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ABSTRACT

Inefficient and irrational use of medicines is a widespread problem at all levels of health care. Lack of discretely documented policies and procedures in respect of medicines management in hospitals is unnecessarily straining the meagre resources resulting into poor inflow of benefits to the patients. Per capita wastage from inefficient and irrational use of medicines tends to be greatest in hospitals. Many of these sources of wastage could be reduced if some basic principles of medicine management and use are followed and a comprehensive medicines management policy framework is developed. An efficient and robust medicines management in hospitals ensures rational selection, quantification, procurement, storage, distribution, use and thereby availability of the right drugs in the right quantities, at reasonable prices, and at recognized standards of quality throughout the year without any stock-out periods in between. Effective medicines management is a collaborative process involving many stakeholders that is required for providing the health care system with a road map for continuous improvement in pharmaceutical supply chain including expense containment with specific goals and outcome measures of success. Existing medicines management and supply chain systems within hospitals have several gaps and shortcomings particularly lack of resources and well documented policy framework. Urgent steps are required to assess, evaluate, and monitor the functioning of supply chain system for bridging up the gaps and rectification of shortcomings. Priority needs to be accorded towards engaging well-qualified manpower, suitably trained in medicines management across the different levels of care.

Key words: Medicines management, Supply chain, Selection, Quantification, Procurement.

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INTRODUCTION

Medicines management

According to World Health Organisation (WHO), medicines involve the second highest expenditure after staff costs in a country's health care system. The statistics of global spending on medicines showed that in 2010, total spending on medicine was 887 billion U.S. dollar and it is estimated that until 2020 the pharmaceutical market will increase to around 1.4 trillion U.S. dollars.¹

The money spent on buying medicines by governments is very large and 40 to 60 percent of entire public sector health budget of any country goes into buying medicines.² Despite such heavy spending, one-third of world population lacks access to essential medicine, which actually goes up to one half in Asia and Africa.3 A major reason for this adverse situation is the mis-management of available resources and according to one estimate up to 70 percent of resources are wasted in any country due to poor drug management systems.⁴ World Bank indicates that in many developing countries, a high percentage of medicine losses occur in the government procurement, storage, distribution, and utilization system. It has also been established that in certain areas, a significant proportion of essential medicines and supplies are misappropriated or diverted. To address this gap judicious management of drug systems is mandatory. Therefore, rational drug management has become an increasingly important topic in order to make optimal use of the drug budget to offer health services of the highest possible standard. The key to safe and appropriate management of medicines is a coordinated approach that supports and encourages continuity in all areas of the community and health care sector. There are two essential components for ensuring the quality use of medicines across the health care continuum. The first is to establish standards of practice that define standard operating procedures and the second is to identify the positions or persons, working within the accepted limits of their roles, who are responsible for implementing each step of the process.5

Medicines management cycle

The management of drug supply is organized around five basic functions of the Medicines Management cycle namely, selection, quantification, procurement, distribution, and use. At the center of this cycle is a core of management support systems, which include organization, financing and sustainability, information management, human resource and quality assurance management.⁶The success of medicines management cycle will depend upon the ability to reliably and consistently supply the standard quality medicines at affordable rates to health facilities at all levels of the healthcare system. Pharmaceutical supply chains are different because they usually have large and extended global pipelines requiring high levels of product availability with high uncertainty in supply and demand. In order to sustain and expand the successful interventions, these supply chains need to be made more robust and flexible through better management and increased investment of resources to achieve supply chain optimization.⁷

Many countries do not routinely monitor supply chain systems and report on their performance. This in itself is a significant indicator of suboptimal performance. Even if monitoring does occur, it is often based on periodic survey data for a limited set of indicators. An assessment about the performance of supply chains is constrained by a number of factors including lack of data and the presence of many confounding factors that impact medicine availability, in particular, financing.⁸

Data sources

A systematic review of the literature on medicines management in hospital settings was undertaken using PubMed, Cochrane database of systematic reviews, EMBASE, MEDLINE, Scopus, Sciencedirect, and International Pharmaceutical Abstracts besides internet search using Google Scholar. Key words used for the primary search included, "medicines" AND "hospitals" AND "management OR selection OR quantification OR procurement OR distribution OR storage OR quality assurance OR use" OR "pharmaceutical supply chain management" OR "hospital drug policies". Selected papers were analysed for their relevance and implications and an additional search was made based on cross-references cited in the papers. Data generated out of secondary search was screened and examined for its content and duplication and the full-text articles that met content criteria were included in the study.

