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Case Study

Strategies to Improve Drug Availability in Healthcare Institutions: A Case Study in Medical Suppliers Division, Ministry of Health, Sri Lanka

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Abstract: Access to safe, effective, quality and affordable essential medicines and vaccines are major aspects in archiving universal health coverage which are targets of sustainable development goals(SGD). National medicinal drug policy (NMDP) of Sri Lanka was formulated in 2015, is to archive above needs. The National Medicines Regulatory Authority (NMRA) Act was enacted to ensure the policy goals. The estimated financial allocation for medical supplies is about 45.025 Billion Rs in 2018 for government healthcare institutions which is about 23% of the total health expenditure. The supply gaps vs. annual estimates are 56.7%, 8.7%, 40.07 % for vital drug items, 23.19%, 17.1%, 18.61% for essential drug items, 21.42%, 26.4%, 20.07% for non-essential drug items during 2016, 2017 and 2018 years respectively. The objective of this study to assess the underlying causes for medicinal drug availability of healthcare institutions in Sri Lanka. Problem identification, analyzing and prioritizing were done by conducting few key informant interviews (KII) and literature review. Approximately 1850 pharmaceutical items are imported and their usual lead time is 11-14 months to reach MSD. It's about 80%-85% from total drug expenditure. Non availability of functionally wide specification, problems in procurement method, lack of monitoring, poor adherence to delivery schedule, inadequacy of storage, prescribing and dispensing issues, issues related to Drugs and Therapeutic Committee (DTC) and issues of regulatory process have contributed the drug availability. Local manufacturing of pharmaceuticals, establishing Specification Development and Control Unit, establishing an e-procurement system and electronic monitoring system at SPC, calling NMRA approved limited tender, establishing electronic prescription methods, regulating drugs and therapeutic committee were among the recommendations.
Keywords: Drugs availability, Medical supplies, e-procurement, NMRA, Annual drug estimates.

Introduction

Access to safe, effective, quality and affordable essential medicines and vaccines are major aspects in archiving universal health coverage which are targets of sustainable development goals (SGD). Rising prices of new medicines, problems of shortages and stock outs of essential medicines, especially for non-communicable disease, increasing numbers of

substandard and falsified medical products have made an additional pressure on health systems in the world. In addition, problems such as antimicrobial resistance and opioid misuse convey a massage to improve appropriate use of medicines for the patients. The Seventy-First World Health Assembly held in May 2018, considered a report by the Director-General (DG) on addressing the global shortage and access to medicines and vaccines. There a request to elaborate a road map was done, on access to medicines and vaccines for 2019-2023 period. The member States of WHO are increasingly seeking the support of WHO for guidance to select, regulate, import, manufacture and wisely use of quality essential medicines and health products to ensure universal access to medicines (WHO, 2019). The Essential Medicines and Health Products (EMP) Department of WHO allocated 100.3 US$ of budget to extend its support to member states during 2014-2015 in strengthening medicine regulation, formulating Essential Medicines list(EML), development of new quality assurance guidelines and strengthening policy framework with the intent of the SDG to promote lasting improvements for all populations.

The objectives of National medicinal drug policy (NMDP) of Sri Lanka formulated in 2015, is to ensure the availability of efficacious, safe, good and quality medicines to the healthcare needs of the people in a sustainable manner, rational use of medicines by healthcare professionals and consumers and promoting of local manufacturers of essential medicines. Additionally it looks in to selection of essential medicines, affordable and equitable access, financial options, supply systems and donations, regulation and quality assurance, quality use of medicines, research, human resource development, monitoring and evaluation aspects.

The need of legislative authority for regulation and quality assurance has been emphasized in NMDP to ensure regulation and control of manufacture, importation, registration, promotion, sale, distribution of medicinal drugs and devices, nutraceuticals and functional foods (NMDP, 2015).

The National Medicines Regulatory Authority (NMRA) Act enacted by Sri Lanka parliament in 2015, to ensure the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices. NMRA is the regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products. Further it encourages the manufacturing of good quality medicines in Sri Lanka. It promotes the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers. It educates the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products.

