Community Trial Of The Use Of Designed Vaccine Cold Chain Coolers In Improving Immunization Coverage In Southwestern Nigeria

Wasiu Olalekan Adebimpe PhD, FWACP
Department of Community Medicine, Osun State University Osogbo Nigeria
All correspondence to:
Dr. WO Adebimpe
Department of Community Medicine,
Osun State University Osogbo Nigeria
Tel: +234 80 3371 2662
Email: lekanadebimpe@gmail.com

Abstract

Background: Despite availability of the traditional vaccine carrier box, maintenance of cold chain during house to house routine immunization especially when reaching rural, remote and hard to reach areas has been a major challenge.

Objectives: This research assessed the efficacy of a designed Vaccine Cold Chain (VACOC) coolers in maintaining cold chain systems during house to house vaccination campaign in Southwestern Nigeria, through a community trial.

Methods: Community trials of 120 designed VACOC flask, which is a modification and improvement on the traditional vaccine carrier box. All arrangement of ice packs and measurements of temperatures followed standard methods. Data was analyzed using the Microsoft Excel software

Results: The minimum to maximum temperature range for the vaccine carrier box and VACOC coolers were from 5^0C to 8^0C and 3^0C to 8^0C respectively. With a baseline at 2^0C, the cumulative or average heat loss stood at 5.45 for vaccine carrier box and 4.8C for the VACOC flask. The vaccine carrier box had an efficacy of 27.3% while the VACOC coolers had efficacy of 31.1% in preventing heat loss from the container. Although VACOC flask gave a slightly better results compared to the vaccine carrier box, there is no statistically significant difference in the ability of both containers to prevent heat loss (OR 0.83, 95%CI 0.4464-1.5181, p 0.2690)

Conclusion: The designed VACOC cooler exhibited better temperature retention property when compared to the vaccine carrier box.

Key words: VACOC flask, Vaccine carrier box, Cold chain maintenance, Efficacy, Osun State

Introduction

Immunization has been named as one of the significant strategic intervention gained by public health, towards reduction in under-five mortality (WHO, 2009). It has received the credit for the worldwide eradication of smallpox, significant lowering of the global incidence of polio by 99% and reduced illness, disability and death from vaccine-preventable diseases (WHO, 2013). However, universal access to immunization is not yet achieved as only about 19% of the GAVI (Global Alliance for Vaccines and Immunization) supported countries in the African region have reached the 80% minimum threshold for the World Health Organization (WHO) recommendations for effective vaccine management (EVM) as at 2016. The majority (75%) of non-immunized children live in 10 countries, including Nigeria (WHO, 2009). In Nigeria, only 25% of children aged 12–23 months completed the prescribed course of routine immunization according to NDHS 2013 (NPC, 2014)

Several challenges faced the vaccination programmes in Nigeria leading to a significant proportion of our children not being fully immunized. Shortfalls in storage and transport facilities and inability to maintain a cold chain system was leading among these challenges. As a coping mechanism to improve access, door to door vaccination programme targeting communities, especially the remote and hard to reach areas have been employed. This is also important because children in hard to reach and rural areas are less likely to access full immunization services (Kassahun, Biks and Teferra, 2015; Hu et al., 2013; Kusuma et al., 2010, Holt, 2013; Senessie, Gage and von Elm, 2007.) Antigen instability is an inherent attribute of some of the common vaccines as they get exposed to heat, and about 1.6 billion people, or one-quarter of the global population, still have limited access to electricity to maintain standard cold chain systems (United Nations/AGECC). Thus, one of the main challenges is the inability to maintain cold chain system before the vaccines get to the end users and this could lead to discard of non potent vaccines and high wastage rates. Eventually vaccine-preventable diseases record persistent occurrence and major source of morbidity and mortality in under five children (WHO, 2012). In order to ensure good quality of vaccine products, their storage and distribution conditions should be monitored from time to time.

Innovations in the field of immunization and vaccine delivery could help in reducing cold chain maintenance related challenges; the two interventions ever introduced to the developing world and known to authors are the vaccine vial monitors and auto-disable (AD) syringes, both of which have been in use over two decades ago (WHO, 2015). Incentive for the private sector, manufacturers of cold chain equipment and researchers to drive innovations is desired and would make usable vaccines available. Apart from the conventional application of controlled temperature chain (CTC) used in many countries to stabilize the cold chain systems (Ren et al., 2009; Halm et al., 2010), other alternative approaches where vaccine doses could be stored safely at a defined temperature within the standard 2–8 °C for a specific duration and temperature are possible.