Medicines selection and quantification

Need for selection

The selection of pharmaceuticals is a basic and extremely important professional function of the suitably qualified and well-trained hospital pharmacist who is charged with making decisions regarding products, quantities, product specifications, and sources of supply. Although the pharmacist has the authority to select a brand or source of supply, he must make economic considerations subordinate to those of quality. In selecting a vendor, the hospital must consider price, terms, shipping times, dependability, quality of service, returned goods policy, and packaging.⁹

Bedrock of drug selection has to be the Essential Drugs List. WHO has defined essential drugs as "those that satisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts in appropriate dosage forms and at prices that an individual and the community can afford". This is a global concept that can be applied in any country, in the private and public sectors and at different levels of the health care system.¹⁰

It has been estimated that there are some 3000-4000 drugs at any point in time, registered in any country of which almost 70 percent are non-essential.¹¹ Ideally, a national list of essential medicines should have 300-400 drugs; a district hospital needs some 150 to 200 drugs, while a health centre can manage with 40-50 drugs. Short and specific lists are easier to manage, procure, and offer to the patients within the resources available.¹² Therefore, selection of essential drugs is very important and is considered as a crucial step in ensuring access to essential drugs and in promoting rational drug use.

Selection pre-requisites

The process of selecting essential drugs for a particular health system will not satisfy and reflect the needs of the users or be accepted by them unless the process is consultative and transparent; the selection criteria are explicit; selection process is linked to evidence-based clinical guidelines; and the lists are divided into levels that are regularly reviewed and updated. Clinical guidelines along with essential drugs list should be reviewed at least every two to three years, and their use and the impact should be monitored on regular basis.¹³

Rational selection

WHO has given its Model List of Essential Drugs in the year 1977, which is updated by the WHO expert committee every two years since then. The current versions are the 19th WHO Essential Medicines List and the fifth WHO Essential Medicines List for Children updated in April 2015.^{13,14} The Model List is divided into the main list and a complementary list and drugs are specified by International Non-proprietary Names (INN) or generic names without reference to brand names or specific manufacturers.¹⁵

A study carried out to check the availability of Essential Drug List (EDL) and adherence to the list for the selection of drugs (give reference) reported only 61 percent of the health facilities with a selection policy re-

stricted to the EDL, while just 39 percent of the facilities actually used the list. Availability of the EDL was found to be very low at district pharmacies, whereas only 64 percent of the sites surveyed reported having the document. The lack of knowledge of the EDL and the existing gaps of the health system create an environment where the use of quality essential drugs cannot be guaranteed.¹⁶ In Raichur India a study revealed that the surveyed health facilities had no essential drugs list. Out of 12 key drugs from the WHO Model List 91.67 percent, drugs were found available.¹⁷ Tamil Nadu, Kerala and Odisha purchase about 260 drugs each year as a part of EDL, and thereby ensure good access and availability of essential drugs.¹⁸

Quantifying needs

Quantification is a key function in health commodity management and it refers to the process of estimating needs for quantities of specific health commodities during a specific period of time. Accurate quantification requires information from various sources. These include the EDL, consumption data, epidemiological (morbidity) data, prescription patterns, minimum and maximum stock levels, frequency of stock-outs, and length of the procurement cycle. All these elements make quantification a complicated exercise, which is highly vulnerable to mistakes. Even when quantification is done accurately, the ability of a health system to ensure a full supply pipeline can be limited by the funds available to health facilities for purchasing required items.¹⁹

