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RESEARCH ARTICLE

CRITICAL ANALYSIS OF THE QUALITY ASSURANCE PROCEDURES OF TIME- AND TEMPERATURE-SENSITIVE PHARMACEUTICAL PRODUCTS IN SELECTED INSTITUTIONS IN SRI LANKA

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ABSTRACT

OBJECTIVE:

This study critically assessed the quality assurance procedures for Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs) in selected institutions of Sri Lanka.

DESIGN:

A descriptive cross-sectional design was employed, involving direct observation and the use of a validated 99-item tool based on the guidelines of the World Health Organisation. Five domains and 18 subdomains were analysed, and scores were compared across institutional levels.

SETTING:

Medical Supplies Division (MSD) of the Ministry of Health, Regional Medical Supplies Divisions (RMSDs), and selected tertiary and secondary hospitals in the North-Western Province of Sri Lanka

MAIN OUTCOME MEASURES:

The study covered five domains: general storage, indicators for temperature-controlled storage, transport, stock management, and general procedures/record-keeping.

RESULTS:

General storage performed best across institutions (mean score 77.6%), with the MSD showing the highest adherence. However, temperature-controlled storage practices were inconsistent, particularly in hospital wards, due to inadequate monitoring, insufficient equipment, and limited preventive maintenance. The transport of TTSPPs showed the poorest performance (31.1%), with minimal temperature monitoring and calibration procedures in place. Stock management practices were stronger at higher-level institutions, largely due to the support of the Medical Supplies Management Information System (MSMIS).

CONCLUSIONS:

Overall, performance declined progressively from central to peripheral levels. Strengthening infrastructure, providing targeted in-service training, and instituting routine supervision using the assessment tool are recommended to enhance the reliability and sustainability of TTSPPs' quality assurance in Sri Lanka.

KEYWORDS

TTSPPs (Time and Temperature Sensitive Pharmaceutical Products), Quality Assurance, Temperature-Controlled Storage, Medical Supplies Division (MSD), Stock Management, Sri Lanka

