Politics, Pills and Procurement: The Challenges of Ensuring Drug Quality in Bihar

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POLITICS, PILLS AND PROCUREMENT:

THE CHALLENGES OF ENSURING DRUG QUALITY IN BIHAR

Abstract

Introduction: In 2014-6 the National Drug Survey, conducted by the Indian government, identified that 10.02% of drugs in the public sector were substandard. This study examined the challenges of ensuring the quality of drugs procured by public tender in Bihar. In 2010, the Bihar Medical Services and Infrastructure Corporation Limited (BMSICL) was established to serve as Bihar's drug procurement agency. It drew on a well-regarded model: the Tamil Nadu Medical Services Corporation (TNMSC). However, to date, the BMSICL has struggled to develop the functionality associated with the TNMSC.

Methods: This qualitative case study examined public procurement in Bihar from 2010 to 2017 and drew on thirty in-depth interviews and three field visits. Data was analyzed using a four-stage qualitative coding approach, supported by Atlas.ti software. Participants were selected using a purposive, expert sampling strategy. Interviews were conducted with pharmaceutical companies, procurement agencies, regulatory experts, companies and pharmaceutical industry representatives. Field visits were conducted to Patna, Vaishali and Chennai. Interview transcripts, grey literature and field notes were reviewed to identify and analyze patterns and themes. This paper is focused on themes relating to state-level factors in Bihar, which were: corruption and vested interests, technical measures and manufacturer incentives and practices.

***Findings*:** Corruption has made it difficult to establish the operational capacity of the BMSICL and compromised efforts to develop the organization's credibility. This political environment has undermined the effectiveness of technical measures, such as blacklisting, eligibility criteria and quality-testing. It has also

affected the behavior of pharmaceutical companies. Reputable companies producing and supplying high-quality products in other markets, both domestic and international, expressed being disinclined to work with the BMSICL. Some explained that the cost of assuring quality prevented their company being able to successfully compete in public sector tenders. Others were deterred by the perception that doing business in Bihar would invoke a power struggle with existing local players, requiring the payment of kickbacks and senior political support to manage disgruntled stakeholders. Participants also explained that low quality suppliers were adopting fraudulent measures, such as diluting active ingredients in products to lower production costs, bribing regulatory and procurement officials and falsifying documentation. This was viewed as an indication of the weakness of the regulatory system.

***Conclusion*:** The BMSICL struggled to achieve the progress offered by replicating the TNMSC model because Bihar's political environment, where corruption and vested interests play a significant role, was not supportive of drug quality being prioritized and ensured. It is a case of what Pritchett and Andrews describe as isomorphic mimicry. On paper, the BMSICL had processes that look like those found in functional states. Establishing measures and processes through written documents has been a hallmark of how the agency sought to replicate the TNSMC model. However, implementing measures without fully addressing corruption and vested interests has led to isomorphic mimicry.

***Implications for policy makers and donors*:** For interventions to improve drug quality they need to consider and address issues such as corruption and vested interests. However, donors and policy makers often opt for technical approaches because the complexities of adaptive approaches, which seek to address people's behaviors and incentives, can compromise the sustainability, risk appetite and relationships of the intervening organization. While the study identified a range of intervention options to support donors and policy makers, two options have been prioritized: a drug inspector enhancement program, and a lab capacity and data improvement program. These options can be framed as technical interventions whilst also providing opportunities to address adaptive aspects of the issue.

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EXECUTIVE SUMMARY

Introduction

The 2014-6 National Drug Survey published by the Indian Government identified that 10.02% of drugs in the public-sector supply chain were spurious or not of standard quality. Substandard drugs pose a public health problem because they can cause avoidable death and disability, they can lead to increased drug resistance, they facilitate medical impoverishment and weaken patient satisfaction and support for health systems. Safe and effective drug provision is determined by factors in six areas: regulation, manufacturing procurement, supply chain integrity, dispensing practices and patient handling. For practical reasons, this analysis focused on the relationship between manufacturing companies and procurement agencies.

The political context and financial capacity of a state are important determinants of a procurement agency's ability to attract reliable suppliers that are consistently able to provide safe and efficacious products. While there is limited literature on drug quality at the state-level in India, relevant literature on drug affordability and availability, as well as case studies of state-level procurement, point to the importance of these two factors. Specific operational features, such as eligibility criteria and blacklisting, can also be used to assure quality; however, the effectiveness of these measures is dependent on political context. In political context where procurement is not negatively affected by corruption and vested interest and where there is a sufficient financial envelope, a procurement agency is more likely to attract reliable suppliers and assure the quality of products procured through public tender.

Study methods

A qualitative case study approach was used to examine the challenges of ensuring the quality of drugs procured by public tender in Bihar. In 2010, the Bihar Medical Services and Infrastructure Corporation Limited (BMSICL), was established to serve as Bihar's drug procurement agency. The

BMSICL drew on a well-regarded model, that of the Tamil Nadu Medical Services Corporation (TNMSC); therefore, the study drew on the experience of the TNMSC, which was a sub-unit.

Thirty in-depth interviews and three field visits were used to collect data, which was then analyzed using a four-stage qualitative coding approach. Participants were selected using a purposive, expert sampling strategy. Interviews were conducted with pharmaceutical companies, procurement agencies, regulatory experts, private sector companies and pharmaceutical industry representatives. Field visits were conducted, to Patna, Vaishali and Chennai. Interview transcripts, grey literature and field notes were reviewed to identify, analyze and report patterns and themes. This paper is focused on themes relating to state-level factors affecting Bihar, which were: corruption and vested interests, technical measures and manufacturer incentives and practices

Findings

Corruption at the district-level has made it difficult to establish the operational capacity of the BMSICL and compromised efforts to address challenges and develop the organization's credibility. This can be seen in district-level procurement officials issuing decentralized procurement tenders, which are separate from the process of the BMSICL and are not subject to quality checks. This limits the BMISCL's capacity to leverage volume to attract manufacturers, oversee and implement quality assurance processes in district-level procurement. Another important by-product of corruption is that it has disincentivized leaders from prioritizing and engaging in procurement processes. Without leadership attendance at key decision-points the BMSICL is not able to mobilize contracts at a reasonable speed and build a reputation as a reliable business partner. This is reflected in its low budget utilization, which participants reported as being approximately 15-20%. The lack of prioritization and political commitment makes supply to at the district level unreliable. As a result, it reinforces the incentives for district-level procurement officials to circumvent the centralized process further entrenching corruption in the system.

Technical measures can be used to ensure drug quality; however, as a result of corruption and vested interests in Bihar these features can lack integrity and be ineffective. Manufacturers regarded the use of quality-specific measures as blacklisting and quality testing to be ineffective because these processes could easily be circumvented. Establishing measures and processes through written documents has been a hallmark of how the agency sought to replicate the TNSMC model. However, implementing measures without fully addressing corruption and vested interests has led to isomorphic mimicry; the BMSICL has the appearance of a high-performing model but lacks the functionality.

Reputable companies, producing and supplying high quality products in other markets, identified four reasons why contracting with the BMSICL was not commercial. Firstly, public procurement is a low margin business and the lack of volume made many of tenders commercially unviable. Secondly, unreliable contracting made it unclear whether payments would be recovered. Thirdly, that the difficulty of doing business was viewed as too high relative to the reward. This included both the operational costs of engaging in contracting and the political challenges of navigating corruption and vested interests. Finally, without clear forecasting plans it was difficult to incorporate public procurement needs into manufacturing plans.

In the context of weak regulation and enforcement low quality suppliers were adopting measures to circumvent quality checks. Procurement officials acknowledged the importance of sending signals to the market that regulation and quality testing were taken seriously and could describe processes to this effect. However, they also noted that the potential for falsification of documents and products was significant and presented an important challenge to the BMSICL's ability to assure quality.

Conclusion

The BMSICL struggled to achieve the progress offered by replicating the TNMSC model because the political context in Bihar, where corruption and vested interests play a significant role, was not

supportive of drug quality being prioritized and ensured. In this regard it is a case of what Pritchett and Andrews describe as isomorphic mimicry. On paper, the BMSICL has the institutions and processes that look like those found in functional states. However, the mutually reinforcing effects of corruption and political leaders de-prioritizing procurement have compromised organizational functionality, which is needed to ensure drug quality in the public tender process.

Implications for donors and policy makers

For interventions to have a realistic chance of improving public sector drug quality they need to consider and address corruption. Donors and policy makers are not unaware of the challenges posed by the corruption and vested interests. However, the adaptive nature of these challenges – that they require sustained engagement and entail managing considerable risk – makes it easier to pursue technical measures. As politicized entities themselves, donors and policy makers face constraints in engaging in approaches that compromise their sustainability, relationships and risk appetite. These limitations are significant; however, they do not lead to the automatic assumption that a focus on technical solutions is the best option.

Two interventions can be shaped to address the adaptive and technical factors inhibiting the state's ability to ensure drug quality. A drug inspector enhancement program and a combined lab capacity and data improvement program stand to be beneficial. Selection was based on the recognition that these interventions can be framed as technical interventions whilst also providing opportunities to address adaptive aspects of the issue, making them more feasible for donors and policy makers.

Drug Inspector Enhancement Program: For a regulatory regime to be effective, the subject of regulation ought to believe that the enforcement capacity of the state is credible. One aspect that contributes to this weakness in Bihar's regulatory system are the limitations of drug inspectors, in terms of their ability to exercise authority, to remain uncorrupted and to safely conduct their responsibilities. In

Bihar regulators fund their travel independently and often face security risks. An inspector who plays a role in convicting a substandard manufacturer on one day can expect to travel on a motorcycle to a remote location the following day, where he or she might be vulnerable to retribution. Improving transportation and security for drug regulators could help to improve the authority of the regulatory regime. It could also be framed as technical regulatory intervention, could help to bolster enforcement capacity and increase the likelihood that inspectors will honestly conduct their job by making them less vulnerable.

Lab Capacity and Data Improvement Program: This is a two-part intervention, which draws on two observations. Firstly, the lack of available testing units limits the efficiency of a procurement system and has impacts on its ability to attract quality conscious manufacturers. Secondly, the lack of information about the quality of drugs limits efforts to advocate for improvements. Improving laboratory capacity can be framed as a technical measure to support the BMSICL in verifying product quality and preventing delays. However, if the information arising from this enhanced capacity is curated and disseminated it has the potential to support communities in understanding drug quality and fostering the development of a norm, where quality is better understood and communities have higher expectations of public sector services providing quality.

While there are choices to be made in the dissemination strategy, the principle of using information to facilitate normative changes is at the heart of this approach. This is based on the recognition that quality is currently not well understood, and that information could encourage political constituencies recognize and advocate for improvements in drug quality. Moreover, increased awareness of one dimension of quality – test results - could help develop support for in-depth mixed-methods analysis of relevant states to understand the specific causes of poor quality. This could help to isolate the interventions that can yield the greatest impact for policy makers and donors.

SECTION I: INTRODUCTION

Substandard drugs matter because they can harm patients; however, it is difficult to know how much of the domestic Indian drugs market is affected by quality concerns and to precisely determine the impact of substandard medication. The Indian Government's 2014-6 National Drug Survey (National Survey) suggests that, on average, 10.02% of drugs in the public sector supply chain[1] were identified to be 'spurious and not of standard quality' (Ministry of Health and Family Welfare, 2017, p. 17). 10% of public-sector supply having the potential to harm patients constitutes a national-level public health problem. As a reference point, in the United States, only 1.1% of drugs were found to be substandard between 2003 and 2013 (United States Food and Drug Administration, 2017). In the context of a largely unregulated market of over 10,000 suppliers (PwC, 2010), the Indian government's most recent Draft Pharmaceutical Policy points to the profile and some causes of the issue:

> the quality assurance of indigenously manufactured drugs is…an area of concern…concerns have been raised on the quality surveillance of the indigenously manufactured drugs for domestic consumption. The inspection of the manufacturing premise and processes are, many a times, perfunctory or absent. Many manufacturing units are not compliant with the World Health Organization's (WHO) good manufacturing practices (GMP) or the good laboratory practices (GLP). All these severally and in combination give rise to grave quality concerns in the pharmaceutical industry (Government of India, 2017; Thakur & Thikkavarapu, 2017).

[1] Public sources were defined as State Government Medical Store Depots, Civil and District Hospital Stores, Central Government Health Scheme dispensaries and Employees' State Insurance Dispensaries in the National Survey.

For the very reasons described in the policy draft, it is feasible to assume that more than 10% of public-sector supply could be substandard; thus, the potential public health implications could be far reaching. However, first it is important to consider: What is a substandard drug and in what ways are substandard drugs a public health problem? What factors are important in determining drug quality and why are state-level factors important? And, finally, what are the gaps in knowledge relating to drug quality and what can a qualitative study contribute?

What is a substandard drug and in what ways are substandard drugs a public health problem?

While there has been debate on what constitutes a 'substandard' product, the National Survey defines quality in terms of chemical formulation, expiry date and packaging.[2] 10% of a nation's public sector supply of drugs being substandard constitutes a public health problem because substandard drugs can harm patients and health systems in at least four ways. Firstly, drugs with no, too much or too little active ingredient can cause avoidable death and disability (Institute of Medicine, 2013; Maiti, Bhatia, Hota, & Padhy, 2015; Wirtz et al., 2016; World Health Organization, 2017). Ineffective drugs can inhibit disease control and toxic drugs can harm patients (Institute of Medicine, 2013; Newton et al., 2010). For example, in 2014, 15 women in Chhattisgarh died because of antibiotic medication was contaminated with rodenticide (Ministry of Health and Family Welfare, 2017b). Secondly, substandard drugs can lead to increased drug resistance compromising the effectiveness of entire drug classes, even for those who have not taken poor quality formulations (Institute of Medicine, 2013; Wirtz et al., 2016; World Bank, 2017a; World Health Organization, 2017). Thirdly, drug quality can also have a substantial bearing on medical impoverishment. In 2013, the Ministry of Health and Welfare identified that 63 million Indians a year were being pushed into poverty through medical expenditure. Several studies have identified drugs as a major driver of high out of pocket (OOP) expenditure (Archana et. al, 2014; Garg & Karan, 2009; Gupt et al., 2013; Shahrawat & Rao, 2012), for example, it was found to be as high as 70% in 2000 (Garg &

[2] The definition will be examined in more detail in the Literature Review.

Karan, 2009). More recently, a study of OOP in Puducherry in Southern India found that 32% of OOP was for drugs (Archana et al., 2014). If the public sector were better able to provide safe and effective medication patients might be less inclined to pay high prices for medication in the private sector. Finally, substandard drugs have implications for the financial management and responsiveness of a health system. Ineffective drugs can also weaken patient satisfaction and trust, as well as political support for health systems (Kumar, 2017; Institute of Medicine, 2013; Nayyar et al., 2015; World Health Organization, 2017).

What factors are important in determining drug quality and why are state-level factors important?

Safe and effective drug provision is determined by factors in six areas: regulation, manufacturing, procurement, supply chain integrity, dispensing practices and patient handling (Layloff, 2012; Strengthening Pharmaceutical Systems Program, 2011; World Health Organization, 2017c). While national programming plays a role and these factors resonant at an national level, in the Indian constitution, health is described as a state-level concern (Glassman & Mukherjee, 2015). The prioritization, management and provision of health are determined by the state, and these aspects vary considerably between states, making it relevant to consider state-level factors in drug quality. The National Survey also demonstrates that drug quality varies by state, with the percentage of substandard drugs ranging from 0% to 33%, as shown in Figure 1 (Ministry of Health and Family Welfare, 2017). This suggests that state-specific factors play a substantial role in drug quality. In Bihar, a state that has a high disease and poverty burden (Singh et al, 2011; The World Bank, 2016; World Bank, 2016) 8.71% of public sector provision was deemed to be spurious. In a state with limited resources to address health outcomes, that almost 9% of the state's expenditure on drugs is being wasted, failing to address or exacerbating the disease burden merits attention and action.

In addition, the National Survey prompts the conjecture that the range of organizations involved in public drug provision can improve their ability to ensure drug quality. Issues could lie with individual organizations or the way in which interdependent organizations, namely procurement agencies, regulators, pharmaceutical companies, payers and international health organizations, interact with each other. Analyzing the political economy of organizations involved with the state's drug provision can help to explain the factors that are determining drug quality at the state-level. This offers the prospect of government and donor organizations being better able to allocate and maximize resources for health improvement and poverty alleviation.

What are the gaps in knowledge relating to drug quality in Indian states and what can a qualitative case study contribute to knowledge about improving quality?

The National Survey and the Draft Pharmaceutical Policy clearly identified the quality of medication as an issue. However, this level of recognition is new (Thakur & Thikkavarapu, 2017) and there is not a well-advanced body of academic literature on state-level drug quality. From academic literature on procurement models, drug affordability and availability it is possible to glean a set of measures, both general and quality-specific, that can support quality assurance. Much of the literature on state level procurement models in India is dominated by descriptions and analyses of the Tamil Nadu model (Narayanan, 2010b; Parthasarathi & Sinha, 2016b; Revikumar et al, 2013; Singh et al., 2012). The Tamil Nadu Medical Services Corporation (TNMSC) was established in 1994 following a drug scam (Singh et al., 2012), it gained recognition as an exemplar, prompting several states to replicate the model. This has fueled the perception that success can be achieved by copying the model. There are examples, such as Rajasthan (Kotwani, 2003; Kotwani, 2009), where the pursuit of replication has worked well in aspects such as drug availability. However, much less is known about how states with different socioeconomic profiles and cultural norms can successfully pursue replication, and the question of how contextually informed replication can support quality is overlooked.

An important starting point in the existing literature is the National Survey, as it is the most specific and systematic document on drug quality at the state-level. The Indian government has conducted successive National Drug Surveys. A government press release about the most recent National Survey described it as "the largest ever scientifically designed and professionally executed drug survey undertaken in the world for determining the quality of drugs…" (Ministry of Health and Family Welfare, 2017a). While the merits of the National Survey have been praised, its limitations are also relevant. During this study, some state representatives argued that the study's methodology was not sufficiently representative and that surprising results raised questions about the reliability of the data. Two comparatively surprising results were that of Tamil Nadu and Bihar. 7.72 percent of Tamil Nadu's supply was identified as being substandard, despite having more advanced and established systems than Bihar (with a percentage of 8.71). In addition, the National Survey focused on test results in its conceptualization of quality, when there are a broader range of a factors that affect quality (Layloff, 2012; Strengthening Pharmaceutical Systems Program, 2011; World Health Organization, 2017).