Eliminating wastage is predicated upon effective inventory and forecasting management, which deals with requirement estimation, analysing consumption patterns and forecasting demand. Trained pharmacists using weekly, quarterly, and annual consumption data are supposed to estimate demand each year.²⁰ There are a number of existing guidance documents on forecasting drug needs. New and underused methods are also used for an assumption building in forecasting when there is no trend data available.²¹ Lijdsman *et al* carried out a study in Rwanda in 2003 and found that 95 percent of the facilities were using consumption data, while 14 percent used epidemiological data. Most of the facilities (95 percent) were using data on minimum and maximum stock levels in quantification. Moreover, stock-out data was found to be used by only 41 percent of the health facilities in quantifying their pharmaceutical needs. Furthermore, eleven percent of the facilities reported cross-checking quantification findings by using different quantification methods.¹⁶

In India, Kerala was able to mitigate the inaccuracy in estimation and forecasting by introducing the option of issuing a second Purchase Order (PO). The initial PO given to the supplier was only for 75 percent of the tender quantity. The procurement authorities have the option to either not issue the second PO or issue it for 25 percent or 50 percent of the tender quantity; thereby building in a flexibility of 25 percent. Furthermore, Kerala and Tamil Nadu use software tools to monitor real-time stock levels and manage inventory and distribution.²⁰

Medicines procurement

Procurement policy

Public procurement may be defined as the purchase of goods and services by governments and state-owned enterprises that generally accounts for a large share of public expenditure in a domestic economy. It encompasses a sequence of related activities starting with the assessment of needs through awards to contract management and final payment.²² Timely supply of drugs, medical supplies and equipments of good

quality, which involves procurement as well as logistic management, is of critical importance in any health care system. Legal, policy and regulatory environment are recognized as providing an important foundation for public procurement in the health sector. A robust procurement policy should have an integrated approach starting from preparation of an essential drugs list; assessment of the quantity of drugs needed; quality assurance from suppliers; procurement process; supply chain management and prompt payment to suppliers.²³

Delivery and distribution of drugs at various levels is not possible without effective drug procurement and inventory control. Various medicine management tools help managers with the process of distributing drugs and supplies to health facilities and ultimately to patients by following a series of steps viz., forecasting needs, tendering, ordering, receiving, storing warehousing, and distribution.7 Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market. The regulatory system in particular as far as public procurement in the health sector is concerned has been relatively weak.24 A study carried out at a tertiary care hospital in India on availability and stock out of key pediatric essential medicines concluded that scattered and sparse budgetary allocations for medicines available with individual hospitals need to be pooled at the central level for optimal utilization of available resources resulting into more efficient procurement since centralized procurement and decentralized distribution has been found to improve access to medicines in all settings.25

Procurement costs

The structure and importance of supply chains for medicines vary from country to country. However, purchasing power of the public limits their significance in all low and middle-income countries (LMICs). In a study carried out in Mali, the commercial market for pharmaceuticals was found to be highly consolidated with two wholesalers controlling about 80 percent of the market.²⁶

As per National Sample Survey Office (NSSO) in developing countries like India, there is a decreasing trend in the supply of free medicines since 1986 and a corresponding increase in the number of people not receiving any medicines at all for outpatient care.^{27,28} In one more study it was estimated that 20-50 percent of the government health budget is used to procure drugs. In Indian context, about 26 percent of the health budget is devoted to procurement thereby making sound procurement system crucial for ensuring quality healthcare services.²⁹

Procurement models and practices

As countries move towards decentralization, the role of Central Medical Stores (CMS) may change or even disappear. In Philippines, there is no CMS. Local governments procure medicines directly from local suppliers except for a limited quantity of priority medicines including for programs like Expanded Programme on Immunization (EPI) and Tuberculosis (TB), which are supplied by the Federal Department of Health. The need for greater efficiencies and improved performance has led many of those involved in EPI supply chains to propose merging these supply chains with those of essential medicines.³⁰

In India, central and state government institutions follow one or more of the afore-mentioned arrangements for public procurement: central rate contract system, pooled procurement either by the government or through an autonomous corporation, decentralized procurement and local purchase. In the centralised model of pooled procurement, the distribution is managed centrally and the onus of the procurement agency is to ensure availability at the user institutions.³¹ In Rajasthan, India, the procurement of drugs, equipments and supplies are carried out by the Store Purchase Organization (SPO) under the Directorate of Medical and Health Services. The SPOs are entrusted with the responsibility of finalizing the rate contract for the majority of drugs and equipments. The rate contracts are finalized as per the General Finance and Accounting Rules for the State.³² The Tamil Nadu Medical Services Corporation (TNMSC) is a widely referred example which was set up by the government of Tamil Nadu as an autonomous corporation in 1994, for the purpose of supplying the essential drugs and services. The success of the TNMSC lies in its centralized drug procurement and distribution system supported by a computerized system of drug management.³³

