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Sensible Factors that Need Strategic Change to Improve the Medical Drug Availability across Healthcare Institutions in Sri Lanka

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EXECUTIVE SUMMARY: Access to medicines remains a major obstacle for people across the world to maintain their health at a desired level. Ensuring an adequate supply of safe and effective drugs of acceptable quality is an integral part of the health policy of Sri Lanka. The medical supplies division is the sole organization responsible for providing all pharmaceuticals, surgical items, laboratory items, radioactive items, and printed materials for government sector healthcare institutions. The establishment of an independent drug regulation authority, the Declaration of a national essential drug list, the establishment of a separate drug procurement entity, Pooled procurement, digitalization of drug management, and expansion of drug storage capacity are key strategies that have been implemented by the Ministry of Health to minimize the drug shortages across the healthcare institutions of Sri Lanka. Despite the implemented strategies drug shortage continue to evolve from time to time as a public outcry in the media. This case study describes the critical issues that need to look at more strategically to improve drug availability.

KEYWORDS: Drug availability, Factors, Medical Sullies Division, Sri Lanka.

INTRODUCTION

Access to medicines remains a major obstacle for people across the world to maintain their health at a desired level. The provision of improved access to medicine is far and wide featured as an objective of national medicines policies of many states. Despite the high priority in policies, the provision of the right medicine of the right quality and quantity to the right people at right time remains the major challenge for any healthcare system around the world [1]. World Health Organization estimated that around two billion people of the world's population are suffering due to the lack of access to basic medicines [2].

Access to medical care in Sri Lanka is free of charge at the point of delivery. However, the non-availability of drugs following a consultation in the public sector is compelling patients to buy them from a private pharmacy. World Bank reports that the out-of-pocket expenditure as a share of current health expenditure in Sri Lanka (2018) is 50.654% [3] which is considerably high in comparison to middle-income countries. Therefore, the availability of essential medicines in a healthcare centre has become one of the factors affecting access to healthcare [4].

The National Medicinal Drug Policy (NMDP) of Sri Lanka is developed to safeguard the rights of the consumers and is based on the essential medicines concept. NMDP objectives ensure the availability and affordability of efficacious, safe, and good-quality medicines along with the promotion of local manufacturing of essential medicines [5].

The history of the Essential Medicine List in Sri Lanka started way back in 1958 by Professor Senaka Bibile. Further, he developed "the Ceylon Hospitals Formulary" to provide information on the use of these medicines. Essential medicines are the intended drugs of assured quality at a price that a country or an individual can afford and to be available in adequate amounts and appropriate dosage sizes, throughout the year within a functioning healthcare institution. The essential drug list of Sri Lanka is revised every three-year considering the criteria; disease prevalence, clinical evidence, drug safety and efficacy and cost-effectiveness [6].

National Medicines Regulatory Authority (NMRA) is an independent authority of the Ministry of Health established in 2015 to change the governance of the Cosmetics, Devices and Drugs Authority through an Act of Parliament with the primary objective of increasing patient access to quality-assured medicinal products. Further, it plays the role of protecting and improving public health by ensuring the availability of medicinal products, and conformity to applicable standards of safety, quality, and efficacy. The National Medicines Quality Assurance Laboratory (NMQAL) of NMRA conducts laboratory tests that are necessary for determining compliance with pharmaceutical product quality, safety, and efficacy requirements [7].

Pooled procurement of pharmaceutical items through an independent agency was started to increase the purchasing power, minimize the cost incurred for medicines, achieve greater efficiency, and keep the timeliness of the goods received [8]. State Pharmaceutical

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Corporation (SPC) is functioning as the independent procurement agency for Medical Supplies Division (MSD). Further, MSD has the authority to procure some medical, surgical and laboratory items (n=236) from local drug manufacturers.

