities is unequal with minimal availability at the primary care level.[39,40] While efforts are being made to shift CVD care to primary healthcare level, lower availability of medication at primary care will prevent patients from seeking care at this level. As a result, usage of these medicines by the population will likely remain low, and these consumption data, in turn, will feed into the forecasting cycle and potentially make future predictions even less accurate. Hence, a better system of forecasting that takes into account stock-outs and lead time in the entire procurement process is needed to generate more accurate estimates of the requirement of medicines.

Fourth, the decentralized procurement in MP has relative advantages and disadvantages compared to a more centralized

procurement process in Telangana. Decentralized procurement provides higher autonomy for districts to decide on the quantity and timing of procurement. However, the decentralized system needs a large-scale capacity building of decision-makers at the district level. Lack of skills in decision-makers for procurement may lead to insufficient planning, shortage, stock-outs and even wastages.[41] Besides, multiple procuring units placing the order of medication with highly variable quantity and timing can lead to uncertainty of requirement at the supplier level, which in turn, may affect the production planning and supply of drugs.[12] In the decentralized system, uncertainty in the quantity of procurement, multinodal coordination and delayed payment demotivate potential suppliers leading to low participation in the tendering process and relatively higher drug costs. For instance, despite having half of the population of MP and thus a smaller bulk of total procurement, rate contract for drugs for CVDs can be lower in Telangana such as the costs for 100 tablets of amlodipine 5 mg (Telangana ₹7.95 *v.* MP ₹13.6]). Centralized procurement has been observed to be more efficient, with relatively lower drug procurement prices and more reliable inventory management to reduce drug stock-outs and increase drug availability at service delivery points.[12,41] Telangana's inclusion of a decentralized procurement component (20%) of the state's overall mechanism helps to empower local facilities to purchase some drugs to meet their specific needs.

Finally, we found that the lead time of the procurement cycle in Telangana and MP, which was defined as the time between calling indents to deliver medicines to the users, was relatively long. Lead time is one of the most critical factors that drive procurement process efficiency because it governs the availability of medicines at the health facilities and helps to determine buffer stocks that are needed to avoid stock-outs.[42] Longer lead times result in freezing of capital in the inventory and prevent the system from meeting unpredictable requirements. Furthermore, considerable variations in the lead time, due to delays or issues in the supply chain management, might lead to unnecessary understocking or overstocking (or both) of medicines at the health facilities.[43] A longer lead time requires health facilities to maintain larger buffer stocks of medicines. Hence, reducing the lead time of the procurement cycle and optimizing the process will help in reducing stock-outs and improving medicine availability at the facility level.

While the procurement and distribution systems of the two states were similar, we identified essential differences, which may affect the availability of medicines, such as stratification of EML as per the health facilities, forecasting process and time lag between forecasting and distribution of medicines to the facilities.

Strengths and limitations
Our study is one of the first to document the variability of the selection of medicines for CVDs at the state level and reporting an in-depth situation analysis of the procurement systems using predetermined indicators providing a macro-level evaluation. Another strength of the study is the use of the RA approach to triangulate data from multiple sources (document review and qualitative methods) providing validity and reliability of the data collected. The study has limitations: first, data on the EMLs at the subnational level were captured only from the publicly available portals; second, data on outcome indicators, such as the availability of medicines at the point of purchase by patients, were not collected. However, our upstream evaluation

can help interpret the results of future studies that capture such data. Our work also suggests that future research efforts should be focused on studying the drug procurement processes at the subnational level and its implications on the availability, accessibility and pricing of essential medicines. Future efforts should also focus on strengthening EMLs at the subnational level and the selection process to match disease burden for rational and evidence-informed decision-making. The management of CVDs is also dependent on the screening and diagnostic capacities of the health system. Finally, in addition to the EML, the WHO has created essential diagnostics lists, which include diagnostic tools such as serum cholesterol monitoring and blood pressure measurement devices.[44] These tools were not the focus of this research study and can be pursued in future research efforts.

