

Journal of Pharmaceutical Research International

**33(42B): 225-236, 2021; Article no.JPRI.73028 ISSN: 2456-9119** (Past name: British Journal of Pharmaceutical Research, Past ISSN: 2231-2919, NLM ID: 101631759)

# Evaluation of the Cold Chain Expanded Program on Immunization at Governmental and Private Health Care Centers in Riyadh City, Saudi Arabia

Abdulrahman Hussain Alqahtani<sup>1\*</sup>, Suhair Alsaleh<sup>1</sup> and Abdulaziz Almana<sup>2</sup>

<sup>1</sup>Ministry of Health, Riyadh, Saudi Arabia. <sup>2</sup> Al-Faisal University, Saudi Arabia.

#### Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

#### Article Information

DOI: 10.9734/JPRI/2021/v33i42B32442 <u>Editor(s):</u> (1) Dr. Papiya Bigoniya, RKDF University, India. <u>Reviewers:</u> (1) Sunil kant Guleri, Government Medical College Shahdol, India. (2) Adam Dawria Ibrahim, King Khalid University, Saudi Arabia. Complete Peer review History: <u>https://www.sdiarticle4.com/review-history/73028</u>

Original Research Article

Received 20 June 2021 Accepted 28 August 2021 Published 02 September 2021

## ABSTRACT

**Objective:** Vaccine storage is essential to ensure optimal vaccine effectiveness. Cold chain is a series of storage and transport links, designed to keep the vaccine at the correct temperature till it reaches the user. To evaluate the Cold Chain Expanded Program on Immunization at Governmental and Private Health Care Centers in Riyadh city, Saudi Arabia.

**Methods:** A cross-sectional study was conducted from March to May 2021 in government and private primary health care centers of Riyadh, Saudi Arabia were included. Data collection was carried out using standardized check list developed by Saudi Ministry of Health (MOH) and World Health Organization (WHO). Data were analysed using IBM SPSS Statistics 26 (C) and IBM SPSS 26 (IBM Inc.)

**Results:** The results showed that the mean score of Room and Refrigerator Elements for governmental PHCs was  $8.8(\pm 0.82)$ , while it was  $8.3(\pm 1.86)$  for private PHCs. The mean temperature monitoring device score for government PHCs was 4.0 (0.0), and the 3.65 ( $\pm 0.92$ ) for PHCs centers. The mean temperature chart (record keeping) score for governmental PHCs was 2.55( $\pm 0.5$ ) and 1.8( $\pm 1.2$ ) for private PHCs. The mean maintenance and operations score for governmental PHCs was 4.6 ( $\pm 0.49$ ), while it was 4.1 ( $\pm 0.84$ ) for private PHCs. The mean scores of all cold chain components differed significantly between government and private facilities (p=0.000).

**Conclusion:** Our study highlights the cold chain management programs Saudi Arabia. More importantly governmental PHC centers in the current settings comply with the standards to the guidelines, provided by Saudi Ministry of Health and WHO, was observed, in comparison to private PHC centers.

Keywords: Vaccines; immunisation; cold chain; health care facilities; Saudi Arabia.

# 1. INTRODUCTION

Immunization programs are widely recognized as one of the most effective means of health intervention. It was revealed that people of all ages need vaccines that help them to cope with multiple diseases. The benefits of vaccination far outweigh the risks of the disease and the side effects from certain vaccines [1]. To make sure that mothers with their children have access to the recommended vaccines, the expanded program on immunization (EPI) was created in 1974. [2,3] Expanded because most programs until then had only used vaccine against Small pox, BCG, EPI would cover two new diseases. [2.3] The BCG vaccine was introduced in 1964, Poliomyelitis in 1969, Measles in 1974, DTP in 1979, MMR in 1991, Hepatitis B in 1991, and finally, Homophiles Influenza Type B in 2002. In addition, vaccination has become an integral component for birth certificate obtainment. After that, in 2002, a new basic immunization schedule was introduced [2,3].

Vaccine storage is essential to ensure optimal vaccine effectiveness. 3 According to world health organization (WHO) and UNICEF, the cold chain management at health facilities should follow some recommendations includes the status of EPI vaccination room that should be as cool as possible, with good ventilation, air circulation and away from direct heat or sunlight. All equipment should be placed on level wooden blocks at least 10 cm high, and each item should be secured when in use. Vaccine refrigerator should be put in the coolest place of the vaccination room near the electric supply far from direct sun light and the wall should be at least 20 cm away from the refrigerator [4]. EPI-Vaccines arrangement and placement inside the refrigerator depend on the vaccine sensitivity to heat, freezing and light [5,6].