MSD of the Ministry of Health Sri Lanka is the sole organization responsible for providing all pharmaceuticals (n = 1337), surgical items (n = 8600), laboratory items (n = 5639), radioactive items, and printed materials for government sector healthcare institutions. Medical Supplies Division is also responsible for supplying dangerous drugs and essential medical items to private medical institutions which are not available in the open market. MSD has a network of stores comprising central medical stores (storage volume = 7796 m3) five large other stores (total storage volume = 28136 m3) and 26 Regional stores at the district level. Annual drug estimation, ordering, monitoring, distribution, and accounting are the other vital functions carried out by MSD apart from the storing of drugs. In 2017 MSD officially launched its Medical Supplies Management Information System (MSMIS) to efficiently manage national medical supplies ensuring the availability of medical items in government health institutions. MSMIS has 16 modules covering all aspects of drug management at MSD.

Despite all the measures taken to improve drug availability in healthcare institutions, the media highlight the public outcry on the unavailability of pharmaceuticals in healthcare institutions across the country.

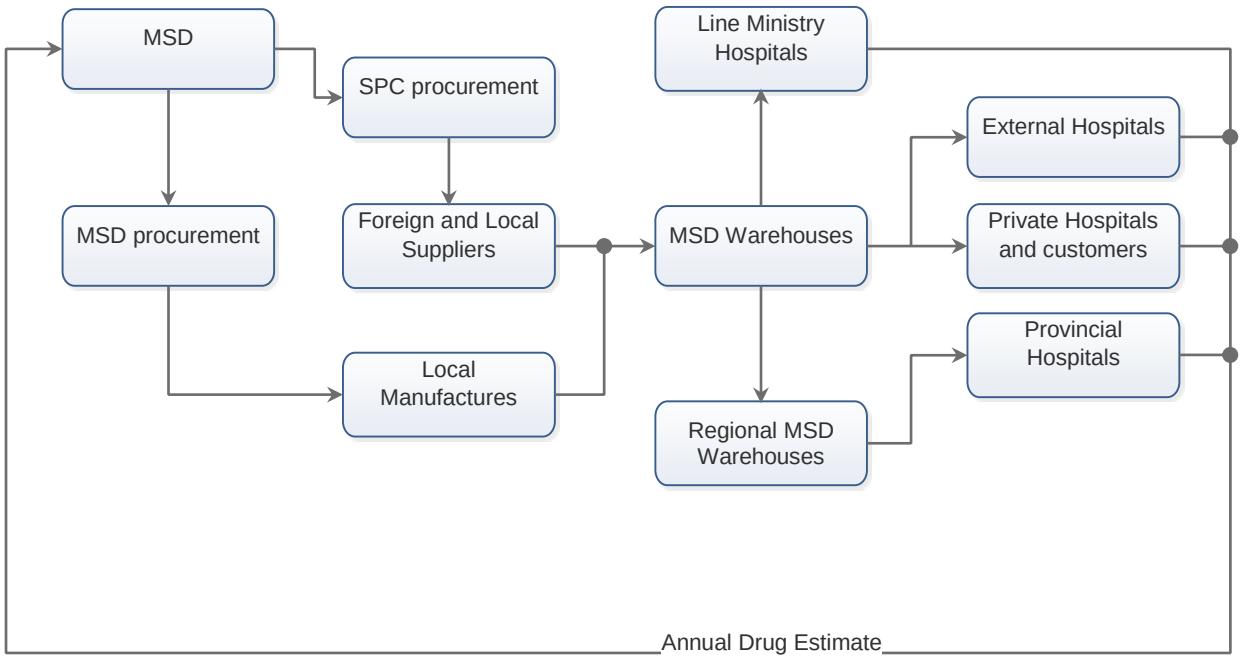

Figure 1: Supply Chain of MSD

Objective

To identify critical issues affecting the drug availability in government healthcare institutions of Sri Lanka.

METHODOLOGY

Following methods were used to identify problems affecting the availability of medicines in healthcare institutions of Sri Lanka.

