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RESEARCH ARTICLE

ASSESSMENT OF EFFECTIVE VACCINE MANAGEMENT TOOLS IN FIXED IMMUNIZATION SITES AT EAST DARFUR SUDAN- 2014

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ABSTRACT

This was a descriptive cross-sectional facility based study, conducted in Northern state; the assessment was conducted during 2010. Total coverage of all working EPI fixed sites in the state in addition to all Localities vaccine store and state vaccine store were included. The data was collected for six months from official records, reports, and plans concerning the vaccine management, plus interviewing the main Health workers in these units. The study showed that there were only 23 fixed vaccination sites had working refrigerators out of 54 fixed vaccination sites in the state (most refrigerators installed from long time and it is an old model. The entire vaccine store manager give the correct storage temperature range for each of the vaccines on the schedule. 100% of the service sites and localities in addition to state center have adequate storage capacity including for mass campaigns. 56% of the service sites, 95% of localities and 71% of state level had good functioning refrigerators/ freezers and all of these were meet WHO specification. There was no an itemized equipment replacement and preventive maintenance plans in the service sites and locality level and it need updated, detailed at state level. 74% of the service sites, 100% of localities and state level had completed records and balances updated for all receipts and dispatches. 100% of localities and state level had established and followed vaccine receipt/distribution plans. The vaccine wastage had monitored at state and localities level, but there were 82% of the service sites had completed periodic immunization reports and forms that are used to monitor vaccine wastage. The study concluded that the cold chain functionality was very weak (42.6% from total No of refrigerators in the state). There were adequate storage capacity at all levels and its accommodate peak stock levels for all the vaccines specified in the national immunization schedule.

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INTRODUCTION

Immunization programs are among the most cost-effective ways to prevent disease. The success of these programs depends heavily upon the maintenance of vaccine potency and stability (Effective Vaccine Store Management Initiative). By understanding and implementing proper vaccine storage and handling practices, staff in physicians' offices and other health care facilities can play a critical role in improving the health by ensuring that the administered vaccines retain their potency and that vaccine wastage was reduced. Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are exposed to heat and/or direct sunlight or fluorescent light.

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For example, certain vaccines lose potency when exposed to room temperature for as little as 30 minutes or when exposed to light. Freezing damages most vaccines. Exposed vaccines can result in a reduced immune response and/or increased local reactions. The loss of vaccine potency cannot be reversed (Vaccine Management Assessment. WHO/IVB/ 05.02. April 2005). The use of VMAT to carry out a rapid review of existing procedures, training, equipment, transport and buildings to Identify any major gaps and weaknesses, especially in areas that the VMAT identifies as critical indicators, Communicate this information to program managers as rapidly and effectively as possible. This preliminary assessment will become the benchmark against which future assessments can be compared, Make time to prepare or update SOP and draw up a program of improvements, Implement the improvement program and Start with improvements to procedures since these can often be improved quite rapidly and at relatively low cost and move it on to improvements in other

areas as resources become available (Federal Ministry of health - EPI - Northern State Micro plan 2010.)

Vaccine storage temperatures: For vaccines to be effective, it is important that they are stored within the temperature range recommended by manufacturers [+2°C to +8°C] to ensure that they remain potent. The vaccination cold chain refers to all the materials, equipment and procedures involved in maintaining vaccines under the required storage conditions from manufacturer to administration. It is becoming increasingly important for those working in primary care to be able to communicate to patients and their careers the benefits of vaccination, the known side effects of vaccines, as well as the safety and efficacy of vaccines to allay fears (Federal Ministry of health - EPI – Comprehensive multiyear plan.). This issue of incorrect storage of vaccines, in the healthcare settings, that could potentially lead to ineffective vaccination leaving patients more susceptible to disease. The nature of this problem means it is very difficult to absolutely demonstrate direct harm as a result of ineffective vaccination, although the evidence brought together in this document demonstrates the potential for this to happen ([http:// www.euro.who.int/vaccine/ 20081205_4/] website, seen on 2/ Sep/ 2010.). The main compartment should have a temperature of 2 to 8o C, and the freezer compartment should maintain a temperature of -5 to -15o C. It should be large enough to store the largest needed capacity.. A voltage stabilizer is mandatory when voltage fluctuations are many and power cuts are frequent. A good well calibrated thermometer is a must; options include a stem thermometer, dial thermometer, digital thermometer, max/ min thermometer or a data logger. The thermometer should be placed in both the freezer and the main compartment in the center and away from the walls, door, air vent or frozen packs and never in the door (Vaccine Storage and Handling Guidelines, Perth district health unit Ontario- Canada, Feb 2009).