The cold chain is defined as a system which uses for storing and transporting the vaccines, within the acceptable range of temperature, from production to the end users. [7] Hence, to maintain the cold chain, knowledge and compliance to the guidelines by primary health care provider plays a key role. [8.9] The recommended guidelines for cold chain are temperature should be maintaining between 2-8 oC, use of thermometers, temperature monitoring charts and shake test. [10-12] To facilitate the process of temperature monitoring and maintaining, vaccine vial monitor (VVM) has been developed for the health workers which enable them to find whether vaccine is damaged due to heat or not. VVM is applied to each vaccine vial by the manufacturer which helps health care workers to find the potency and efficacy of the vaccine at the time of use. [13-17].

In Saudi Arabia, the national immunization program was introduced with the aim of eliminating or reducing the incidence of certain infectious diseases. [18,19] In order to work the cold chain system properly, there must be an assigned well-trained person to be responsible for vaccine storage and handling, EPI vaccine management and other operational record. issues. [20,21] Critical management and equipment failure may result in the destruction of large quantities of vaccine resulting in high cost and can place the immunization services of an entire country at risk. Cold chain management can enhance the quality, safety and efficacy of an immunization program. So, it would be beneficial to assess and analyze the cold chain system at health care centers and locate the deficiencies in vaccines storage and practice among health workers. Therefore, this study aimed to evaluate the current status of the vaccine cold chain maintenance in Health Care Facilities in Riyadh city, (2) to locate the deficiencies in the different aspects of vaccines storage and handling in various health Care Facilities in Riyadh (3)to provide recommendations to improve the cold chain in EPI-program at PHC centers in Riyadh.

## 2. MATERIALS AND METHODS

#### 2.1 Study Design and Study Population

Across sectional, observational study was carried out in both governmental and private health care facilities in capital of Saudi Arabia, over a period of 3 months from March 2021 to May 2021 using structured self-administered paper based questionnaires. The total number of governmental primary health care centers is 130, and the private dispensaries is to 371. The Primary Health care centers are considered the main location for providing EPI.

# 2.2 Sampling

A stratified random sampling technique was used. The first sampling unit consisted of health facilities which were stratified into governmental primary health centers and private dispensaries. We mainly included the middle, northern, eastern, southern and western sectors in Riyadh. A random sample will be taken from these health facilities with a sample size of 80 (40 GPHC and 40 PPHC) calculated by WHO sample size determination.

# 2.3 Data Collection

For data collection, a standardized check list was designed according to cold chain criteria set by the Ministry of Health (MOH) and World Health Organization (WHO) [22,23]. This data instrument was designed both to evaluate cold chain components in each health center and to collect specific information from health workers. It included worker's demographic information such as gender, nationality, place of work, and the duration of experience. The questionnaire also documents the status of EPI vaccination room and refrigerator, temperature monitoring devices EPI vaccines and records. and their management inside refrigerator, EPI vaccine record, management and other operational obtaining permission issues. After from Directorate for the Health affairs of Riyadh, the investigator should visit each health institute to observe and evaluate cold chain in EPI program. Questionnaire had total of 139 questions. A correct answer was given a score of 1 and incorrect answer was given a score of 0. As a result, the maximum score for room and refrigerator assessment was 12, temperature monitoring devices 5, records keeping 3, and maintenance 6. Each criterion's mean score was computed.

## 2.4 Data Analysis

Data were analysed using IBM SPSS Statistics 26 (IBM Inc., Chicago, IL, USA) and IBM SPSS 26 (IBM Inc.). Variables were expressed using descriptive statistics, including frequencies and percentages. Comparison was made for each question in comparison with type of primary health care clinics (government and private), chisquare test was used for this comparison. The significance level was set at p< 0.05.

# 3. RESULTS

Total number of primary health care facilities included in the study was 80 in which 40 were governmental and 40 were from private sector. In both sectors, all health workers in vaccination were females. Furthermore, services in governmental PHC all staff were Saudis while in private PHC all non-Saudis were working in the vaccination services. With regards to years of experience of the workers in relation with the sectors was summarized in Table 1. It was found that 50% (n=20) of the government and 70% (n=28) of the private sector workers had experience up to 5 years while similar percentages both of private and government sector workers had working experience over 6 years 20%(n=08). The pictorial presentation of the distribution of workers according to their years of experience in comparison with sectors were presented in Fig. 1.

