

**Infectious Diseases Conf 2019: 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- University of Malawi**

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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. Investigation was done on strong clinical suspected cases, throat swabs were collected. Diagnosis was done by clinical findings, direct microscopy, bacteriological culture and PCR for Tox A gene detection.

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. All three cases were of age > 10 years, unimmunized or partially immunized. Diphtheria is a resurgent problem in our region with a significant age shift towards adult. The present study demonstrated that strains of *C. diphtheriae* are circulating in this geographical location which indicates the need for constant epidemiological

surveillance ensuring early detection of diphtheria and review the efficacy of immunization programme.

The market for infectious disease molecular diagnostics tests incorporates reference research centres, hospitals, blood banks. Size is predicted to grow at 9.42% CAGR from 2018 to 2023 and it is determined that the Middle East and Africa market was valued at USD 1.35 billion in 2018 and is depended upon to accomplish USD 2.12 billion by 2023. Diagnostics of the Infectious disease includes a different technique to check for the presence of a foreign antigen/organism with the assistance of numerous diagnostic tools. Conditions of the Infectious disease are highly widespread in underdeveloped regions due to the lack of awareness for individual cleanliness, minimal health care expenditures, and absence of effective physician services. Rising instances of infectious diseases in developed economies are additionally expected to help the market development. This has resulted in vitro diagnostic gadget makers to invest in emerging countries. These organizations are making efforts to develop and popularise cost-effective tools for the diagnosis of infectious diseases.

Disease diagnostics are utilized for are utilized for in form of a quick, precise test result. Disease diagnostics are on a rise even if it is time-consuming. The infectious disease epidemics are spreading around the world, thereby increasing the demand for diagnostic tests. Additionally, the occurrence of AIDS, malaria, and other diseases are also on increase, creating a vigorous demand for infectious disease diagnostics. Many government-financed programs all over the globe are progressively providing free screening and tests in order to increase awareness, precisely diagnose diseases, and limit the chances of infection. Such activities are foreseen to help the market development

in the following couple of years. However, diagnostic kits are highly priced and manufacturers still have a poor assortment channel for working across emerging economies. These two components are anticipated to be the key difficulties to rapid revenue growth of the global infectious diseases diagnostics market.

The Middle East and Africa Infectious Disease Therapeutics Market accounts for USD 8.42 Billion in 2018 and assessed to achieve 12.29 USD Billion by the end of 2023 with a developing potential of 7.877 %. The Middle East and Africa Infectious disease therapeutics market are categorized based on Mode of treatment into Drugs and Vaccines. The drugs are further segmented into oral administration, topical, injections and others. Based on the target organism the market is categorized into antibacterial, antifungal, antiviral, antiparasitic and others. Based on infection type the market is categorized into Bacterial, viral, fungal, parasite and others. Based on distribution channels the market is categorized into hospitals, clinics and others. Based on Geography, the Middle East and Africa Infectious disease therapeutics market is analyzed under various regions namely the Middle East and Africa. The global infectious disease therapeutics market size was valued at USD 46.88 billion in 2016 and is projected to grow at a CAGR of 6.6% during the forecast period. Zika virus is the current outbreak occurring from in many countries. It is affected to people primarily through the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*). Zika can also be passed through sex from a person who has Zika to his or her sex partners and it can also spread from a pregnant woman to her fetus.

#### 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.