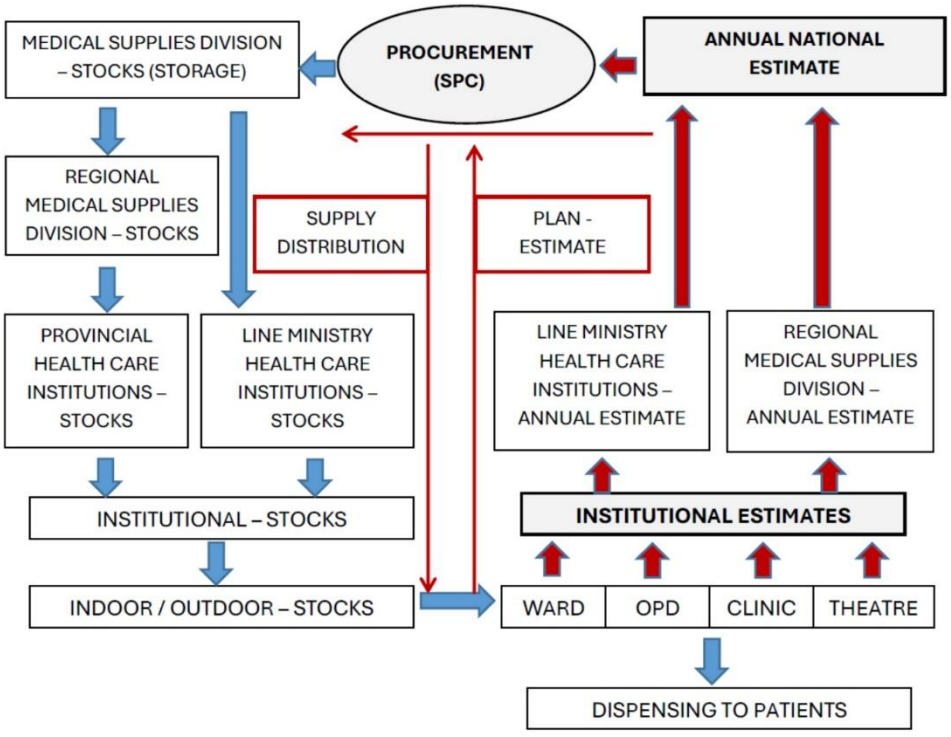
INTRODUCTION

Any health system must ensure adherence to robust systems, processes, and strategies in the supply chain of essential medicines to ensure the quality, safety, and efficacy of medicines are delivered to recipients from the manufacturer. Time and Temperature Sensitive Pharmaceutical Products (TTSPPs) are the most challenging medical products to ensure these quality assurance procedures [1, 2]. TTSPPs are defined as "pharmaceutical goods or products which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, are degraded to the extent that they no longer perform as originally intended" [3]. The "Manual of Management of Drugs" of the Ministry of Health, Sri Lanka, depicts the scope of quality assurance as "the total sum of the organised activities performed with the object of ensuring that pharmaceutical products are of required quality for their intended use" [2].

The Sri Lankan health system is mainly divided administratively and functionally into the curative and preventive health systems, though there are overlaps in the service delivery [4]. There are three levels of care in the curative health system, namely tertiary, secondary, and primary [3]. Sri Lanka is providing free health services at the point of service delivery, including free medicines to all three levels of healthcare. Ensuring the availability of medical supplies is one of the most critical and sensitive issues.

The Medical Supplies Division (MSD) of the Ministry of Health of Sri Lanka is the main central organisation that has the responsibility for the fulfilment of this task, and it should ultimately ensure the right drug is available at the right time at the right place in the right quantity and quality, without any cost to the service recipients [5]. The MSD directly supplies healthcare institutions, including those of the line ministry and provincial healthcare institutions, through the Regional Medical Supplies Division (RMSD). The supply chain of MSD is depicted in Figure 1.

FIGURE 1: SUPPLY CHAIN OF MEDICAL SUPPLIES DIVISION



Source – Manual of Management of Drugs 2008 [2]

In addition to MSD, the National Medicines Regulatory Authority (NMRA) plays a foremost role in protecting and enhancing the healthcare delivery process by ensuring the safety, quality and efficacy of medicines, through the related regulations and the National Medicines Quality Assurance Laboratory (NMQAL), which is under the purview of the NMRA, assigned with the responsibilities of analysing the quality and safety of medicinal products [6]. The "Manual of Management of Drugs" outlines the primary dimensions for ensuring the quality of TTSPPs at the local level, specifically storage and transportation. There are two primary strategies to ensure compliance with these quality assurance dimensions: training and documentation [2].

In Sri Lanka, the expenditure for TTSPPs comprises a notable proportion of the total health expenditure. In 2019, 100 TTSPPs accounted for approximately one-fourth (13 billion) of the total expenditure for medical supplies, which was 54 billion rupees [5]. The 14th International Conference of Drug Regulatory Authorities recommended: "collecting best practices in respect of implementation of quality management systems (QMS) by national regulatory authorities and exploring the possibility of creating a model QMS for medicines regulatory authorities with guidance for its implementation" [7]. There is a lack of comprehensive quality assurance procedures related to TTSPPs in the supply chain management of pharmaceuticals within the Sri Lankan health system. Since TTSPPs represent an essential component of pharmaceuticals, a critical analysis of the quality assurance procedures will help minimise the harm due to the quality failures of TTSPPs, further minimising healthcare costs and improving patient safety.

The present study aimed to conduct a critical analysis of the quality assurance procedures of TTSPPs in the Central MSD, RMSDs, and Tertiary and Secondary Care Hospitals (up to the base hospitals) in the North-Western Province, using a validated tool based on World Health Organisation guidelines and other related guidelines. (Please refer to the Annual Health Bulletin, 2026 regarding the Sri Lankan hospital categorisation, according to the levels of care) [8]. Accordingly, Sri Lankan hospitals are categorised as Tertiary Care, Secondary Care and Primary Care. Tertiary Care hospitals are further classified as Teaching Hospitals, Specialised Hospitals, Provincial General Hospitals and District General Hospitals. Secondary Care Hospitals only include Base Hospitals, and they are the lowest stratum of care, where medical specialists are available. The lowest level is primary care, and we have excluded primary care hospitals from this study.