Table-1 displayed various elements indicating cold chain performance. The availability of a separate vaccination room was found to be significantly higher in governmental PHCs than in private PHCs (p=0.000). In terms of ventilation availability, a significantly higher proportion of governmental (85%) PHC canters had both AC and ventilators/windows available, compared to (40%) of private centers (p=0.000). All private centers included in the study had only one refrigerator available to store vaccine while 80% of the centers owned by government had two or more refrigerators available. Refrigerators using to store the vaccines in 85% of private centers had both sections (fridge and freezer) while refrigerator using in all government centers were without freezer (p=0.000) hence in government centers facility to keep the vaccine below 2 C° was not available. The possibility of direct sunlight over the refrigerator in government centers (20%) was significantly higher than in private centers (5%) (p=0.000). Furthermore, 75% of government refrigerators and 5% of private refrigerators contained water bottles at a lower level. The P-value was statistically significant (p = 0.000). The mean score for governmental PHC centers was 8.8, while the mean score for private PHC centers was 8.3. which was almost significantly different (p=0.051). A detailed description was given in Table-1.

Table-2 shows the status of different temperature monitoring devices and records at health facilities visited in government and private sectors. In government PHC, 100% of facilities had thermometer to maintain and monitor the temperature of refrigerators while 95% of private PHC had the devices. Regarding placement of thermometer, 90% of government centers placed the thermometer in the shelf while 5% placed in the doors of refrigerators, in private centers 47.4% placed the device in the freezer compartment while 42.1% placed the device in the shelf. The difference was statistically significant with p-value 0.000. Thermometer reading was taken at the time of visit, average reading from government centers was 4.1(±0.97) while from private centers the average reading was 6.1(±2.6). Difference in average readings between government and private centers was found significantly different with p-value 0.005. Overall average score of temperature monitoring device was 3.83(±0.67) which was varying between 0 to 4. The score for governmental PHC centers was 4 and the score for private PHC centers was 3.65, which was statistically significant (p=0.019).

Temperature chart was available in 100% of governmental health facilities and 70% in private health facilities. P-value was significant (p-value

= 0.000). About 95% of governmental health facilities, the number of temperature recorded during last 7 days was 10 or more while in Private 50% of health facilities the number of temperature recorded during last 7 days was 10 or more. P-value was statistically significant (Pvalue = 0.000). In the governmental clinics, 55% recorded the last temperature less than 12 hours ago while in private 50% of the facilities recorded the last temperature less than 12 hours ago. Pvalue was statistically insignificant (p-value = 0.057). Overall average score of temperature chart was 2.18(±0.98) which was varying between 0 to 3. Score for governmental PHC centers was 2.55 and private PHC was 1.8 which was significantly different (p=0.000).

Table-3, showed that, in government PHC, all the visited health facilities had OPV, MMR, BCG, MCV 4. Varicella and Diluents vaccines. 95% had PCV and Measles vaccines. 90% had Hexa and Hepatitis B vaccine, 85% had RV, 80% Hepatitis A. 75% had DTaP and 65% had DT vaccine. While in Private, all the visited health facilities had MCV 4. 85% had MMR and DTaP. 80% had Diluents, 75% had OPV, 60% had Hexa, 40% had Hepatitis B, 25% had BCG, 15% had PCV, measles and DT and only 5% of private PHC had Hepatitis A, RV and varicella vaccines available. Availability of vaccines in comparison to government and private sectors was found significantly different in most of the cases (Table 3A and 3B).

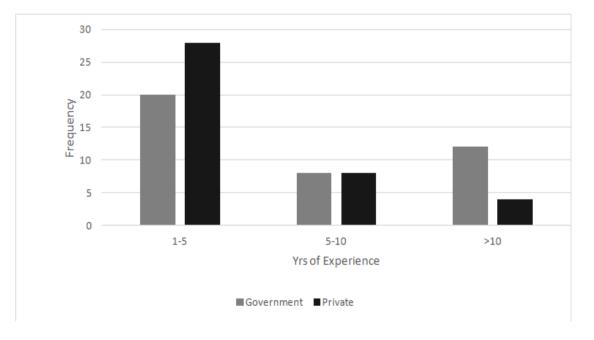


Fig. 1. Years of experience in comparison with type of sector

All the opened vials in both regions meet WHO regulations. Regarding the duration for storing of the vaccine after vial opening which should be 6 hours for OPV and meningitis vaccines, and 24 hours for DPT DT, H1B vaccines, all the visited health facilities apply this role and none of the

opened vaccine kept beyond its time limit. Opened vials of freeze dried vaccines (measles and BCG) once reconstituted must be discarded at the end of each immunization session or at the end of six hours whichever comes first.