1. Key informant interviews (KII)
2. Secondary data review
3. Desk reviews

Key Informant Interviews were conducted with the Director, Deputy Director, Accountant Suppliers and Assistant Directors of MSD. Further, Interviews were conducted with the Chief Pharmacist of two different District General Hospitals, four Base Hospitals and five Divisional Hospitals in the Western Province of Sri Lanka.

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Secondary data related to the drug supply chain was obtained from databases and registers of MSD and relevant healthcare institutions and desk revive was carried out for a broad understanding of the drug supply chain.
Notes of all KIIs were synthesized according to common words and coded into thematic areas. Each thematic area was then converted into the following information.

RESULTS

Problems related to government health care institutions

1. Irrational prescription of medicines by prescribers
2. Prescription of an unnecessary number of drugs to a simple health condition
3. The nonavailability of a scientifically agreed upon list of substitute drugs of the same efficacy to use when medicines are out of stock
4. Non-adherence of prescribers with the available treatment guidelines
5. Lack of reference to morbidity data in preparing annual drug estimates
6. Estimation errors such as over or underestimation
7. Unfavourable or inadequate drug storing conditions at healthcare institutions
8. Delayed receipt of drugs to healthcare institutions
9. Receipt of drugs less than the annual institutional estimate
10. Communication gaps between MSD & healthcare institutions
11. The nonavailability of MSMIS for some Base and all Divisional Hospitals
12. Quality failure of drugs

Problems related to MSD

1. Inadequate usage of drug utilization data for preparing the annual drug estimate
2. Less consideration of morbidity and mortality data for annual drug estimate
3. Inability to take real-time medicines stocks availability in most of the hospitals
4. Inadequate or over-estimation of pharmaceuticals
5. Considerable lead time in preparing order recommendations, prizing and order lists at the MSD level
6. Unacceptable lead time at SPC in procuring
7. Lack of e-procurement facilities for bidders
8. Lack of adequate and favourable storing facilities for consignments
9. Lack of adequate laboratory facilities for quality assurance
10. Inadequate store space due to delayed disposal of quality failed drugs
11. Lack of adequate and modern vehicle fleet to transport drugs to healthcare institutions
12. The delayed receipt of Financial Imprest to the MSD

Problem prioritization

The Pareto Principle of Vilfredo Federico Damaso Pareto was used to prioritize the critical problems causing the unavailability of medicines in healthcare institutions and is discussed in detail in the discussion. Similar issues were collated together to make the discussion more understandable.