METHODS

The study was conducted as a descriptive cross-sectional study from September 2019 to November 2019. The MSD in Colombo, as well as the RMSDs, served as the study settings, along with secondary and tertiary care hospitals, i.e. up to Base Hospitals in the North-Western Province, which comprises two districts: Kurunegala and Puttalam. The study sample was "TTSPPs storage and transport components of central level institutions" and "TTSPPs storage and transport components of institutions above Base Hospitals in North-Western Province". The selected institutions for the study are summarised in Figure 2.

Hospitals below Base Hospitals were excluded from this study. These hospitals do not have medical specialists-led clinical care services and are only managed by medical officers. Therefore, the scale of service provision and the range of pharmaceuticals available in hospitals below base hospitals are substantially minimal compared to higher-level hospitals.

North Western Province is one of the nine provinces in Sri Lanka and consists of more than 50 hospitals with in-ward care and more than 75 Primary Medical Care Units (9). According to provincial data sources, these institutions received 487,493 admissions in 2017 (Kurunegala District – 340,217, Puttalam District – 147,276), which is approximately 7.1% of the patient admissions to government hospitals in Sri Lanka. Moreover, these hospitals are responsible for providing 3.1% of outpatient services (1,286,279 in Kurunegala and 416,828 in Puttalam) in Sri Lanka. The distribution of drugs within the province is coordinated by the Regional Drug Stores at the district level.

FIGURE 2: INSTITUTIONS INCLUDED IN THE STUDY SAMPLE

Central level	Regional (district) level	
	Puttalam	Kurunegala
• Central Medical Supplies Division	• Regional Medical Supplies Division- Puttalam • District General Hospital- Chilaw • Base Hospital-A Puttalam • Base Hospital-B Kalpitiya • Base Hospital-B Anamaduwa • Base Hospital-B Marawila	• Regional Medical Supplies Division- Kurunegala • Teaching Hospital- Kuliyapitiya • Provincial General Hospital- Kurunegala • Base Hospital- B Galgamuwa • Base Hospital - B Polpitigama • Base Hospital - B Nikaweratiya • Base Hospital - B Dambadeniya

For the central-level institution (i.e., the Medical Supplies Division), stores and temperature-controlled vehicles were included in the data collection. For the district level, the units (Main drug stores, Indoor dispensary, a randomly selected medical unit, a randomly selected surgical unit, a randomly selected gynaecology and obstetrics unit, a randomly selected paediatrics unit, a randomly selected Intensive care unit, and a randomly selected Operating Theatre) related to the logistical handling of TTSPPs in each of the above district-level institutions were included.

A validated questionnaire based on the World Health Organisation guidelines (3) was used to measure the performance of the quality assurance system. The tool included two sections, i.e., administrative details of the institution and 99 items covering five domains. Each of the 99 items and five domains carried equal weightage. The tool was utilised as an interviewer-administered questionnaire by a panel of three trained experts (including the first author), who visited the relevant institutions and made direct observations. The data were initially entered into a pre-designed Microsoft Excel template, which was then exported into the Statistical Package for Social Sciences version 21. The item scores for each assessment were obtained according to the following scoring guide. When the responses were in dichotomous form, either 0 or 5 marks were given according to the content (i.e. if the response was favourable according to the content of the question, 5 marks were given; if not, 0 was given). For the items with a 3-point Likert scale, either 0,3, or 5 marks were given according to the content. For items with responses on a 6-point Likert scale, a score ranging from 0 to 5 was assigned.

The main domains were further subdivided into 18 subdomains. Scores were calculated for each domain and sub-domain by adding the marks obtained for each item. Each domain and sub-domain score was expressed as a percentage by dividing the added score by the maximum possible score. When any item becomes unrelated according to a setting, the denominator (i.e., the maximum possible score) is adjusted accordingly. For each setting, 18 quality assurance sub-domain scores and five quality assurance domain scores were calculated.