It regulates the promotion and marketing of medicines, medical devices and borderline products, and ensures the availability of the medicines in Sri Lanka. It's the body which regulate all matters pertaining to the conduct of clinical trials in Sri Lanka. Further it conducts post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products (NMRA, 2015). The health system in Sri Lanka is responsible for procuring, distributing, storing, prescribing and dispensing medicinal drugs to ensure the delivery at national, provincial, regional or institutional level.

The Medical Suppliers Division (MSD) of Ministry of health (MOH) is the responsible body established for above purpose functioned under Deputy Director General MSD (DDG MSD) to cater the medicinal supply to all government healthcare institutions island wide.

The institutions should start preparing the estimates at August and must complete before October the year. The MSD consolidates the national estimates by next January and place the order at State Pharmaceutical corporation (SPC) which is the procurement agent for MSD. SPC usually takes eleven months lead time and able to supply relevant stock on next year. The drugs procured are sent to the MSD by the SPC for storage and distribution to all 26 Regional Medical Supplies Divisions (RMSD) at regional level and line ministry hospitals for storage and distribution. The institutional stocks are dispensed for patients by institutional physicians (Figure 1)(Manual on Management of Drugs, 2008).

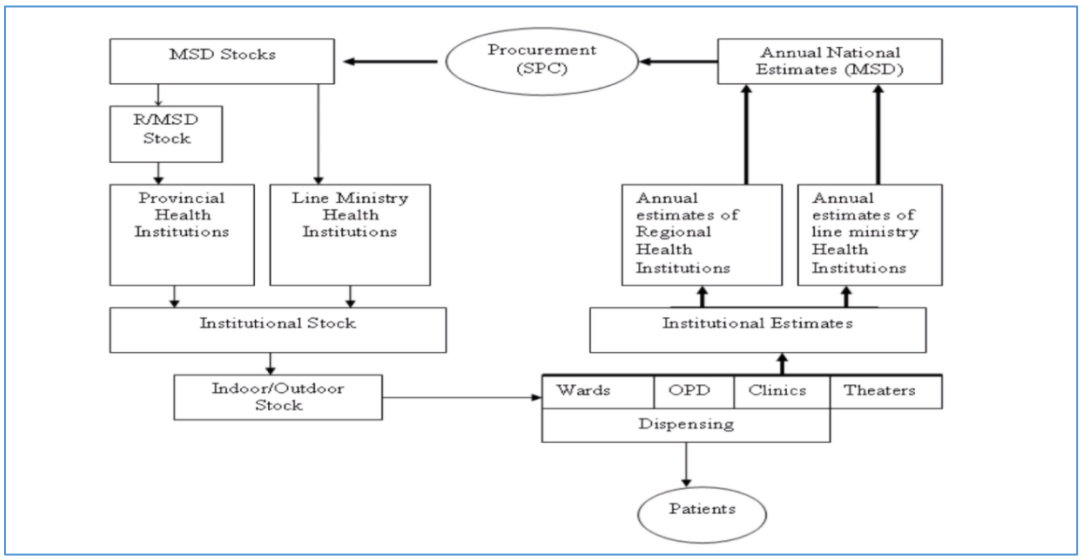

Figure 1. Management cycle of pharmaceuticals

The estimated financial allocation for medical supplies in 45 Billion Rs in 2016, 45.1Billion Rs in 2017 and 45.025 Billion Rs in 2018 for government healthcare institutions(MSD reports, 2016-2019) and this figure was 2.81 Billion Rs in 2000, 5.34 billion Rs in 2007. The present drug budget is around 23% of the total health expenditure which is 200 Billion Rs in 2018 (Budget estimate, 2018) and drug budget was 10% of total healthcare expenditure in 2007 (Manual on Management of Drugs, 2008). This shows that expenditure on drugs have been increased nine times during ten year duration and allocation for drug expenditure has also been doubled during this period.