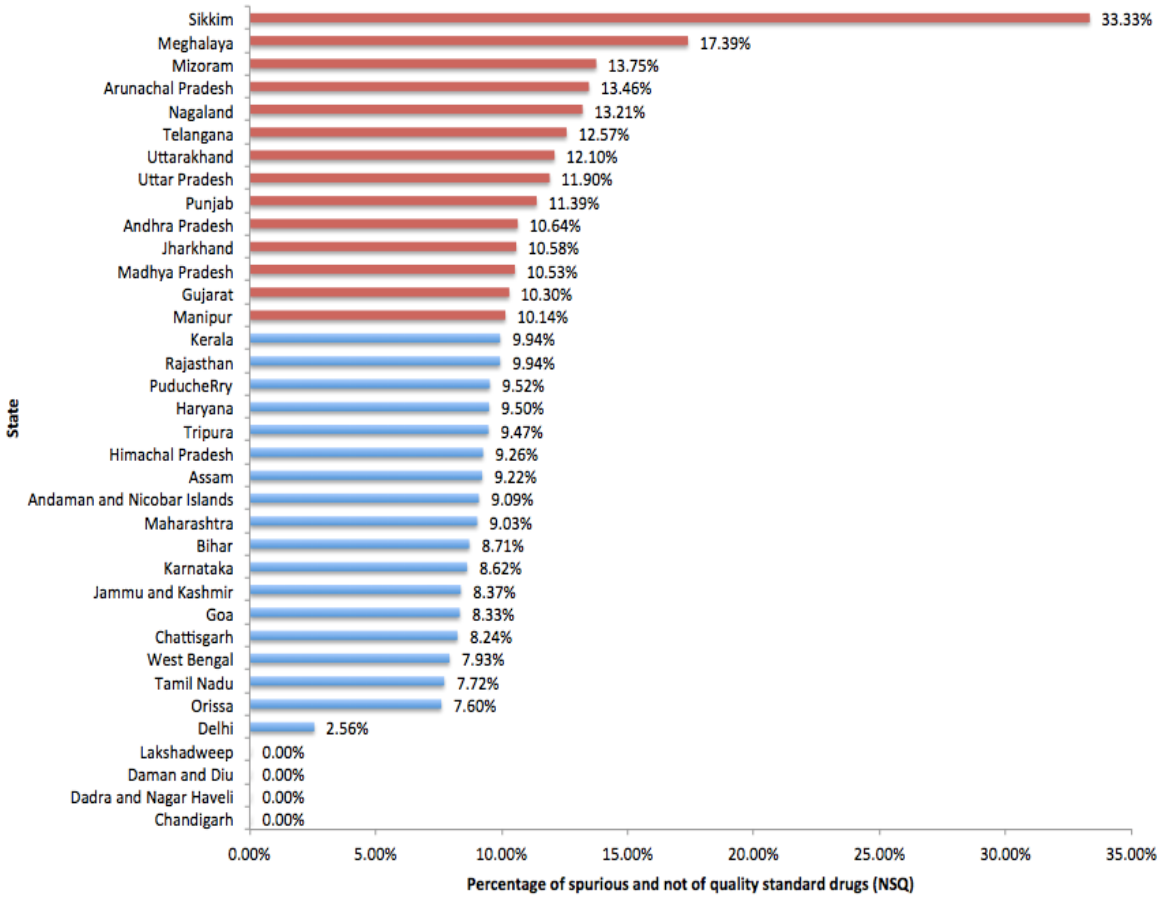
Academic literature on state-level procurement primarily focuses on procurement models, availability and affordability (Chokshi et al., 2015; Estavillo, 2012; Ezziane, 2014; Kotwani, 2009; Kotwani et al., 2007; Pratap, 2017; Singh et al., 2012). While this literature is not specific to quality, it identifies and lists attributes that enable a procurement agency to function well from an operational perspective. That functionality is important because it has a bearing on an agency's ability to assure quality and manage manufacturer relationships. In 2013, Singh et al. conducted a comparative analysis of state procurement systems. This analysis identified fifty-three attributes of procurement agencies that can have a bearing on their ability to provide medication. Within this analysis, specific mechanisms that can be used to assure quality were discussed, including: eligibility criteria, blacklisting and quality-testing. However, across this literature there is limited analysis of the dynamics of the relationship between procurement agencies and manufacturers and how this has an impact on quality.

Bihar is an important case of this knowledge gap, particularly given how different its socioeconomic profile is from southern states such as Tamil Nadu, as shown in Figure 2. The Bihar Medical Services and Infrastructure Corporation (BMSICL) was established in 2010, in the aftermath of a drug scandal, similarly to the TNMSC. On paper, BMSICL has the institutions and processes that look similar to those found in functional states. However, the organization's struggle to establish its credibility over the last seven years and the fact that procurement officials reported that only 15% of Bihar's drugs budget was utilized last year suggests that replication has not been a success story. BMISCL appears to be a classic case of what Pritchett and Andrews have described as isomorphic mimicry (Andrews et. al, 2017; Krause, 2013; Prichett, 2013; Pritchett et. al, 2010).While the institutions and processes in a weaker context look like those found in a functional state, the BMSICL does not have the functionality of the TNMSC model, particularly with regards to ensuring quality.

A qualitative case study examining the factors affecting drug quality in Bihar offers an opportunity to draw lessons from a case study in isomorphic mimicry (Andrews et. al, 2017; Krause, 2013; Prichett, 2013; Pritchett et. al, 2010) and support Indian states in moving beyond the pitfalls of replication. To date, attention has been focused on transplanting the TNMSC with limited focus on how to make a model functional, for the benefit of quality assurance, in a more challenged context. The purpose of this qualitative case study was to examine the impact of replicating a procurement model on drug quality. It aimed to address the specific question of what factors could explain the challenges of ensuring the quality of drugs procured by public tender in Bihar. To afford the study with a manageable remit the theoretical framework focused on the relationship between manufacturers and the state procurement agency, and interviews were conducted with participants with experiences of these types of organization. To provide context, additional interviews were conducted with domestic regulatory experts, international regulatory

and governance experts, private sector health companies, domestic civil society organizations, think-tanks and non-governmental organizations.

Figure 1: Percentage of spurious and not of standard quality (NSQ) drugs in government sources, by state



Source: (Ministry of Health and Family Welfare, 2017b)

Figure 2: Socioeconomic profile of Bihar and Tamil Nadu

	All India	Tamil Nadu	Bihar
% NSQ in government sources % (2014-6)	10.02	7.79	8.71
Location	-	South India	North India
Per capita income 2005 Indian rupees	42,647	59,185	13,482
Population million (2011)	1121	72	104
Poor million (2012)	270	9	36
Urban share %	31	70	11
Poverty rate % (2012)	22	12	34
Maternal Mortality per 100,000 live births (2013)	167	79	208
Infant Mortality per 1,000 live births (2013)	40	21	42
Electrification % of households (2012)	80	98	31
Road density km per million people	3231	3152	1306

Source: (Government of National Capital Territory of Delhi, 2017; World Bank, 2016, 2017b)

SECTION II: LITERATURE REVIEW

Introduction

This section will begin by briefly reviewing definitions of drug quality. It will then discuss existing frameworks of the pharmaceutical sector and describe a six-part framework for the purposes of this study. Thereafter, it will review the existing literature on drug procurement in Indian states, which considers: the impact of the social, political and financial context in which a procurement agency is developed; the structure and governance of an agency; and, the operational features that have a bearing on quality.

Academic interest in state-level procurement in India has focused on Tamil Nadu, and much of this literature considers the development and merits of the state's drug procurement model. Comparative analyses of state systems have provided insights from Odisha, Kerala, Delhi, Bihar, Punjab and Maharashtra. These have helped to identify factors that are important for drug procurement in general and, specifically for quality control and assurance (Chokshi et. al, 2015; Singh et al, 2013, Singh et. al, 2012). However, overall, there is limited literature on drug quality in India, and its specific determinants at the state-level.

Defining drug quality

In the absence of a single definition of drug quality (Attaran et al., 2012; Institute of Medicine, 2013; Layloff, 2012; Newton et al., 2011; World Health Organization, 2017a, 2017d) there has been significant debate and refinement of the definitions relating to quality. Until recently the WHO used the terminology of Substandard, Spurious, Falsely Labelled, Falsified and Counterfeit (SSFFC). However, it was recognized that the terminology created confusion, particularly around what constituted a public health issue. In 2017, the World Health Organization (WHO) revised the definitions of Substandard and Falsified medical products. Substandard drugs, also known as 'out of specification' products, are

authorized medical products that fail to meet either their quality standards or specifications, or both (World Health Organization, 2017d). Unregistered/unlicensed products are medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation (World Health Organization, 2017d). Falsified products are those that deliberately or fraudulently misrepresent their identity, composition or source.

Substandard and falsified drugs were deemed to constitute a public health issue, particularly in terms of drug quality (World Health Organization, 2017, p. 3). Counterfeit drugs were defined as a trade and international relations issue (World Health Organization, 2017, p. 3). In addition, within the guidance on SSFFC the WHO also differentiated between accidental and intentional acts to mislead any person in relation to a medical product. This distinction was important in terms of the potential remedies. Deliberate or intentional acts to mislead are more likely to prompt criminal sanctions. Accidental error may be better managed with a regulatory response to support and incentivize further compliance with good manufacturing or distribution practices. Finally, substandard drugs can be the result of intentional and unintentional practices, unlike falsified drugs, which are the product of intentional practices.

The National Survey provides the Indian government's definition of quality (Ministry of Health and Family Welfare, 2017b). The National Survey's methodology focuses on the chemical formulations of drugs and pharmaceutical tests to determine whether a drug can be classed as being of adequate or inadequate quality:

> … the sampled formulations were to be subjected to physical inspection and laboratory tests. Based on physical inspection and subsequent verification, each sampled formulation was to be classified as Spurious or not. Further, based on laboratory tests formulations were to be classified as Spurious/NSQ or not…."

Testing of government sources drew on the outcomes of up to 27 tests (e.g. assay, dissolution, related substances, description, particulate matter, uniformity of content, clarity of solution, disintegration test, uniformity of dispersion, pH, bacterial endotoxin test, uniformity of filled weight, extractable volume, sterility, uniformity of weight). Analysis also considered expiry dates, packaging and dosage information.

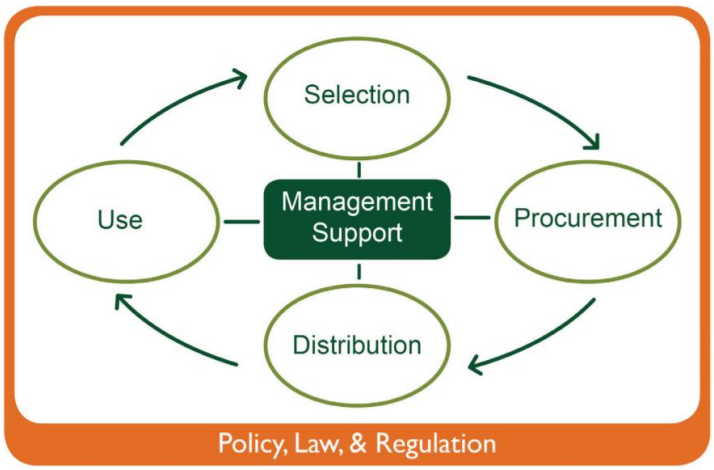
Frameworks on the determinants of drug quality

Both the 2013 Institute of Medicine report into Countering the Problem of Substandard and Falsified Drugs, and the more recent 2016 Lancet Commission on Essential Medicines have acknowledged the challenge of providing high quality drugs in developing country settings. Both reports make recommendations for a range of stakeholders, including governments, regulatory agencies, payers, procurement agencies, pharmaceutical companies, international organizations and consumers. The range of interdependent organizations that are relevant brings significant complexity to the challenge of providing high quality medication. Each of these stakeholder groups has a role and where these roles are performed well, governments will be better placed to assure the quality of public sector medication. However, the dysfunction in these relationships can often become entrenched and make it difficult to re-align incentives so that quality is assured.

From a conceptual perspective, the framework described by the Strengthening Pharmaceutical Systems (SPS) Report, which focuses on governance, captures the importance of relationships between interdependent organizations and individuals. The SPS program draws on the United Nation's definition of governance as 'the process of decision making and the process by which decisions are implemented, or not implemented' (United Nations Economic and Social Commission for Asia and the Pacific, n.d., p. 1). The report articulates a view that governance is dependent on relationships between individuals or institutions and the way in which decisions are made and implemented at all levels of the system. The SPS program's definition discusses governance in the context of the pharmaceutical system:

> …a functioning pharmaceutical system encompasses the interdependent processes of selection, procurement, distribution, and use of medicines together with pharmaceutical services that support patient care and treatment. These activities and services are enabled by a strong management support system that includes financing, organizational, human resources and information management…
>
> (Strengthening Pharmaceutical Systems Program, 2011, p. 4)

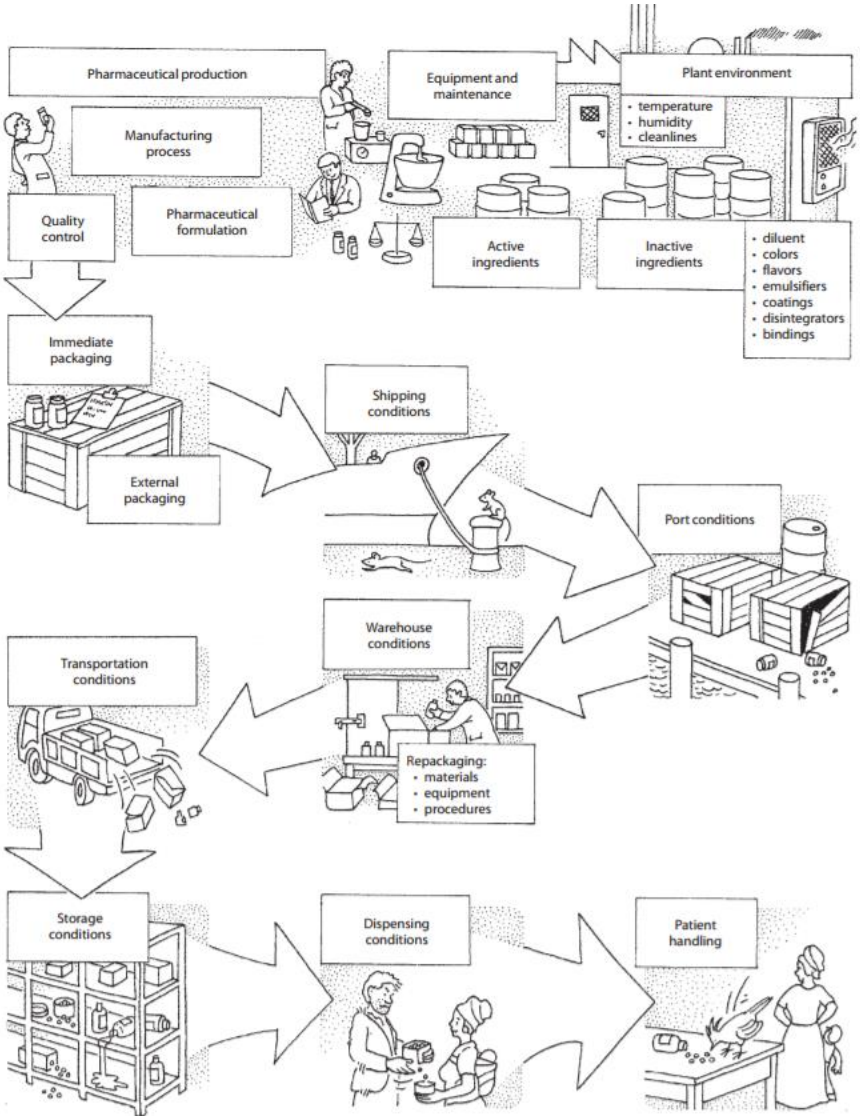
Figure 3: Strengthening Pharmaceutical System's Pharmaceutical Management Framework



Source: (SPS Program)

This approach underpins the main framework used in the literature produced by the SPS Program, which is provided in Figure 3. Within this framework pharmaceutical services include procurement, provision, rational use of drugs and monitoring of medicine use to achieve desired health outcomes. Other components are also recognized as being important, including informational campaigns to improve public health, the development and implementation of policies and practices to improve pharmaceutical care and the training of healthcare workers. Crucially, the framework also recognizes the importance of policies, laws and regulations.

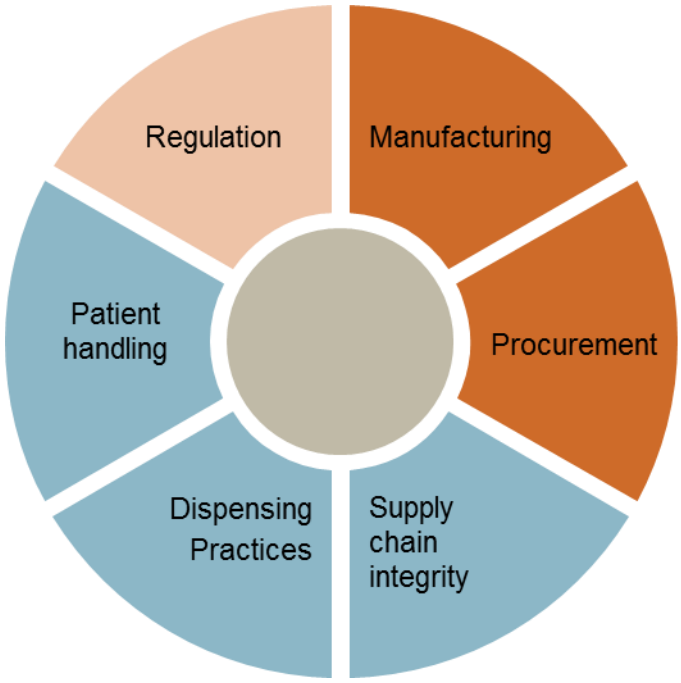
Figure 4: Determinants of Pharmaceutical Quality



Source: (Layloff, 2012, p. 19.6)

From a more practical perspective, Figure 4, provides a graphical overview of the determinants of pharmaceutical quality. Analysis of this diagram indicates there are at least six areas (as outlined in Figure 5) in which quality improvements can be made to facilitate improvements in the provision of public sector drugs: regulation, manufacturing, procurement, supply chain integrity, dispensing practices and patient handling.

Figure 5: System components of improving public sector drug quality



Source: Author

Regulation

Regulation can been defined as 'the monitoring and enforcement by a government or other institution with authority of laws, statues and codes as they pertain to a particular technology and its production, procurement, distribution, use and sale in the market' (Frost & Reich, 2008, p. 228). Regulators play a role in setting the terms for how quality should be safeguarded across the other five areas, both at the international and national level. International organizations define global standards and best practice, while national and regional governments need to prioritize, fund, manage and enforce regulatory regimes across each of the other five areas. The WHO also plays a role in assessing national regulatory bodies, in terms of their maturity and capacity to produce high quality products (Seiter, 2012; WHO, 2016; World Health Organization, 2017b). In turn, national regulatory bodies are responsible for incentivizing their attainment of quality standards. This includes building systems to detect substandard products and implementing surveillance and monitoring programs. Finally, the 2016 Lancet Commission highlights the

role that regulators can play in engaging the public. Despite medicines being a credence good, the report indicates that the public can play a role in promoting the quality and safety of medicines (Wirtz et al., 2016).

The state of regulatory capabilities in India remains limited. In 2003, a committee commissioned by the Indian government (The Mashelkar Committee) proposed a series of regulatory reforms (Ministry of Health and Family Welfare, 2003). The Committee noted that, despite the Drugs and Cosmetics Act having been in place for over five decades at the time, the level of regulatory enforcement across states was variable and unsatisfactory (Ministry of Health and Family Welfare, 2003), and the main cause of substandard drugs. The Committee then went further to specify that regulatory failures lay in: inadequate or weak drug control infrastructure, at the state and central level; inadequate testing facilities; the shortage of drug inspectors; non-uniformity of enforcement; the lack of specially trained cadres for specific regulatory areas; the lack of data and data structure; the lack of accurate information. Since then, some steps have been taken to address some of those concerns (Ministry of Health and Family Welfare, n.d.). However, regulatory capacity remains an area where there are many opportunities to improve drug quality.

Manufacturing

Manufacturing can be defined as processing raw materials into finished products for use or sale (Frost & Reich, 2008, p. 19). The 2013 Institute of Medicine report indicated that a lack of adherence to good manufacturing practices, owing to the high cost of maintaining quality, was the primary cause of substandard drugs (Institute of Medicine, 2013). Figure 4 illustrates the manufacturing aspects that influence quality. These include materials, plant-environment, equipment, the technical know-how in developing and manufacturing the product (Layloff, 2012, p. 19.7), the management of the facility and the quality controls. From a regulatory perspective, international and domestic guidelines articulate how

manufacturers can assure quality. At a global level, the WHO's Good Manufacturing Practices (GMP) (World Health Organization, 2007b) provides guidance on how pharmaceutical companies can assure the quality of their products. In practice, however, the costs of maintaining quality and the strategic and commercial priorities of organizations can often determine how well quality is controlled and assured in the manufacturing process.

In India, national guidelines and political dynamics play a determining role on manufacturing practices. Export focused manufacturers are required to comply with the standards of the export destination, for example, GMP standards- or United States Food and Drug Administration- (FDA) standards. However, the legally required standard for domestic procurement is defined in legislation known as Schedule M (Ministry of Health and Family Welfare, 2001). Comparative analysis of Schedule M and the WHO's GMP standards suggests that the WHO standard is higher (Cohen et. al, 2007; Nautiyal, 2017). Nevertheless, the Indian courts have ruled that Schedule M is the legal standard for public procurement and this points to one of the reasons why quality in the domestic quality is different to export quality. Earlier in 2017, it was announced that measures would be taken to align Schedule M and the GMP standards (Nautiyal, 2017). Overall, however, the variation between standards goes some way to explaining why quality is often not treated as a binary variable in the Indian context.