The domain scores were found to be non-normally distributed when assessed for normality using Q-Q plots, Box and Whisker diagrams, and the Kolmogorov-Smirnov test. The mean, median and interquartile ranges were presented for each domain, stratified by setting, and a summary of all units for district-level institutions is presented. The associated categorical correlations of the domain scores (e.g. level of the institution) were determined with the Kruskal-Wallis test. Post-hoc analyses were subsequently conducted. The significance level was set at 5%.

Ethics approval was obtained from the Ethics Review Committee of the Postgraduate Institute of Medicine, University of Colombo (PGIM/ERC/2019/157). Permissions were also obtained from the Deputy Director General (Medical Supplies), Director (Medical Supplies Division) and from the Provincial Director of Health Services of the North-Western Province.

RESULTS

The overall quality domain scores are outlined in Table 1, and the domain scores for each institution and setting are illustrated in Table 2.

TABLE 1: DISTRIBUTION BY OVERALL QUALITY DOMAIN SCORES

Domain	Mean (SD)	Median (IQR)
Domain 1 – General storage	77.6 (3.95)	77.5 (77.5 to 77.78)
Domain 2 – Indicators for Temperature Controlled Storage	46.1 (10.26)	44.0 (41.14 to 49.14)
Domain 3 – Transport of TTSPPs	31.1 (3.83)	30.0 (30.0 to 30.00)
Domain 4 – Stock Management of TTSPPs	55.7 (9.83)	50.0 (50.0 to 60.88)
Domain 5 – General Procedures and Record-Keeping of TTSPPs	65.3 (9.52)	64.0 (60.0 to 67.27)

The practices related to "general storage" (i.e., domain 1) were observed to be relatively well implemented across all institutions, with the highest overall score among all five domains (77.6%). Expected quality performances in relation to have been almost achieved by the MSD (i.e. 95.56%), and the performance of RMSDs, tertiary care and secondary care institutions ranged from 77-78% of that of expected. However, some elements, such as "uninterrupted power supply," were observed to have the near-lowest scores in all the latter institutions.

The "indicators for temperature-controlled storage" domain (i.e. domain 2) demonstrated the second lowest performance among the five main domains (mean score of 46.1), with around 85% adherence to recommendations in general in MSD and RMSDs. The tertiary and secondary care hospitals had lower scores, ranging from 40 to 55%. For tertiary care hospitals, a wide variation in performance was observed between institutions. In most indoor dispensaries, wards, and units, preventive maintenance and contingency plans were not observed, resulting in a score closer to 50%. However, drug stores, indoor dispensaries, and wards complied with FEFO and other requirements by achieving a score above 84 for the subdomain "Arrangement of Stock of TTSPPs".

TABLE 2: MEAN DOMAIN SCORES OF EACH INSTITUTION

Domain	MSD	RMSD	Teaching Hospital		Provincial General Hospital		District General Hospital		Base Hospitals	
	Mean	Mean (SD)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Domain 1 – General storage	95.50	78.89 (7.86)	77.57 (0.13)	77.50 (77.50 to 77.71)	77.29 (0.71)	77.50 (77.50 to 77.50)	77.98 (8.35)	82.50 (68.96 to 82.50)	77.22 (2.52)	77.50 (77.50 to 77.50)
Domain 2 – Indicators for Temperature Controlled Storage	85.41	84.08 (3.41)	50.74 (8.68)	48.29 (43.29 to 58.57)	44.25 (8.94)	42.29 (38.86 to 52.09)	45.43 (3.75)	45.14 (41.71 to 48.57)	43.54 (6.23)	42.86 (40.00 to 46.86)
Domain 3 – Transport of TTSPPs	18.18	44.17 (8.25)	31.04 (2.94)	30.00 (30.00 to 30.00)	31.04 (2.94)	30.00 (30.00 to 30.00)	30.00 (0.00)	30.00 (30.00 to 30.00)	31.14 (2.90)	30.00 (30.00 to 30.00)
Domain 4 – Stock Management of TTSPPs	100.00	75.73 (3.03)	56.37 (8.55)	52.50 (50.00 to 63.11)	55.73 (10.62)	50.00 (50.00 to 67.21)	53.24 (6.19)	50.00 (50.00 to 57.50)	54.42 (7.78)	50.00 (50.00 to 58.33)
Domain 5 – General Procedures and Record-Keeping of TTSPPs	78.46	90.77 (4.35)	75.14 (9.89)	68.00 (68.00 to 87.13)	67.14 (12.09)	60.00 (60.00 to 80.09)	57.17 (5.96)	58.00 (54.05 to 62.00)	63.54 (6.39)	64.00 (60.00 to 64.00)