The authors of this manuscript have re-designed the traditional vaccine carrier box being used for house to house immunization programme using appropriate technology that would drastically reduce heat loss to conduction, convention and radiation thereby supporting the maintenance of vaccines favourable temperatures within the designed vaccine cold chain coolers (VACOC coolers). This research assessed the efficacy of designed VACOC coolers in maintaining cold chain systems during house to house vaccination campaign in Southwestern Nigeria, through a community trial.

Materials and Methods

Study area: The study area for this trial was Osun State in Southwestern Nigeria. The State has a population of about 3.5 million people distributed among 30 Local Government Areas (NPC, 2016). The immunization coverage rate was 57.8% which is short of the recommended 80% WHO target for immunization, while the under 5 mortality rate in the state stood at 68 deaths per 1000 live birth which is comparable to the national average (NDHS, 2018). Vaccination programmes are being carried out mainly by primary health care (PHC) facilities under the control of Local Government Authority health systems.

Study design: This is a quasi-experimental study. It is a community intervention trials of designed VACOC flask, which is a modification and improvement on the traditional vaccine carrier box; with a view to maintain temperature of vaccines within the coolers better than that of the traditional vaccine carrier box during house to house immunization campaign

Study population: Designed VACOC coolers, and the conventional vaccine carrier boxes.

Sampling methodology: Out of the 30 LGAs in the State, two thirds (20) were selected through simple random sampling method employing simple balloting. Out of the 10 PHCs per LGAs, six were selected through simple random sampling method employing simple balloting. A functional non-mutilated vaccine carrier box was collected from each PHC, and this was matched by a VACOC cooler for the purpose of house to house immunization within a movement period of 3 hours

Allocation of VACOC coolers: In this non-randomized trial, randomization into group was not carried out, likewise manipulations in any of the groups. A single blinding mechanism was utilized by a supervisor who knew the source of each cooler relative to the assigned LGA. However equal number of coolers was matched with equal number of vaccine carrier box per PHC.

Study instruments: A checklist was applied to document temperature changes within the 2 sets of boxes before leaving the PHC (usually at 2^0C) and after the 3 hour period. A calibrated thermometer was used and values were read within 10 to 15 seconds of monitoring.

Design and modifications in the VACOC coolers: The following modifications were introduced in the designed VACOC coolers:

1. Instead of the separated 4 plastic containers of the vaccine carrier box (containing the ice packs), the containers was molded as a single block.

2. The vaccine carrier box had no bottom plastic container to hold any ice blocks. In the VACOC cooler a bottom plastic was moulded together with side plastics.

3. A round space 2.5cm in diameter was created within the bottom plastic of the VACOC cooler to host three different live vaccines, and in such a way to prevent direct contact with the ice packs and freezing.

4. The upper lid was more airtight to prevent health losses to the surrounding through a slight increase in the bulkiness of the solid foam parking.

5. The insulation is similar to that of the vaccine carrier box (Bouton, 2016).

Several standard regulations were followed in the design of the VACOC coolers. In support of CDC guidelines, temperatures were documented twice and with the standard crystalline glass thermometer used with the conventional carrier box.

Measurement of outcome variables: Temperature measurements were in degree centigrade (^{0}C), and raw readings were generated in the original baseline data. Cumulative average of minimum and maximum temperature was calculated by adding the raw readings per group of six in the LGA and dividing by 6. Heat loss was calculated from the difference between maximum and minimum cumulative readings per group. Overall efficiency was calculated by comparing the heat loss as a fraction of the cumulative maximum temperature readings to determine the efficacy of how each of the methods was able to sustain the temperature within the box/cooler.

Data collection: A total of 120 designed VACOC coolers were deployed. A set of 3 health care workers trained in the input and arrangement of prepared ice packs, arrangement of vaccines and placement of thermometer were employed in data collection per PHC and they handled a pair of the VACOC cooler and the conventional vaccine carrier box. The State temperature as forecasted earlier on Nigerian Television Authority was considered and data collection done on a cool or an averagely sunny day. In addition data was collected in the morning between 9am and 12 noon thus presenting a similar average environmental temperature despite a movement over a period of 3 hours. The ice parks were prepared over the same time period and same freezing conditions, and carefully selected to be sure that they are still iced. Opening of either the cooler or vaccine carrier box was only twice (at take off and upon arrival).

Limitations: This included our inability to correlate temperature changes with GPRS basic data. In addition, the use of the standard calibrated glass crystalline thermometer normally used in the vaccine cold boxes does not measure temperature changes over time but the temperature at the precise time they are read.

Ethical approval: The ethical approval to conduct the study was obtained from Osun State University Health Research Committee, while further permissions were obtained from the LGA health authority.

Data management: Raw data generated from the field were entered into the computer system and analyzed using the Microsoft Excel software. Tables and charts were generated. Major outcome variables were as earlier described.