It is assumed that large manufacturers, such as Cipla and Lupin, have the scale that allows them to invest in running high-quality factories. While they have faced quality challenges (Harris, 2014; Patel, 2016) they have been responsive to concerns and have successfully been serving global markets and international organizations. However, the cost of maintaining quality means that they are not always able or willing to offer the lowest price in the domestic market. Thus, they are unattractive to budget-constrained payers in lower-income states. Similarly, public procurement agencies are not an attractive consumer to high quality companies. Faced with the complexity of interacting with procurement agencies

of varying capabilities, where there are challenges around securing payments and information, larger, quality-conscious companies often focus their attention on export markets where both the commercials and ease of doing business can be more favorable. As a result, a plethora of domestically-focused manufacturers play a determining role in drug quality for the Indian public sector.

Reports indicate that there are more than 10,000 domestic manufacturers (PwC, 2010). For smaller scale manufacturers, the cost of maintaining quality to international standards, be they for the US FSA or WHO-GMP requirements, is considerable. For example, verification processes, maintaining sterile water filtration and air handling systems, and working with quality-assured suppliers can be costly business processes. In response, small and medium sized manufacturers can cut corners and struggle to maintain quality. Smaller firms also often offer lower prices. As a result, they win public procurement tenders, which prioritize the lowest offer, but fail to value and consider quality. However, they can have a significant impact on quality: the National Survey notes that 14 domestic manufacturers contributed to 42.55% of the NSQ formulations from Government sources (Ministry of Health and Family Welfare, 2017, pp.196-7).

Procurement

Reich and Roberts define procurement as the "process of purchasing health technologies from private or public suppliers and includes all decisions related to the specific quantities obtained, prices paid and the quality of health technologies received" (Roberts & Reich, 2011, p. 19). Within the procurement process a range of aspects can facilitate a health system's ability to provide high quality products (Singh et. al, 2013). Layloff has presented three sets of procedures that are relevant for ensuring the quality of medical products (Layloff, 2012, p. 19.8). The first two sets of procedures are directly relevant for procurement: Firstly, procedures to ensure that only products that meet quality standards are bought. This includes product and supplier selection, analysis for each product batch, GMP certification, batch certification and

the inclusion of detailed product-quality specifications in the contract. Secondly, procedures to verify that shipped goods meet the specifications, including pre- and post-shipment inspections and analytical pharmaceutical testing.

While the ideals of public procurement have been noted, the component is often identified as being vulnerable to corruption and mismanagement (Kohler et. al, 2016; Cohen et al., 2007; Strengthening Pharmaceutical Systems Program, 2011), particularly in the areas of quality control and assurance. Cohen et. al have identified several factors which contribute to this vulnerability, including: the complexity of the supply chain and the number of stakeholders involved in the process; the scale of pharmaceutical budgets; the high market value of medicines, which makes them vulnerable for theft; the scope for discretion in processes such as product registration, tendering and supplier selection; the asymmetry of information between patients, procurement agencies, payers and manufacturers; the difficulty in monitoring quality standards in medicines provision; the availability for suppliers to use different prices for the same product; weak governance and poor documentation.

There is also significant variation in how payment and procurement organizations operate. From an organizational perspective, procurement, distribution and payment systems can vary in the degree of centralization. In terms of governance, some agencies are autonomous from government entities while others are embedded within government. Decision-making processes also vary. Some agencies draw on a range of stakeholders from across an agency, as well as relevant government units, while others may confine authorization to a narrow group of procurement officials. As noted by Singh et. al (2012) the effectiveness of procurement agencies may be compromised by: the capability of staff; procurement processes; the structure of the procurement agency and its decision-making process; the ability of procurement agencies to predict and communicate demand; the ability of agencies to store products in appropriate conditions; the availability of funds to engage higher quality manufacturers; the availability of funds to conduct adequate quality assurance processes; the ability of an agency to manage complex

payments; and, an agency's ability to implement and draw upon prequalification criteria. While there are a series of features that agencies can implement to optimize their structure, the governance and culture of organizations can be harder to establish (Strengthening Pharmaceutical Systems Program, 2011). Governance, however, can often be critical to ensuring that organizations are well placed to procure high quality products.

Supply chain integrity

Supply chain integrity can be viewed as ensuring the quality of products through distribution and delivery. Reich and Roberts define distribution as the process of moving technologies through public or private channels, or a public private mix (Roberts & Reich, 2011, p. 19). Where storage environments do not comply with standards, the risk of products deteriorating becomes a concern. Procurement agencies need to be able to store drugs, as well as develop systems to dispatch drugs by sell-by-date to avoid stock piling of out of date products. Delivery is defined as the point in the supply chain at which the technology is physically transferred to its intended end-user by private or public channels (Roberts & Reich, 2011, p. 19). This includes ensuring that quality is maintained during storage and distribution procedures, that defects are identified and managed and that pharmacovigilance programs are well-established.

Dispensing practices and patient handling

Dispensing practices refers to the way in which physicians, nurses, pharmacists and other health professionals provide information and guidance about the use of products. Patient handling refers to how patients take on and adhere to this information in their use of drugs. Dispensing practices and patient handling will not be a focus area of this study; however, it is important to note that the ability of drugs to have the desired impact on patients is dependent on how pharmacists and physicians, as well as patients, have and respond to dispensing guidelines and information. Information can change perceptions about the quality and utility of an experience good (Caswell & Mojduszka, 1996; Dranove & Jin, 2010; Mathios,

2000). In markets where information asymmetry is significant, economists have pointed to the role that expert opinion, branding and advertising can play (Ackerberg, 2001; Ippolito & Mathios, 1990; Zhen & Zheng, 2015). Oral recommendations provided by an 'expert', or a respected authority, are likely to be more salient than labeling and pre-existing information about drug quality. In addition, quality and price can intersect in patient handling. For example, a patient may purchase a branded product at a higher cost and take a sub-optimal dosage to maximize the life of the medicine. This has consequences for the resistance capability of drugs and the effectiveness of high quality drugs.

Overall, a brief exploration of the areas that contribute to quality raises two important considerations. Firstly, that improving drug quality is unlikely to be facilitated by a focus on test results alone, rather, quality control and assurance mechanisms needs to be understood and built across regulation, manufacturing, procurement, supply chains, in dispensing practices and during patient handling. While this study will not delve into each of these areas in detail, interventions would need to be cognizant of the constellation of relevant actors. Secondly, in developed markets such as Japan, Europe and North America quality is often taken for granted and viewed as a binary variable. In India, however, structural aspects facilitate the presence of different gradations of quality, making it more likely for quality to be viewed as a continuous variable.

Focus on procurement and manufacturing

The rest of the review will focus on literature relating to procurement agencies and manufacturing companies. Thereafter, the theoretical framework will describe a proposed set of relationships for how interactions between procurement agencies and manufacturing agencies have an impact on quality. The reason for focusing on these two areas of the framework was chiefly driven by practical considerations. Firstly, to afford the study with a manageable scope, given the time limit constraint of five months. Secondly, because existing networks with procurement agencies and manufacturers make it feasible to

conduct a study, in limited time, on a sensitive subject. Thirdly, the funding organization has already undertaken extensive analysis in supply chain integrity. Finally, a study addressing patient handling and dispensing practices was not likely to be feasible given the time constraint.

The impact of the social, political and financial context of procurement system on drug quality

Tamil Nadu's experience of implementing procurement reform benefited from two state-specific preconditions: the political environment and commitment, and sufficient budget in 1994, when the TNMSC was established. Refom was primarily driven by concern about availability, but it was also recognized that quality was important (Revikumar et al., 2013). Following a significant drug scandal, the state introduced reforms to the purchase, storage and distribution of drugs (Singh et. al, 2012). The TNMSC was established as an autonomous agency, through the Tamil Nadu Transparency in Tenders Act (1998). Grassroots political pressure to address drug shortages and quality concerns was built up in the press and the government was pushed to invest resources in developing a plan to improve the availability and quality of drugs (Narayanan, 2010; Revikumar et. al, 2013). The state government had a desire to implement reforms, and the establishment of the TNMSC was one of many health improvement programs (Parthasarathi & Sinha, 2016a). Political leadership and the wider program of work signaled the state's commitment, which enabled it to secure external funding from the Danish International Development Agency and The World Bank.

Much less information is available about the experience of other states but Delhi's experience affirms the importance of funding and political support. In 1994, Delhi also went through an overhaul of its drug procurement processes and attempts to replicate the 'The Delhi Model' were funded by the WHO (Chaudhury et al., 2005). Prior to 1994, hospitals were procuring ad-hoc, at high prices, there were no regular quality control mechanisms. It was estimated that nearly 15-20% of drugs were counterfeit and/or substandard (Chaudhury et al., 2005). The recognition that government facilities faced constant shortages, that drug quality was poor and that patients were unsatisfied pushed politicians and policy makers to act.

In 1994 Delhi became the first Indian state to have a dedicated drug policy: The Drug Policy for the National Capital Territory of Delhi. A non-governmental organization – The Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD) – was set up to support the state government and universities with identifying how to address the limitations of the existing system. The organization, supported by the policy and it had a specific purpose to improve the availability and quality of drugs (Roy Chaudhury et al., 2005). It was also led and supported by a committed group of technocrats and bureaucrats, and had high-level political support. Leadership worked in a voluntary capacity, which eased funding pressures during the set up of the organization. However, later on the Delhi model experienced funding limitations. The state was not able to sustain funding for factory inspections of all vendors in line with WHO standards, demonstrating that the sustainability of reforms to assure quality are dependent on funding and political commitment.

Delhi's experience also highlights how the introduction of quality assurance mechanisms were one part of a set of reforms intended to support the state in improving rational drug use, access and affordability. For example, the establishment of the first Essential Drug List and Centralized Pooled Procurement of Drugs were key aspects of the reform. These measures went hand in hand with efforts to improve quality. While the focus of this study is on quality, it is important to note how these other aspects support quality improvement.

The structure and governance of a procurement agency

As noted earlier in the section, there is considerable variation in the organizational structure and governance of procurement agencies and these attributes can affect drug quality. There are not straightforward relationships between these organizational and governance approaches and quality assurance; however, in each context these features may hinder and facilitate an agency's ability to secure and maintain drug quality.

In Tamil Nadu, the political environment and funding sources allowed the bureaucrats responsible for establishing the TNMSC to consider how to optimize its structure. This focus on governance and organizational culture can be hard to secure (Strengthening Pharmaceutical Systems Program, 2011); however, these aspects can often be critical to ensuring that organizations are well placed to procure high quality products. In Delhi, much like Tamil Nadu, political support and the involvement of influential individuals provided space for intellectual input and innovation in governance. For example, the establishment of a Special Purchase Committee (SPC). The SPC gave authority to stakeholders outside of the Ministry of Health, in addition to a cadre of committed and motivated staff members, and helped to establish the organization. Similarly to Tamil Nadu, there was also the recognition that it was important to engage a wide range of stakeholders to afford the organization with credibility. Another reason for the importance of governance is the vulnerability of procurement systems to corruption and mismanagement, particularly the areas of quality control and assurance (Kohler et. al, 2016; Cohen et al., 2007; Strengthening Pharmaceutical Systems Program, 2011). Organizations with strong governance structure are better placed to limit the scope for processes related to quality being corrupted.

Specific operational features

There is a range of operational features that can be used to facilitate an agency's ability to purchase safe and effective medication and assure its quality through service delivery, which are listed in Figure 6. These features are documented in comparative analyses of public procurement agencies and in health systems delivery literature (Chokshi et. al, 2015; Kotwani, 2009; Narayanan, 2010; Parthasarathi & Sinha, 2016b; Singh et. al, 2013; Singh et al., 2012). The measures can be grouped as follows: quality testing and control mechanisms, procurement processes, payment mechanisms, supplier management and supply management. The first group relates directly to quality, while the others are more general; however, they can still have a significant impact on an agency's ability to assure quality.

Quality testing and control measures include the use of mandatory external quality testing, testing before distribution, blacklisting of substandard quality suppliers and penalties for quality failures. Procurement processes include combined state level-financing and procurement mechanisms, technology systems to support forecasting, tendering, quality control and payment inventory management. Payment mechanisms include an agency having a state budget allocation for drugs, an emergency drug budget

Figure 6: Operational features of procurement agencies documented in existing literature

Area	Feature
Quality testing and control	Mandatory external quality testing
	Testing before distribution
	Blacklisting of substandard quality suppliers
	Penalty for quality failure
Procurement processes	Combined state level financing and procurement mechanisms
	IT systems to support forecasting, tendering, quality control, payment, inventory management and overall procurement process management
	State budget allocation for drugs
	Emergency drug budget allocation
	Two-envelope bidding process
	Process for tenders with no bidders
Payment mechanisms	Autonomous payment body
	Pre-requisites for payment disbursements
Supplier management	Prequalification criteria for suppliers e.g. minimum turnover criteria, quality certification requirements, market standing requirements, production capability, exclusion criteria
	Supply schedule
	Protocols for regular inspection of supplier premises
	Penalty for defaulting on the supply schedule
Supply management	Demand estimation and forecasting
	Warehouse and inventory
	Flexibility to change purchase orders
	Supply tracking
	Real time stock monitoring at warehouse and facility level
	Vehicles for warehouse-facility transfers
	Customized Essential Drug List validated by multiple stakeholders

Sources: (Chokshi et. al, 2015; Kotwani, 2009; Narayanan, 2010; Parthasarathi & Sinha, 2016b; Singh et. al, 2013; Singh et al., 2012)

allocation. The division and control of this budget can have a bearing on the political control and dynamics between an agency and other government institutions. Agencies can also use two stage bidding processes, where bids are first evaluated on their technical merits, in terms of whether a supplier meets

quality requirements and pre-qualification criteria, and then on its financial merits. They can also require that prerequisites be met before payments are disbursed.

Supply management can also play an important role in facilitating an agency's ability to engage with manufacturers. Agencies that can estimate demand and provide forecasts, have the capability to check real-time stock levels at the warehouse and facility level and issues purchase orders based on inventory, are better placed to engage reputable companies, as those companies often value having visibility over demand. Finally, supplier management capabilities are crucial to an agency's ability to secure drugs. For example, agencies can establish prequalification criteria for suppliers to screen out low-quality suppliers. They can ask for supply schedules to gain assurance of supply, and support this by introducing penalties for suppliers that default on the supply schedule. They can conduct inspections of supplier premises to ensure that equipment is kept in good working condition and that standards are upheld.

Considering three features in more detail – centralized drug procurement and distribution, mandatory external quality testing and pre-qualification criteria – through the experience of Tamil Nadu can help to explain why the procurement agency is perceived to be more effective than others within existing literature. It can also illustrate the way in which these features have an impact on drug quality, but it is important to note that these are not causal relationships and that they are context-specific.

Centralized drug procurement and distribution, enabled by an effective information technology system, has been identified as a key success factor of the TNMSC model (Chokshi et. al, 2015; Kotwani, 2009; Narayanan, 2010; Parthasarathi & Sinha, 2016b; Singh et. al, 2013; Singh et al., 2012). Drugs are purchased by the TNMSC at a central level. Products are then dispersed, using vehicles and warehouses, to a network of health facilities. Each facility is given a financial envelope or allocation, and they can obtain any drug in the approved list provided they have the funds available in their allocation. This is

supported by a Drug Distribution Management System, which is used to monitor the procurement and distribution of drugs. Each warehouse is linked to the central procurement office through a computerized system. As drugs are purchased and issued to facilities the system is automatically updated.

The TNMSC draws on external quality testing measures to verify the quality of products before distribution. The measures are described on its website (Tamil Nadu Medical Services Corporation, 2017) and in academic literature (Singh et al., 2013). A sample from every drug batch is tested in an empaneled laboratory. Following a successful test, the batches are then distributed to institutions. Random samples are drawn from warehouses and de-coded. De-coded samples are then sent for testing. Once the agency obtains a quality certificate and indicates its samples are up to standard, the batch is released for distribution to government institutions. Drug samples are also randomly selected when drugs are in storage, until their expiry date, and tests are conducted in empaneled and government laboratories. If a drug batch fails either quality test the remaining warehouse stock is frozen, the products are recalled and returned to the supplier. If three batches of a drug fail within the tender period or shelf-life then the product is blacklisted for five years. If a supplier is responsible for more than one item and 50% of their products fail testing during the tender period, then they are blacklisted for five years. Finally, blacklisted products and suppliers are noted publicly on the TNMSC website.

Pre-qualification criteria for manufacturers also plays a role in enabling the state to maintain quality standards. Suppliers are required to have a minimum turnover of Rs. 3 crore, to have a WHO-GMP, US FDA or International Organization for Standardization (ISO) certification, and assurance of available production capacity, have been in business for three years and have no exclusion criteria for factory inspections (Singh et al., 2013). The use of pre-qualification criteria draws on guidance from the WHO (World Health Organization, 2002, 2007a) and mirrors the processes used by international organizations

such as Gavi and the Global Fund. However, while processes can be drawn up in guidelines and documentation, success in terms of practical implementation is oftentimes much harder to secure.

SECTION III: THEORETICAL FRAMEWORK

Introduction

The existing literature on procurement agencies in India can be synthesized to form a three-part theoretical framework to describe how state-specific factors may be affecting drug quality, as illustrated in Figure 7. This framework focuses specifically on the relationship between procurement agencies and manufacturing companies. It informed the design of the interview protocol (see Appendix A) and the codes and categories used during data analysis (see Appendix B).

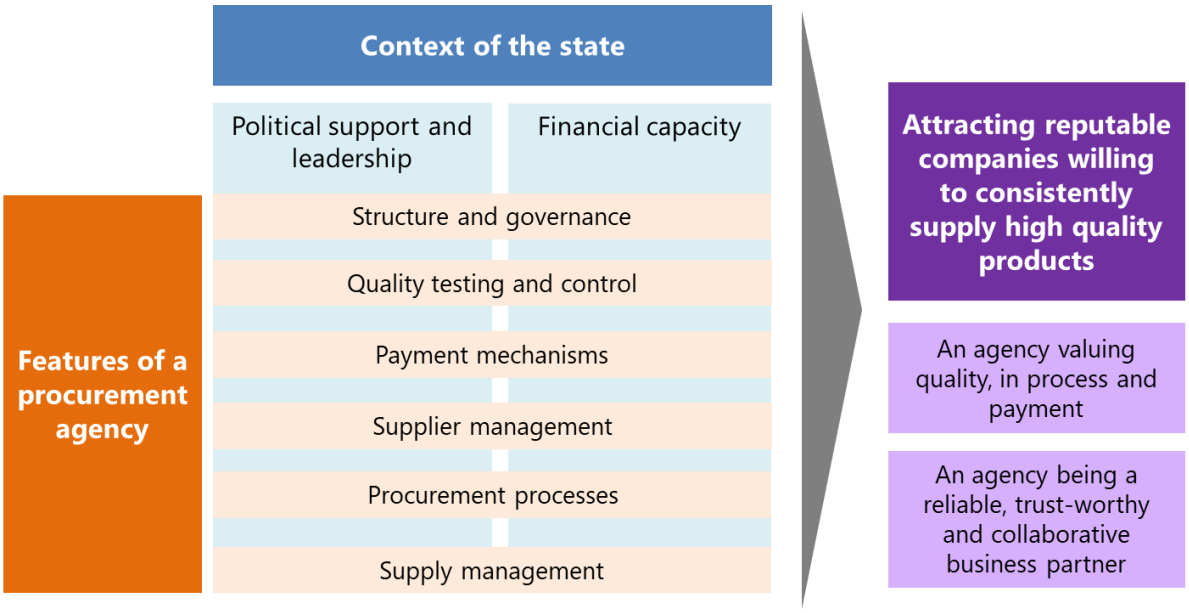
In brief, preconditions or enablers within the state and specific features of the procurement model can have a determining impact on the relationships between agencies and companies. Enablers or preconditions include aspects such as the political or economic context of a state. Quality-specific procurement features includes measures such as the blacklisting of substandard suppliers. For example, in a state where there is strong leadership, which express low tolerance for fake products, measures to screen out low-quality suppliers are likely to be better upheld. As a result, a reputable company, which produces safe and effective medication, may be more inclined to supply one agency over another because it believes it will be rewarded for its endeavors and that the quality of its products will be valued. This does not translate to a set of causal relationships but rather a description of how relationships between the relevant stakeholders can function.