Sensitivity to Heat: Although all vaccines are sensitive to heat, some vaccines are more sensitive to heat than others. Polio vaccine is the most sensitive to heat, while tetanus toxoid is the least sensitive. Vaccines do not change their appearance when potency is lost. A complete laboratory test is the only means to assess whether a vaccine in a vial has lost its potency. The following vaccines are listed in order of heat sensitivity.

- Oral Polio Vaccine (OPV)
- Measles (lyophilised)
- Bacillus Calmette Guerin (BCG)
- Tetanus toxiod (TT).
- Rota Virus Vaccine.
- Pentavalent Vaccine (PENTA).
- Pneumococcal Vaccine (PCV).
- In activated Polio Vaccine (IPV).

It is important to note that all freeze-dried vaccines become much more heat sensitive after they have been reconstituted with diluents (Guidelines for the use of the Vaccine Arrival Report in UNICEF shipments, NNICEF, April 2002.)

Sensitivity to Freezing:-Some vaccines are also sensitive to extreme cold. For these vaccines, freezing or exposure to temperatures below zero degrees Celsius can also cause loss in potency and render the vaccines useless. For these vaccines, it is therefore essential to protect them not only from heat, but also from freezing. The vaccines sensitive to freezing (as well as to heat) are:

- Pneumococcal Vaccine (PCV).
- Pentavalent Vaccine (PENTA).
- Rota Virus Vaccine.
- Tetanus toxiod (TT).

Sensitivity to Light:- Some vaccines are also very sensitive to strong light. For these vaccines, exposure to ultraviolet light will cause loss of potency, so they must always be protected against sunlight or fluorescent (neon) light. BCG, Measles, Measles and Rubella (MR), Measles, Mumps and Rubella (MMR) and Rubella vaccines are sensitive to light (as well as to heat). Normally, these vaccines are supplied in vials made from dark brown glass, which gives them some protection against damage from light. However, care must still be taken to keep them covered and protected from strong light at all times. They should not be stored in a cooler with a glass door, and should preferably be stored in the dark. Most heat-sensitive Least sensitive to freezing Most sensitive to freezing Least heat-sensitive Storing Diluents for Vaccines:-

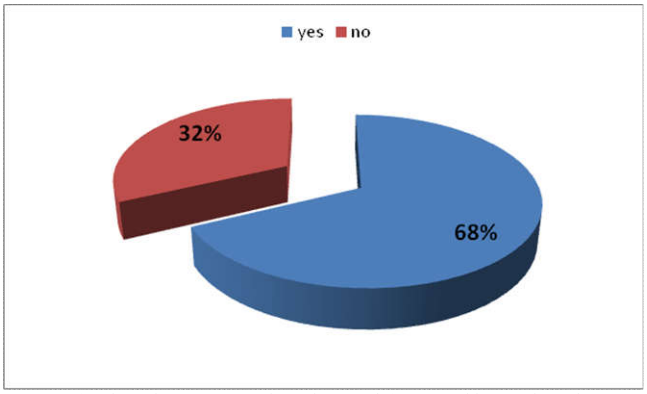
- Diluents for vaccines are less sensitive to storage temperatures than the vaccines with which they are used, but may be kept in the cold chain between +2oC to +8oC if space permits.
- Diluents vials must never be frozen. This may cause the glass to crack and cause contamination of the contents. Diluent vials must never be kept in a freezer, or allowed to be in contact with any frozen surface.
- When vaccines are being reconstituted, the diluents should be at same temperature as the vaccines. Therefore, sufficient diluents for daily needs should be kept in the cold chain at the point of vaccine use (e.g. health centre or vaccination post).
- Freeze-dried vaccines and their diluents should always be distributed together in matching quantities. The vaccines must be kept in the cold chain between +2oC and +8oC at all times, or optionally, at -15oC to -25oC if cold chain space permits.
- To maintain cold chain when transporting vaccines, cold boxes or vaccine carriers with ice packs need to be used. The diluents do not need to be kept in the cold chain unless they are to be used for reconstituting vaccines within the next 24 hours. However, diluents must be transported with the vaccines at all times, and the diluents must always be of the correct type and from the same manufacturer as the vaccines that are being transported.
- Diluents may appear to be simple water, but in fact contain a variety of salts, chemicals and additives required to stabilize a specific vaccine after reconstitution.