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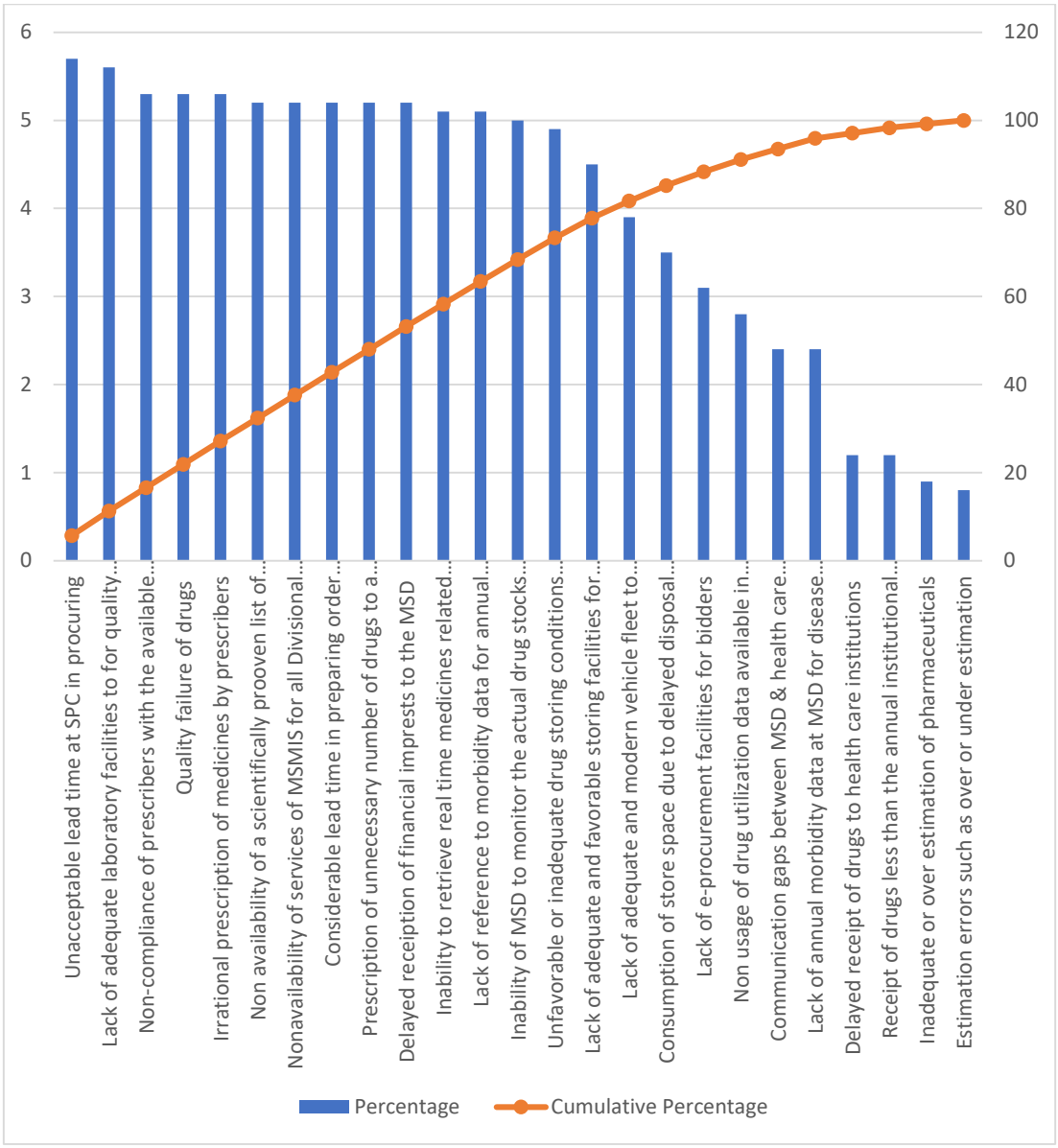

Figure 2: Pareto Chart: Prioritization of problems causing unavailability of medicines

DISCUSSION

1. Unacceptable lead time at SPC in procuring medicines and considerable lead time in preparing order recommendations at MSD

SPC is the sole procuring entity which is responsible for annual and emergency procurements of medicines. Placing customarily orders by MSD to SPC starts every January. SPC calls for bids from NMRA registered suppliers in the following manner.

- Worldwide open bidding - close after 42 days.
- Restricted bidding - Close in 21 days
- Direct bidding - If sole suppliers

Once the bids have been received, SPC appoints thousands of Technical Evaluation Committees (TEC) and procurement committees for each item. Procurement committees will be of three different types depending on the value of the bids, and the time taken for bid evaluation is shown below.

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- Cabinet Procurement Committee – for bids with a value of more than 100 million (LKR) and usually takes more than 24 months.
- Ministerial Procurement Committee – for bids with a value from 10 to 100 million (LKR) and usually take 15 – 18 months.
- Departmental level

After the process of evaluation, the bids will be offered to the most substantially responsive bidders. Finding a minuid deviation in the given drug specifications will result in referring those bids back to the MSD for further clarifications which is an additional delay. After all, the successful bidders will be given three months to supply the consignments to the MSD.