Preconditions or Enablers

Preconditions or enablers within a state play a significant role in determining the state's ability to prioritize and focus on drug provision and quality. The two main enablers that were consistent themes, particularly in literature on Tamil Nadu (Narayanan, 2010a; Parthasarathi & Sinha, 2016b; Revikumar et

al., 2013; Singh et al., 2012; World Bank, 2017b) and Delhi (Chaudhuary, 1999; Chaudhury, 2004; Chaudhury et al., 2005) were political support and leadership and financial capability. Political support and leadership were critical to enabling the establishment of effective organizations and the provision of expertise to facilitate innovation and transparency. Financial capability was important to invest in developing procurement structures that can value quality testing and inspire confidence in an agency's ability to work well with relevant organizations.

Figure 7: Summary of the theoretical framework



Features of a procurement agency

As described in the literature review, within a strong enabling environment, an agency can adopt a range of organizational and operational features. These features cover a broad range of aspects, including: structure, governance, quality assurance, payment mechanisms, supplier management, procurement processes and supply management. However, the effectiveness of these features is related to the context of the state. Where there is strong political support and funding the features are more likely to be effective and an agency will be better placed to assure quality.

Attracting reputable companies willing to consistently supply high quality products

Where there is a strong enabling environment, where corruption and vested interests do not negatively affect procurement and quality is a political priority, and a set of organizational features that are optimized within the local context, a procurement agency is better placed to assure the quality of medical products. The pathway to achieving this capability is through the relationship between agencies and companies. This can be viewed in terms of agency valuing quality, in process and payment, and an agency being a reliable, trust-worthy and collaborative business partner.

Agencies with well-established systems and protocols for conducting business can signal to companies and other organizations that they are trustworthy and that conducting business will offer a recoverable financial reward. Agencies that can establish and operate their systems on on-going basis and earn reputations as reliable organizations stand a better chance of continuously engaging with quality-conscious companies. For quality-conscious companies that invest in the equipment, training and personnel, the professionalism and the autonomy of the organization can provide an assurance that business relationships will be rewarding. In this context, reward relates not only to the commercial value of the contract but also the cost and ease of doing business. The TNMSC supplier list, while it does not provide detailed information on supplier volumes and prices, indicates that the procurement agency has been able to work with Abbott, Bristol Myers Squibb, Cipla, Dr. Reddy's, Eli Lilly, Glaxosmith Kline, Johnson and Johnson, Merck, Novartis, Pfizer and Sun Pharmaceuticals. While these firms are not immune to quality concerns, they have sufficient size and reputational incentives to maintain stringent quality standards and to respond to quality breaches. Finally, agencies whose systems indicate that they value quality, either through testing, screening out inadequate quality suppliers or other mechanisms, can signal to the market that they wish to and will only work with reputable suppliers.

SECTION IV: METHODS

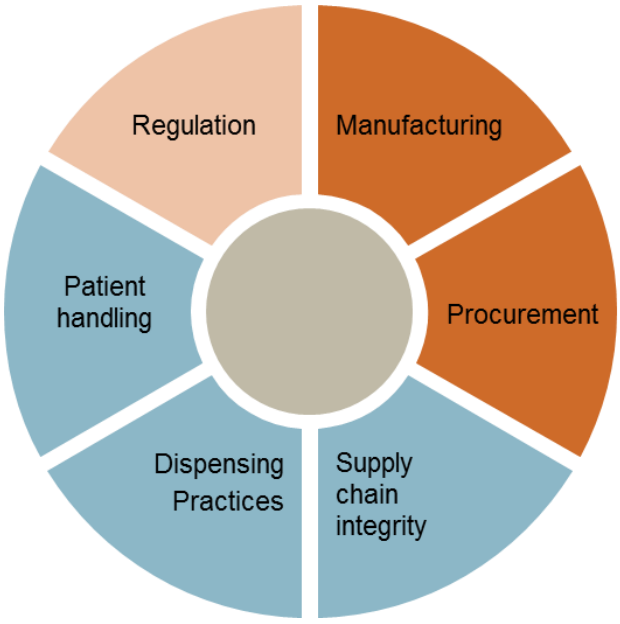
Introduction

This section will describe the methods used for the study. Following on from the purpose statement, the section will discuss the qualitative research approach and case selection. This will be followed by detailed case descriptions of the BMSICL and TNMSC. Thereafter, the section will describe: the participants, sampling strategy, data collection tools, data analysis approach and procedures. Finally, the section will address the validity and reliability of the study, as well as its limitations. For more information, Appendices A and B provide the detailed interview protocol and codebook.

Purpose of the study

The purpose of this qualitative case study was to examine the factors explain the challenges of ensuring the quality of drugs procured by public tender in Bihar. In this context, drug quality can be viewed in terms of the safety and efficacy of a drug. Building on the literature review, drug quality was conceptualized as the perception that a drug would not be safe or efficacious, and that this would be the result of limitations in capabilities and processes across the six components of the system illustrated below. This reflected the qualitative nature of the study as drug quality was not only determined by a set of pharmaceutical tests.

Figure 5 (repeated): System components of improving public sector drug quality



Source: Author

Qualitative Research Approach

The study used a qualitative case study approach to address the research question of what factors explain the challenges of ensuring the quality of drugs procured by public tender in Bihar. A qualitative approach was chosen because of the limitations of quantitative assessments of drug quality and the recognition that drug quality is determined by the actions of multiple organizations and various stakeholders. The limited range of existing literature that is specifically focused on the factors determining drug quality at the state-level in public procurement also supported the use of a qualitative approach. The interview protocol reflects the exploratory nature of the study, as it contains a broad set of questions. However, material for this paper was focused on factors that related to the BMSICL's ability to assure quality.

A case study approach was chosen because of the focus on examining contextual factors affecting drug quality assurance (Baxter & Jack, 2008; Yin, 2013). The case study type was explanatory (Baxter & Jack,

2008; Yin, 2013), because the study sought to explain presumed causal links between the intervention of replicating a high functioning model in a weaker environment and drug quality.

Case selection

The unit of analysis for this study (Baxter & Jack, 2008) was the phenomenon of replication by procurement agencies, with a focus on one procurement agency: the BMSICL. The intent was to analyze how a procurement agency's organizational features and contextual relationships, particularly with pharmaceutical companies, affected its ability to assure drug quality in public tenders. To afford the study with a manageable focus the case was bound (Baxter & Jack, 2008; Creswell, 2014) to focus on the state of Bihar and the relevant timing was from 2010, when the agency was established, to the point of the study, in 2017. As the case study focused on replication, it was necessary to consider the TNMSC model. In this respect, the study drew on between case analysis and treated TNMSC as a subunit.

Case description

Between 2008 and 2010 Bihar's medical purchasing system was caught up in a corruption and fraud scandal (Bhatial, 2014; Raj, 2017; S. Singh, 2017). The Enforcement Directorate of the Government of India charged 15 people (Raj, 2017). Officials were reported as stating that the case was one of embezzlement by two drug inspectors, state clerks, state employees and suppliers (Kumar, 2017). Those who were charged were accused of collaborating to procure medical products at inflated prices and larger volumes than needed. The scam was reported as having cost the state exchequer Rs 12.6 crore between 2008 and 2010 (Raj, 2017). Following the scandal, the BMSICL was established to improve drug procurement. Responsibilities for drug procurement were then distributed between the State Health Society and the Corporation. However, in 2013 the BMSICL was also embroiled in a scandal (Bhatial, 2014). Newspapers reported that Rs. 14.48 crores worth of drugs were purchased at inflated prices and that Rs. 19.6 crores worth of medication was purchased from blacklisted companies (Kumar, 2017).

Precisely what happened in these scams is difficult to discern because of the sensitivities surrounding drug scams, and because of the intensity with which scams are politicized. For example, the 2013-4 scandal saw partisan political clashes between the Janata Dal United (JDU) Party and the Bharatiya Janata Party (BJP) ("Nitish fires drug scam letter to Modi," 2014). However, the impact of these types of scandals is clearer to identify. In the short term, the scandals made it difficult to mobilize procurement contracts ("Spectre of scam limbo," 2017). Staff and officials were reluctant to be involved with procurement and suppliers were unwilling to engage, because of the risk of being accused and charged with corruption. In the medium term, institutions are weakened and the state's ability to attract suppliers, staff and manage procurement are all compromised. A former Chief Minister of Bihar described the limbo effect of scams to a newspaper stating that:

> It leads to administrative paralysis. Officials stop taking decisions on files and usually try to pass the buck….Also, whenever scams take place, some innocent and good officials, too, face the brunt of police investigation and have to go to jail. Thereafter, officials try to avoid a scenario where any decision can be traced to their desk…Before the scams, Bihar used to be a deficit state, having to go to the Centre for more money to pay its employees. After the scams it suddenly became a financially surplus state ("Spectre of scam limbo," 2017)

Despite being established in 2010, the BMSICL did not purchase medicines for its first two years ("Spectre of scam limbo," 2017). Newspaper reports attribute this to purchase committee members not attending meetings in fear that they would be caught in another scam and, pharmaceutical companies being reluctant to respond to tenders (Bhatial, 2014; Raj, 2017; "Spectre of scam limbo," 2017).

The persistence of corruption scandals, particularly with regards to health expenditures, is not specific to Bihar. Similar challenges have been documented in other Indian states and procurement literature

identifies corruption as a recurring issue in drug procurement (Cohen et al., 2007; Cohen et. al, 2007; "NRHM scam: 2 former UP ministers to appear before CBI - Indian Express," 2011, "NRHM scam: CBI files charge sheet against former UP minister | The Indian Express," 2017, "Uttar Pradesh NRHM scam: Former CMO shoots self | Hindustan Times," 2018; Rai, 2012). For example, between 2008 and 2011, Uttar Pradesh (UP) was racked by a prominent and disruptive scandal ("NRHM scam: 2 former UP ministers to appear before CBI - Indian Express," 2011, "NRHM scam: CBI files charge sheet against former UP minister | The Indian Express," 2017, "UP health scam: 5th official found dead, family cries murder - Indian Express," 2012). Leading politicians were alleged to have fraudulently siphoned US$ 1.6 billion from the National Rural Health Mission ("Mayawati misused funds for rural health: PM- The New Indian Express," 2012). The scam emerged after two Chief Medical Officers were murdered, and four others who were connected to the scam were later murdered (Rai, 2012). While the experience in UP was bloodier than that in Bihar, it goes some way to describing the environment of fear, distrust and opportunism that can surround drug procurement. The ability of a state government to overcome corruption scandals and establish functional and effective institutions is critical, and in this regard the development and state of Bihar's procurement capabilities has wider relevance.

Bihar also has a broader relevance because it has received considerable support from external organizations and donors. From 2008 funding from the UK Department for International Development (DFID) provided technical support to the Government of Bihar. This was delivered through a consortium, which included CARE, IPE Global and Options Consultancy Services. Together they supported the Bihar Technical Assistance and Support Team (BTAST) (Bihar Technical Assistance Support Team, 2015). BTAST provided support to the Department of Health, the Social Welfare Department and the Public Health and Engineering Department, the State Health Society, the State Institute for Health and Family Welfare and the BMSICL through the Sector Wide Approach to Strengthening (SWASTH) health program. SWASTH aimed to improve health and nutrition by strengthening systems, developing

organizations and improving coordination across major departments (Bihar Technical Assistance Support Team, 2015). Technical Assistance was provided to the BMSICL to "…improve and relaunch its procurement and supply chain functions, following its temporary closure due to mismanagement allegations last year…" (Bihar Technical Assistance Support Team, 2016). This also included introducing measures to address corruption, such as the Special Vigilence Unit to pursue corruption allegations against senior civil servants. The program consistently received high ratings (DFID, 2015). Thereafter, in 2011, CARE International established a Technical Support Unit (TSU), in conduction with DFID, UNICEF, UNFPA, NIPI, WHO, Emory, Janani, BBC Media Action, Engender Health, Abt Associates and the BMGF. The program, like BTAST, addressed a wide range of programmatic areas. The aim of the TSU was '…to overcome system and policy level barriers to bring about the requisite systemic changes, develop government leadership with a focus on outcomes, promote the use of data and accountability, and build technical and managerial skills at both outreach and facility levels…." (DFID, 2015).

Tamil Nadu's procurement model was a sub-unit within the study. TNMSC was drawn upon because: it informed the design of the BMSICL and the model has had a wider role in establishing and promoting ideas on how state governments can establish effective procurement institutions. Since the late 1990s the TNMSC has been regarded as an exemplary model for Indian states, and it informed the design and development of the BMSICL in 2010. The context of the TNMSC is significantly different to that of BMSICL. For example, the two states differ in terms of their socio-economic profile (for details see p. 6), as well as the reputation and maturity of their drug procurement capacities. However, there are some similarities. Although it has not been documented as having as violent or prominent an impact on drug procurement, corruption is often regarded as a significant undercurrent in Tamil Nadu, after all, the impetus for the TNMSC developed after a drug scandal (Revikumar et al., 2013).

Much of the dialogue around Tamil Nadu has focused on its exemplary nature and how it its model can be replicated by Indian states. Far less is written about how those ideas can be maximized within a different

context and how states can develop, rather directly transplant, institutions. Analysis of Tamil Nadu and Bihar can help contribute to discussions about how to avoid isomorphic mimicry, where it is assumed that replicating the institutional structures found in functional states will lead to success in weaker environments. Understanding how the TNMSC and the BMSICL differ is intended to support the relevance of the study to other procurement agencies, particularly those from states with a socioeconomic profile and developmental position, in terms of institutional capacity, similar to that of the BMSICL. However, there are important limitations to this comparison, which are noted toward the end of this section.

Participants and Sampling Strategy

Given the focus on procurement agencies and pharmaceutical companies, participants were selected on the basis of their expertise, research experience or engagement with a pharmaceutical company with experience in the Indian market or a drug procurement function in low-income settings. In-depth, semi-structured interviews were conducted with thirty participants between August and November 2017.

Purposive, expert sampling was used to recruit experts from procurement agencies and pharmaceutical companies. To provide context, additional interviews were conducted with domestic regulatory experts, international regulatory and governance experts, private sector health companies, domestic civil society organizations, think-tanks and non-governmental organizations. This approach was used because this research was exploratory, there was a lack of reliable empirical evidence and uncertainty about the quality of drugs at the state and national level (Baxter & Jack, 2008; Yin, 2013). In addition, three field visits to undertaken interviews and view relevant procurement sites. This included a two-day field visit to district-level facilities was conducted. District selection was based on feasibility and security of travel and availability of staff for interviews and facility tours.

Data Collection Tools

A literature review was conducted to develop a theoretical framework of interactions between procurement agencies and manufacturers. This informed the development of a broad interview protocol (see Appendix A), which reflected the nature of the study, and iterations of the research question. The interview protocol was tested with a senior procurement expert and revised accordingly. During the interviews, questions were tailored to participants, as described in the protocols. Participants with expertise in the Indian domestic market were primarily asked about drug quality in Bihar and India. International and national experts were asked about their view on contexts such as Bihar, as well as the broader challenges across contexts. This paper presents a sub-set of the data collected and analyzed and is specific to state-level factors in Bihar.

Procedures

Participants were recruited, through email, by foundation staff in the New Delhi Office. Each participant was asked for his or her consent to record the interview and for detailed notes to be taken. Where consent for recording was provided, interviews were transcribed verbatim. Where consent for note taking but not recording was obtained, interview notes were transcribed immediately after the interview to limit recall basis as much as possible. Participants were interviewed over the phone, at the offices of the India Country Office of the Bill and Melinda Gates Foundation (BMGF) or in their own organizations. The detailed interview protocol, which also provides directions on how interviews were tailored to participants' areas of expertise, is provided in Appendix A.

Interviews lasted between thirty minutes and two hours and were conducted in a private setting. The interviews were conducted in English and Hindi, with an English translator, and transcribed in English. Field notes, including summaries of reflections and observations immediately following interviews, and grey literature provided to the team from participants were collected and included in data set that was

collected and analyzed. Transcripts were password protected and saved on the secure internal servers. Participants' names were removed from the transcripts to safeguard anonymity. The study was reviewed by the Institutional Review Board and met the criteria for exemption.

Data Analysis

This analysis was focused specifically on themes relating to state-level factors within Bihar, namely corruption and vested interests, technical measures and manufacturer incentives and practices. A four-stage thematic analysis was conducted to identify, analyze and report patterns themes from interview transcripts, grey literature and field notes. In Stage 1, data was closely read and re-reviewed for general impressions to create an initial set of codes. On this basis a preliminary set of codes was identified based on repetitive patterns or meaning in the data that provided research into the aims of the study (Boyatzis, 1998; Braun & Clarke, 2006, 2014). Both preset codes, defined before working with textual data and during or after data collection, and emergent codes (defined after the data), were used. Preset codes were informed by the literature review, which considered relevant concepts, theories and evidence identified a preliminary set of sub-codes based on repetitive patterns or meaning in the data that provided insight into the research aims of this study (Boyatzis, 1998; Braun & Clarke, 2006, 2014). Atlas.ti software was used to facilitate data analysis in Stage 1, and thereafter manual coding was adopted.

In Stage 2, the coded data was further examined for relationships and intersections to identify categories (Boyatzis, 1998; Braun & Clarke, 2006, 2014). In Stage 3, categories were populated with data, including respondent quotations (Boyatzis, 1998; Braun & Clarke, 2006, 2014). In Stage 4, the categorized data was re-reviewed to identify themes (Boyatzis, 1998; Braun & Clarke, 2006, 2014). Figure 8 provides a summary of the themes and categories that were used. Details on each of themes, categories and codes can be found in Appendix B. This includes details on inclusion and exclusion criteria.

Figure 8: Summary of themes and categories

Themes	*Categories*
Political Environment	Local Political Factors
	Prioritization of Procurement
Technical Measures	Quality-Specific Measures
Manufacturing incentives and practices	Commercial incentives to supply the BMSICL
	Production and sales practices

Source: Author

Limitations and Potential Research Bias

As described in the literature on case studies (Baxter & Jack, 2008; Yin, 2013) there are challenges to the validity and reliability of this method, particularly for explanatory case studies. Recognizing these challenges, activities were undertaken in data collection and analysis to support the study's validity and reliability.

Generalizability

An ideal study design could have included multiple case studies, with cases being selected on the basis of relevant similarities and differences, enabling the derivation of causal relationships. The constraint of limited timing made it possibly to only research a single case, which has important limitations on aspects such as the generalizability of the study. This study design was intended to examine factors that explain the challenges of ensuring the quality of drugs in the context of a weak state seeking to replicate the model designed in a stronger enabling environment. It offers insights about replication in relation to Bihar in this instance, and can inform analysis of similar contexts. However, the study has no formal

generalizability and it is not possible to make generalized inferences. In addition, there are examples where replication has been more effective, such as Rajasthan as noted previously.

Participants' willingness to share information

Participants may have been reluctant to share detailed information. They may also have been reluctant to be truthful about their perspectives and experiences because of the sensitivity of the subject matter. As described in the literature review procurement is often regarded as an area that is vulnerable to corruption, which brings a sensitivity to discussions. Some participants described significant risks to their well-being and security, for example they had received death threats following their engagement with procurement and regulation activities. It is not clear how this affected their contributions to the study, but it is feasible that it had an impact on how much they were willing to divulge.

There was potential for bias given that the research was funded by a private foundation. However, it is unclear how this bias may have taken effect. For example, interviewees may have presented more challenges or difficulties if they believe funding could have been secured to address issues. Alternatively, they may have been conscious of presenting a good impression, particularly on a commercially sensitive topic, and have been reluctant to share information. In addition, the researcher's presence during data collection may have changed subject responses and, to some extent, much of data collection is dependent on personal interaction and rapport.

To mitigate limitations in this area, data was frequently triangulated during data collection and analysis. In addition, multiple data sources were considered and analyzed together. This included interview transcripts, government reports, field notes from interviews and field visits. During data collection, data was triangulated to inform upcoming interviews and support the tailoring of interviews. During data

analysis, themes and patterns emerging were cross verified and those that were selected arose from the perceptions of multiple participants and were evident across multiple sources.