The entire process of procuring, distributing, storing, prescribing and dispensing medicinal drugs is a responsibility of MOH. The regulatory actions of this process entirely managed by NMRA which is an independent body functioning under Minister of health(NMRA, 2015). There are identified problems in this process affecting institutional drugs availability of government healthcare Institutions. There is remarkable discrepancy of national annual estimates and MSD supply of pharmaceuticals to institutions annually. Some items are over supplied exceeding the annual estimates. But generally there is a huge gap of annual estimates and the supply. In Table 1 the annual supply gap is expressed as a percentage of annual estimates. The supply gaps are 56.7%, 8.7%, 40.07 % for vital drug items, 23.19%, 17.1%, 18.61% for essential drug items and 21.42%, 26.4%, 20.07% for non-essential drug items during 2016, 2017 and 2018 years respectively. Hence it seems there is remarkable supply gap in institutions nationally. This fact is confirmed by media information regarding institutional drug unavailability which happens time to time. The objective of this study to assess the underlying causes for medicinal drug availability of healthcare institutions in Sri Lanka.

Methodology

Problem analysis was done using Ishikawa diagram. The problems were identified and prioritized by conducting few key informant interviews (KII). Several KII were held with Senior Assistant Director (SAD), Superintendent Pharmacist (SP) at stock control unit (SCU), Assistant Director (AD) dispatch unit, AD pharmaceuticals, AD stores and chief Accountant at MSD.

Literature was reviewed about well-functioning health systems for effective problems analysis. Document such as NMDP, Manual on Management of Drugs, NMRA Act, WHO reports, MSD data statistics and reports at account department of MSD were reviewed to ensure accurate problem analysis and generation of conclusions and recommendations.

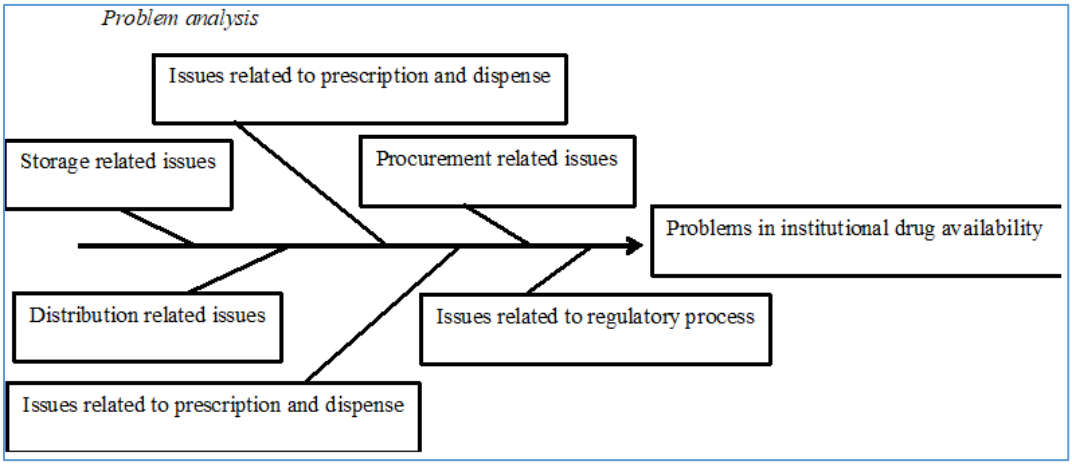

Figure 2. Ishikawa diagram describing problems related to drugs availability

Problems in institutional drugs availability

There are root causes leading to institutional drug unavailability. Those are factors influencing the chain of actions from manufacturing process to consumption level by the patient.

Table 1. Comparison of estimated and issued quantity of drugs from 2016-2018

Year	2016			2017			2018		
Drug Classification	Estimated quantity[1]	Issued quantity by MSD[1]	Gap[2]	Estimated quantity	Issued quantity by MSD	Gap	Estimated quantity	Issued quantity by MSD	Gap
Vital	103067014	44630262	56.7	40970554	37383027	8.76	40964406	24551173	40.07
Essential	7152161192	5493279104	23.19	6372043490	5280571762	17.1	6177761101	5027882065	18.61
Non-Essential	1151147196	904571143	21.42	983259178	723365471	26.4	1235752097	987763592	20.07

[1]There are 18 number of vital, 637 number of essential and 460 number of non-essential drug items by year 2018. The total number of quantity estimated and issued per each drug item were considered in calculations.