(MSD – Medical Supplies Division, RMSD – Regional Medical Supplies Division)

The stock management of TTSPPs (i.e., domain 4) had a mean score of 55.7, ranking third among the five main domains. A notable advanced score of 100.00 was seen in the MSD, and a mean score of 75.73 for RMSD. The practices of the tertiary care (55.11) and secondary care (54.42) hospitals were observed to be relatively lower. MSD had a well-planned system of stock management and fulfilled all the considered factors of receiving, issuing and returning procedures through MSMIS, including RMSD and main stores in the tertiary and secondary care hospitals. However, MSMIS had not been introduced to indoor wards and units at the time of data collection.

The overall domain score for "general procedures and record-keeping of TTSPPs" (i.e., domain 5) was 65.3, the second-highest among the main domains. The highest scores were observed in the RMSDs (90.77), followed by MSD (78.46), and the lowest in secondary care institutions (61.87). At the hospital level, drug stores and indoor dispensaries were performing better than the ICU & theatres and wards.

Statistically significant differences were observed in domains 2, 3 and 4 between central (MSD), district-level (RMSDs) and lower-level (institutions up to the Base Hospitals) institutions, as depicted in Table 3. After the significance adjustments, the differences remained for domains 3 and 4. With the post-hoc analyses of domains 3 and 4, differences were observed between MSD and RMSD, as well as between "secondary and tertiary hospitals" (i.e., no significant difference was observed between secondary and tertiary hospitals).

TABLE 3: ASSESSMENT OF DIFFERENCES IN DOMAIN SCORES BETWEEN INSTITUTIONS

Domain score	Difference between the levels
Domain 1 – General storage	P=0.124
Domain 2 – Indicators for Temperature Controlled Storage	P=0.013*
Domain 3 – Transport of TTSPPs	P<0.001*
Domain 4 – Stock Management of TTSPPs	P=0.009*
Domain 5 – General Procedures and Record-Keeping of TTSPPs	P=0.051

*Statistically significant at 5% level

DISCUSSION

This is the first documented research project to explore the quality assurance system of Time and Temperature Sensitive Pharmaceutical Products (TTSPPs) in Sri Lanka. A judgmentally validated quality-assurance assessment tool with 99 items, covering the five main recommended domains, was used in assessing the processes related to the quality assurance of TTSPPs. This tool was used to assess the quality assurance dynamics in three national and district-level stores, as well as in 11 hospitals (including 75 settings within them).

Even with several notable exceptions, it was generally observed that the "transport" domain had relatively lower domain scores while the "general storage" domain had higher scores. To ensure more utility, these five domains were further divided into 18 sub-domains. The domain scores were stratified according to the category of institutions: MSD, RMSDs, tertiary care hospitals and secondary care hospitals. Post-hoc analyses were conducted because significant differences were observed in three domain scores. Once adjusted, there were significant differences in domain 3 (MSD versus RMSD, MSD versus secondary hospitals, RMSDs versus tertiary hospitals, RMSDs versus secondary hospitals) and in domain 4 (RMSDs versus secondary hospitals).