Medicines storage and inventory management

Storage requirements

Proper environmental controls like proper temperature, light, humidity, conditions of sanitation, ventilation and segregation must be maintained wherever drugs and supplies are stored. It is extremely important to have warehouses with sufficient storage space, fitted with heavy-duty racking system to avoid wastage of space along with pallets, hydraulically operated hand-trolleys and pedestrian controlled electric stackers to handle the medicines scientifically and efficiently. Storage areas must be secure; fixtures and equipments used to store drugs should be constructed so that drugs are accessible only to designated and authorized personnel. Such personnel must be carefully selected and supervised. Safety is an important factor, and proper consideration should be given to the safe storage of poisons and inflammable compounds.³⁴

The American Production and Inventory Control Society (APICS) defines inventory management as the branch of business management concerned with planning and controlling inventories.³⁵ The role of inventory management is to maintain the desired stock level of specific products or items. The systems that plan and control inventory must be based on the product, the customer, and the process that makes the product available.³⁶ An effective and dedicated storage space provides the correct environment for the storage of medicines and commodities and assists the efficient flow of supplies.

Inventory and information system

Pharmacy inventory management is a complex but critical process within the health care delivery system. Without adequate pharmacy inventory management practices, health care facilities run the risk of not being able to provide patients with the most appropriate medication when it is most needed. Addressing pharmacy inventory management and the revenue cycle effectively can enable organizations to improve financial performance, adhere to regulatory requirements, reduce risks relating to patient safety, and ensure availability of drugs without frequent stock outs.^{37,38} Many organizations utilize pharmacy management systems as a means of ensuring appropriate accountability over pharmaceuticals and ensuring the traceability of inventory from purchase through administration to the patient or disposal level. Effective and transparent tracking systems that allow pharmacies to accurately record inventory components, such as medication expiration dates and physical quantities, also have the potential to reduce adverse patient outcomes.^{39,40}

In Uganda, it was estimated that 86 percent of the facilities had regular inventory controls. Record-keeping practices on stocks using bin cards

were being poorly done. There were a number of mistakes in filling out bin cards, and stock balances were frequently not recorded. On the reliability of bin/stock card records, there were discrepancies between card balances and physical balances (after on-the-spot physical counts) at all levels.⁴¹

Medicines distribution and use

Distribution management

The primary drug distribution management goal is to maintain a steady supply of pharmaceuticals and supplies to facilities where they are needed, while ensuring that resources are being utilized in the most effective manner. Distribution costs, which include costs related to storage and transportation, are a significant component of the expense of running a public health supply system. Transportation costs alone can represent a significant percentage of the value of medicines distributed to remote locations. Designing a system for storing and distributing pharmaceuticals, medical supplies, and equipments is complex and important. Effective pharmaceutical distribution relies on good system design and good management.⁴¹ Adequate and dedicated transportation facilities laced with cold chain maintenance are an important factor in maintaining timely distribution of quality medicines round the clock at health facilities.

To maintain the quality of pharmaceutical products, all stakeholders in the distribution chain must comply with the applicable legislation and regulations. Every activity in the distribution of pharmaceutical products should be carried out in accordance with the guidelines on Good Storage Practices and Good Distribution Practices as applicable.^{42,43,} In any hospital, a drug distribution system is required to supply the medication prescribed for each inpatient.