Further, almost all steps of the procurement process are manual and this has resulted in adding extra duration to the lead time. Figure 3 shows the order quantities placed in the year 2020 and their delays beyond the usual lead time (11 months). Further, it shows only 13 consignments have been received within the expected lead time.

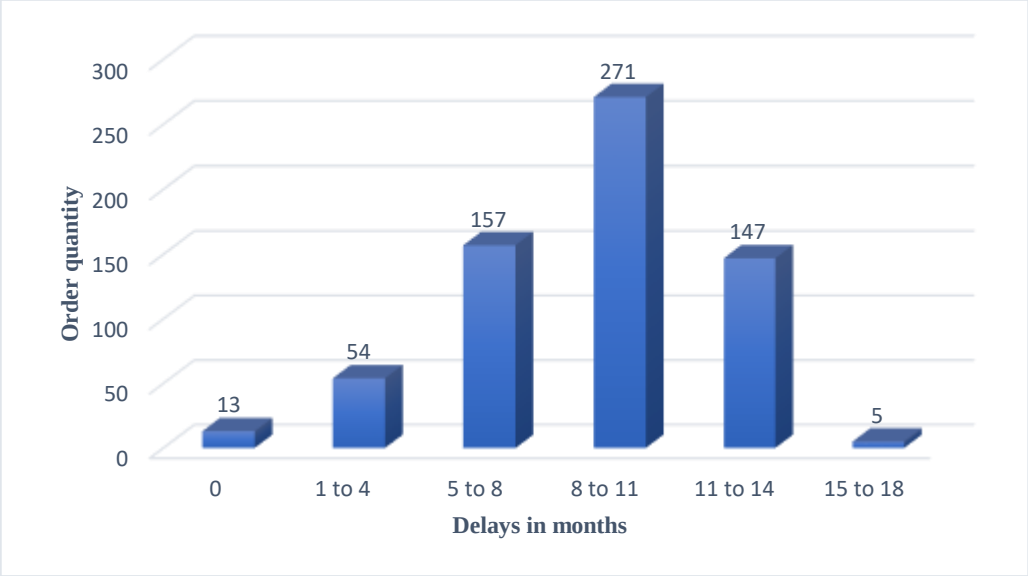

Figure 3: Delays beyond the lead time (11 months) for orders in 2020

Apart from the procurement process delays for some items have occurred due to a narrow supplier base to compete for bids. Sometimes no supplier bids have been received for orders due to reasons such as small quantity, bidding price, delayed payments of previous orders, and pharmaceutical standards-related issues. This situation leads to calling new bids from unregistered suppliers and that causes an unprecedented delay as these suppliers need to get registration or no objection letter from NMRA.

2. Quality failure of drugs and lack of adequate laboratory facilities for quality assurance of drugs

A pharmaceutical product should not be contaminated and must deliver the properties described on the label. NMRA and NMQAL ensure the quality of drugs in two steps; Pre-market and Post-market quality assurance. Appearance, identity, purity, uniformity, packaging, and labelling are the main characteristics considered in quality assurance. Pre-market quality assurance focus on the quality of drugs during the registration process, bidding, and pre-consignment samples. Post-marketing Quality Assurance is carried out by random checks for drug samples collected from government healthcare institutions, private healthcare institutions, and the market. In addition, government healthcare institutions and MSD directly send their samples of suspected quality for analysis. The laboratory owned by SPC also carries out quality checks of consignments. However, the final decision on quality is made upon the results released by NMQAL. Annually, due to several reasons, a considerable number of drugs are removed from usage due to quality failure. Clinicians suspect that the quality failure occurs due to the purchase of low-quality products and in return drug suppliers argue it is due to inappropriate storing and transport conditions. Discussions held with pharmacists revealed that both the quality of drugs and the storage conditions may have attributed to the quality failure. However, the inadequate capacity of the NMQAL is hindering the evaluation of the quality of each consignment at the time of delivery to MSD drug stores.