DOMAIN 1 – GENERAL STORAGE

All pharmaceuticals, especially TTSPPs, should be stored under recommended conditions to prevent contamination, deterioration, and to prevent losing their potency and effectiveness [10-12]. A study done in Pakistan reported that the lack of facilities to maintain temperature during power outages was the main drawback of the storage of TTSPPs [13]. Similarly, a study done in Ethiopia reported that only 42.5% of the facilities had the presence of a standby power supply

(14). Both these studies are similar to the findings of our study. This may be a common occurrence, yet it can lead to serious consequences in resource-constrained settings with frequent and prolonged power outages, exposing systems gaps and managerial oversight that need immediate attention.

Out of the study settings, MSD had relatively higher mean scores for domain 1 and 2 (temperature-controlled storage) related sub-domains and maintained systems, as per the recommendations [2, 3, 15] including an uninterrupted power supply (UPS). Despite the operational manual stipulating the requirement of having a UPS system, exposing noncompliance and system defects at the district level, the importance of the UPS is highlighted even in the manual of the WHO under its section 3.9 [3]. As evident from the findings, hospital settings had relatively lower scores compared to central and district-level settings. and were comparable with the results globally, which is observed when the recommendations are not met [16]. Even in the absence of published comparable literature in relation to the government sector in Sri Lanka, a study done in two Sri Lankan districts involving private pharmacies has documented similar substandard performance in storage conditions [7].

DOMAIN 2 – INDICATORS FOR TEMPERATURE CONTROLLED STORAGE

A similar observation of a gradual decline in performance from the central level to the institutional level was also evidenced in this domain. As highlighted by Papiya in 2012, efficient temperature control is crucial, and storage conditions are an important factor in determining its success [18]. Although an Ethiopian study reported 61.7% of the facilities had acceptable cold chain storage, it was noteworthy that approximately 40% had unacceptable cold-chain storage, and participants attributed this weakness to inadequate in-service training [14]. These weaknesses were also noted in our study, particularly in hospital and unit settings, mainly due to the unavailability of thermometers and the non-maintenance of temperature charts, which is an alarming situation regarding the quality assurance of TTSPPs. Similar to the Ethiopian study, this can be attributed to a lack of awareness. Even though in-service training and continuous professional development made a significant contribution to enhancing the management capacity of TTSPPs [9], statutory enforcement of SOPs is a must. Ethiopian participants also emphasised the importance of training in cold chain management, storage, and handling of cold chain medicines, as well as record-keeping [14]. As cold chain monitoring is a fundamental element, providing equipment, other facilities, supervisory vigilance and training is a prerequisite in the pharmaceutical supply chain. These gaps are system errors that have not been attended to by the decision makers, as well as at the managerial level. Hence, all factors mentioned above contributing to this low performance need urgent attention.

DOMAIN 3 – TRANSPORT OF TTSPPS

For a tropical country like Sri Lanka, the temperature during transportation can increase beyond 50 °C, leading to even ordinary medicines losing their efficacy [13]. Therefore, temperature control of medicine during transport is a critical and vulnerable factor, especially in TTSPPs. Our study also reported that performance during transport comparatively showed the lowest out of all five domains. In addition to delays, packaging failures, and incorrect handling, TTSPPs are more prone to deterioration of quality with the extreme variations in temperature, such as freezing of some liquid drugs (insulin) [19]. Holistically, limited available literature on this topic reported that innovative safety packaging, meticulous tracking with reliable information, upgrades to the storage facilities and transportation infrastructure, combined with improved education, training and regulations, can improve logistics management of medications, including TTSPPs, especially during transportation [19, 20). Although education and training are highlighted in many studies as possible interventions, without proper transportation facilities, monitoring mechanisms, and a system to swiftly act on lapses will not be sufficient to improve performance. During transport, monitoring of the temperature was rarely done, which can incur a significant impact when transporting TTSPPs over long distances [21]. Instituting a stringent regulatory framework for cold chain monitoring with designated officers and remote sensing equipment is unlikely to break the current culture of ignorance.