Distribution models

Accurate and safe distribution of medications to the patients is an integral responsibility of the hospital pharmacy.⁴⁴ Distribution models tend to be either push or pull depending on whether the Ministry of Health (MoH) determines how much to ship where and when, and the pull model is triggered by order requests received from the facilities.⁴⁵ The distribution process is generally driven by an order process, which occurs on a regular basis, either monthly or quarterly as determined by the system. There tends to be limited visibility into actual patient demand, stock on hand, and how products are managed in facilities. That is often the responsibility of a separate pharmacy department within the MoH or in devolved settings, local authorities. These structures are supposed to monitor facility performance in managing their medicines, however; they suffer from lack of resources, tools, and capacity to fulfill this function.⁴⁰

An efficient drug distribution system ensures availability of the right medicines in sufficient quantities procured at the lowest prices to secure the maximum therapeutic value to the largest number of beneficiaries with the available and additional resources. The two main beneficiaries in this context are the government and the patient.²⁰ Efficient distribution management includes the availability of an efficient network of storage facilities, keeping reliable records of drug stock balance and consumption, maintaining accountability procedures, ensuring adequate and secured storage, reliable transport systems and reinforcing, reporting and supervisory practices, Matse⁴⁶ in 2005 reported that a third of procurement and distribution processes are compromised due to a lack of adequately trained staff. He also stated that "the professionals who are

expected to ensure proper purchase, utilisation and appropriate use of those drugs often lack basic knowledge on the management of drug supplies. A study conducted by Tahvilian⁴⁷ *et al* in Iran observed that that all of the hospitals had partial compliance in writing orders clearly on prescribed forms, 30 percent had deliveries by a health worker overseeing the delivery.

Rational Drug Use

Hospital Pharmacy Services are designed to meet the primary needs of all customers and it is crucial to enhance the inclusion of patients also in all processes involved in healthcare delivery.⁴⁸ Such services include dispensing of pharmaceuticals in accordance with country regulations, appropriate inventory maintenance functions, drug monitoring, patient drug assessment functions, appropriate record keeping, drug information, education services and performance improvement functions.⁴⁹

Several terms like the rational use of medicines, responsible use of medicines, quality use of medicines, improved use of medicines etc are used to describe appropriate practices and procedures leading to the most prudent use of medicines.

World Health Organization (WHO) has been putting a continuous effort for promoting rational use of medicine. The ultimate goal is to achieve the situation when patients receive medication appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest possible cost. However, roughly more than 50 percent of all medicines are prescribed, dispensed, or sold inappropriately, while 50 percent of patients fail to take them correctly worldwide and about one-third of the world's population lack access to essential medicines.⁵⁰

CONCLUSION

The effectiveness of the medication management system depends on adherence to policies (broad, general statements of philosophy) and procedures (detailed guidelines for implementing policy). The authority to enforce drug procurement policy and procedures must come from the administration of the institution, with an endorsement of the medical staff, via the Drugs and therapeutics committee (DTC) and/or other appropriate committee(s). Since we are living in an era of evidence-based medicine, high-quality research evidence is essential for the development of effective hospital medicines management policies. Need of the hour is to generate evidence for improving use of medicines, convert evidence into policy framework and eventually translate policy into action. Medicines management is a highly technical and professional activity that can only be achieved by suitably qualified, adequately trained, sufficiently skilled man power both at managerial and ground level. Appropriate measures need to be taken in the forms of decisions, actions particularly for proper selection, quantification, forecasting, procurement, distribution, and use of medicines to make the supply chain more robust and efficient. All the activities related to medicines management and supply chain need to be carried out in accordance with standard guidelines and good practices involving only qualified and professional manpower. A structured and rigorous evaluation of supply chain interventions is of immense importance. Evaluation of supply chain should be carried out regularly to monitor its performance. Facility specific policies and procedures with SOPs should be developed and adhered to for better compliance with existing standards. This would help hospitals to carry out an in-depth assessment of their existing practices, which would further help them to make the best and efficient use of their available resources for making quality medicines available and affordable to their patients throughout the year without any breakups.

CONFLICT OF INTEREST

None

ABBREVIATIONS USED

APICS: American Production and Inventory Control Society; TNMSC: The Tamil Nadu Medical Services Corporation; GSP: Good Storage Practices; GDP: Good Distribution Practices; DTC: Drugs and therapeutics committee; WHO: World Health Organisation; INN: International Non-proprietary Names; EDL: Essential Drug List; PO: Purchase Order; LMICs: Low and Middle-Income Countries; NSSO: National Sample Survey Office; CMS: Central Medical Stores; EPI: Expanded Programme on Immunization; SPO: Store Purchase Organization; MSH: Management Sciences for Health.

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