[2] The gap is expressed as a percentage of estimated quantity.

Source: MSMIS electronic information system, MSD 2019

Table 2. Payment summary for medical supplies from 2016-2018

	Expenditure item	2016 (Rs)	2017 (Rs)	2018 (Rs)
LM items[1]	Surgical Gauze	540,298,380	564,311,220	426,588,150
	SPMC Supplies	1,976,838,600	2,379,865,800	4,093,138,465
	Other LM items	3,085,825,980	2,595,140,885	4,438,049,309
	Sub total	**5,602,962,960**	**5,539,317,905**	**8,957,775,924**
Imported items		**32,399,851,140**	**32,983,301,035**	**34,372,870,418**
	Total	**38,002,814,100**	**38,522,618,940**	**43,330,646,342**

[1]LM-Locally Manufactured items *Source: Accounts dept., MSD, 2016-2018; Treasury report, MSD, 2016-2018*

Table 3. Supply details of pharmaceutical items

Pharmaceutical items supplied to MSD	Number of Items
Local Manufacturers	
Local private Manufacturers[1]	89
SPMC[2]	
SPMC Direct Manufacture	43
SPMC involved Joint venture	16
SPMC involved Triple aggrement[3]	46
Imported supplies	1006
Total	**1200**

[1] sixteen currently registered local manufacturers
[2] State pharmaceutical Manufacturing corporation
[3] A new agreement currently these items are not supplied to MSD
Source: Statistics, MSD 2019

Procurement related issues

The procurement lead time declared by SPC is 11 months but it's about 14 months at current context. There are identified factors leading to increased lead time. Approximately 148 pharmaceutical items out of 1200 of total are manufactured and supplied by local manufacturers (LM) (Table 3).

The total expenditure for the pharmaceuticals and gauze worth 5.6 Billion Rs, 5.5 Billion Rs and 8.9 Billion Rs during 2016, 2017 and 2018 respectively. This sum is 15%, 14%, 21% from total expenditure for pharmaceutical and surgical items annually in 2016, 2017 and 2018 respective years (Table 3). The lead time of for the supplies of LM are remarkably low comparatively imported items (Solaman, P D, personal communication, 20 August 2017).

Absence of specification adapted to local setup for procurement process Specification is "a detailed description on the goods or services required, and forms part of an invitation to supply or invitation for expressions of interest document which reflects the need of the customer"(Procurement specification guideline, 2019). The specification should be able to compete for widest possible supplier base. Current MSD uses specifications made by British pharmacopeia, US pharmacopeia which is not totally match to the local context.

The MSD still unable to develop a wide specification which matches to the local setting. When the MSD produces specification for local need that has to be approved by the NMRA for legal validity. Such specifications are developed without much research evidence and has

narrow functional validity. Hence registered bidders may be restricted, and they do not tend to quote for procurement. This leads unregistered bidders to bid in open tenders. No objection letters (NOL) from NMRA is essential to allow such imports and this causes delay in procurement procedure. Such NOL are issued by NMRA allowing MSD to import with its own risk. NMRA is not responsible for such quality issues but MSD doesn't have own laboratory facilities to ensure their quality. Nonstandard, non-updated specifications compulsorily need Technical Evaluation Committee (TEC) approval at procurement process which further increases procurement lead time (PLT). Usually this technical evaluation is a manual and lengthy process which further lengthen the PLT (Nethsinghe N A A S, personal communication, August 20, 2019).

The bidding process gets unnecessary delay due to open tender procedure (OTP)
According to NMRA Act, only registered suppliers at NMRA can bid on tender. But SPC calls suppliers from worldwide for OTP. Once the bidders complete their bidding, the unregistered suppliers are disqualified at TEC. This adds unnecessary lead time to procurement process which is approximately takes between 45-90 days. OTP will further delayed due to long TEC process compared to limited tender.