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3. Irrational prescription of drugs, and non-adherence to the available treatment guidelines,

The treatment guidelines have been developed by professional colleges and Sri Lanka Medical Association for rational management of diseased patients. However, as these guidelines are not mandatory to follow in Sri Lanka patient management guidelines may differ from one clinician to another. This practice has led to the creation of biases towards specific drugs and polypharmacy. This artificially high demand for one drug may end up in a shortage of some drugs. Once a drug is out of stock most clinicians do not prefer to switch to an alternative drug. A study conducted in a teaching hospital in Sri Lanka to evaluate the magnitude of irrational prescription of drugs in outpatient clinics and inward settings reported a high degree of polypharmacy and a need for overall improvement in rational prescribing [9]. Further, most countries urge the need of formalizing and implementing generic and therapeutic substitutions by health care institutions, with the consent and cooperation of all the stakeholders as guided by the World Health Organization [10]. The Australian Government has taken an extraordinary step by allowing community pharmacists to substitute specific medicines without prior approval from the prescriber in situations where a particular medicine is unavailable at the time of dispensing [11].

4. Unfavorable or inadequate drug storing conditions at MSD and health care institutions

The storage capacity of MSD has a direct link to drug availability. The storage capacity of the MSD central warehouse (7796 m3) was designed to fulfil the demand for drugs in 1980. With the addition of other warehouses, the current MSD store capacity has increased up to 35932 m3. Figure 4 shows the percentage of different types of stores available at MSD.

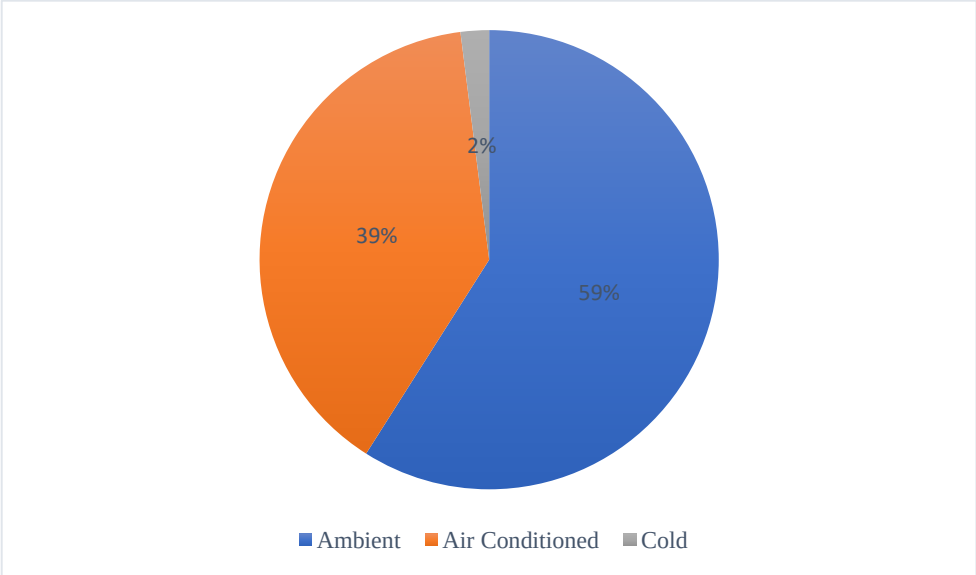

Figure 4: Percentage of different stores availability at MSD

By 2022, the demand for drugs has increased dramatically and Figure 5 shows the additional storage capacity required to maintain a five-month buffer stock.