Access to participants

An ideal study design could have included interviews, observations and field-visits with stakeholders from more than three segments of the framework (procurement agencies, manufacturers and one drug inspector were interviewed). However, in addition to timing constraints, there were also limitations arising from the study being funded by a private, foreign foundation. During the study scoping it was recognized that discussions with current government officials and regulators could be perceived negatively (Najar, 2017; Ross, 2017). As a result, we did not actively reach out to these stakeholders. In addition, while the position of the funding organization placed constraints on access to participants, it also facilitated access in other areas. The foundation's networks across industry and non-governmental organizations enabled rapid and substantive access to several participants in limited time.

To mitigate this limitations in this area, regulatory experts and participants with experience of the regulatory system were sought out. Acknowledging the importance of identifying and analyzing credible data and amassing a body of data, thirty participants were interviewed to afford the study with a range of perspectives. In addition, participants provided grey literature, field visits were conducted and efforts were made to visit participants in their setting to facilitating understand the context of the information being provided.

SECTION IV: RESULTS

Introduction

Participants were invited to comment on the factors that challenged the ability of the BMSICL to ensure the quality of drugs. This section will begin with a presentation of attitudes towards the replication of the TNMSC model. Thereafter, the findings across three categories (political environment, technical measures and manufacturer incentives and practices) will be presented. These findings demonstrate the capability traps that emerge from the BMSICL having similar institutions and processes to the TNMSC, but not the same functionality.

Background

The attitude that following the TNMSC model is a path to success could be seen from the way in which several participants discussed the model and its role in informing other procurement agencies, which sought guidance from experts familiar with the TNMSC. After describing specific processes, participants made generalized statements that positioned the TNMSC as the established role model for India. In 2010 officials from Bihar sought out advice from experts with experience of the TNMSC model to understand features that could be used in the development of Bihar's model. Procurement officials discussed the TNMSC as an exemplar from which the BMSICL had drawn guidance:

> *"…So we directly follow the TNMSC model but we do mostly what TNMSC, RMSC or KLMSC are doing. Same thing, because TNMSC is the role model…So it was established around 21 years ago and we established ourselves 5-6 years ago…" – Procurement official in Bihar*

In their discussions, participants conveyed the view that the BMSICL had failed because it had not fully replicated the TNMSC model and that completed replication would have enabled success:

"…if they are replicating TNMSC it should be a complete replication…" – Procurement official in Bihar

Experts discussed Bihar's limitations in terms of a technical failure to replicate specific features and processes. This was prominent in discussions of the BMSICL approach to warehouses. Senior procurement experts cited the lack of district-level warehouses as a reason for the challenges facing the BMSICL. In comparison to Tamil Nadu, which had established 38 district-level warehouses, Bihar had only 3 warehouses that were well set up to ensure the quality of products. External experts also described this as a significant limitation to the agency's ability to ensure product quality, an attitude that was indicative of the view that complete replication could have facilitated success.

"*For districts, we have 38 warehouses, each district has its own warehouse, which are under the control of each district. But for us, we have 3 warehouses." – Procurement official in Bihar*

"…years ago I advised them on the set up of their procurement agency. They have not fully taken on the concept, for example they only have three warehouses across the state, not district warehouses across the whole state like Tamil Nadu. So, they have not adopted critical aspects of the whole model. It's not a Tamil Nadu model, they have not followed it. They don't have the IT infrastructure, and several of their processes are not up to standard. That is why I call it a failed model." – Senior procurement expert

While some participants could draw out the differences between states and engage in detailed discussions about adapting to political, social and economic realities affecting functionality, others struggled to view replication as a nuanced process. One participant, a senior health official, reduced replication to 'cutting and pasting' the TNMSC model.

"…Just cut and paste the TNMSC model. Simple. Cut and paste…." – Health official

Political Environment

Political environment refers to the relationships, practices and dynamics, which have a bearing on the procurement of drugs at the state-level. This includes relationships between businesses, governments and procurement officials. Within this theme, two categories will be discussed: firstly, corruption and vested interest, and secondly, the prioritization of procurement.

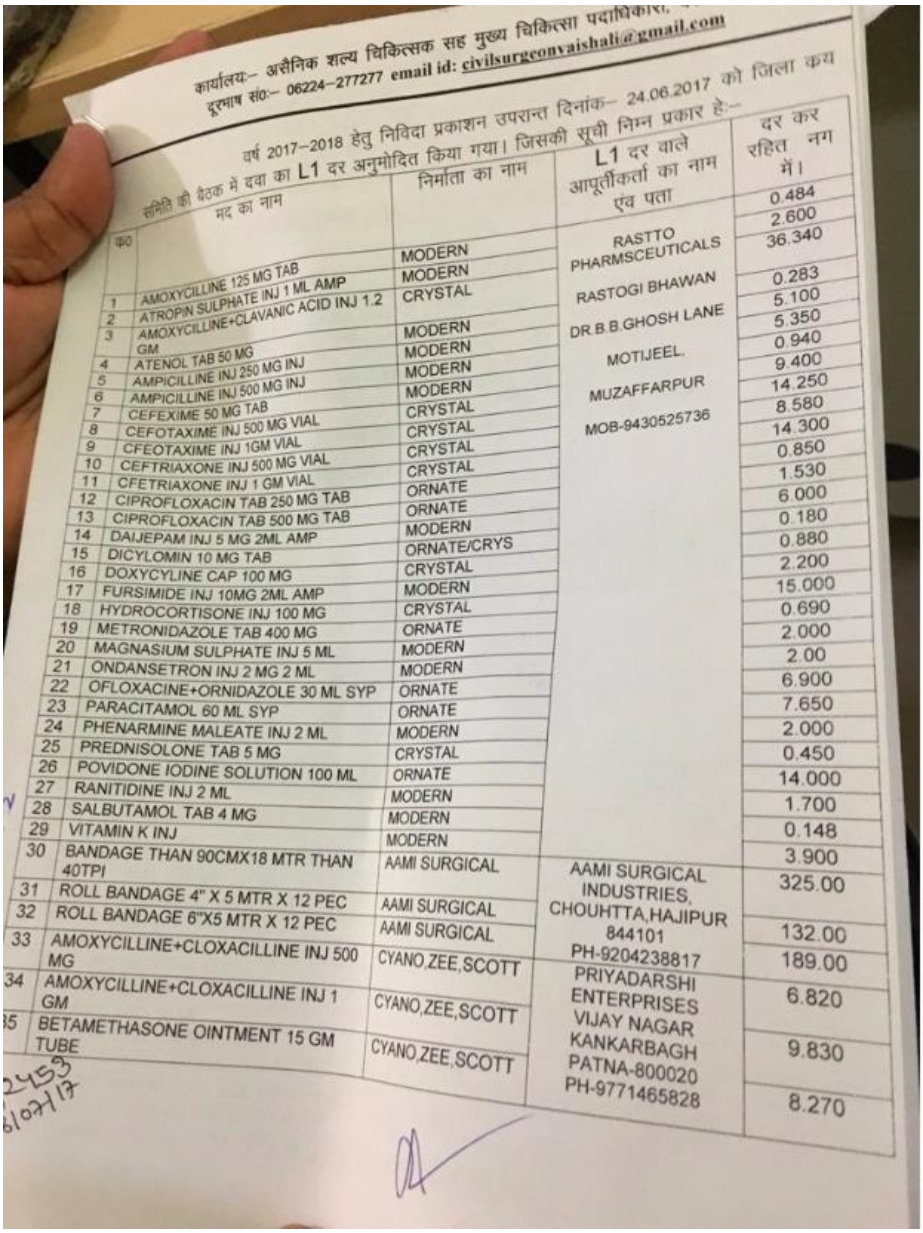
Corruption and vested interest

Participants described the importance of political will and discussed how corruption across Bihar's districts had made it difficult to establish the operational capacity of the BMSICL. Corruption was identified as compromising efforts to overcome challenges and build organizational credibility. The key example of this were perspectives on district-level procurement officials contracting outside of the BMSICL framework. Decentralized procurement is not necessarily negative, but in the case of Bihar it was described as having a negative impact for three reasons.

Firstly, ad-hoc contracting between a district-level procurement official and a local distributor was not subject to quality checks. It was not part of the state-level operation and subject to its processes. Figure 9 in provides an example of an ad-hoc district-level procurement contract. The procurement official initiated the contract in response to unrest from local patients over shortages. Secondly, district-level procurement limited the BMSICL's capacity to leverage volume across the state and build competitive contracts and framework agreements with manufacturers. Paper-based contracting between a district procurement officer and a local distributor circumvented the state-level operation. Despite attempts to set up an autonomous, technology-enabled state procurement agency, much of Bihar's drug procurement remains decentralized. As a result, the state could not draw on district-level demand and incorporate it into centralized planning and engagement with manufacturers. Figure 10 provides an example of a

district-level procurement office, that was largely operated on paper as opposed to a technology-enabled system. This is distinct from a system of decentralized procurement, where decisions and payment can be

Figure 9: Ad-hoc district-level procurement contract with a local distributor



कार्यालय:– असैनिक शल्य चिकित्सक सह मुख्य चिकित्सा पदाधिकारी,
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वर्ष 2017–2018 हेतु निविदा प्रकाशन उपरान्त दिनांक– 24.06.2017 को जिला क्रय समिति की बैठक में दवा का L1 दर अनुमोदित किया गया। जिसकी सूची निम्न प्रकार है:–

क्र0	मद का नाम	निर्माता का नाम	L1 दर वाले आपूर्तीकर्ता का नाम एवं पता	दर कर रहित नग में।
1	AMOXYCILLINE 125 MG TAB	MODERN	RASTTO PHARMSCEUTICALS RASTOGI BHAWAN DR.B.B.GHOSH LANE MOTIJEEL, MUZAFFARPUR MOB-9430525736	0.484
2	ATROPIN SULPHATE INJ 1 ML AMP	MODERN		2.600
3	AMOXYCILLINE+CLAVANIC ACID INJ 1.2 GM	CRYSTAL		36.340
4	ATENOL TAB 50 MG	MODERN		0.283
5	AMPICILLINE INJ 250 MG INJ	MODERN		5.100
6	AMPICILLINE INJ 500 MG INJ	MODERN		5.350
7	CEFEXIME 50 MG TAB	MODERN		0.940
8	CEFOTAXIME INJ 500 MG VIAL	CRYSTAL		9.400
9	CFEOTAXIME INJ 1GM VIAL	CRYSTAL		14.250
10	CEFTRIAXONE INJ 500 MG VIAL	CRYSTAL		8.580
11	CFETRIAXONE INJ 1 GM VIAL	CRYSTAL		14.300
12	CIPROFLOXACIN TAB 250 MG TAB	ORNATE		0.850
13	CIPROFLOXACIN TAB 500 MG TAB	ORNATE		1.530
14	DAIJEPAM INJ 5 MG 2ML AMP	MODERN		6.000
15	DICYLOMIN 10 MG TAB	ORNATE/CRYS		0.180
16	DOXYCYLINE CAP 100 MG	CRYSTAL		0.880
17	FURSIMIDE INJ 10MG 2ML AMP	MODERN		2.200
18	HYDROCORTISONE INJ 100 MG	CRYSTAL		15.000
19	METRONIDAZOLE TAB 400 MG	ORNATE		0.690
20	MAGNASIUM SULPHATE INJ 5 ML	MODERN		2.000
21	ONDANSETRON INJ 2 MG 2 ML	MODERN		2.00
22	OFLOXACINE+ORNIDAZOLE 30 ML SYP	ORNATE		6.900
23	PARACITAMOL 60 ML SYP	ORNATE		7.650
24	PHENARMINE MALEATE INJ 2 ML	MODERN		2.000
25	PREDNISOLONE TAB 5 MG	CRYSTAL		0.450
26	POVIDONE IODINE SOLUTION 100 ML	ORNATE		14.000
27	RANITIDINE INJ 2 ML	MODERN		1.700
28	SALBUTAMOL TAB 4 MG	MODERN		0.148
29	VITAMIN K INJ	MODERN		3.900
30	BANDAGE THAN 90CMX18 MTR THAN 40TPI	AAMI SURGICAL	AAMI SURGICAL INDUSTRIES, CHOUHTTA,HAJIPUR 844101 PH-9204238817	325.00
31	ROLL BANDAGE 4" X 5 MTR X 12 PEC	AAMI SURGICAL		132.00
32	ROLL BANDAGE 6"X5 MTR X 12 PEC	AAMI SURGICAL		189.00
33	AMOXYCILLINE+CLOXACILLINE INJ 500 MG	CYANO,ZEE,SCOTT	PRIYADARSHI ENTERPRISES VIJAY NAGAR KANKARBAGH PATNA-800020 PH-9771465828	6.820
34	AMOXYCILLINE+CLOXACILLINE INJ 1 GM	CYANO,ZEE,SCOTT		9.830
35	BETAMETHASONE OINTMENT 15 GM TUBE	CYANO,ZEE,SCOTT		8.270

Source: Author

Figure 10: District-level Procurement Offices, Bihar

Source: Author

made at the local level, but information about volumes is fed through technology systems and used at the central level to secure more favorable contracts.

> *"...post 2010, the Government of Bihar decided to have a centralized procurement agency: BMSICL... for almost 2016 to 2017 it's a complex situation. A complex situation means that BMSICL is gaining its tradition again. It has got some successful tenders, but at the same time there are districts also doing the rate contracts, for those medicines which are not under rate contract at this time."*
>
> *– Procurement advisor to BMSICL.*

Thirdly, corruption, initiated and perpetuated by district-level procurement, limited the scope to improve the BMSICL and build its credibility. Sub-markets were created across at the district level. Each district was described as having different prices for products, and the price reflected the terms of the local market and various actors who were benefiting from kickbacks. This financial reward and power structure made it difficult to change the system or to move towards a model where quality could be assured. Participants

described how they were reluctant to make changes to improve the system. The risk that disgruntled stakeholders who stood to lose power or money could easily compromise the system by making corruption allegations was viewed as too great a threat to the organization's credibility. In making this assessment, participants also presented the organization as one that was still recovering from a series of drug scandals, that was evolving and trying to build its reputation.

> *"….the kind of settlements happening between the district manufacturer and the procurement. See, if you talk about procurement we cannot deny settlements and all these things, which are related to monetary motivations. Illegal monetary motivations. So there is some settlement between the district and the manufacturer…But to change it…if all these margins are cut so people will be angry, and they will come up with various issues for BMSICL…saying BMISCL is providing not standard quality drugs, they are not providing volume. So, all these things they come in the newspaper and we will end up legal burden…" – Procurement expert*

Prioritization of Procurement

Participants highlighted the implications on quality of procurement not being prioritized by political leaders, senior officials and decision-makers in the health system. They discussed the lack of prioritization in two ways. Firstly, the importance of political commitment with regards to the skill, attention and commitment required by officials to securing high quality medication. In particular, they highlighted the importance of political commitment in securing the engagement of officials to facilitate a timely procurement process that could attract reputable suppliers. Secondly, that challenges in the wider governance infrastructure for health were indicative of health not being a priority beyond the state-level. Firstly, participants discussed the need for leaders to prioritize procurement. This was based on the recognition that technical input alone was not sufficient. Participants with experience across systems

noted the importance of senior procurement officials being able to manage the political environment and facilitate the agency's capacity to operate in a given political landscape.

> *"…Ultimately, it does come down to political will…The head of the procurement agency talked about how he's constantly under threat of being shut down by the state's Chief Minister. However, the success of the organization has been so high that despite the Chief Minister making threats in every meeting, the benefits are obvious and that acts as a huge counterweight…far more than any technical capacity we can provide or support, it really comes down to political will, that's absolutely crucial. It's no coincidence that the southern states, where there is leadership and where there is funding, are better able to secure quality medicines. Technical input is just not enough."* – *Senior international regulatory expert*

> *"Tamil Nadu was entirely about strong leadership. It's very hard to write about leadership and to explain the impact and relationship but, across India, I can think about specific programs and initiatives or agencies that have worked because of one or two people's leadership. Similarly, in Maharashtra, TNU and Kerala – every time I think of a successful program it's because of the role of specific leaders." – Senior procurement expert*

Political commitment also had substantial impacts on the timing and predictability of the procurement process, as well as budget utilization. Senior procurement officials in Bihar were described as having limited experience of procurement and up to 5 other roles, which placed competing demands on their time. Scheduling meetings to finalize tenders was difficult and decision-making could be delayed by months, bringing uncertainty to the procurement process and making it harder to attract quality conscious manufacturers. The lack of political commitment was described as a reflection that procurement and the

provision of medication had yet to gain traction as a priority, and of political norms within the health economy. In contrast, senior procurement officials from the TNMSC were described as having extensive experience in procurement and a single focus on the agency's business because ensuring the supply of high quality drugs was a political priority within the state. Procurement officials and technical advisors also cited low utilization of the Bihar's drug budget, which was said to be 15-20%, as an indication of the challenges facing the BMSICL's operational capacity.

Secondly, participants identified the external governance infrastructure as being a factor inhibiting quality, and one that was reflective of health being de-prioritized beyond the state-level. Participants cited the challenges facing the regulatory system in managing the volume and complexity of the pharmaceutical industry with a legislative framework dating back to the 1940s. Some participants noted that the regulatory system had been improving. They pointed to the number of new drug inspectors and improvements in the guidance around drug specifications. However, most participants identified the weaknesses in the regulatory system as a critical barrier to effective procurement. Cited issues included: a lack of clarity and coordination between state and central regulatory systems; unclear and unpredictable approval processes; insufficient funding for drug inspectors and regulatory activities; long and complex processes for holding substandard manufacturers accountable; and, a narrow focus on laboratory testing, as opposed to a broader regulatory framework that could incentivize desired practices across procurement, manufacturing and dispensing. These attributes were identified as incentivizing substandard manufacturers to produce substandard products at lower prices than quality conscious companies. At a broader level, participants often concluded that many of the challenges posed by the regulatory system and the allocation of funding to support improvements were reflections of health not being a political priority.

"Bihar has been looking to replicate the TNU model and it's always so difficult to get a straight forward replication because TNU had a very different and specific leadership

differences. Health was a priority and the budgets were much larger, so there was more scope to be effective. In Bihar and Orissa, probably even in UP, just setting up the administration for a procurement function and ensuring that it could operate would likely cost as much as the state's budget. In some many states, it's a structural problem and the state isn't prioritizing quality." – Health expert

Given the challenges posed by health not national priority, health and procurement experts described it as all the more important that political commitment was strong at the state-level. In particular, they described how the procurement system relied on the commitment and tenacity of leaders to deliver on such a complex task in a challenged environment. Success also necessitated leaders having the skills and business acumen to manage to the business and political environment.

"…Given the way in which financing works, the leadership needs to forge a link between political success (in obtaining votes) and making improvements. They need to be able to show they can get things done but also work within certain financial limitations, given the way that financing for health operates. Not many people are able to do that, particularly given that spending on health has been relatively stagnant. I think it's tracked at about 1%, in comparison with education, which has been at about 3-4% of GDP. Health is longer term so it isn't valued in the same way…" – Procurement expert

Impact of corruption and prioritization on manufacturers

Considering both corruption and prioritization, public and private experts took stock of the constraints and described the factors as having an impact on engagement with suppliers. However, they were hopefully and several participants presented the system as one that was improving. Nevertheless, in comparison with mature procurement agencies that had been established for 20 years the BMSICL was less likely to attract reputable suppliers. Thus, participants indicated that building the credibility of the organization was a means to facilitate its ability to deter low-quality suppliers. They attributed the ability of an agency to signal that it would be a reliable, predictable and stable business partner as an important motivation for quality conscious companies to be willing to do business with a public-sector procurement agency.