DOMAIN 4 – STOCK MANAGEMENT OF TTSPPS

Accurate record keeping is a vital element for proper stock management of any pharmaceutical and to prevent out-of-stock of medicines [22]. If stock-out or over stoking to be prevented, MIS need to be updated and monitored at each level daily. The system needs to be instituted up to the dispensing point of the medicines and automatically updated with each transaction. At present, Sri Lankan MIS fall short in large hospitals and even in the hospital's main medicines stores. This prevents real-time data from entering the system, preventing actual stock status monitoring. Further, lapses in

monitoring and regular updating of stocks at the institutional level hinder regional and central level forecasting of individual products to be procured to prevent stockouts and overstocking. Hence, for proper supply chain management, systemic issues need to be attended to with upgrading of MSMIS up to the dispensing point and ensuring real-time data entry and remote monitoring. A study conducted in Ethiopia reported 63.1% accurate reports of Logistics Management Information Systems (LMIS), but also reported high product wastage of 55.3% and a stock-out rate of 26.2% [14], which was similar to other settings [22, 23]. However, our study reported better performance in this domain, which can be mainly attributed to the Medical Supplies Management Information System (MSMIS), available at every institution.

DOMAIN 5 – GENERAL PROCEDURES AND RECORD-KEEPING OF TTSPPS

As highlighted by Reddy and others in 2012, a proper system must not only have analysis, measurement, and control facilities, but also validated record-keeping [24]. An Ethiopian study reported that only 44.7% of facilities had accurate inventory records; however, our study reported comparatively better performance in this domain [14]. However, comparatively lower scores were reported in hospitals and units for 'contingency arrangements' and 'ensuring documents, accessibility, safety and retrievability', since responsible staff in the wards and units had not been trained to take appropriate actions in the event of identified emergencies.

The study reported relatively good performance of TTSPPs management in relation to "general storage" (77.6%), "general procedures and record-keeping of TTSPPs" (65.3%), and "stock management of TTSPPs" (55.7%) despite having lower performance scores for "indicators for temperature-controlled storage" (46.1%) and "transport of TTSPPs" (31.1%). Overall, there was a gradual reduction of performance from the central level to the district-level, then to the institutional level and finally to the unit levels.

CONCLUSIONS AND RECOMMENDATIONS

Overall, this study reported a decline in performance across institutional levels, from the central to the regional and institutional levels. For example, although this study was not intended to determine the factors contributing to the limited extension of MSMIS to the ward level, the overall findings suggested that the benefits of digital stock management were more pronounced at the higher levels of the supply chain and did not extend to the point of dispensing, which created a possible discontinuation of information flow. Additionally, strengthening TTSPP quality assurance requires more than the provision of equipment and training; it requires governance arrangements that define responsibilities across MSD, RMSDs, hospital management, pharmacy services and ward-level units, together with mechanisms for information sharing, supervision and accountability across these interfaces. Comparatively, weaker performance at the wards and unit levels indicates that central policies and systems are not necessarily translated into operational practice at the point of care.

It is recommended to provide the necessary infrastructure and equipment for the management of TTSPPs and ensure their proper maintenance in line with the recommended standards. Moreover, many issues can be rectified with improved awareness through in-service training and continuous professional development (20, 25). Additionally, regular monitoring and supervision using the developed tool is recommended to enhance the sustainability of implementing measures (20). Improving awareness through training, monitoring, and supervision does not require additional funds, and a system should be in place at every level.

AUTHORSHIP

HMKW was involved in conceptualisation, data collection, formal analysis, and writing the original draft. DD, LP, and MW contributed to the formal analysis and refining of the methodology, as well as supervision, review and editing of the writing. All authors approved the final manuscript.

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CONFLICTS OF INTEREST:

HMKW was the Director of the Medical Supplies Division, DD was the Director, Medical Services, and LP was the Deputy Director General (Medical Services), Ministry of Health, Sri Lanka, at the time of conducting this study. Additionally, LP was the Former Deputy Director General (Medical Supplies). MW is the current chairman of the Sri Lanka Pharmaceuticals Corporation.

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