Conclusion
India is one of the largest producers of generic medicines in the world. All six classes of essential drugs for CVDs are manufactured in the generic version in India, and state-level public health departments can potentially procure them at relatively low costs. Addressing the challenges that we identified in our study, namely listing on EMLs at the subnational level, appropriate forecasting and reducing lead time in procurement may help to ensure that essential medicines required to prevent, treat and control CVDs are available. Our study provides an in-depth analysis of how policies and processes for medication procurement at the subnational level.

Conflicts of interest. None declared

REFERENCES
1 World Health Organization. *Global action plan for the prevention and control of noncommunicable diseases 2013–2020.* Geneva:WHO; 2013:102.
2 World Health Organization. *Equitable access to essential medicines: A framework for collective action.* Geneva:WHO Policy Perspectives on Medicines; 2004:1–6. Available at *http://apps.who.int/iris/handle/10665/68571* (accessed on 16 Jun 2018)
3 World Health Organization. Global Action Plan for the Prevention and Control of NCDs 2013-2020. WHO. Published Online; 2015. Available from: *http://www.who.int/nmh/events/ncd_action_plan/en/* (accessed on 16 Jun 2018).
4 Indian Council of Medical Research, Public Health Foundation of India, and Institute for Health Metrics and Evaluation. *India: Health of the Nation's States: The India State-Level Disease Burden Initiative.* New Delhi, India:ICMR, PHFI, IHME; 2017.
5 India State-Level Disease Burden Initiative Collaborators. Nations within a nation: Variations in epidemiological transition across the states of India, 1990–2016 in the Global Burden of Disease Study. *Lancet* 2017;**390:**2437–60.
6 Anchala R, Kannuri NK, Pant H, Khan H, Franco OH, Di Angelantonio E, *et al.* Hypertension in India: A systematic review and meta-analysis of prevalence, awareness, and control of hypertension. *J Hypertens* 2014;**32:**1170–7**.**
7 Prabhakaran D, Jeemon P, Roy A. Cardiovascular diseases in India: Current epidemiology and future directions. *Circulation* 2016;**133:**1605–20.
8 Newman C, Ajay VS, Srinivas R, Bhalla S, Prabhakaran D, Banerjee A. Drugs for cardiovascular disease in India: Perspectives of pharmaceutical executives and government officials on access and development—A qualitative analysis. *J Pharm Policy Pract* 2016;**9:**1–11.
9 National Mental Health Programme. New Delhi:Directorate General of Health Services Ministry of Health and Family Welfare, Goverment of India; 1982:1–8.

Available at *http://dghs.gov.in/content/1351_3_NationalProgramforPalliative Care.aspx* (accessed on 17 Sep 2018).

10 State Program Implementation Plans (PIPs)—Government of India. Available at *http://nhm.gov.in/nrhm-in-state/state-program-implementation-plans-pips.html* (accessed on 17 Sep 2018).

11 Chokshi M, Farooqui HH, Selvaraj S, Kumar P. A cross-sectional survey of the models in Bihar and Tamil Nadu, India for pooled procurement of medicines. *WHO South East Asia J Public Health* 2015;**4:**78–85.

12 Singh PV, Tatambhotla A, Kalvakuntla R, Chokshi M. Understanding public drug procurement in India: A comparative qualitative study of five Indian states. *BMJ Open* 2013;**3:**e001987.

13 SEX-RAR Guide: The rapid assessment and response guide on psychoactive substance use and sexual risk behaviour; 2002. Available at *http://apps.who.int/iris/bitstream/10665/42681/1/9241545585.pdf* (accessed on 30 Oct 2017).

14 Beran D, Yudkin JS, de Courten M. Access to care for patients with insulin-requiring diabetes in developing countries: Case studies of Mozambique and Zambia. *Diabetes Care* 2005;**28:**2136–40.

15 Beran D, Miranda JJ, Cardenas MK, Bigdeli M. Health systems research for policy change: Lessons from the implementation of rapid assessment protocols for diabetes in low- and middle-income settings. *Health Res Policy Syst* 2015;**13:**41.