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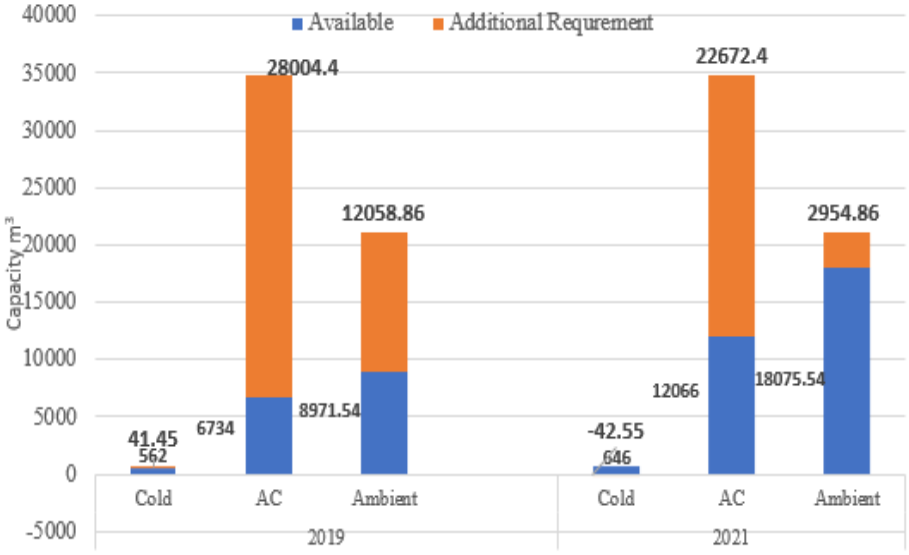

Figure 5: Available store capacity (year 2019 and 2021) and additional store capacity needed to maintain a five months buffer stock

The ambient store capacity has increased significantly from 2019 to 2021 (Figure 5). However, the airconditioned store capacity needs to be increased considerably to reach the required storage capacity.

5. Lack of adequate and modern vehicle fleet to transport drugs to health care institutions

MSD has its vehicle fleet for the timely transportation of drugs to healthcare institutions across the country. At the end of every quarter, MSD prepares an advanced program for distributing drugs to the RMSDs and other healthcare institutions. The date and mode of dispatch of the drugs are also indicated in this document. However, frequent breakdowns of vehicles disturbed the continuous supply of drugs and led to a shortage of drugs in healthcare institutions. The age of the vehicle fleet, substandard preventive maintenance, poor quality corrective maintenance, incomplete vehicle record keeping, and excessive delays in getting approvals for vehicle repairs have attributed to a greater extent to increasing vehicle off-road time.

6. Nonavailability of services of MSMIS for all Divisional Hospitals

In 2015 MSD officially launched MSMIS to improve the effectiveness of drug management. It has a large number of modules namely ordering, general ledger, requests & sales order, formulary revision, inventory management, estimation, advance warehousing, fixed assets, inventory quality assurance, advance forecasting, transportation, e-procurement, account receivable, dashboard, account payable, extension to base & divisional hospitals. At its inception, MSMIS linked MSD with SPC, 26 RMSDs and 57 hospitals under the direct governance of the Ministry of Health. Despite having a broad range of management functions MSMIS is being used only for a handful of functions such as drug ordering, annual drug estimation and verification. Further, to fully enable its intended functions the expansion of the MSMIS project was started linking MSD with all Provincial Hospitals (Base Hospitals Type A & B, Divisional Hospitals Type A, B, & C). Despite the ongoing expansion, this project has contributed to identifying additional system-related issues such as less user-friendliness, slowness of software and inadequate bandwidth. Further, it was identified that the opportunities available for further improvement and customization of MSMIS are limited to being a virtual private network. In addition, functions like preparing annual drug estimates and monitoring real-time stock availability also have been affected due to the unavailability of MSMIS beyond the drug stores of the healthcare institutions.

7. Delayed reception of Financial Imprest to the MSD

WHO reports that the pharmaceutical expenditure in most South East Asian countries is less than US$ 25 per person per year, and it has almost no change during the last decade [12]. The availability and expenditure on drugs mostly depend on the receipt of

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financial allocations. Figure 6 shows the shortage of receipt of Financial Imprest to MSD during six months from November 2020 which is necessary for day-to-day payments.