Results

Figure 1 shows the minimum and maximum temperature readings by LGA group for the Vaccine carrier boxes which was average 2^0C at baseline minimum temperatures. The maximum temperature range is from 5^0C to 8^0C. Figure 2 shows the minimum and maximum temperature readings by LGA group for VACOC coolers which was also an average 2^0C at baseline minimum temperatures. The maximum temperature range is from 3^0C to 8^0C. Figure 3 shows the heat loss recorded when minimum and maximum temperatures were compared in the conventional vaccine carrier box. The cumulative or average heat loss stands at 5.45^0C. Figure 3 also shows the heat loss recorded when minimum and maximum temperatures were compared in the VACOC coolers. With a baseline at 2^0C, the cumulative or average heat loss stands at 4.8^0C. Figure 4 shows the vaccine carrier box have a relative efficacy of 27.3% while the vaccine cold chain (VACOC) coolers have relative efficacy of 31.1% in preventing heat loss from the container. Though VACOC flask gave a slightly better results compared to the vaccine carrier box, there is no statistically significant difference in the ability of both containers to prevent heat loss (OR 0.83, 95%CI 0.4464-1.5181, p 0.2690).

Discussions

Adverse temperature recording in vaccine's cold chain is a major issue worldwide. This study compared efficacy of the VACOC flask in improving cold chain systems compared to the traditional or conventional vaccine carrier box.

While the dearth of comparative studies limits this discussion, the non-statistically significant difference observed in the 2 containers (VACOC coolers and vaccine carrier boxes) supports findings from another study but that used different models of refrigerating systems to assess adequacy of vaccine storage (Peter, 2001). Though the VACOC coolers bring a better heat conservation and more efficacious compared to the vaccine carrier box, we will not hasten to recommend that VACOC coolers should replace the vaccine carrier box. As there is room for improvement in future designs, attempts would be made to introduce the use of barns since a 2009 study by Troxel and Barham found refrigerators located in barns were colder -35.6 degrees Fahrenheit. (Stoots, 2019)

Conclusion: Maintenance of the cold chain system is important during house to house immunization programmes. Though the VACOC coolers are better at conserving heat, the comparative efficacy of the VACOC coolers to the vaccine carrier box is low to recommend that VACOC coolers should replace the traditional vaccine carrier box. More studies with better designs are needed to replace the use of the traditional vaccine carrier box However when such studies are carried out, it may not be out of place to recommend this or similar designs for use in resource-constrained areas even when the conventional vaccine boxes are available

Acknowledgement: The authors wish to thank the Local Government health authority of the 20 LGAs used in data collection, as well as the health care workers who willingly volunteered to participate in the field work.

Conflict of interest: None to declare.

Funding: This study received funding from the Nigerian Tertiary Education Trust Fund (Grant No: UNIOSUN/TETFund/14/008) distributed under the auspices of Osun State University Osogbo.

References

WHO, UNICEF World Bank. State of the World's Vaccines and Immunization. 3rd ed. Geneva: World Health Organization (2009). (Accessed December 12,

2019) Available online at: https://www.unicef.org/immunization/files/SOWVI_full_report_english_LR1.pdf

World Health Organization. Poliomyelitis. Fact sheet No. 114, Geneva, WHO 2013. (Accessed December 12, 2019). Available from:www.who.int/mediacentre/factsheets/fs114/en/

World Health Organization; 2012. Children: reducing mortality. WHO Fact sheet no. 178. (Accessed December 12, 2019) Available from www.who.int/mediacentre/factsheets/fs178/en/:

National Population Commission ICF Marco. Nigeria Demographic and Health Survey *2013*. Abuja (2014).

Kassahun MB, Biks GA, Teferra AS (2015). Level of immunization coverage and associated factors among children aged 12–23 months in Lay Armachiho District, North Gondar Zone, Northwest Ethiopia: a community based cross sectional study. BMC Res Notes, 8:239

Hu Y, Li Q, Chen E (2013). Determinants of childhood immunization uptake among socio-economically disadvantaged migrants in East China. Int J Environ Res Public Health, 10:2845-56

Kusuma YS, Kumari R, Pandav CS, Gupta SK (2010). Migration and immunization: determinants of childhood immunization uptake among socioeconomically disadvantaged migrants in Delhi, India. Trop Med Int Health, 15:1326-32

Holt E (2013). Ukraine at risk of polio outbreak. Lancet, 381:2244

Senessie C, Gage GN, von Elm E (2007). Delays in childhood immunization in a conflict area: a study from Sierra Leone during civil war. Confl Health, 1:14

United Nations/AGECC; New York: Energy for a sustainable future: summary report and recommendations, (Accessed December 12, 2019). Available from 2010.www.un.org/wcm/webdav/site/climatechange/shared/Documents/AGECC%20summary%20report%5B1%5D.pdf

