ABSTRACT

Introduction : The World Health Organization has identified access to essential medicines, vaccines and technologies as one of the six building blocks of a health system, which signifies the importance of pharmaceutical products in the healthcare system. Out of these, ensuring safety and quality of Time and Temperature Sensitive Pharmaceutical Products (TTSPPs) is a key requirement in any health system and will reflect the true capacity and capability of overall supply chain management of medicines since these represent the most sensitive products for quality and safety issues. In the Sri Lankan healthcare system, there is a lack of scientific data on comprehensive quality assurance procedures in relation to TTSPPs in the supply chain management of pharmaceuticals.

Objective : To develop and validate a tool to evaluate the quality assurance system of TTSPPs, using it to perform a critical analysis of the quality assurance procedures in the central and regional Medical Supplies Divisions, tertiary and secondary care hospitals in the North Western Province and to explore the challenges associated with the adherence to the recommended guidelines.

Methods : The component 1 of the study was to develop and validate a quality-assurance assessment tool covering the main 5 recommended domains i.e. general storage, temperature control storage, transport, stock management and documentation / record keeping, through comprehensive literature review and expert opinion. The judgmental validation was done in four rounds using the modified-Delphi technique with the consultation of 24 experts who were purposively selected from multi-disciplinary fields.

In the component 2, a descriptive cross sectional study was conducted to assess the degree of adherence to the quality assurance guidelines of TTSPPs in Central Medical Supplies Division, Colombo, 2 Regional Medical Supplies Divisions, 11 Secondary and Tertiary care hospitals, The study population consisted of the units involved in the logistical handling of TTSPPs. Scores were calculated for each domain and subdomains, and expressed as a percentage score. Descriptive statistics, Kruskal Wallis test with post-hoc analyses were used.

A qualitative study was conducted as component 3, with semi structured in-depth interviews (IDIs) to explore the barriers to adhering to the quality assurance system of time and temperature

sensitive pharmaceutical products. The officers who are responsible for maintaining quality assurance system in the institutions were included for the IDIs. Purposive sampling method was applied in selecting the key informants and data collection was concluded when the principal investigator was satisfied that the theoretical saturation point was reached. A total of 29 in- depth interviews were conducted. Audio recordings of the interviews were later transcribed and thematic coding was done. Ethical Clearance was obtained from the Ethical Review Committee, Post Graduate Institute of Medicine, University of Colombo.

Results : General storage domain scores in the MSD was 95.56% and the scores of RMSDs, tertiary care and secondary care institutions ranged from 77-78. However, the score for uninterrupted power supply was lower in RMSD as well, being similar the hospital scores. The temperature-controlled storage‖ domain demonstrated relatively lower score of 46.1. The tertiary and secondary care hospitals had mean score range of 40 to 55, compared to the MSD and RMSDs (mean Score ≈85). MSD and RMSD had maximum scores of 100 for storage of TTSPPs‖, ―temperature controlling and monitoring equipment‖ and preventive equipment maintenance‖. For tertiary care hospitals, a wide variation of performances was observed between institutions. In most of the indoor dispensaries, wards and units, preventive maintenance and contingency plans were not observed giving a score closer to 50%. The following three sub-domains showed exceptionally lower scores: monitoring for temperature and humidity‖ (19.58), ―alarm system requirements‖ (0.0) and equipment calibration‖ (1.66). Similarly, secondary care hospitals had lowest scores for monitoring of temperature and humidity‖ (9.80), ―requirement of alarm systems‖ (0.0) and equipment calibration‖ (0.0). Most of the time it was observed that drug stores, indoor dispensaries and wards comply with FEFO and other requirements achieving above 84 score for the sub domain Arrangement of

Stock of TTSPPs‖.

Overall domain score of transport was 31.1%. The institutional domain scores were below 45% with unit wise domain scores in the range of 30- 40%. During transport, monitoring of the temperature was done rarely. This incurs a significant impact when transporting TTSPPs for long distance. No system was observed at least at the institution level to monitor temperature during transportation giving the subdomain score of <25%. Regular calibration of the monitoring devices and control devices were not done at institutional or unit level, giving the lowest score for the calibration subdomain (<5%).

The stock management domain also had lower mean score of 55.7. The MSD and RMSD had higher scores than the tertiary care (55.1) and secondary care (54.4) hospitals. A notable advanced score of 100.0 was seen in the MSD and mean score of 75.7 for RMSD. MSD had a well-planned system of stock management and fulfils all the considered factors and does all receiving, issuing and returning procedures through MSMIS system. RMSD and main stores in the tertiary and secondary care hospitals used MSMIS in stock management However, MSMIS system had not been introduced to indoor, wards and units at the time of data collection. Hence, drug stores were performing better compared to others with a mean score of 70.5 with indoor dispensaries with 5 points lower. The other two units were having scores on or closer to 55.

The overall domain score for ―General Procedures and record-keeping of TTSPPs‖ was 65.3. The highest scores were observed in the RMSDs (i.e. 90.77) followed by MSD (78.46) and the lowest in secondary care institutions (61.87). In the hospital level, drug stores and indoor dispensaries were performing better than other two units. However, for the latter units (i.e. ICU and theatres and wards) were having scores between 60 to 65. For the subdomain of contingency arrangements, both MSD and RMSDs had a score of 73.33 whereas the hospital showed a relatively lower score of 53.33 and 51.88 respectively for tertiary and secondary care. Similar pattern was observed for the second sub-domain.

Following factors were identified as barriers to adhering to the quality assurance system in the in-depth interviews; unavailability of designated storage place, facilitates and space, unavailability of basic temperature monitoring and humidity control system, limited access to MSMIS system, no proper emergency and preventive maintenance system, lack of temperature controlled transport vehicles and cool boxes, poor maintenance and calibration of temperature monitoring equipment, non-availability of training programs on TTSPPs, poor documentation process, and lack of human resources.

Conclusions and Recommendations : The developed and validated tool could be effectively use to evaluate the quality assurance system of TTSPPs in Sri Lanka. Across all institutions, the transport domain was observed to be with the lowest scores and the ―general storage‖ with the highest. It was noticed in general that although MSD and RMSD were performing relatively better, the performance of institutional units and wards were not up to the standard in quality assurance of TTSPPs. Further studies in the areas of quality assurance related to registration and

procurement, quality assurance process and association between adherence to quality assurance guidelines and effect on product quality/safety and efficiency is recommended.

Keywords: Time and Temperature Sensitive Pharmaceutical Products, Quality assurance, TTSPPs, Good Distribution Practices, Storage of drugs, Transport of drugs