On the other hand unregistered suppliers tend to bid in open tender and the process of granting NOL will add further delay in PLT approximately about 3 to 4 weeks. Further unnecessary disqualifying process will lose genuine suppliers due to frustration.

Transparency issues of procurement process
The manual procurement process may lead to conflicts of interests which may affect genuine supplier base but increased profit motives to hang on. But there are no factual evidence to prove this incident. Anyhow currently globally reputed companies do not seem to be bidding on SPC tenders. This is partly due to lower quantity of demand for 2 million population in Sri Lanka. There is a possibility of deliberate delay in routine supplies making an artificial out of stock situation in public healthcare settings by suppliers. This may result in increasing local purchase process for higher prices. But the current manual procurement and monitoring system finds it difficult to prove this with evidence. Further, the system for black listing the bad suppliers usually doesn't happen.

Lack of monitoring of order administration process (MOAP)
Currently there are large number of rolled off supply orders pending from foreign suppliers. The manual system is currently unable to monitor this smoothly. It is approximately about 20000 orders which are pending currently by the year 2019. There is no such MOAP and maintenance of supplier performance index which enables SPC to cancel delayed orders. This will further lengthen the PLT.

Delay in custom clearance
For unregistered suppliers NOL should be issued by NMRA. The time taken for NOL process is added to custom clearance process of pharmaceuticals.

Issues at demand-supply process
According to Table 1, the demand supply mismatch is remarkably high for vital drugs: 56.7% in 2016 and 40.07% 2018 comparatively to essential and non-essential drugs in same years. This conveys that supply is not matched according to the demand. This may be due to conflicts of interests or inability of the manual procurement system to evaluate, forecast and supply the demand gap.

Non adherence to delivery schedule

The delivery schedule of supplies are handed to SPC at early in the year. But that schedule is agreed by the supplier on placing the order with letter of credit (LC) after procurement process. Due to delay in procurement process, negotiations are usually taken place with the supplier regarding the delivery schedule. But MSD formulated delivery schedule is subjected to alter several times before the goods reaching the MSD. Further, suppliers do not tend to start manufacturing till the orders are confirmed with LC due to usual payment delays. These factors have badly affect the delivery schedule of supplies (Nethsinghe N A A S, personal communication, August 20, 2019).

Distribution related and Storage related issues

Ideally the storage levels of the drug supply such as MSD, RMSD and Institutional stores must be defined and capacity must be adequate. This can accommodate continuous supply flow avoiding under stocks. The delivery schedule of the supplier must be synchronized with MSD store capacity and capacity of peripheral drug stores. Still the storing capacity including buffer stocks are not defined at central level or peripheral levels. At MSD level buffer stock capacity is considered to have 1-3 months. But it's not functioning accurately due to unavailability of continuous supply flow to MSD. In spite of this, there is additional 80000 square feet currently needed due to sudden closure of one sub store at Angoda due to sudden flood situation and evacuation of one sub store due to an administrative issue. Further, about 1% of quality failed and expired drugs are stored at MSD. Also additional warehouses have not been developed for last 5years for ongoing healthcare demand (Nethsinghe N A A S and Ranathunga U, personal communication, August 20, 2019).

Issues related to prescription and dispense

The medicinal drugs are prescribed mostly in a manual system by physicians at hospitals in Sri Lanka. Electronic prescribing technics have been introduced only for few hospitals. Usually drugs are prescribed for 3 days in outpatient department (OPD) and 4 weeks in clinic setting(Manual on Management of Drugs, 2008). Usually the time taken by the physicians and dispensers for patient education is limited due to overcrowding in public hospitals. This ultimately results in poor patient compliance. Limited number of researches have been done to evaluate drug wastage at OPD or clinics after the process of dispensing. Further, manual system allows drug pilferages through fraudulent prescriptions. This is a difficult task to be investigated within a manual system (Nethsinghe N A A S, personal communication, August 20, 2019). The prescribing pattern and disease trend has been changed over past decade leading to increase medicinal demand resulted in institutional unavailability of drugs (Sakunthaladevi V, personal communication, August 15, 2019).