Those external to the state, with extensive industry expertise, identified corruption and the risks associated with engaging with the local political environment as a deterrent for quality-conscious manufacturers to supply the BMSICL. They expressed the view that the political climate was improving rapidly but that, at present, that low margins and comparative ease of doing business in states where there were stronger cultural norms around the provision of medication made engaging with the BMSICL commercial unviable. Several participants identified the local political environment as an important signal to the market about the demand for safe and effective drugs:

> *"…It's difficult to do business out there… I personally believe the world over, there is nothing called a clean thing. You go to US, you go to London, there is always an amount. We don't want to go there because there are other ways of growing. We'll not dirty our hands so much there. It's unfortunate, we just don't want to go there right now. But, the present government is Bihar is really trying…But it's not going to happen in one year… The playing rules will change. You should have the guts to come. You'll be stepping on someone's toes, but you'll have the government to take care of you, so there*

is someone to take care of that stepping on someone's toes. It may be possible, with the government being proactive…" – Industry representative

They also inferred that where the political leaders and procurement officials were less able to indicate to suppliers that quality was valued it was more likely that substandard products were likely to be provided to and purchased by the state's procurement agency.

Technical Measures

Technical measures refer to the quality-specific measures that can be used by procurement agencies to optimize the ability to assure drug quality. This included measures such as eligibility criteria, blacklisting, and quality-testing. These measures are often established through written practices and documentation; however, their effective implementation is not guaranteed by documentation alone. As a result, the effectiveness of the measures to ensure quality can be compromised and were dependent on aspects of the political environment, such as the level of corruption and the prioritization of drug quality.

Quality-specific measures

Participants described the specific processes that were in place to ensure the quality of drugs including eligibility criteria, blacklisting and quality-testing. Procurement officials in Bihar and technical advisors described the use of eligibility criteria to establish the credibility of a manufacturer and improve the likelihood of securing safe and effective products. Criteria such as limits on turnover, the requirement that a supplier be compliant with Schedule M and have not been blacklisted below, were described as an important technical enabler that had been adopted from the TNMSC, and were in widespread use across many procurement agencies. Officials described the use of an online portal for document verification, which was then reviewed by drug inspectors and procurement officials for further review by a technical committee.

"GMP is mandatory, for any of the suppliers BMSICL, has to be GMP. They need to have the certificate, which is already there in the tender. This is the minimum eligibility criteria." – Procurement official from BMSICL

Participants in both the TNMSC and the BMSICL indicated that higher eligibility criteria were not affordable for the public sector and that raising the requirement from compliance to United States Federal Drug Administration (FDA) standards, for example, was not feasible.

"…No supplier is having US FDA or MHA, mostly it is WHO GMP certified…." – Procurement official from TNMSC

"…They [manufacturers] should have capacity and experience...so all these aspects are assessed during the document assessment process…" – Procurement official from BMSICL

Blacklisting was described by several procurement officials as a useful policy for screening out substandard manufacturers. In theory, blacklisting by a public procurement agency can see a supplier be prevented from supplying to all government procurement agencies for three years. They described it as one of many mechanisms that could be used by procurement agencies to signal to manufacturers that they valued quality. Officials from the TNMSC described how blacklisting was effective because the TNMSC's blacklists were often upheld when subjected to legal challenge, which had boosted the credibility and threat of a blacklist issued by the TNMSC:

"Blacklisting has worked pretty well, for two reasons. One, I'll give you one small example. As a mature organization, we have a lot of – including specialties and EDL – we have close to 300 suppliers. You can imagine how many people have been blacklisted in all these years. The number of organizations who have been blacklisted by TNMSC

and been quashed by a court of law, we can count on one or two hands. So, it shows that our blacklisting has been well accepted." – Tamil Nadu Procurement Official

In addition to blacklisting, procurement officials in Bihar described a multi-layered quality testing process. Officials and technical experts recognized the value of testing for the purpose of ensuring the quality of products but also in signaling to manufacturers that the agency valued quality.

"In Orissa they don't go for batch checks on every one, only on some. In our state [Bihar], we require batch checking for quality checking for everything. If any batch fails we take action. And they [manufacturers] know that, that every batch will be checked and that if any batch fails they don't have any leverage. So, they have to do the best standards, so it has to be clear from the procurement side what we want."- Procurement official

The quality testing approach for the BMSICL was developed based on the TNMSC model and includes: manufacturers being required to provide a certificate demonstrating the quality of their products; testing of a sample from each batch procured by the state and release of the batch, and payment, being conditional on a satisfactory quality test from an empaneled or National Accreditation Board for Testing and Calibration (NABL) accredited laboratory; testing of samples in warehouses and facilities. Owing to the lack of laboratories in Bihar, the procurement agency had partnered with India Post to establish faster turnaround for sample testing. Procurement officials also described the value of using accredited laboratories in a bid to assure that the integrity of the testing process as much as possible:

"*…for quality you need to have good labs… Honesty is the most important, because once you lose honesty, everything goes. So, for making them honest you need to be very much vigilant…All our labs are NABL accredited and went through an open tender. We*

have empaneled here…they are well equipped because we have all the criteria in our tender, and only then they are given the tender." – Bihari Procurement Official

Process limitations

Participants in Bihar, Tamil Nadu and industry lobbyists described the limitations of processes to assure quality at a general level and noted how these challenges were more pronounced in Bihar. This could be seen across eligibility testing, blacklisting and quality-testing.

In the BMSICL's case, despite site verification being listed in the eligibility criteria of tenders, the practical realities demonstrated the limitations of the measure. The weakness in the regulatory infrastructure meant that there was limited funding and too few staff to conduct site verification. Some manufacturers were also reported to have prevented officials from conducting audits:

"…And, in side verification, there is a chance that the drug inspectors go there and the manufacturers do not allow them to visit the site. That happens in Bihar. Similarly, if they make a site verification also, there are chances also that these drug inspectors are paid to give a fake report..." – Procurement official

In Tamil Nadu, regulatory visits were organized more systematically and better funded. Procurement officials described the importance of not sending staff from the procurement agency to conduct inspections, to prevent corruption and a weakening of relationships. They also provided funding for inspectors' travel expenses:

"…In terms of this verification, we don't want to create a situation where we are verifying manufacturers facilities. It builds up animosity over the years. So, we only look at GMP certification…inspections are carried out by people who are not staff of TNMSC. We send our drug controllers inspectors, and the people who use our products. …If one person has been sent to one facility one year, the same person will not be sent to the same

facility the next year. We have a panel of 10-15 inspectors and they are randomly distributed to facilities, along with a doctor from a government facility. We pay their expenses, and they give us the report…The same person may come again, but he will not be given the same facility. What do you say, familiarity breeds contempt, well it breeds corruption too…" – Procurement official

In contrast, in Bihar, inspectors travelled at their own cost and without detailed consideration of the relationship challenges. Inspectors who had recently been involved in prosecuting local drug criminals were traveling to locations independently and expressed feeling vulnerable.

"There's no such thing as blacklisting. That doesn't exist. You just reshape the company under another shell company name. It's nothing to do with blacklisting. You can reform a company and sell the same drugs in another state." – Industry lobbyist

Participants described how blacklisting was compromised by a lack of coordination between state and national level regulatory bodies. Regulatory action undertaken by one state might not be implemented in another state. Given the size and complexity of the market, industry experts indicated that it was often easy for companies to reform themselves under another name. More established procurement agencies were able to describe how they managed this type of challenge, through site visits and inspections.

Quality testing was also described as a process that could be effective, but also as one that compromised the efficiency of the procurement process and that was vulnerable to forgery. Officials from Tamil Nadu highlighted the national level constraints to this part of the regulatory system. Participants described how regulators were not always able to test more complex products or faced considerable backlogs, even for more well-established systems with laboratories in the state:

"…There are some weaknesses. For example, the regulator has been telling us that the amount of samples they take is quite high and so there is a backlog. The state government

is funding….is improving their capacity, by establishing new labs, for example in Madurai, to be able to clear that backlog…The regulatory system has two challenges – the geographical spread of labs, and number two is that they struggle with equipment. They are relatively well equipment for most of the drugs we use. The feedback from them is that for them to test the niche drugs, is more challenging..." – Procurement official in Tamil Nadu

Officials in Bihar reflected similar concerns with delays, but also noted the potential for reports to be falsified and corrupted. As a result, the BMSICL had implemented additional procedures to verify labs:

"… if BMSICL people are not good and they have some moral…you know…issues, things can be bad. Drug inspector does the same thing. But the main thing with the drug inspectors is that the samples that they send to Central Drug Laboratory for report, this report takes a longer time, much longer time to get back to the state. It's more than six months." – Procurement Official in Bihar

"We are trying to ensure that the quality should not be manipulated at any time. With labs, labs can also manipulate…you really don't know…You cannot trust labs…So what we have started implementing, we do lab audit every six months…Second part, we are going to implement another thing…dummy medicines we are sending now. So that, suppose that the medicine is paracetamol, I am sending it in some other name and if you are doing the dummy kind of testing, you will pass the product. If we find such things, they will be strictly taken care of. These are the practices we are trying to do to avoid malpractices for quality, because quality is very important." –Procurement Official

Another challenge, was the effect of quality testing on the length of the contract period, particularly when compared with the private sector. As there was not always a requirement for quality checking in the private sector, the ease of doing business was higher and therefore more attractive. For those manufacturers supplying the public sector, officials in Bihar described how manufacturers had tried to circumvent quality testing to speed up the contracting process:

> *"There are the vendors who try to manipulate sometimes. Recently we have recognized that the same batch of drugs, which is passed from the corporation, it comes after 25-30 days or 45 days. …the batch which they have sent in the past, which is passed, they are pasting the label of the that batch, just to avoid the quality time so that the payment can be fast.…we have found that fault, so even if the same batch comes after 14 days we again send it for the quality test." – Procurement official in Bihar*

Manufacturer incentives

Manufacturer incentives refers to how manufacturers are encouraged to supply procurement agencies from a commercial perspective and the production methods they use to fulfil contracts. Within this theme, the two categories were: commercial incentives to supply the BMSICL; and, production and sales practices.

Commercial Incentives to supply the BMSICL

In their discussion of incentives, several participants described the impact of low margins, price control, the cost of assuring quality during manufacturing and the business environment as factors that made it commercially unappealing for manufacturers to supply public procurement agencies, particularly in Bihar. State procurement officials expressed the view that, with sufficient volume, sufficient reward was attainable. The perception of there being sufficient reward differed between participants, some companies

viewed price control negatively whilst others did not see it as prohibitive. However, the majority of participants acknowledged the difficulty of doing business as a deterrent to quality-conscious companies. Overall, participants viewed the implication of these financial dynamics on the BMSICL as an important factor constraining its ability to attract companies that have invested in quality.

Low margins for government contracts were viewed as necessitating that an agency aggregate procurement needs across the state to offer an attractive contract, with sufficient volume, to a supplier. As discussed in previous sections, the BMSICL lacked the ability to aggregate across the state, making it harder to offer sufficient volumes to attract higher quality suppliers:

> *"The challenges faced by manufacturers…First thing, there is no motivation for manufacturers, as in other states, I think volume, large volume is a motivation for manufacturers. So, volume is a big problem in Bihar. Again, as I mentioned the complex situation in Bihar right now…the state is doing some rate contracts, districts are doing some. You know Bihar is highly populated state, as per census of 2011…11 crores people. So, BMSICL is unable to get reports to generate volume and that is where actually manufacturers don't see motivation. Second, is, uh, payment. So, in Bihar a payment is still decentralized. – Procurement advisor to BMSICL*

Price control was viewed as another downward pressure on commercial incentives by several participants, although some believed that price control facilitated a fair reward. Several manufacturers indicated that broader policies around pricing made it challenging to engage in public procurement. International regulatory experts and pharmaceutical companies discussed the impact of price control as a race to the bottom for quality, because of the impact on manufacturing practices and raw materials:

> *"I'm a big proponent of abolishing price control. I think it is creating incentives which are not right for the real public health problems of India… A molecular antibody cannot*

be sold at thousand rupees, whatever the government wants to say. It has a certain biological process, a fermentation process. You need to do that to deliver a high-quality, potent drug to the patient. Some drugs cannot be cut in terms of prices, because otherwise you are selling junk in the market place." – Executive from a large Indian Pharmaceutical Company

There were some industry representatives and procurement officials who felt that price control was not prohibitive and that it allowed companies to make a reasonable level of profit. However, they acknowledged that the challenges arising from delays and lengthy bureaucratic processes, in addition to price control, were likely to deter manufacturers with the capacity to invest in quality:

"Normal profits are ensured if you supply given the state procurement systems. The question is how you look at profit, and what level of profit. At the point of ordering, the price given is justifiable. Commercially justifiable. Question is the amount of interest that they incur on delayed payments. Or in delayed acceptance of supplies at some point of time." – Technical advisor to public procurement agencies

Drug inspectors and some procurement officials suggested that there were sufficient commercial incentives, because of the agency's ability to offer large contracts and payment being assured. Other procurement officials, technical advisors and industry representatives presented a different perspective. They indicated that the price points that a public procurement agency, such as the BMSICL, offered made it commercially unviable for quality-conscious manufacturers with a strong export business to respond to BMISCL tenders for essential medicines. However, tenders for specialist medicines at higher prices were seen to be commercially viable:

"In many of these state government organizations, what we have found, that our level of quality and the cost that we have for our products, for most of the small molecules, we are non-competitive. What we can supply to these government bodies, are differentiated products, where there is some uniqueness. Or, we are able to supply other drugs where we have licensed it from companies the US or Europe." – Executive from a large Indian Pharmaceutical Company

Several experts noted that the cost of quality, such as personnel and equipment, presented a commercial challenge for domestically-focused suppliers. Given the considerable costs of investing in machinery and hiring personnel to verify that products are consistently of good quality, manufacturers expected to be rewarded. As a result, they were either likely to target the private sector, given the relative ease of doing business when compared to the public sector, or to seek out clients in regulated markets. Having made the investment in quality, the price sensitivity of the domestic market was viewed as being prohibitive of manufactures realizing their return on investment. Therefore, there was often the perception that only multinational companies, or companies with an export business, could invest in quality:

"As far as quality checks are concerned, multinational companies have more systematic checks to assure the quality. As I have said, the products would meet the specification afforded in the monograph, and in the specifications what is suggested but in terms of multinational companies they are more organized in terms of quality systems. It is not that Indian companies are not organized, there are good Indian companies. But, there are small manufacturers…with India being a vast country….there some small scale industries who may not be able to comply with the assurance of quality." – Pharmaceutical Executive

"In terms of quality, there's no doubt that GMP and other FDA quality are extremely expensive. That's an issue. But companies have to get a GMP certificate, we're currently

at 10%. But we're looking at 10,000 manufacturers. About 150 are large ones, the rest is small scale industry. They don't have that kind of bandwidth to invest in GMP." – Academic pharmaceutical specialist

Participants also discussed the ease of doing business with the public sector. They raised the difficulty of finalizing contracts and the lack of predictability and forecasting information. As discussed in previous sections, the lack of political commitment served to extend the contracting process making it lengthier and more burdensome on the supplier, particularly compared with the private sector. To highlight this challenge, participants discussed one tender that had been delayed by two years. During the two years, changes had been made to the tax system and the price of raw materials had increased significantly. The final decision meeting was still pending, two years later. They viewed it as unrealistic for the majority of companies to sustain interest in a single tender for two years.

In addition, reputable manufacturers whose core business was focused on foreign clients and the private sector noted that the lack of forecasting from the public sector meant that decisions about whether to contract with public sector procurement agency could be dependent on whether ad-hoc tenders could be accommodated within the company's production capacity. The lack of forecasting prevents the BMISCL from being able to offer manufacturers certainty and competitive contracts. One manufacturer, with a strong export business and a strong track record in terms of the quality of its supply, indicated that decisions to supply BMISCL were dependent on whether the company could manage the additional, unplanned volume of products, and whether the commercials of the tender were attractive:

"If they are able to compete with the price and whatever then they would decide. But as far as supply is concerned, it is based on capacity because these are not signaled requirements. Tenders are not planned in advance so in case company gets a tender or order from the tender business, then this can be accommodated in the manufacturing business. Based on that, it is a joint decision between the manufacturing side – whether

they are able to take up the additional volumes from a manufacturing point of view – and if the commercial people feel there is a sense in terms of financials, then the project goes ahead, the deal goes ahead, whatever. But, as far as quality is concerned, it's the same." – Executive from a large Indian Pharmaceutical Company

Production and sales practices

Building on a discussion of the commercial realities of the market, participants discussed the production and sales practices used by businesses in response to the dynamics of the market. Discussion on production and sales practices largely focused on the lengths that companies would go to produce counterfeit and substandard drugs. Smaller manufacturers with a focus on a local market were described as adopting practices that had a negative impact on quality. In addition to falsifying batch details and quality reports, manufacturers were reported to be compromising on the quality of materials:

"…And they are going to the lowest tender, so some distributors won't try to make the lowest tender…So what happens, 10%, he may try to give you ten tablets of an inferior quality…." – Leading pharmaceutical distributor

Drug cartels and mafia organizations were also reported to be tampering with the expiry date of products.

"The drug mafia are doing expired drugs. Re-stamping to increase shelf-life. They are doing press label, press labels on the bottles. We caught them red-handed, while they were doing this…Suppose one drug is expired in month of August, 2017. They got relabeled for 2018. Then they were sending." – Drug inspector on practices in Bihar

In contrast to the majority of participants, some procurement officials described the low likelihood of defects being intentional and took the view that substandard medication was more likely to be the product of accidental error:

"…This by mistake. But, very rare. All companies, all manufacturers have their quality control department and they are getting it checked by them. They have also QC department, they check properly with respect to each component of the manufacturer. …If there is a gross negligence, which comes that assay is less than 50% that means gross negligence, it could be a mistake but it's gross negligence meaning that people in their company, quality people, are not very much vigilant. So, it's a crime. They try to put in different raw materials, to save on the product cost. After 10% you are into that territory…Very rarely that is below 10%. The message has gone to each supplier very clearly. Each and every batch is going to quality check…."

However, not all participants were as forgiving. International regulatory experts with experience in the Indian market offered a different view. Far from being a mistake, some participants described how manufacturers were tailoring the quality of production materials and processes to the specifics of the market. Accordingly, they were supplying Indian domestic consumers with lower quality products because they felt able to take advantage of the weaker regulatory environment.

"…Some of the stories I've heard from regulators, for example, to meet the price requirement has a detrimental impact on quality. What companies do is produce the product with the minimum API requirement. You can produce a product with 95 to 102% API, and they produce it to the lowest end of the specification: 95%. That product is unlikely to last for more than 6 months, but it may be packaged to last for 5 years. Ultimately, within a short period of time you get a substandard product on the shelf…"

While it is not possible to determine the extent of these practices, it is possible to identify how the nature of the market has the potential to dis-incentivize domestic companies from high quality production. In the context of a weak regulatory environment, these incentives poses a threat to quality, particularly in Bihar.

SECTION V: DISCUSSION

The BMSICL struggled to achieve the progress offered by replicating the TNMSC model because Bihar's political environment, where corruption and vested interests play a significant role, was not supportive of drug quality being prioritized and ensured. As a result, its procurement system cannot consistently ensure the quality of medication. It is a classic case of what Pritchett and Andrews describe as isomorphic mimicry. On paper, the BMSICL has institutions and processes that look like those found in functional states. However, the mutually reinforcing effects of corruption and political leaders de-prioritizing procurement have compromised the organization's functionality, which is needed to ensure quality in the public tender process. As a result, the impact of corruption, vested interests and the opportunism of low quality suppliers have limited the state's ability to draw on technical measures to ensure quality. Given these factors it is likely that the extent of the issue is greater than the 8.71% identified by the National Survey. The risk to public health and the potential to use public funds more prudently demands the development of pragmatic interventions. Unless interventions draw on strategies to address corruption, vested interests and the prioritization of quality, drug quality is not likely to improve. This section will analyze the challenges of ensuring drug quality in public tenders in terms of each of the three themes (political environment, technical measures and manufacturing incentives) and will describe potential interventions after each thematic analysis. It will then discuss three prioritized interventions. Finally, it will describe future research options that could help to address gaps in current knowledge.

Political environment

Corruption across Bihar's 38 districts has made it difficult to establish the operational capacity of the procurement agency and compromised efforts to address challenges and develop the organization's credibility. This can be seen in district-level procurement officials conducting decentralized procurement tenders that are entirely separate from the centralized procurement agency and are not subject to quality

checks. This limits the BMISCL's capacity to leverage volume to attract manufacturers and oversee and implement quality assurance processes in district-level procurement.

