

COLD CHAIN STATUS AND VACCINATION ACTIVITIES AT VACCINATION CENTERS IN TRIPOLI, LIBYA (2015)

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ABSTRACT

Effective immunization program requires a stable cold chain to maintain potency of vaccines from national stores through to delivery sites. The integrity of the cold chain is depend on not only the equipment used, but also the people involved and the practices they undertake. To assess the condition of cold chain equipment and the practices adopted for cold chain maintenance by the vaccinators. The study was designed as cross-sectional, conducted at the vaccination centers in Tripoli. Cold chain equipments were assessed with regards to their condition, along with the practices of vaccine providers. The study was conducted during the period from December 2014 to February 2015. The data was analyzed using SPSS program, and results were presented as frequency and percentage. All vaccination centers in Tripoli were assessed, according to World Health Organization recommendations, 95.7% of refrigerators had proper site, appropriate vaccine packing was detected in 55.3% and proper temperature was found in 42.6% of refrigerators. During vaccination session 66% of nurses used to wash their hands, most of them were handling the child properly, while all of them checking the type, the dose of vaccine and reconstitute the vaccine as it should be. Only 10.6% of nurses did not counsel the mothers about the side effects of vaccine and did not remind them about the time of the next visit, and 95.7% of the nurses handle the needles and syringes safely. Cold chain maintenance and practice need improvement; regular staff training and supervision.

KEY WORDS : Immunization, Vaccine, Cold chain, Vaccine providers, Assessment.

INTRODUCTION

Immunization is the most successful global health intervention and one of the most cost-effective ways to save lives and prevent diseases⁽¹⁻³⁾.

The number of deaths caused by vaccine preventable diseases have fallen from an estimated 0.9 million in 2000 to 0.4 million in 2010⁽⁴⁾.

Vaccines have the power not only to save, but also to transform lives giving children a chance to grow up healthy, go to school and improve their life prospects⁽⁵⁾.

Vaccine storage and handling errors can result in the loss of vaccines worth millions of dollars. The administration of mishandled vaccine can affect a large number of patients. Failure to adhere to required protocols for storage and handling can reduce vaccine potency, resulting in inadequate immune responses, as well as inadequate protection against disease⁽⁶⁾.

The system of transporting and storing vaccines within recommended temperature range of +2C⁰ to +8C⁰ from the place of their manufacture to the point of vaccine administration is called the cold chain⁽⁷⁻¹⁰⁾.

The key elements of cold chain are personnel to manage vaccine storage and distribution; equipment to store and transport vaccine; and procedures to ensure that vaccines are stored and transported at appropriate temperature⁽¹¹⁾.

All staff members who handle or administer vaccines should be familiar with the storage and handling policies and procedures at their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts shipments or who may have access to the units where vaccines are stored⁽⁶⁾.

The vaccine refrigerator should be placed in a cool room, away from direct heat or sunlight, at least 10cm to 20cm from the wall and with at least 40cm of clear space above. The room should be well ventilated so that the heat from the refrigerators and freezers will not make the room too hot. If several refrigerators or freezers are kept in one room, they should be properly spaced, at least 30cm from each other⁽¹⁰⁻¹²⁾.

Adequate cold air circulation helps each vaccine reach a consistent temperature throughout its mass, and is necessary for the storage unit to maintain a consistent temperature. Packing any vaccine storage unit too tightly can negatively affect the temperature⁽⁶⁾.

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A storage unit is only as effective as the temperature monitoring system inside. Accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management⁽⁶⁻¹²⁾.

As recommended that do not keep food and drink in a refrigerator used for vaccine storage. Frequent opening of the refrigerator to retrieve food items can affect the temperature of the unit and thus affect the efficacy of the vaccines. It may also result in spills and contamination inside the unit⁽⁶⁻¹²⁾.

With the exception of Bacillus Callmette- Guérin (BCG) vaccine, injectable vaccines are administered by the intramuscular or subcutaneous route. Deviation from the recommended route of administration might reduce vaccine efficacy or increase the risk for local adverse reactions⁽¹³⁾.

For the majority of infants, the anterolateral aspect of the thigh is the recommended site for injection because it provides a large muscle mass⁽¹³⁾.

To prevent inadvertent needle-stick injury or reuse, safety mechanisms should be deployed after use; needles and syringes should be discarded immediately in labeled, puncture-proof containers located in the same room where the vaccine is administered⁽¹³⁾.

So, this study was conducted with the aim to assess the condition of cold chain and the practice of vaccine providers at vaccination centers.