The vaccines can be placed as follows

- Freezer compartment: BCG, OPV and Measles.
- Refrigerator compartment: DTP, Pentavallent, TT, Combination vaccines, Hepatitis B, Hib, PCV7, influenza, rotavirus vaccines. (8)

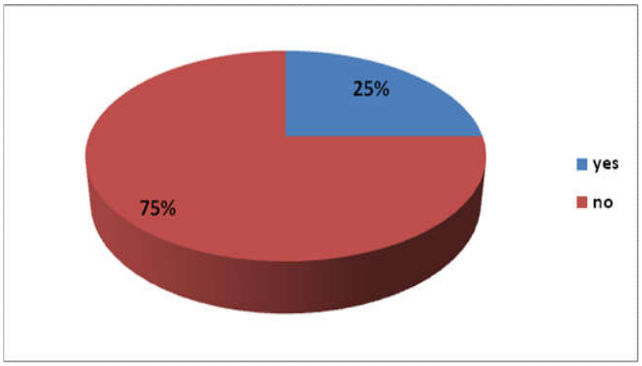
MATERIAL AND METHODS

Study design: The study was designed as Descriptive cross-sectional facility based study.



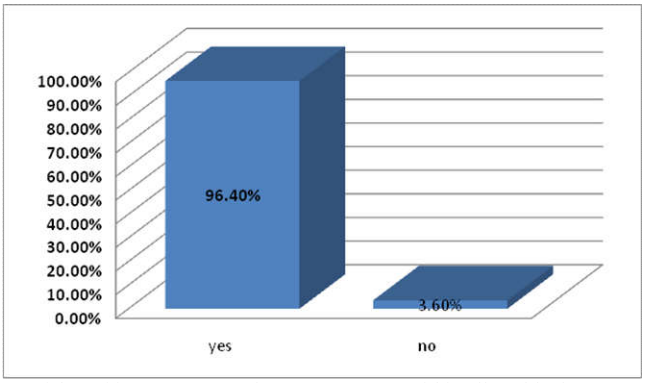
(68%) of equipment was function and (32%) of it not function.

Figure .4-2 Showing the refrigerators which have thermometers with vaccine, East Darfur State, 2014



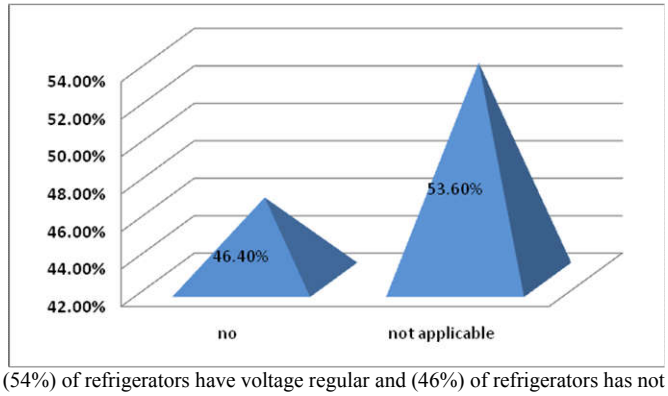
(25%) of refrigerators hade thermometers with vaccine and (75%) of it had not thermometers with vaccine.

Figure 4-3 **Showing the refrigerators keep temperature within allowable degree, East Darfur State, 2014**



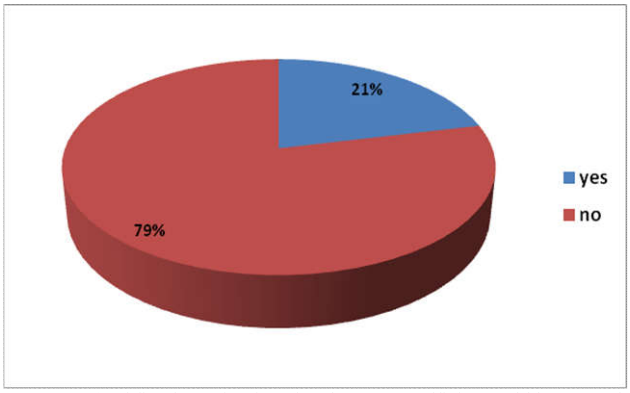
Most of the refrigerators (94%) keep temperature within allowable degree.