Table 1. Room and refrigerator elements affecting the performance of cold chain and their
status at different health facilities participated in the study

Category	Sect	P-value	
	Government No. (%)	Private No. (%)	
Separate Vaccination room a	vailable		
Yes	40(100)	4(10)	0.000*
No	0(0)	36(90)	
Room ventilation available	. ,		
Ac only	6(15)	8(20)	0.000*
Ventilators/window only	0	16(40)	
Both	34(85)	16(40)	
No. of refrigerators available			
One	8(20)	40(100)	0.000*
Two or more	32(80)	0	
Type of refrigerator	( ),		
Refrigerator only	40(100)	6(15)	0.000*
Refrigerator and freezer	0	34(85)	
freezer available to keep vac	cines below 2 C°	· · /	
Yes	0	34(89.5)	0.000*
No	40(100)	4(10.5)	
refrigerator functioning	· · · ·	( )	
Yes	40(100)	40(100)	NA
No	0	0	
Distance from nearest wall (c	m)		
< 30	2(5)	26(65)	0.000*
≥ 30	38(95)	14(35)	
Possibility of direct sun light t			
Yes	8(20)	2(5)	0.000*
No	22(55)	38(95)	
Not sure	10(25)	0(0)	
Refrigerator door closes well	- \ /	- (-)	
Yes	40(100)	40(100)	NA
No	0	0	•
Refrigerator stable while ope	•	-	
Yes	36(90)	34(85)	0.737
No	4(10)	6(15)	
Ice in freezer compartment	.()		
Yes	0	34(85)	NA
No	40(100)	6(15)	
Water bottles present in lowe			
Yes	30(75)	2(5)	0.000*
No	10(25)	38(95)	5.000
Section score		00(00)	
Average (SD)	8.8(±0.82)	8.3(±1.86)	0.051

Category	Sector		
	Government No. (%)	Private No. (%)	_
Thermometer available			
Yes	40(100)	38(95)	0.49
No	0	2(5)	
Quantity			
1	14(35)	38(95)	0.000*
2	26(65)	0	
Location			
Freezer compartment	0	18(47.4)	0.000*
Shelf	38(95)	16(42.1)	
Door	2(5)	4(10.5)	
Thermometer reading	Mean (SD)	Mean (SD)	
Reading 1	4.1(0.97)	6.1(2.6)	0.005*
Reading 2	4.69(1.03)	2.67(1.53)	0.137
Section score			
Average (SD)	4.0(0)	3.65(0.32)	0.019*
Temperature Chart Available			
Yes	40(100)	28(70)	0.000*
No	0 ` ´	12(30)	
When was the last time temperature r	ecorded	. ,	
< 12 hrs	22(55)	20(50)	0.057
> 12 hrs	18(45)	20(50)	
No. of reading last 7days is 10 times of		. ,	
Yes	38(95)	20(50)	NA
No	2 (5)	20(50)	
Section score		. ,	
Average (SD)	2.55(±0.5)	1.8(±1.2)	0.000*

Table 2. Status of different temperature monitoring devices and records in comparison with
health facilities participated in the study

Labelling of vaccine, either in government or private health facilities, was found 100% except OPV. 75% of private centers labelled the OPV whereas 100% government centers had labelled OPV. Regarding the correct location to place the vaccine in refrigerator, which was the first shelf. In government vs private health centers, 80% vs 66.7 of OPV, 30% vs 47.1 of MMR, 45% vs 60% of BCG, 22.2% vs 58.3% of Hexa, 50% vs 25% of Hepatitis B, 37.5% vs 100% of Hepatitis A, 5.9% vs 0% of RV, 15.8% vs 33.3% of PCV, 21.1% vs 50% of measles, 15% vs 10% of MCV 4, 20% vs 100% of Varicella, 60% vs 35.5% of DTaP, 23.1% vs 0% of DT and 5% vs 25% of Diluents vaccines were found in the correct place. Statistical significance in the difference of proportions were added in table 4. Regarding space between vial, in all visited government health facilities, space between the vials was observed. However, over 70% of the visited private health facilities were keeping the vials with proper space in between. Presentation of VVM on polio vaccines was found in all government health facilities and no case of poor

temperature maintenance was indicated by VVM. While, in private, 15 out of 19 (78.9%) of health facilities had VVM available for polio vaccine in which 3 out of 15 (20%) were indicating poor temperature maintenance (Table 2). Overall average score of this section was 39.43(±16.17) which was varying between 14 to 62. Score for governmental PHC centers was 54.25 and private PHC was 24.6 which was significantly different (p=0.000).