MATERIALS AND METHODS

This study is a descriptive, cross-sectional type; conducted to assess all vaccination centers in Tripoli. Administrative approval was obtained from primary health care office in Tripoli. The list of vaccination centers was prepared and the time schedule to visit all vaccination centers was decoded. The study was carried out during the period from December 2014 to February 2015. Cold chain equipment was assessed using a pre-constructed checklist, regarding to their condition and practices of health personnel for cold chain maintenance. A vaccination session was observed to assess the performance of vaccine providers at the time of vaccine administration.

The study tool was a pretested questionnaire, designed according to cold chain criteria set by world health organization (WHO)⁽⁵⁾, which consisted of two sections; section one includes a checklist to assess the vaccination room, refrigerator, cold box and vaccine carriers; the second section deals with questions to assess the practice of those providing immunization and managing the cold chain at vaccination centers.

SPSS software version16 was used for data analysis, descriptive statistics were used and results presented as frequency and percentage.

RESULTS

Vaccination activities in Libya are provided in all health care levels, in different health units and for every one free of charge. Vaccination centers in Tripoli according to the list obtained from primary health care

office were evaluated in this study, and (table 1) shows their distribution according to the type.

(Table 1) Distribution of vaccination centers according to the type of health facility in Tripoli (2015)

Type	Frequency	%
MCH	2	4.2
Dispensary	3	6.4
Health center	31	66
Polyclinic	6	12.8
Hospital	5	10.6
Total	47	100

This study showed that the majority of vaccination rooms had proper waiting facility (72.3%), appropriate ventilation (78.7%), and suitable washing facility (70.2%). Most of vaccination rooms (89.4%) were clean and all centers have proper disposal facilities that include puncture proof containers and safe boxes (table 2).

(Table 2) Situation of vaccination room at vaccination centers in Tripoli (2015)

Character	Proper	Improper	Total
Waiting facility	34 (72.3%)	13 (27.7%)	47 (100%)
Ventilation	37 (78.7%)	10 (21.3%)	47(100%)
Light	39 (83%)	8 (17%)	47(100%)
Washing facility	33 (70.2%)	14 (29.8%)	47(100%)
Disposal facility	47 (100%)	0	47(100%)
Cleaning	42 (89.4%)	5 (10.6%)	47(100%)

The study revealed that all vaccination centers had refrigerators and 87.2% had deep freezer, only 2.1% of vaccination centers had shortage in injection equipment.

Daily electricity failure was noted in 85.1% of vaccination centers and only 38.3% had stand-by generator and fuel was available in 21.3% of them (table 3).

(Table 3) Cold chain equipment in vaccination room in Tripoli (2015)

Equipment	%	Not %	Total
Refrigerator	36 (76.6%)	0	47(100%)
ILR	11 (23.4%)		
Domestic			
Deep freezer	41 (87.2%)	6 (12.8%)	47(100%)
Injection equipment	46 (97.9%)	1 (2.1%)	47(100%)
Vaccination poster	8 (17%)	39 (83%)	47(100%)
Electricity failure	40 (85.1%)	7 (14.9%)	47(100%)
Generator	18 (38.3%)	29 (61.7%)	47(100%)
Fuel	10 (21.3%)	37 (78.7%)	47(100%)

Regarding the refrigerator state, 76.6 % of refrigerators were of ice lined type (ILR), 95.7% of refrigerators were placed at proper site that away from direct sun light exposure and 85.1% had appropriate distance away from the wall as recommended by WHO. Proper vaccine packing was observed in 55.3% and proper temperature (2°C – 8°C) was seen in only 42.6% of

refrigerators in vaccination centers which make the vaccine potency in that centers questionable (table 4).

(Table 4) Status of refrigerators at vaccination centers in Tripoli (2015)

Status of refrigerator	Proper	Improper	Total
Site	45 (95.7%)	2 (4.3%)	47(100%)
Distance	40 (85.1%)	7 (14.9%)	47(100%)
Temperature	20 (42.6%)	27 (57.4%)	47(100%)
Vaccine packing	26 (55.3%)	21 (44.7%)	47(100%)
Ice pack freezing	11 (23.4%)	36 (76.6%)	47(100%)

In present study, thermometer was found in only 48.9% of refrigerators, 8.5% of refrigerators were leaked and temperature recording sheet and vaccine expiry sheet were absent in 78.7% and 57.4% of refrigerators respectively. Food was present in 4.3% of refrigerators. Diluents which needed for reconstitution of vaccine were present inside 72.3% of refrigerators at vaccination centers (table 5).