Figure .4-4 **Showing the refrigerators have voltage regular, East Darfur State, 2014**



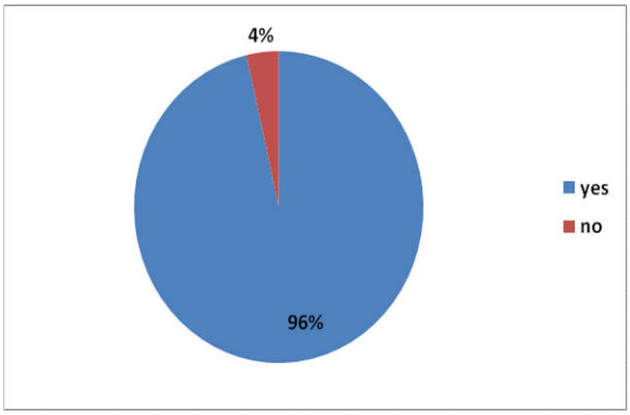
(54%) of refrigerators have voltage regular and (46%) of refrigerators has not voltage regular.

Figure 4-5. Showing the sufficient cold boxes and vaccine carriers, East Darfur State, 2014



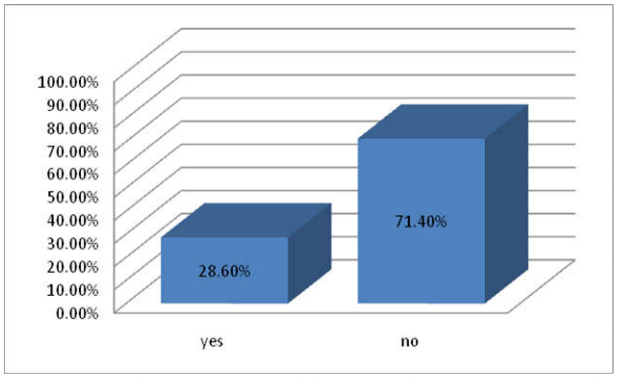
Most (79%) of fixed vaccination sites have not sufficient cold boxes and vaccine carriers.

Figure 6-4. Showing the workers knowledge about ice packs preparation during transportation, East Darfur State, 2014



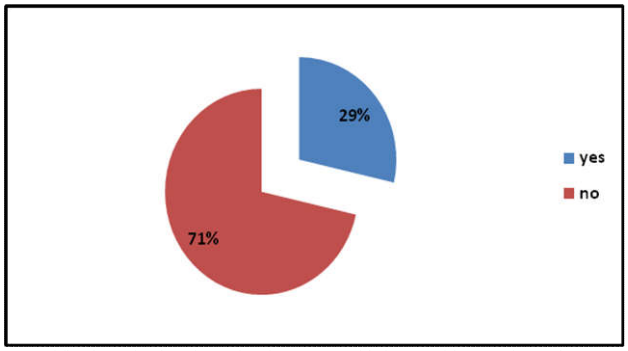
Most (96%) of workers have knowledge about ice packs preparation during transportation.

Figure 7-4. Showing the temperature recorded twice a day, East Darfur State, 2014



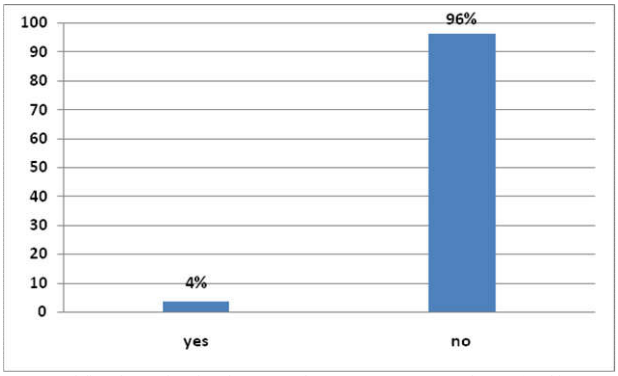
Most (71%) of fixed vaccination sites did not record temperature twice a day.

Figure (8-4): Showing the using of freeze tag, East Darfur State, 2014



(29%) of fixed vaccination sites using freeze tags with free sensitive vaccine and (71%) of fixed vaccination sites not using freeze tags with free sensitive vaccine

Figure 9-4. Showing the stock out occurrence, East Darfur State, 2014



(4%) of fixed vaccination have stock out occurrence and (96%) of it not occurrence.