16 Balabanova D, McKee M, Koroleva N, Chikovani I, Goguadze K, Kobaladze T, *et al.* Navigating the health system: Diabetes care in Georgia. *Health Policy Plan* 2009;**24:**46–54.

17 Risso-Gill I, Balabanova D, Majid F, Ng KK, Yusoff K, Mustapha F, *et al.* Understanding the modifiable health systems barriers to hypertension management in Malaysia: A multi-method health systems appraisal approach. *BMC Health Serv Res* 2015;**15:**254.

18 World Health Organization. *WHO Model List of Essential Medicines—20th List (March 2017)*. Geneva:WHO; 2017. Available at *www.who.int/medicines/publications/essentialmedicines/en/* (accessed on 16 Aug 2020).

19 Yusuf S, Islam S, Chow CK, Rangarajan S, Dagenais G, Diaz R, *et al.* Use of secondary prevention drugs for cardiovascular disease in the community in high-income, middle-income, and low-income countries (the PURE Study): A prospective epidemiological survey. *Lancet* 2011;**378:**1231–43.

20 Annual Health Survey (AHS) in 8 EAG States and Assam—Release of District Level Factsheet; 2010-11. Available at *www.censusindia.gov.in/vital_statistics/AHSBulletins/files/Final_Press_Release_DLFS.pdf* (accessed on 27 Dec 2018).

21 Srivastava A, Thomson SB. Framework analysis: A qualitative methodology for applied policy research. *J Administration Governance* 2009;**4 (2):**72–9.

22 Government of Telangana. Telangana State Portal. Published 2015. Available at *www.telangana.gov.in/about/state-profile* (accessed on 16 Aug 2020).

23 Department of Health, Medical and Family Welfare, Government of Telangana. Available at *http://health.telangana.gov.in/* (accessed on 24 Nov 2018).

24 Telangana State Medical Services Infrastructure and Development Corporation (TSMSIDC). Available at *www.tsmsidc.telangana.gov.in/eaushadi.php* (accessed on 4 Oct 2018).

25 Government of Madhya Pradesh. Published 2008. Available at *https://mp.gov.in/* (accessed on 16 Aug 2020).

26 Directorate of Health Services, Government of Madhya Pradesh, India. Available at *www.health.mp.gov.in/en* (accessed on 16 Aug 2020).

27 Madhya Pradesh Public Health Services Corporation Limited (MPPHSCL)–IMCS. Available at *https://mpphsc.in/* (accessed on 16 Aug 2020).

28 Welcome to Government Order Issue Register 3. Available at *http://goir.telangana.gov.in/reports.aspx* (accessed on 30 Aug 2018).

29 Madhya Pradesh (MP) Government Drug Policy 2009 1; 2009. Available at *https://mpphscl.in/Files/PDF/0ac5767a-22d2-4e71-8ae2-3859358a4c4c_0_Drug Policy 2009-english.pdf* (accessed on 30 Aug 2018).

30 Madhya Pradesh (MP) Government Drug Policy 2009 1. Directorate of Health Services, Madhya Pradesh; 2009:1–23. Available at *https://mpphscl.mp.gov.in/Files/PDF/0ac5767a-22d2-4e71-8ae2-3859358a4c4c_0_Drug%20Policy%202009-english.pdf* (accessed on 16 Aug 2020).

31 Mehrtash H, Laing R, Wirtz VJ. Comparative analysis of essential medicines for cardiovascular diseases in countries of the WHO Eastern Mediterranean Region. *East Mediterr Health J* 2018;**24:**427–34.

32 Mendis S, Fukino K, Cameron A, Laing R, Filipe A Jr, Khatib O, *et al.* The availability and affordability of selected essential medicines for chronic diseases in six low-and middle-income countries. *Bull World Health Organ* 2007;**85:**279–88.

33 Wirtz VJ, Kaplan WA, Kwan GF, Laing RO. Access to medications for cardiovascular diseases in low- and middle-income countries. *Circulation* 2016;**133:**2076–85.

34 Bazargani YT, Ugurlu M, de Boer A, Leufkens HG, Mantel-Teeuwisse AK. Selection of essential medicines for the prevention and treatment of cardiovascular diseases in low and middle income countries. *BMC Cardiovasc Disord* 2018; **18:**126.