(Table 5) Storage requirement of refrigerator at vaccination centers in Tripoli (2015)

Storage requirements	%	Not %	Total
Thermometer	23 (48.9%)	24 (51.1%)	47(100%)
Leaking	4 (8.5%)	43 (91.5%)	47(100%)
Temperature recording sheet	10 (21.3%)	37 (78.7%)	47(100%)
Expiry date sheet	20 (42.6%)	27 (57.4%)	47(100%)
Food	2 (4.3%)	45 (95.7%)	47(100%)
Vaccine Diluents in refrigerator	34 (72.3%)	13 (27.7%)	47(100%)

The study demonstrated that 97.9% of cold boxes were in good condition, there were no thermometers inside cold boxes during our visit. 36.2% of ice packs were arranged improperly in cold box and the temperature inside these cold boxes was not known if within recommended range or not (table 6).

(Table 6) Characteristics of cold boxes at vaccination centers in Tripoli (2015)

Character	Proper	Not proper	Total
Condition	46 (97.9%)	1 (2.1%)	47(100%)
Ice packs arrangement	30 (63.8%)	17 (36.2%)	47(100%)
Vaccine packing	45 (95.7%)	2 (4.3%)	47(100%)
Thermometer inside cold box	0	47 (100%)	47(100%)
Closed tightly	46 (97.9%)	1 (2.1%)	47(100%)

During vaccination session only 66% of nurses wash their hands before administration of vaccine, most of them (97.9%) were handling the child properly, all of the vaccine providers were inspecting the type of vaccine, checking if vaccine frozen and only 48.9% of them read the vaccine vial monitor (VVM), to know whether the vaccine has been damaged by heat or not. Also during the same session, all the nurses reconstitute the vaccine properly, vaccinate the child at correct site and route and were given the correct dose of Polio

and Rota vaccines and recorded all information in immunization card and vaccine register files.

Only 10.6% of nurses did not counsel the mothers about the side effects of vaccines and did not remind them about the time of next visit. Most of nurses (95.7%) were handling the syringe safely and all of them were disposing the needle and vaccine vial properly (table 7).

(Table 7) Nurses' performance during vaccination session at vaccination centers in Tripoli (2015)

Practice	Yes	No	Total
Washing hands	31 (66%)	16 (34%)	47(100%)
Proper child handling	46 (97.9%)	1 (2.1%)	47(100%)
Checking type of vaccine	47 (100%)	0	47(100%)
Checking frozen vaccine	47 (100%)	0	47(100%)
Reading VVM	23 (48.9%)	24 (51.1%)	47(100%)
Proper reconstitution	47 (100%)	0	47(100%)
Proper handling of syringe	45 (95.7%)	2 (4.3%)	47(100%)
Proper Cleaning technique	37 (78.7%)	10 (21.3%)	47(100%)
Correct site	46 (97.%)	1 (2.1%)	47(100%)
Correct route	47 (100%)	0	47(100%)
Correct polio dose	47 (100%)	0	47(100%)
Correct Rota vaccine dose	47 (100%)	0	47(100%)
Recording	47 (100%)	0	47 (100%)
Health education	42 (89.4%)	5 (10.6%)	47(100%)
Proper Disposal	47 (100%)	0	47(100%)

DISCUSSION

Failure to adhere to recommended specifications for storage and handling of immunobiologics can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient. Inadequate vaccine storage also can result in the loss of thousands of dollars' worth of vaccine inventory and the cost of inventory replacement⁽¹³⁾.

To provide any health service, proper waiting facility should be available in each health unit to relieve anxiety and to decrease over crowding at doors, hence provision of good services by health personnel. Each vaccination room should be well ventilated, with suitable lighting and proper washing facility to conduct safe immunization activities. In current study, some of vaccination rooms lack these requirements because of lack of continuous maintenance.

In this study, vaccination centers showed remarkable improvement in cold chain management, as compared with previous studies conducted by Omar (1996)⁽¹⁴⁾, Ehmadi (2000)⁽¹⁵⁾, Ehmadi (2003)⁽¹⁶⁾. But some vaccination centers suffered from shortcomings, which may affect immunization program these include failure to adhere to expanded program on immunization recommendations and guidelines for cold chain and vaccination activities.

In the present study, 76.6 % of refrigerators were of ice lined type (ILR) and they were placed in proper site and had proper distance away from the wall. Similar results found in a study done by Naik AK in western India⁽¹⁷⁾.