Study area: East Darfur State is about 52,000 kilometers² lies in western Sudan in Darfur zone and it was spitted from south Darfur in 2011, it had 424 areas and village, and administratively the state was divided to 9 localities and 19 administrative unite. The EPI services are provided by:

- Fixed site 28
- Out reach 75
- Mobile team 16.

Study population: The study population was involved vaccinators & Cold chain equipments in Immunization sites.

Inclusion Criteria: All fixed sites immunization sites in the State.

Exclusion Criteria: Out-reach and mobile sites**.**

sampling and sample size: Due to the small size of study population (28) the study followed the total coverage as strategy of sampling.

Method of data collection

The data was collected by

Questionnaire: Questionnaire was designed and conducted pre- test on a small group of the target in order to ensure the comprehensiveness and understanding of the questions.

Data Analysis and presentation: The data organized, entered and analyzed using Statistical Package for Social. Sciences (SPSS) soft ware and finally represented in figures and tables by excel

Ethical consideration: A written informed consent was obtaining from respondents before the study start.

RESULTS AND DISCUSSION

The study showed The cold chain functionality was very weak (68%) from total No of refrigerators, because there were only 19 fixed vaccination sites had working refrigerators out of 28 fixed vaccination sites in the state (most refrigerators installed from long time and it is an old model (BP)). (75%) of refrigerators had not thermometers with vaccine and this is against WHO standard which said the thermometers should be placed in both freezers and refrigerators (Guidelines for the use of the Vaccine Arrival Report in UNICEF shipments, NNICEF, April 2002.).(4%) of the refrigerators not keep temperature within allowable degree and this is against WHO standard which said the main compartment should have temperature of +2 to +8 C and the freezers compartment should maintain temperature of -15 to -25 C (Guidelines for the use of the Vaccine Arrival Report in UNICEF shipments, NNICEF, April 2002). (79%) of fixed vaccination, sites had not sufficient cold boxes and vaccine carrier and this not match with the country and state policy of cold chain (Expanded Program on Immunization in Sudan committed to maintain cold chain when transportation cold boxes and vaccine carriers with ice packs need to be used)(Guidelines for the use of the Vaccine Arrival Report in UNICEF shipments, NNICEF, April 2002.). (29%) only of fixed vaccination sites recorded temperature twice day but others (71%) did not register temperature especially during weekends and holidays. Although all (100%) health workers know, vaccines damage by freezing but (82%) of them not knows conduct the shake taste. (57%) of health workers do not trained on vaccine management. (96% of the service sites, workers do know how to condition icepacks and how to pack transport boxes. (71%) of fixed vaccination sites not using freeze tags with free sensitive vaccine , this not meet the WHO standards which said freeze tags require because Some vaccines are also sensitive to extreme cold. For these vaccines, freezing or exposure to temperatures below zero degrees Celsius can also cause loss in potency and render the vaccines useless. For these vaccines, it is therefore essential to protect them not only from heat, but also from freezing (Vaccine cold storage Supporting Information, National Patient Safety Agency, UK January 2010). 4% of the service sites had registered stock out of each vaccine throughout the past six months. (50%) of fixed vaccination sites had not sufficient storage to meet WHO standard which said to be Ensure that your refrigerator capacity is large enough to store your vaccine supply. There must also be enough room to allow air to circulate around the vaccine packages (Guidelines for the use of the Vaccine Arrival Report in UNICEF shipments, NNICEF, April 2002). All (100%) of fixed vaccination sites had not contingency plan to meet WHO standard Suitable posters should be designed and pasted on machines with clear instructions in local languages on how to handle such emergency situations when breakdowns in equipment/electricity failure. All (100%) of health workers know what VVM mean. (93%) of fixed vaccination sites had supervisory visit from higher level, this EVM requirement to support vaccine management in vaccination sites but (73%) of health workers not use the supervisory reports to maintain the shortage in their vaccination sites .

Recommendation

The study recommended the following

- Provide urgent maintenance and replacement equipments for the not functioning refrigerators by state ministry of health.
- Introduce new equipments to increase capacity at all fixed vaccination sites in the state
- Provide freeze indicators, thermometers devices and generators to the lower level.
- Prepare records for proper and complete registration of temperature.

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