Most participants reflected on the importance of political will and support in enabling a procurement agency to be effective and secure quality. They noted that the political support for the quality of health provision was weaker than that in Tamil Nadu, at both a senior and grassroots level. While this is acknowledged in some of the literature (Singh et al., 2012) the challenge of how to capture and sustain political support for health receives far less attention, even though it has a determining impact on drug quality. In the absence of political will, it is all the more important for interventions to identify how to build political support. Whether it be a donor, a local organization, an existing member of the system or an international organization, addressing political constraints to improving quality, such as corruption and vested interests, requires understanding the relationships between relevant stakeholders and then determining a sustainable approach. These types of intervention require wrestling with the adaptive nature of the challenge, they are likely to be riskier and, in comparison to a implementing a technical solution, there may be less clarity over how to proceed (Andrews et al., 2017; Pritchett, 2013; Pritchett et al., 2010). In addition, the assumption that the technical features of the TNMSC model can be replicated has endured for almost two decades. The mindset can be difficult to breakthrough; it was often assumed that technical measures, such as quality checks and blacklisting, could be transplanted from the TNMSC model. For example, two of the three experts with extensive experience of the Tamil Nadu model were insistent that the BMSICL had failed because it had not directly copied all aspects of the Tamil Nadu model. This rhetoric was also apparent amongst procurement officials, who articulated their aspirations for Bihar in terms of implementing aspects of the TNMSC, as opposed to a contextually specific diagnostic of what was most needed to facilitate improvements.

A diagnostic approach can be understood as a state undertaking a tailored analysis of how each of the relevant components of a state's procurement or health system are performing in relation to quality. This analysis could then be used as the basis for developing a systematic approach to improving procurement and quality control mechanisms. Instead, there is often a rush to replicate the best performing system, in the hope that technical measures alone will see improvements in drug quality and availability (Pritchett et al., 2010). For states that receive external support from donors, a diagnostic approach may support their ability to articulate where help stands to be most beneficial. Similarly, a diagnostic approach can support a procurement agency to build its organizational credibility, particularly given the demands of being a business-facing organization. Local procurement officials and advisers were able to articulate the challenges facing businesses in engaging with government agencies, and to propose solutions and ideas. Translating this type of analysis and building it into a plan for developing organizational credibility can help to build the functionality required for quality assurance.

Another important by-product of corruption is that it has dis-incentivized leaders from prioritizing procurement and engaging in procurement processes. Participants relayed examples of meetings being stalled because of leaders not being available to attend decision-meetings. They also described political leaders as having responsibility across different parts of the state administration and of procurement being the least desired, because of fears that it would result in entanglement in a corruption scandal and accusation of wrong doings. The impact of the lack of prioritization is that the BMSICL is not able mobilize contracts at a reasonable speed and build a reputation with manufacturers that it will be a reliable business partner. As a result, the incentives for district-level procurement officials to circumvent the centralized process are reinforced, further entrenching corruption in the system.

In Tamil Nadu, procurement officials spoke about the importance of fostering successful business partnerships and officials regarded this as a critical part of being able to screen out substandard suppliers and assure quality. Officials from the regularly meet with manufacturers and during the field visits, two

manufacturers came to discuss contracting aspects with senior officials. In Bihar, some procurement officials also reflected the importance of leaders signaling to the market that a procurement agency had no tolerance for substandard suppliers. Other participants noted the reluctance of senior officials to prioritize procurement meant that there were few forums for manufacturers and the agency to meet and build a rapport and resolve contracting issues. As a result, supplier disputes were often left unresolved and this deterred higher quality suppliers from engaging with the agency.

Figure 11: Area surrounding Vaishali district hospital, Bihar

Source: Author

In terms of building and executing a strategy to improve prioritization and support for quality, the contrast between Tamil Nadu and Bihar is informative. The norms described by officials in the two states were distinct. Officials from the TNMSC described the expectation that drugs provided by the public sector would be available, safe and effective. The TNMSC officials pointed to the fact that main women's hospital in Chennai, a short walk from the TNMSC offices, did not have private pharmacies surrounding its premises. In contrast, as shown in Figure 11, facilities around the Vaishali district hospital in Bihar

were surrounded by private pharmacies. The BMSICL officials discussed the norms of corruption and vested interest having a dominating impact. While the absence of a state laboratories for regular product testing makes it difficult to assess quality in advance of consumption, information can be used to build awareness, raise expectations can help to facilitate normative changes. Where these are expressed in the political environment, over the longer term, they may be able to help secure a political environment that is more conducive to ensuring drug quality.

Intervention options to address the challenges of the political environment

Procurement Agency Diagnostic Framework

From low to high performing states, there is a critical gap in understanding how best to establishing procurement agencies, both in terms of the technical and adaptive aspects. It is difficult to access relevant knowledge on an on-going basis, particularly when it comes to understanding the trade-offs and implications of organizational and operational features. Current manuals are based on a 1990s model that was built in a specific socio-political context. This lack of understanding constitutes a critical gap in professionalizing and de-risking engagement in procurement. A framework to support states in understanding the weaknesses of their existing models and the potential options to progress could help to address this knowledge gap.

While there are international guidelines (World Health Organization, 1999), an India specific-analysis of what has enabled and inhibited success in the last 20 years can help to facilitate a procurement agency's ability to procure high quality drugs. The purpose of a framework would not be to assert that a given set of features is required, but to describe the benefits and disadvantages of different features and to highlight how these features have been optimized in varying settings. The framework could also provide a sense of the competencies of a low, medium and high performing procurement agency to indicate of the steps that

a state government might take to improve procurement, and overcome the perception that high-performing models can be transplanted in a short space of time and without a considered assessment of enablers.

Data Improvement Program

Several participants were surprised by Bihar's comparatively strong performance in the National Survey and this points to the challenge of knowing the proportion of substandard medication in the public-sector system, as the relative impact of a given cause. Participants were often unsure of what exactly was causing substandard medication, and cited factors such as substandard active ingredients, poor procurement processes, criminal activity or poor manufacturing processes. Study participants signaled that poor quality is likely to be the result of a combination of these factors. This study has explored a range of factors; however, it does not provide a causal determination and cannot identify the level of substandard provision. This knowledge gap makes it difficult to articulate the problem to policy makers, donors and relevant decision makers. Therefore, implementing interventions to improve the understanding of the extent of substandard medication could be powerful and effective.

Establishing a system to regularly assess the level of substandard provision could help to improve awareness and understanding of the issue. This option draws on the recognition that the normative expectation between Tamil Nadu and Bihar was described as a significant difference in the local context. Facilitating this type of normative change could begin with improving information about drug quality. The information could be gathered through the development of local university laboratory systems or the use of external actors or international actors, such as The World Health Organization, to conduct regular testing of a basket of medications. Until this information is more readily available and understood, it is unlikely that the norm of expecting higher quality products will not be achieved because it is difficult for a consumer to know whether a drug is safe and efficacious.

Moreover, where the norm of expecting safe and efficacious products can be established there will be more scope and likely a greater appetite for in-depth analysis of relevant states to understand the specific causes of poor quality. It is this type of analysis that could also help to isolate the interventions that can yield the greatest impact for policy makers and donors; however, it is unlikely that this type of analysis would be sponsored at the state-level without the issue of drug quality being better understood as a public health concern.

A key assumption in this approach is that information can change be used to change accountability. While the evidence is not conclusive, studies have highlighted the importance of being precise about how the information is used and the type of community engagement that is required. Community 'participation' can be used as a vague term (Kamuzora et al., 2013; Mubyazi & Hutton, 2012)) and is distinct from a community or political constituency using information about service quality to hold authority figures accountable for improvements (Besley et al., 2002; Björkman & Svensson, 2009). There is evidence to suggest that this can work. For example, Besley and Burgess note the impact of issues being circulated in newspapers on the responsiveness of governments (Khemani, 2007) in the India. Further thought would need to be given over the collection and curation of information, as well as the political constraints facing an implementing organization.

Technical measures

Technical measures can, in theory, be used to support a procurement function. However, in the context of Bihar's political environment, these features can lack integrity and be ineffective. Establishing measures and processes through written documents has been a hallmark of how the BMSICL sought to replicate the TNMSC model. However, implementing measures without fully addressing the political environment has led to isomorphic mimicry. This was reflected in manufacturers regarding the use of quality-specific measures as ineffectual because they could be easily circumvented or documents could be falsified.

The BMSICL officials and technical advisors described a range of quality-specific measures that were in use to ensure quality. However, they quickly noted the vulnerabilities to corruption and forgery. Therefore, while measures such as blacklisting, the use of eligibility criteria and testing are useful and important technical mechanisms, ensuring the integrity of the measures remains a challenge. This can be seen across three areas. Firstly, several participants noted that testing capacity and availability is not sufficient, and Bihar has no facilities in the state. This makes the BMSICL reliant on postal systems, and vulnerable to lengthy delays that deter reliable suppliers.

Secondly, the nuance around the impact of using quality measures on the commercial environment present agencies with trade-offs. Accessing information about how best to secure quality in the context of these trade-offs can be challenging to acquire. For example, officials from the TNMSC described how it uses low financial thresholds and high-quality thresholds to reap price benefits from a market of many suppliers, having secured the quality of its supply. Officials recognized that its established position enables it to do this in a way that may not be available to organizations such as the BMSICL.

> *"…the bar has to be strong enough to weed out the fringe players, the bad players…But, it also has to be short enough to ensure there's competition. We have relatively a lower financial threshold, but in terms of the technical threshold, in terms of their compliance to regulatory norms, compliance to GMP, in terms of facility inspection…we keep the threshold high. So, we allow a chance for people of lower turnover to participate, subject to their having met the manufacturing conditions and that their manufacturing practices have been certified, even if you're a player with high turnover if you don't have certified processes, we don't let you participate…." – TNMSC Procurement official*

Finally, the link between quality measures and auxiliary systems, particularly regulation, deserves further consideration. The regulatory system is affected by local and national factors that are out of the control and responsibility of a state procurement agency. Yet, the capacity of the regulatory system is essential in

supporting a procurement agency to signal its interest in quality and willingness to uphold standards. The BMSICL officials emphasized the importance of being stringent in upholding standards. Nevertheless, interviews with other participants indicated that the state's regulatory system was underfunded, with drug inspectors facing death threats from criminal groups and having little protection. As a result, it was reasonable to infer that the regulatory system was not viewed as strong and that enforcement capacity could be improved significantly.

Interventions to enhancing the ability of technical measures to support quality assurance

Drug Inspector Enhancement Program

For a regulatory regime to be effective, the subject of regulation ought to believe that the enforcement capacity of the state is credible. Industry experts, regulatory experts and procurement specialists all identified Bihar's regulatory system as being weak. One aspect that contributes to this weakness are the limitations of drug inspectors, in terms of their ability to exercise authority, to remain uncorrupted and to safely conduct their responsibilities. In Tamil Nadu, state regulatory activities, such as the travel expenses of drug inspectors, are funded by the state. The state also randomly allocates regulators and facilities to prevent the risk of regulatory capture. In Bihar, regulators fund their travel independently and often face security risks. An inspector who plays a role in convicting a substandard manufacturer on one day can expect to travel on a motorcycle to a remote location the following day, where he or she might be vulnerable to retribution. Improving transportation and security for drug regulators could help to improve the authority of the regulatory regime.

Lab Capacity Improvement Program

The efficiency of a procurement system has impacts on its ability to attract quality conscious manufacturers and keep prices low. In procurement agencies that have adopted the TNMSC model, for

example in Bihar, batch releases are dependent on laboratory verification of quality. Currently, in Bihar, the state has collaborations with courier and postal services, but the lack of laboratories in the state makes it dependent on external labs. Efficiency is often hindered by long waits for quality reports for batches pending release. Lab reports can also often be faked. Even participants from more mature systems, such as the TNMSC, note that the volume of reports required relative to the availability of testing facilities often leads to a backlog. They also note that fewer labs have the capacity to test more sophisticated drug formulations. By providing additional labs, with external verification to limit the scope for falsification, there is potential to increase the speed of procurement, improve data reliability and improve the business environment in poorer states.

Manufacturer incentives (commercial incentives, production and sales practices)

In the context of Bihar's political environment, large, quality conscious manufacturers regarded public procurement with the BMSICL as being unattractive. They also noted that substandard suppliers affected the state's market. Reputable companies, producing and supplying high-quality products in other markets, identified four reasons why contracting with the BMSICL was not commercially incentivized. Firstly, government contracts are a low margin business and the lack of volume made many of tenders commercially unviable. Secondly, the lack of reliability around contracting made it unclear whether payments would be recovered. Thirdly, that the difficulty of doing business was viewed as too high relative to the reward. This included both the operational costs of engaging in contracting and the political challenges of navigating vested interests within the state. Finally, without clear forecasting plans it was difficult to incorporate public procurement needs into manufacturing plans.

To attract quality conscious suppliers, there is scope for Bihar to do more to improve the business environment. The BMSICL would likely benefit from identifying ways to reduce delays, assure reliable

manufacturers of reasonable payment and approval timelines, provide forums for regular interaction and from improved forecasting to offer greater reliability. While some of the infrastructure, such as e-procurement systems, are in place to support this way of working, being proactive towards the market across multiple areas, such as incentivizing desired behaviors, managing competition, improving the ease of business and reducing the cost of business, poses a considerable challenge. Nevertheless, the competitive realities of the market – not least the comparison to the private sector, where there is less bureaucracy and payments can be secured quickly – make it important to consider these aspects if the BMSICL is to improve its ability to secure drug quality. The low utilization of the budget – at approximately twenty percent – suggest that the BMSICL may have flexibility to use its financial envelope to incentivize quality-conscious manufacturers.

In addition, in the context of a political environment with weak regulatory structures due to procurement being de-prioritized, low quality suppliers were adopting measures to circumvent the existing system. While procurement officials acknowledged the importance of sending signals to the market that regulation and quality testing was taken seriously and could describe processes to this effect, the potential for falsification of documents and products was significant. Existing literature provides some analysis on the interaction between manufacturers and procurement agencies, in terms of quality. For example, the Institute of Medicine report identifies the root cause of substandard medication as being poor manufacturing process. It proposes the pathway that, given the high cost of upholding and ensuring quality standards, manufacturers in weak regulatory environments cut corners and compromise the quality of medication (Institute of Medicine, 2013). This is an important pathway, as acknowledged by several of the study's participants from procurement officials, experts and regulators. In Bihar, the weakness of the wider regulatory environment has a significant impact on incentivizing manufacturers to cut corners. It points to the importance of efforts to improve the state's enforcement capacity.

An intervention to address the disincentives for high quality suppliers

Quality Premium

Study participants have described the Indian market as very price sensitive and procurement agencies are under pressure to maximize their budget allocation for drugs. As described in the literature review, the pursuit of the lowest possible price can come at the cost of quality. However, where companies have invested in quality, they are faced with the competition from less quality conscious companies, in the form of lower prices. A quality premium could help incentivize companies to uphold higher manufacturing and process standards by providing a commercial reward. This might also help to attract quality conscious manufacturers or those that are traditionally export-focused manufacturers.

Policy Recommendations

For interventions to have a realistic chance of improving drug quality they need to consider and address corruption and vested interests. While the study identified a range of intervention options to support donors and policy makers, two options have been prioritized: a drug inspector enhancement program, and a lab capacity and data improvement program. This was based on the recognition that these interventions can be framed as technical interventions whilst also providing opportunities to address adaptive aspects of the issue. Therefore, they are more likely to be feasible for donors and policy makers, who often favor technical approaches in challenging political environments where explicitly adaptive approaches can compromise the sustainability of intervening organizations.

Drug Inspector Enhancement Program

The weaknesses of the regulatory system pose considerable challenges for drug quality improvement. and external actors face limitations in their ability to improve regulation, given that it

is a sensitive, domestic issue. Nevertheless, a small and targeted intervention may be a way to contribute to improvements. This intervention could be framed as a technical, regulatory intervention, could help to bolster enforcement capacity and increase the likelihood that inspectors will honestly conduct their job and be less vulnerable to corruption.

The sustainability of the intervention would also need to be considered. Given that Bihar utilizes a small proportion of its drug budget (15-20%, as reported by participants) a case could be made for drawing on unutilized funds for system-level improvements. An external actor could then match state-funding and another external actor could help to provide oversight, given the risk of corruption. The intervention could also be given a 2-3 year time frame to demonstrate a proof of concept and to understand whether it is effective in improving drug quality and the strength of the regulatory system.

Lab Capacity and Data Improvement Program: This is a two-part intervention, which would combine two of the interventions noted above. Improving laboratory capacity can be framed as a technical measure to improve the ability of a state to verify product quality. However, if the information arising from this enhanced capacity is curated and disseminated it has the potential to support communities in understanding drug quality and fostering the development of a norm, where quality is better understood and communities have higher expectations of public sector services providing quality.

In relation to the technical measure, batch releases are dependent on laboratory verification of quality and the lack of laboratories in the Bihar makes the BMSICL dependent on external labs, and the extensive wait can delay contracting. Lab reports can also be faked. By providing additional labs, with external verification to limit the scope for falsification, there is potential to increase the speed of procurement, improve data reliability and improve the business environment in poorer states.

With additional laboratory capacity comes the opportunity to gather and disseminate information on the quality of drugs in a state and to conduct regular state-level diagnostics of the state of quality. While this will not help identify the precise causes of drug quality, not least because quality is the result of multiple factors, the information can help to improve the understanding of drug safety and efficacy if it is curated and disseminated in an effective manner. For donors, there are options in how to manage dissemination:

- A donor might also see its primary role to provide the information on a public platform rather than to engage in dissemination campaigns
- In more sensitive political situations, particularly where a donor has a close or dependent relationship with a local government, information could be gathered and discussed internally with the government.
- In other scenarios, a donor may be able to support civil society actors in publicizing information and build the ability of local organizations to curate and advocate based on quality testing information. It might also support other actors, such as The World Health Organization, to engage in dissemination.

Overall, while there are choices to be made in the dissemination strategy, the principle of using information to facilitate normative changes is at the heart of this approach. This is based on the recognition that quality is currently not well understood, and that information could encourage political constituencies to recognize and advocate for improvements in drug quality. Moreover, increased awareness of one dimension of quality – test results - could help develop support for in-depth mixed-methods analysis of relevant states to understand the specific causes of poor quality. This could help to isolate the interventions that can yield the greatest impact for policy makers and donors.

Further research options

From a research perspective, the field of drug quality in India is relatively immature, particularly given the size and sophistication of the market. Research-focused participants noted the challenge of advocating for improvements in quality without a comprehensive understanding of the extent of the problem and the specific causes. While the National Survey was a significant step forward, several participants raised

challenges to the methodology and articulated a need for focused state-specific diagnostics to understand the extent and causes of poor drug quality at the state-level. Most participants anticipated that state-specific quantitative studies to demonstrate the economic and social impact of exposure to substandard medication would be an important step to convincing policy makers to safeguard quality. Corruption and procurement experts highlighted the challenge of being able to pinpoint corruption and encouraged the use of a state-specific diagnostic to understand the extent of corruption and be able to shape appropriate responses. Finally, practitioners spoke of the importance of improving awareness and information about drug quality to increase the salience of the issue. Across the spectrum of thirty experts there was recognition that more could be done to understand the nature of the issue, as well as potential interventions.

SECTION VII: CONCLUSION

The BMISCL is a case study in isomorphic mimicry because its attempt to replicate the TNMSC model saw it gain the apparatus of a high-performing procurement model without the functionality. The functionality of a procurement model has an important bearing on its ability to assure drug quality. This demonstrates the perils and difficulties that have arisen from a commonly-held assumption that the TNMSC model could simply be replicated. While there are limitations to the case study approach used in this study, analysis of the BMSICL suggests that the political environment was a dominating factor in inhibiting quality assurance. This had implications on the integrity of the technical measures that it had adopted from the TNMSC to assure drug quality, and often saw them vulnerable to corruption and forgery. As a result, it failed to set up incentive structures to attract and manage high quality suppliers and deter low quality manufacturers. What does that mean for donors and policy makers and why should they care? The BMSICL has broader relevance because it highlights the importance of donors, policy makers and stakeholders building adaptive strategies to the public health issue of ensuring high quality drug provision in public facilities.