World Health Organization, 2015.VVM history and milestones. Accessed December 12, 2019). Available at: http://www.who.int/immunization_standards/vaccine_quality/VVM_history_milestones.pdf?ua=1

Ren Q, Xiong H, Li Y(2009).Evaluation of an outside-the-cold-chain vaccine delivery strategy in remote regions of western China. Public Health Rep, 124:745-50

Halm A, Yalcouyé I, Kamissoko M (2010).Using oral polio vaccine beyond the cold chain: a feasibility study conducted during the national immunization campaign in Mali. Vaccine, 28:3467-72

Bouton M (2016): In: Ciottone's Disaster Medicine (Second Edition); 2016, Pages 178-184

Peter R. Lewis PR, Reimer RF and Dixon AJ(2001). Evaluating the efficacy of vaccine storage in the general practice setting. Australian and New Zealand Journal of Public Health, 2001; 25(6):547-50;

Stotts D (2020). Temperature is important for vaccine efficacy. Western Livestock Journal.

Accessed December 12, 2019). Available at:https://www.wlj.net/opinion/

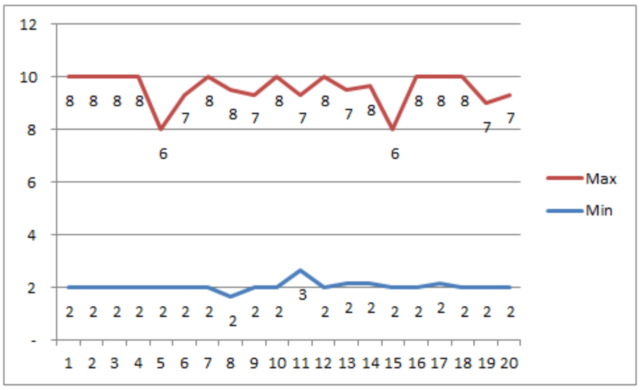

Figure 1 shows the heat loss recorded in the conventional carrier box for all 20 samples.

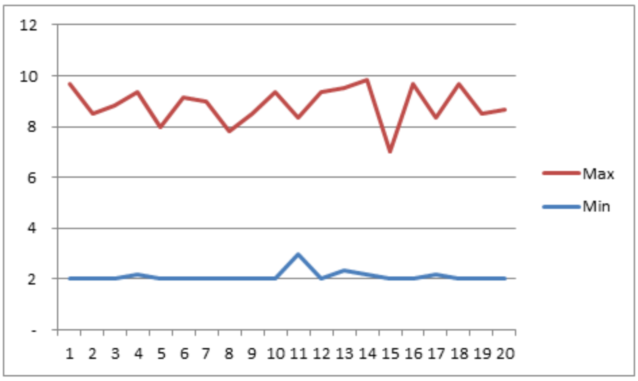

Figure 2 shows the heat loss recorded in the VACOC coolers for all 20 samples.

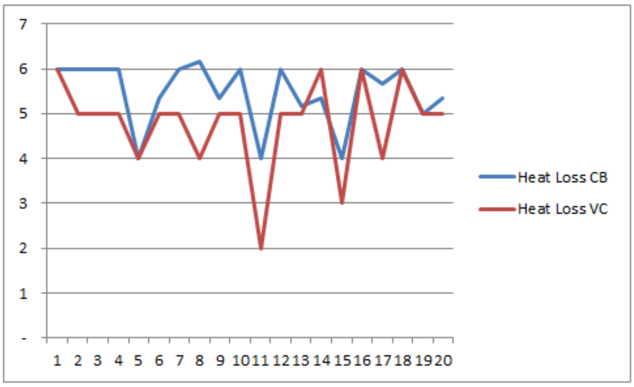

Figure 3 shows the comparative heat loss recorded in the conventional carrier box and VACOC coolers for all 20 samples.

% EFFECTIVENESS

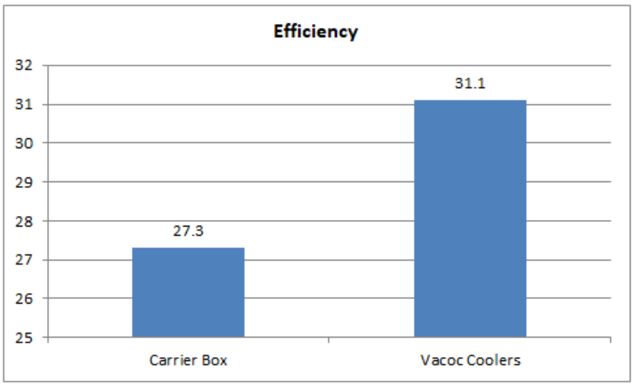

Figure 4: Relative efficiency of VACOC coolers and vaccine carrier box compared