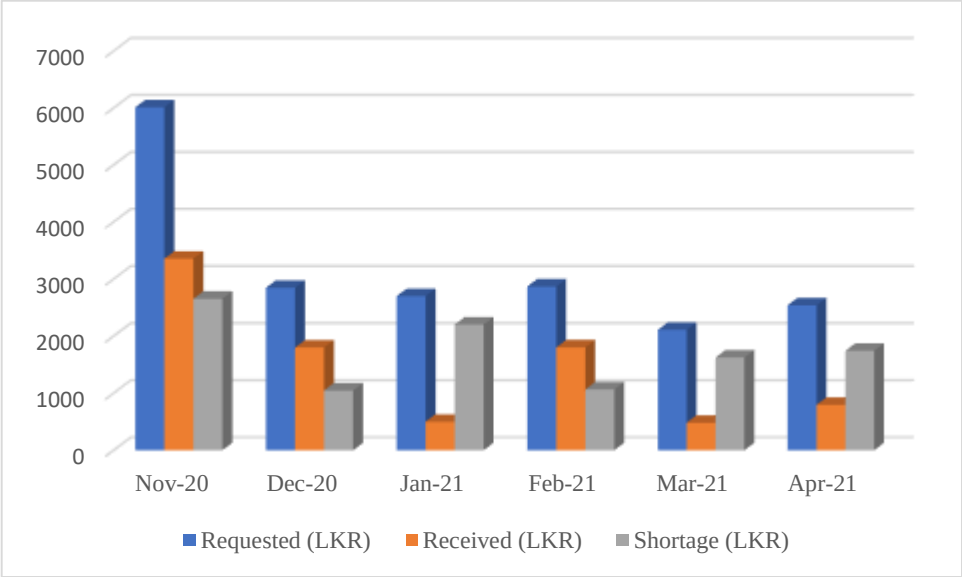

Figure 6: The receipt of Financial Imprest to MSD

CONCLUSIONS

The availability of essential drugs across all healthcare institutions of the country is an essential quality element of the Health System of Sri Lanka. Nevertheless, the availability of drugs throughout the year has become a challenging theme for MSD for various reasons. Finding solutions for every single reason is an impossible task. Hence, it's worthwhile that MSD focuses its attention on finding workable strategies to overcome the critical issues that influence drug shortage the most.

RECOMMENDATIONS

1. Implementation of the electronic government procurement method in Sri Lanka is an essential component in reducing the current lead time. In addition to reducing lead time, this will increase efficiency, transparency, competitiveness and audit compliance with bids.
2. Most developed countries have contracts with accredited external laboratories for the quality assurance of drugs. This action has prevented delays in getting quality failure reports. NMQAL should take the necessary steps to recognize an adequate number of laboratories which is appropriate to get quality failure reports without delay.
3. Establishment of an independent quality assessment agency that can monitor compliance with quality and safety guidelines and legally act upon the persistent noncompliance of such. The Care Quality Commission of the United Kingdom and the Health Insurance and Assessment Service of South Korea are two examples of such organizations.
4. Having an adequate capacity of suitable drug stores and a modern vehicle fleet is of utmost importance to keep a buffer stock and timely deliver drugs across healthcare institutions. However, the prevailing economic situation will impose limitations on such capital expenditure. Hence public-private partnerships for expanding store capacity and outsourcing transport would be the ideal alternatives that can go ahead.
5. Digital transformation of manual MSD drug management is the most suitable strategy that can provide answers for most prevailing issues. Nevertheless, it is important to find the correct digital partner as most digital transformation initiatives have failed across many countries.
6. Allocation of health finance depends on the income of a country. The prevailing economic crisis in the country has made financial allocation more complex. However, MSD needs to identify priority expenses and new strategies such as the use

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