Donors and policy makers are not unaware of the challenges posed by corruption and vested interests. The adaptive nature of these challenges – that they require sustained engagement and have considerable risk – makes it easier to pursue technical measures. As politicized entities themselves, donors and policy makers face constraints in engaging in approaches that compromise their sustainability and relationships, and are therefore beyond their risk appetite. These limitations are significant; however, they do not lead to the automatic assumption that a focus on technical solutions is the best option. Contexts can be analyzed and better understood. On that basis, strategies can be developed, with relevant local actors, that can build in components to address the binding constraints of corruption and vested interests.

Value for money is a common concern amongst donors and it is one of the primary reasons why addressing the political environment is becoming increasingly important. As this case shows, corruption can have a significant impact on the technical measures that donors and policy makers often resort to using. The efficiency and effectiveness of using these measures alone does not facilitate achieving value for money in donor programing. There are advantages to using technical measures. Sometimes they are the most appropriate solution. They can help move systems forward so that they are ready when political environments evolve. They can also build trust and provide inroads for impact activities. They are often more neutral and politically feasible. At first glance, they are more easily defensible to the audiences faced by donors, particularly international organizations and government development agencies. Technical measures, through their specific and measurable outputs, can give an illusion of progress. 10 warehouses have been built, 20 training programs have been conducted. But, those types of interventions do not always help to achieve the overall outcome of improved drug quality, if the political environment inhibits their functionality. Both donors, policy makers and local stakeholders need to be critical of how tinkering with technical measures can form part of a credible theory of change of how an intervention will sustainably improve health status, financial risk protection and system responsiveness.

Finally, this study explored drug quality through the relationship between manufacturers and a public procurement agency. More specifically, this was understood as the likelihood that a procurement agency could attract reputable companies willing to consistently supply high quality products. What emerged is a system where actors are not incentivized to act in the best interests of people's health. That is often easy to spot. It's also more straightforward to develop consensus around how to manage substandard suppliers, because they are undesired by those who value health. What is more difficult to reconcile is how to establish constructive incentives for quality-conscious manufacturers. Companies who supply the products do so in pursuit of commercial reward and without engaging them by improving the business

environment, developing mutually-beneficial contracting mechanisms or through commercial rewards, the burden of disease only stands to get larger and more complex.

APPENDIX [A]: INTERVIEW PROTOCOL

Introduction

This section documents our interview approach and it documents the interview structure, questions and includes notes on stakeholder management.

Interview Structure

Section	Purpose	Notes
Introduction	• To provide interviewees with an outline of the purpose of the study and the interview • To establish a working relationship and to encourage participants to share their expertise and perspective	• Introduces the interviewers and interviewees • Outlines the purpose of the meeting • Outlines the objectives of the study/project • Provides a plan for the session relating to context, hypotheses and interventions • Outlines the foundation's current interest in the project as preliminary research • Discusses the confidentiality preferences
Context	• To open with general and broad questions, which enable the interviewees to outline the context in which they work and the way in which they understand and approach the issue of public sector	• Invites the participants to share information on their roles and experiences • Provides context on the relevant interviewer

	drug quality	
Hypotheses	• To test hypotheses about state-specific factors that have been identified through the literature review • To provide space for interviewees to raise new areas that have not yet been fully considered by the interviewing team.	• See questions in the protocol • See directions on stakeholder management for guidance on how questions will be targeted towards different groups
Interventions	• To assess the feasibility of intervention ideas and to gather insights on ideas that are more amenable to BMGF support. • Where BMGF is identified as a relevant organization, to seek feedback to maximize the potential impact of a prospective intervention	• Invites participants to offer guidance on potential interventions • Seeks information on what can be done to improve the feasibility • Seeks guidance on whether BMGF is an appropriate partner
Close	• To acknowledge and thank the interviewees for their time and contribution • To provide interviewees with a clear sense of how information will be used.	• Summarizes the key points addressed in the interview • Reconfirms the interviewees' confidentiality • Summarizes how the information obtained will be used in producing a report for BMGF

Stakeholder Management

To be respectful of interviewee time and expertise, questions from the protocol will be selected to reflect the expertise and background of the interviewee.

Discussion area	**Relevant interviewees**
Procurement features	• Academics specialising in procurement, corruption and quality • Policy makers responsible for, or with experience of, designing procurement functions
Commerical incentives to engage with public procurement	• Pharmaceutical companies • Industry bodies • Industry experts
Key enablers	• Academics • Policy makers • Companies
Companies' previous experiences with procurement agencies	• Companies • Industry experts • NGO teams liaising with companies
Structural features of the tendering process	• Academics • Policy makers • Where possible, procurement officers and regulators
Prioritization of quality	• Academics • Policy makers • NGO teams liaising with companies
Quality testing and control mechanisms	• Academics • Policy makers

	• Companies • Where possible, regulators and procurement officers
Procurement agency personnel	• Policy makers • Procurement experts • Supply chain experts • Companies
Political economy of market structure	• Academics • Companies • Industry experts • NGO teams liaising with companies e.g. CHAI's Supplier Facing Teams
Black-listing and bans of low-quality manufacturers	• Procurement experts • Industry experts • Where possible, regulators and procurement officers
Private retail companies	• Procurement experts • Industry experts • Companies
Commercials of the domestic and export markets	• Procurement experts • Industry experts • Companies • Where possible, regulators and government officials
The role of structural aspects in the market structure	• Procurement experts • Industry experts • Companies • Where possible, regulators and government officials

Interview Questions

A series of questions and prompts were developed to guide interviews.

Discussion area	Questions and prompts
Role and previous experience	• What exposure have you had to the issue of drug quality in your work?
General views	• The National Survey identified that 10% of drugs from government sources were substandard. What's your view on the issue of poor quality drugs and the nature of the problem? • The National Survey indicates that drug quality varies significantly between states, between 0 and 33%, what's your view on the variation between states?
Procurement features that can be adopted to enable procurement agencies/functions to be better positioned to value, maintain and assess quality	• What is your view on the perception that procurement functions/agencies can implement specific features, such as prequalification criteria, to improve their ability to value, maintain and assess quality? o Do you think procurement functions/agencies prioritize quality? o What do you think their priorities are, if not quality? • What attributes do you think are most important for a procurement function/agency to have to value and maintain quality? o Based on our literature review we've identified up to 53 different features, but they can be broadly grouped into structure and governance, quality testing and

	control, procurement processes, payment mechanisms, supplier management and supply management. Please review the handout – Do you have any views on how [interviewer to choose] can improve a procurement function's ability to assure quality?

Commerical incentives for high-quality manufacturers to engage in public procurement are low, and manufactureres are also disincentivised by the hgh cost and difficulty of doing business with state procurement agencies/functions	• What is your view on the commercial incentives for high quality manufacturers to engage with public procurement?
	  o How do government policies affect commercial incentives?
	  o What's your view on the assumption that engaging high quality manufacturers is a mechanism for improving quality?
	• What is your view on the interaction between procurement agencies and high quality manufacturers, in terms of the ease of doing business?
	  o What have you heard from export-focused/high quality manufacturers on their previous experience in engaging with public procurement?
	  o What do you think can be done to address the incentives so that high quality manufacturers are supply the public sector?

Key enablers, such as a sufficient budget and political leadership, are essential to engaging high-quality manufactureres because these enablers act as important signals of the business environment	• How are state health budgets and quality of drugs linked in your view?
	  ○ How do you think a state with a limited budget can improve quality?
	  ○ Do you think volumes are essential to a state being able to improve quality and affordability?
	  ○ What mechanisms, financing or otherwise, have you seen state's use to improve quality?
	  ○ What is your view on a state using volume guarantees?
	  ○ What's your view on state's partnering with other states to be in a better position to leverage volume?
	• What is your view on the relationship between a state's leadership and its ability to procure and deliver high quality drugs?
	  ○ How important do you think leadership is in the drive to improve quality?
	  ○ What mechanisms, in terms of leadership development or prioritization, be used to improve quality?

Companies' previous experiences of engaging with procurement agencies/functions shape their on whether quality is valued and whether the organizations is a reliable	• How do you think high quality companies make decisions about whether to engage with public sector procurement? • What is your view on the assumption that improving the ease of doing business would incentivize high quality manufacturers to engage with public procurement? • How have you seen companies evaluate the cost and ease of

business partner, in the absence of specific features that signal these attriutes a high-quality manufacture has few incentives to engage in public procurement	doing business in terms of engaging in public sector procurement?
Political factors affect the definition of quality and drive a tolerance for a two-tier market in terms of quality, as signaled by the presence of Schedule M	• Features such as the presence of Schedule M indicate that there is a tolerate for variations of quality within the domestic market, when compared with the export market. What factors drive this tolerance? • What can be done to reduce the tolerance for lower quality products in the domestic market?

Structural constraints prevent procurement agencies/functions from valuing quality in the tendering process	• What's your view on whether procurement agencies can value quality?
	  ○ What mechanisms have you seen agencies use to value quality?
	  ○ What mechanisms are most effective in valuing quality?
	  ○ What structural constraints have you seen facing procurement agencies in their attempts to value quality?

Quality is not a priority because of political considerations and a lack of funding	• What's your view on how states prioritize quality of drugs in their approach to procurement and provision? • Do you think there are constraints to states being able to prioritize quality?

	• What role does funding play in the prioritization of quality?
Procurement processes lack **quality testing and control mechanisms**	• What's your view on quality testing and control mechanisms that are used by procurement agencies/functions? • What mechanisms can be used to improve storage facilities?
Procurement agencies/functions **do not have personnel who are well trained** in assessing and implementing standards that can safeguard quality	• What role does training of staff, to assess and implement quality standards, have in a state's ability to assure quality? • What can be done to improve training of staff?
Black-listing and bans of low-quality manufacturers are less likely in states where there is a higher percentage of NSQ drugs	• What is your view on the effectiveness of blacklisting and bans in enabling procurement agencies/functions to provide higher quality products? • What can be done to improve the use of blacklisting and bans?
Private retail companies are better able to provide high quality products because they are better at screening out poorer-quality manufacturers	• What is your view on the assumption that private retail companies offer better quality products? • What is your view on the hypothesis that private retail companies are more proficient than the public sector at screening out poorer-quality manufacturers?
Commercials of the domestic and export markets are so distinct that domestically-focused manufacturers have few incentives to adopt practices that improve product quality	• What is your view on the separation between the domestic and export markets being entrenched to the appoint that domestic manufacturers are not incentivized to improve product quality? • What can be done to improve the ability of domestic manufacturers to meet export-quality? • What will inhibit domestic manufacturers reaching the export

	quality standard?
Technological spillovers from the export to domestically focused manufacturers are limited by structural aspects which make the two markets distinct	• What role do structural features (such as political dynamics, health financing and procurement structures) support the two-tiered nature of the pharmaceutical market? • What can be done to improve the technological spillovers from export-quality manufacturers to domestic manufacturers?

APPENDIX [B]: CODEBOOK

Introduction

This section describes the themes and categories that were used to analyze the interview transcripts. In Stage 1 the transcripts were read, and re-reviewed, for general impressions. Textual data was iteratively assessed using thematic content analysis. In Stage 1 transcripts were read, and re-reviewed, for general impressions. The data was then inductively coded by identified themes. Both preset codes, defined before working with textual data and during or after data collection, and emergent codes (defined after the data), were be used. Preset codes were informed by the literature review, which considered relevant concepts, theories and evidence. Atlas.ti software was be used to facilitate data analysis in Stage 1, and thereafter manual coding was adopted on large prints outs of the transcripts. The codes that were used in this stage are listed in each of the categories in the tables below.

In Stage 2, coded data was categorized. Categories were populated with data, including respondent quotations where possible. Figure B.I provides a summary of the themes and categories that were used. The tables below provide a definition of each category, as well a definition of themes and codes. They also provide inclusion and exclusion criteria for each category.

In Stage 3, axial coding was performed, by organizing the categories to evaluate similarities and differences both within and across respondents. This facilitated an analysis of patterns within and across categories. The categories were then organized into high-level themes, which are also described in Figure B.I. The three themes were: political environment, technical measures and manufacturer incentives and practices. The definition for each theme is also provided within the tables.

Summary of themes and categories

Figure B.1: Summary of themes and categories

Themes	*Categories*	*Codes*
Political Environment	Corruption and Vested Interests	Procurement Model
		Organizational Development of the Agency
		Local Political Factors
		Replication of the TNMSC
	Prioritization of Procurement	Leadership
		Decision-making
		Skills
		External Government Infrastructure
Technical Measures	Quality-Specific Measures	Blacklisting
		Eligibility Criteria
		Quality Testing
		Process Limitations
Manufacturer incentives and practices	Commercial incentives to supply the BMSICL	Price control
		Manufacturer's cost of quality assurance
		Sufficient reward
	Production and sales practices	Forecasting
		Low margins
		Volume
		Ease of doing business

Key

A priori categories	Emergent categories

Theme: Political Environment

Definition: Political relationships, practices and dynamics, which have a bearing on the procurement of drugs at the state-level.

Themes	*Categories*	*Codes*
Political Environment	Corruption and Vested Interests	Procurement Model
		Organizational Development of the Agency
		Local Political Factors
	Prioritization of Procurement	Replication of the TNMSC
		Leadership
		Decision-making
		Skills
		External Government Infrastructure

Categories	Details
Corruption and vested interests Codes: • **Procurement Model**: The organization, governance and structure of the procurement function • **Organizational Development of the Agency**: the maturity and organizational credibility of an organization • **External Government Infrastructure**: The apparatus of government, including authority	**Definition:** Dishonest and/or fraudulent conduct by individuals exercising leadership or holding decision-making power at any stage of the procurement process, and usually involving an illegal financial reward. **Inclusion:** The respondent describes and discusses the local political landscape, in terms of the challenges and opportunities presented by vested interest, as well as networks of corruption, fraud and patronage. The respondent then explains how these local factors affect a

structures, authority figures, political and regulatory systems, that are external to the procurement agency but which have an impact on its ability to safeguard drug quality. • **Replication of the TNSC:** activities related to copy, in whole or in part, the procurement model and practices of the TNMSC.	procurement agency's ability to safeguard drug quality. This may include a discussion of how local politics affect perceptions of manufacturers, in terms of their willingness to do business with the procurement agency. **Exclusion:** The respondent discusses the local political context in general terms that are not relevant, indirectly or directly, to a procurement function's ability to assure drug quality.
Prioritization of Procurement Codes: • **Leadership:** the practice of holding authority within a power structure that is responsible for the procurement of drugs • **Decision-making:** the act of deciding on an outcome • **Skills:** the capabilities and aptitude to carry out a procurement-related task • **Replication of the TNMSC:** activities related to copy, in whole or in part, the procurement model and practices of the TNMSC.	**Definition:** The willingness authority figures exercising leadership in relation to procurement functions, to prioritize procurement and bring commitment to the issue **Inclusion:** The respondent discusses the role of leadership, decision-making and skills in terms of the agency's ability to assure drug quality. This can include political willpower and interest in procurement, management and operational capabilities and leadership skills, both technical and managerial. This may also include: comparative analysis of different states; the impact of culture and norms on leadership style and effectiveness; and national level factors that

	have a bearing on state-level quality. **Exclusion:** The respondent discussed leadership, decision-making and skills at a general level and did not articulate how these related to drug quality.

Theme: Technical Measures

Definition: Technical measures refer to the quality-specific measures, that can be used by procurement agencies to optimize its ability to assure drug quality, and their limitations. This included measures such as eligibility criteria, blacklisting, and quality-testing. These measures are often established through written practices and documentation. However, their effective implementation is not guaranteed by documentation alone. As a result, dependent on the political environment, the effectiveness of the measures to ensuring quality can be compromised.

Themes	*Categories*	*Codes*
Technical Measures	Quality-Specific Measures	Blacklisting
		Eligibility Criteria
		Quality Testing
		Process Limitations

Categories	Details
Quality-Specific Measures	**Definition:** Quality specific measures refers to technical measures that can be used by

Codes: • **Blacklisting:** Pharmaceutical companies that fail to comply with national legislation and medical standards can be blacklisted by procurement agencies. Blacklisting refers to the practice of one government entity banning a company from supply a given product to any other government entity, where there are concerns about the efficacy and safety of a product. The impact of blacklisting varies based on the organization issuing the sanction. • **Eligibility Criteria:** The range of measures that a procurement agency can implement to establish that a given supplier is of good standing and is likely to provide high quality suppliers. • **Quality Testing:** The testing of products by suppliers and government organizations to verify whether the product meets the manufacturing specifications. • **Process limitations:** Weaknesses or vulnerabilities in processes designed to assure quality of drugs	procurement agencies, which have a direct impact on quality assurance and control. **Inclusion:** The respondent states, implies or discusses the use of practices or process, often built into the design of a procurement model, for addressing the challenges of ensuring and maintaining drug quality. This may include the respondent discussing the strengths and limitations of a given measures, their previous experience of using the measure and their views on how it can be improved in future. **Exclusion:** The respondent states, implies or discusses the use of general practices or processes that are either indirectly related to quality or not specific to quality. This could include measures such as the implementation of technology systems to support the procurement process.

Theme: Manufacturer incentives and practices

Definition: Manufacturer incentives and practices refers to how manufacturers are encouraged to supply procurement agencies from a commercial perspective and the production methods they use to fulfil contracts. Within this category the key themes were commercial incentives and production and sales practices.

Manufacturer incentives and practices	Commercial incentives to supply the BMSICL	Price control
		Manufacturer's cost of quality assurance
		Sufficient reward
	Production practices	Forecasting
		Low margins
		Volume
		Ease of doing business

Categories	Details
Commercial incentives to supply the BMSICL Codes: • **Price control**: a government policy regulated the retail price of products in the Indian market • **Manufacturer's cost of quality assurance**: expenditures undertaken by a manufacturer to produce a product that is a high-quality standard, this may expenditure on staff, training, equipment and materials • **Sufficient reward**: that the remuneration received for producing a product is commensurate with the cost of production	**Definition:** Perceptions of the financial reward of engaging with the BMSICL by a manufacturer/supplier. It also considers the ease of securing the financial rewards, which is separate to the reward itself. **Inclusion:** The respondent discusses the role of commercial incentives in determining the incentive(s) of a given supplier, or set of suppliers, to contract and supply BMISCL. This includes both the financial reward from a contract, and may involve discussion of the profit and margins on a product or categories of a products. It also includes the ease of doing

• **Forecasting**: the ability of a procurement agency to identify demand for medication across its given jurisdiction • **Low margins:** A low level of profit • **Volume:** the quantity of supply of a product • **Ease of doing business:** an assessment of the complexity of engaging with a procurement agency in a commercial agency. This may include non-financial and financial aspects of business practice, such as the cost of submitting tenders and the cost of recovering reward on outstanding bills. • **Investments in quality:** Financial and non-financial investment that a company may be required to make to consistently ensure the quality of its product. This may include equipment, hiring of staff with quality assurance expertise and training programs.	business, or of securing the financial reward. It also considers how the financial reward may change over time, or during the course of a contracting period or contract. **Exclusion:** The respondent discussed commercial dynamics that were not relevant to the domestic market or to quality example. This could include discussion of how the company or market was managing foreign markets, without the discussion being relevant to understanding features of the Indian market.
Production and sales practices Codes: • **Low margins:** A low level of profit • **Ease of doing business**: an assessment of the complexity of engaging with a procurement agency in a commercial	**Definition:** Activities undertaken by firms in relation to the manufacturing and sales of medical products and in response to the market dynamics. **Inclusion:** The respondent discusses the manufacturing process used by pharmaceutical

agency. This may include non-financial and financial aspects of business practice, such as the cost of submitting tenders and the cost of recovering reward on outstanding bills. • **Falsification of documents:** the practice of forging documentations required by authorities in procurement and quality assurance processes	companies in producing the product and supplying it to the procurement agency, and how this had an impact on quality assurance and drug quality. This could include the treatment of materials, equipment and the management of skilled staff, as well as the process of securing approval for a contract from a procurement agency. **Exclusion:** The respondent discussed manufacturing or sales practices that were not relevant to quality assurance.

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