35 Embrey MA. Management Sciences for Health (Firm). Quantifying pharmaceutical requirements. Part II: Pharmaceutical management. In: MDS-3 Managing Access to Medicines and Health Technologies [Internet]. 2013; p. 20.1-20.29. Available at *https://msh.org/wp-content/uploads/2013/04/mds3-ch20-quantifying-mar2012.pdf* (accessed on 16 Aug 2020).

36 Sharma S, Choudhary RR. Improving availability and accessibility of medicines: A tool for increasing healthcare coverage. *Arch Med* 2015;**7:**1–9.

37 Arokiasamy P. India's escalating burden of non-communicable diseases. *Lancet Glob Health* 2018;**6:**8–9.

38 Jeet G, Thakur JS, Prinja S, Singh M. Community health workers for noncommunicable diseases prevention and control in developing countries: Evidence and implications. *PLoS One* 2017;**12:**e0180640**.**

39 Elias MA, Pati MK, Aivalli P, Srinath B, Munegowda C, Shroff ZC, *et al.* Preparedness for delivering non-communicable disease services in primary care: Access to medicines for diabetes and hypertension in a district in south India. *BMJ Glob Health* 2017;**2** (3 Suppl**):**e000519.

40 Prashanth NS, Elias MA, Pati MK, Aivalli P, Munegowda CM, Bhanuprakash S, *et al.* Improving access to medicines for non-communicable diseases in rural India: A mixed methods study protocol using quasi-experimental design. *BMC Health Serv Res* 2016;**16:**421.

41 Millington KA, Bhardwaj M. *Evidence and experience of procurement in health sector decentralisation*; 2017. Available at *https://assets.publishing.service.gov.uk/media/59845568e5274a1707000065/108-Evidence-and-experiences-of-other-countries-health-procurement.pdf* (accessed on 16 Aug 2020).

42 Goyal V, Anand H, Siddharth V, Koushal V. Lead time in drug procurement: A study of tertiary care teaching hospital of North India. *Int J Res Found Hosp Healthcare Admin* 2016;**4:**16–19.

43 Chandra C, Grabis J. Inventory management with variable lead-time dependent procurement cost. *Omega* 2008;**36:**877–87.

44 World Health Organization. *Second WHO model list of essential in vitro diagnostics.* Geneva:WHO; 2019. Available at *www.ghdonline.org/uploads/EDL_ExecutiveSummary_15may.pdf* (accessed on 16 Aug 2020).

Supplementary TABLE I. List of documents retrieved for review at the subnational level

Level of policy	Documents	Web links
Madhya Pradesh	Government Drug policy, 2009	*www.health.mp.gov.in/drug/Drug%20Policy%202009-english.pdf*
	Drug procurement guidelines	*www.health.mp.gov.in/drug.htm*
	Madhya Pradesh drug budget (Sardar Vallabh Bhai Patel Free Drug Distribution Yojana)	*www.health.mp.gov.in/drug-distribution.htm*
	Sardar Vallabh Bhai Patel Nishulk Aushadhi Vitaran Yojna website	*www.nhmmp.gov.in/WebContent/MPTast/Abstracts_PPT_Posters_presented_in_conferences/The_Free_Drug_For_All_and_Free_Diagnostics_For_All_Scheme_an_i.pdf*
	Essential medicines list, 2018	*www.health.mp.gov.in/drug/edl-2018.pdf*
Telangana	Government order of the combined state, 2015	*http://goir.telangana.gov.in/reports.aspx*
	TSMSIDC website	*www.tsmsidc.telangana.gov.in*
	Essential medicines list, 2015	*http://goir.telangana.gov.in/reports.aspx*
	Report of the Comptroller and Auditor General of India on General and Social Sector for year 2016	*https://cag.gov.in/sites/default/files/audit_report_files/Report_No_1_of_2017_Telangana_GSS.pdf*

TSMSIDC Telangana State Medical Services and Infrastructure Development Corporation