Issues related to Drug and therapeutic committees (DTC) and annual estimates

DTC is a very useful forum to monitor supply, distribution and consumption of drugs. This forum allows for decision-making by consensus among representatives of different units involved in the management of drugs. DTC functions at national and provincial levels should meets 3 monthly. Regional levels should meets 2 monthly and institutional level should meet monthly (Manual on Management of Drugs, 2008). But these committees are poorly functioning at each levels which may lead to unavailability of medicines at institutional levels. The institutional annual estimates preparation starts in August in each year to ensure a complete national estimate at January, ready for procurement process. There are lot of health professionals involve in this endeavor but, the medicines for national estimate for following year reaches the country in 3rd year due to long PLT of 11-14 months (Nethsinghe N A A S, personal communication, August 20, 2019).

Issues related to regulatory process

Ideally samples of pharmaceuticals must be taken at pre-marketing and post marketing stages. At pre-marketing stage, the drug samples are checked at the drug registration process by NMRA and pre consignment stage by SPC. A pre delivery sample is taken by the quality department of MSD for physical checking which includes checking of serial numbers, batch numbers, manufacturer, date of manufacture and date of expiry for each consignment to ensure the conformity of the order. Ideally a sample for quality assurance must be taken at pre delivery stage. At post-marketing stage, random samples should be collected from both government institutions and private sector pharmacies. The National Drug Quality Assurance Laboratory (NDQAL) governed under NMRA should do quality surveillance of above stages(Manual on Management of Drugs, 2008). But they assure quality at drug registration process. Island wide random sample checking doesn't happen efficiently. Pre deliver sample checking never happens at current context. Poor quality surveillance may lead to loose supplier accountability resulting with bulks quality failure of pharmaceuticals leading to institutional unavailability of drugs (Wanniarchchi L C, personal communication, 20 August 2019). The NDQAL is under function due to lack of human resource (HR) and unable to expand its capacity for upcoming demand. The NMRA recently started to fix the price to ensure reasonable prices of medicines to the patients. This price fixing need much market research and updating the prices accordingly. But that doesn't happen, ultimately resulting in suppliers not quoting prices for bidding, leading to many NOL issues and further delay in Procurement process (Nethsinghe N A A S, personal communication, August 20, 2019).

Discussion

In Sri Lanka, approximately about 38 to 43 billion rupees worth expenditure has been done for medicinal supplies in recent years by ministry of health(Table 2). This sum is 23% of total health expenditure in 2018. But there is a positive estimate-supply mismatch ranging between 20%-50% approximately in recent years nationally. This figure is badly seen for vital drugs which are used for life saving procedures(Table 1). Meantime there are only 16 registered LM and the SPMC currently manufacture 148 pharmaceutical items out of 1200 items which is about 15%-20% from total supplies expenditure. Hence still 80-85% of supplies are imported to the country annually although NMDP emphasizes on more priority for LM. There are many problems identified in procurement process of medicinal supplies from importers. On development of procurement specification, many aspects such as broad base functional validity for local use, published research data for users in local setting, market availability of supplies, NMRA expert advice, the world standards on the formula, the pharmacopeia standards and the standards in published documents must be considered. On the development of such specification, needs separate independent Specification Development and Control Unit (SDCU) consists of expertise of the field. This should function under Director General of Health Services (DGHS). This SDCU should function on survey, research and consultancy of experts to ensure development of unbiased specifications. Every year that specification has to be updated due to reasons such as alteration of customer demands and introducing new products to the market. But it's a very hard task to develop such specifications for 10000 to 15000 pharmaceutical and surgical items of MSD supplies.