Presence of thermometers in vaccine fridge is one of the cold chain recommendations that measure the temperature, which should be maintained between 2°C- 8°C, if there is no thermometer in the fridge, the vaccine is in danger. In this study, nearly the half of refrigerators had thermometers and proper temperature was available in 42.6% of refrigerators. Similar results confirming this study were achieved by national cold chain assessment 2008 in India; they reported that Cold chain management was poor in some places (including private practices), particularly for temperature recording and risk of freezing the freeze-sensitive vaccines⁽¹⁸⁾.

As the results showed that more than two thirds of refrigerators deficient in temperature recording sheet, this explains lack of responsibility and supervision.

Study done by Ministry of health in Malawi, from 2011 to 2015 revealed that, of the 1,045 working refrigerators at the time of the survey, 88.4% had at least one temperature monitoring device⁽¹⁹⁾.

In a study conducted in Cameroon by Atendjieu et al.,2013, It was noted that the temperature was not systematically recorded on charts twice daily as required in 11 (40.7%) of the health facilities⁽²⁰⁾.

Other study, done by Widsanugorn et al., 2011 in Thailand, revealed that the findings from direct observation about equipment and practices regarding the cold chain system in primary care units were 86.7% of them, the temperature inside refrigerators was in the range of 2–8°C⁽²¹⁾.

Vaccine loading was as recommended in 55.3% of refrigerators in present study. Proper storage of vaccine was in 78.6% of refrigerator in study done in Cameroon⁽²⁰⁾ and 90% in a study done by Rao et al., at costal south of India⁽²²⁾.

Presence of other item with vaccine as Food and drug was in only 4.3% of refrigerators in this study; hence unnecessary opening of doors which leads to fluctuation of temperature was avoided. Other studies were conducted in different countries, were getting similar finding^(17,22).

In current study the electricity failure, which may harm immunization program was present in 85.1% of vaccination centers, only 5 hospitals and 2 polyclinics had continuous electricity supply; generators were available in 38.3%, and fuel was accessible only in 21.3% of health centers. But, most of refrigerators were ice landed refrigerators (76.6 %), so the cold chain will not be affected by the electricity failure for 48-72 hours. While, the results in the previous study conducted by Ehmadi demonstrated that electricity failure was rare or none in 90% of vaccination units⁽¹⁵⁾.

In study done in India out of the 574 sites assessed, generators were available at 173 sites⁽²³⁾. Same finding

was in other study conducted in western India the lack of generators was in 85% of health centers⁽¹⁷⁾.

Persons administering vaccinations should follow appropriate precautions to minimize risk for spread of disease. Hands should be cleansed with an alcohol-based waterless antiseptic hand rub or washed with soap and water before preparing the vaccine and between each patient contact. Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccinations, unless persons administering vaccinations are likely to come into contact with potentially infectious body fluids or have open lesions on their hands. If gloves are worn, they should be changed between patients⁽¹³⁾.

If an alcohol swab is used, it must be allowed to dry for at least two minutes, otherwise alcohol may be tracked into the muscle, causing local irritation and alcohol may also inactivate a live attenuated vaccine⁽¹⁰⁾.

The vaccine providers were observed during vaccination of the children only 66% of them washed their hands before or after vaccination, this contribute to lack of washing facility in some vaccination rooms and absence of this habit from the nurse practice. 78.7% of nurses practice correct cleaning technique and allow skin to be dry before injection of the vaccine. Study done in Dammam by Mugarbel et al in 2007, found that hand washing was practiced by 18.2% of government health facilities⁽²⁴⁾.

This study reported remarkable improvement in the practice among vaccine providers when compared to a study done in Tripoli in 2003⁽¹⁶⁾, regarding reconstitution and administration of vaccine in correct dose, site, route and following safe mechanism of needle and syringe disposal as recommended by WHO and center of disease control (CDC); this improvement contributed to good training program which conducted under supervision of national center for disease control and primary health care office in Tripoli.

CONCLUSION

In conclusion, there were some gaps in maintenance and practices regarding the cold chain system among health care workers in vaccination centers at Tripoli. Continuous training and regular supervision on national immunization program and the cold chain system are necessary to ensure optimal immunization effectiveness.

RECOMMENDATIONS

All healthcare providers who administer vaccines should evaluate their vaccine cold chain procedures to ensure that vaccine storage and handling best practices are being followed; organize to prevent power interruption in health facilities by stocking alternative sources of power; and training should occur whenever recommendations are updated and when new vaccines are added to maintain staff competency and to enhance practice skills for the management of cold chain.

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