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Short Communication

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

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Background

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.

Methods

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.

Results

The research pharmacy temperature ranged from 2.0 degrees Celsius to 5.3 degrees Celsius with a mean of 3.5 degrees Celsius. The credo temperature, ranged from 4.2 degrees Celsius to 12 degrees Celsius with a mean of 5.6 degrees Celsius.

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 degrees Celsius (The recommended temperature for cold chain is 2 degrees Celsius to 8 degrees Celsius). Cold chain can be well managed at different sites as evidenced here provided staff involved in handling are well trained. Good cold chain management ensures quality and gives confidence that pharmaceutical compounds were managed according to Good Pharmaceutical Practice.

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