

14th International Conference on

INFECTIOUS DISEASES, PREVENTION AND CONTROL

March 21-22, 2019 Dubai, UAE

Cold chain management at Malawi Liverpool Wellcome Trust research pharmacy and at selected vaccination sites: The phase III randomized, double-blind, controlled trial of the clinical efficacy of Typhoid Conjugate Vaccine (Vi-TCV) among children age 9 months through 12 years in Blantyre (TyVAC), Malawi study - A case report**John Masiye Ndaferankhande**

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Background & Aim: Cold chain management is integral in clinical trials. However, it is a challenge to maintain cold chain at the quality levels required when administration of the pharmaceutical product takes place in the field. Here we describe the temperature control as a major aspect of cold chain management as was the case in the TyVAC study.

Method: The study enrolled 28,000 participants randomized 1:1 to receive Vi-TCV (typhoid vaccine) and MenAfrivac Meningococcal Group A Conjugate vaccine (MCV-A). The vials were stored at the research pharmacy and transferred daily to vaccination field. Temperature records of field credos were analyzed from February 28, 2018 through to July 08, 2018. These records were compared to the research pharmacy vaccine refrigerator temperature recordings from a beyond wireless remote temperature monitoring system.

Result: The research pharmacy temperature ranged from 2.0 °C to 5.3 °C with a mean of 3.5 °C. The credo temperature ranged from 4.2 °C to 12 °C with a mean of 5.6 °C.

Conclusion: Temperature recordings for both the pharmacy and the credo cubes were within range except on a single occasion in which the credo temperature was 12 °C (the recommended temperature for cold chain is 2 °C to 8 °C). Cold chain can be well managed at different sites as evidenced here provided staff involved in handling is well trained. Good cold chain management ensures quality and gives confidence that pharmaceutical compounds were managed according to Good Pharmaceutical Practice.

Biography

John Masiye Ndaferankhande has completed his Honors degree in Pharmacy from the College of Medicine, University of Malawi. He is the Lead Pharmacist of Malawi Liverpool Wellcome Trust.

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