Broader comprehensive such specification will attract wider base of bidders which enables the MSD to get reliable and good suppliers. Up-to-date specification may not need Technical Evaluation Committee (TEC) decisions which further reduces incurring conflicts of interests. This may further improves PLT (Procurement specifications guideline, 2019, Nethsinghe N A A S, personal communication, August 20, 2019). The lead time of technical evaluation due

to open tender can be reduced up 21 days or further if limited quotations are called by NMRA registered suppliers.

Introduction of E- procurement system (EPS) consists of bidding, bid closing, scheduling, tender evaluation and procurement committee decisions will reduce human interference creating more transparent environment for genuine suppliers. Electronic procurement or e-procurement, defines the automation of procurement and supply chain processes using internet based applications and technology. This expands enterprise resource planning systems, automating of internal business processes, thus providing a platform that supports automation at a global level. It allows procurement professionals across the world to communicate information simply, efficiently, streamlining the global procurement process; reducing the cost and the time without compromising on standards and quality. It reduces transaction time, enables using e-catalogues allowing organizations to market their product offer electronically. It allows wider spread supplier bases and simplified global procurement by supporting various languages, international taxation and financing, shipping regulations, worldwide communication and co-operation. It gives a simple configuration and scalability which suits the individual needs to both the buyer and the supplier. It improves productivity allowing wider business processes handled by employees and ensures free time for the team to spend on more strategically significant functions and tasks (Oxford College of Procurement and supply, 2019). It reduces time and cost of transactions. Approximately there is 80% of time saving in e-procurement compared to a manual system (Mathur, V. 2019). Independent decisions and comments on tender at EPS will remarkably reduce conflicts of interests which can be easily trackable at audits. Electronic monitoring system for MOAP and an E-based supplier performance index must be introduced for huge amount of orders placed annually. Thereby non-compliant orders can be cancelled and suppliers must be subjected for more accountability.

The distribution flow of supply must be synchronized from manufacturer to the end user at periphery. For such flow, the decisions at each level must be automated without much human interferences. Electronic information systems can play a big role in archiving this. Electronic prescription system allows more efficient medicinal delivery at user level. This allows introduction of automated dispensing machines to dispensaries where there may be more time for dispensers in giving information to patients for good compliance. This system can eliminate pilferages, medication errors and improve efficient queue management, quality of dispensing and 24 hour operations. Further, an automated system of this nature at periphery can give real time estimates and prediction at MSD level by avoiding current, 6 months waste of estimating time (Nethsinghe N A A S, personal communication, August 20, 2019).

The DGHS minutes have emphasized that regulatory and supervisory visit should happen to institutional DTC by DDG MSD and Director of MSD to ensure efficient and effective DTC meetings (DGHS minutes, 2019). The NDQAL must be a well-functioning laboratory that should be able to cater sufficient and effective quality assurance program for medicinal supply for entire country. The NDQAL must be equipped with sufficient HR and physical resources to ensure that task.

Conclusions and Recommendations

There is obvious supply demand mismatch of MSD medicinal drugs leading to institutional drugs unavailability. This gap is remarkable in vital items in some years comparatively to essential and non-essential items. Approximately 1850 pharmaceutical items are imported and their usual lead time is 11-14 months to reach MSD. This sum is 80%-85% from total

expenditure of medical supplies. The government must give top priority to establish local manufacturers to increase medicinal supply. There are many procurement related factors influence institutional drug availability such as non-availability of functionally wide specification, calling for world wide open tender procedure while NMRA disqualifying unregistered suppliers, lack of MOAP and poor adherence to delivery schedule. The storage inadequacy, prescribe and dispensing issues, issues related to DTC and annual estimates and issues of regulatory process have contributed the drug availability of healthcare institutions. Development of fully functioning SDCU in the MOH and fully functioning e-procurement system at SPC can resolve long PLT contributing to institutional drugs unavailability. Establishing electronic MOAP at SPC, calling limited tender from NMRA approved suppliers may further reduce the PLT. Priority must be given to bulk drugs ordering institutions to establish electronic prescription methods. DTC must be well functioned in all levels to ensure proper estimates to avoid drugs wastage.

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Conflicts of interest
The authors declare no conflicts of interest.

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