Table-4 summarized the results regarding the vaccine stock management, all the visited health facilities in government and private sector had at least one person assigned for EPI cold chain maintenance. In government centers, manual for cold chain was available in 60% of visited centers whereas none of the private center had manual available at the time of visit. Vaccine expiry record was available in all government (100%) facilities while 90% of private health facilities had record for expired vaccines. Similarly, continuous updating of vaccine record was found in all 40 visited government health

Sector	OPV n(%)	MMR n(%)	BCG n(%)	Hexa n(%)	Hep. B n(%)	Hep. A n(%)	RV n(%)	PCV n(%)	Measles n(%)
Available									
Government	40(100)	40(100)	40(100)	36(90)	36(90)	32(80)	34(85)	38(95)	38(95)
Private	30(75)	34(85)	10(25)	24(60)	16(40)	2(5)	12(5)	6(15)	6(15)
P-value	0.001*	0.026*	0.000*	0.004*	0.000*	0.000*	0.000*	0.000*	0.000*
Labelled									
Government	40(100)	40(100)	40(100)	36(100)	36(100)	32(100)	34(100)	38(100)	38(100)
Private	30(75)	34(100)	10(100)	24(100)	16(100)	2(100)	2(100)	6(100)	6(100)
P-value	NÀ	NÀ	NÀ	NÀ	NÀ	NÀ	NÀ	NÀ	NÀ
Location									
Government	32(80)	12(30)	18(45)	8(22.2)	18(50)	12(37.5)	2(5.9)	6(15.8)	8(21.1)
Private	20(66.7)	16(47.1)	6(60)	14(58.3)	4(25)	2(100)	0(0)	2(33.3)	2(50)
P-value	0.001* ´	0.002*	0.264	0.000*	0.15	0.292	0.718	0.364	0.094
Contain sediments									
Government	0	0	0	0	0	0	0	0	0
Private	0	0	0	0	0	0	0	0	0
P-value	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vial Expired									
Government	0	0	0	0	0	0	0	0	0
Private	0	0	0	0	0	0	0	0	0
P-value	NA	NA	NA	NA	NA	NA	NA	NA	NA
Space between vial									
Government	40(100)	40(100)	40(100)	36(100)	36(100)	32(100)	34(100)	38(100)	38(100)
Private	22(73.3)	26(76.5)	8(80)	18(75)	10(62.5)	2(100)	2(100)	4(66.7)	6(100)
P-value	0.001*	0.001*	0.037*	0.003*	0.000*	NA	NA	0.016*	NA
Opened vial									
Government	14(35)	40(100)	0	0	0	0	0	0	0
Private	2(6.7)	34(100)	0	0	0	0	0	0	0
P-value	0.008*	NA	NA	NA	NA	NA	NA	NA	NA

Table 3A. Vaccine status and management inside EPI refrigerator at health facilities participated in study

\*Statistically significant at 0.05 level of significance

Sector	MCV 4 n(%)	Varicella n(%)	DTaP n(%)	DT n(%)	Diluents n(%)
Available					
Government	40(100)	40(100)	30(75)	26(65)	40(100)
Private	40(100)	2(5)	34(85)	6(15)	32(80)
P-value	NA	0.000*	0.402	0.000*	0.005*
Labelled					
Government	40(100)	40(100)	30(100)	26(100)	0
Private	40(100)	2(100)	34(100)	6(100)	4(12.5)
P-value	NA	NA	NA	NA	NA
Location					
Government	6(15)	8(20)	18(60)	6(23.1)	2(5)
Private	4(10)	2(100)	12(35)	0(0)	8(25)
P-value	0.000*	0.108	0.000*	0.154	0.000*
Contain sediments					
Government	0	0	0	0	0
Private	0	0	0	0	0
P-value	NA	NA	NA	NA	NA
Vial Expired					
Government	0	0	0	0	0
Private	0	0	0	0	0
P-value	NA	NA	NA	NA	NA
Space between vial					
Government	40(100)	40(100)	30(100)	26(100)	40(100)
Private	32(80)	2(100)	28(82.4)	6(100)	26(81.3)
P-value	0.005*	NA	0.026*	NA	0.006*
Opened vial					
Government	0	2(5)	6(20)	4(15.4)	0
Private	0	0	0	0	0
P-value	NA	1.00	0.008*	0.566	NA

 Table 3B. Vaccine status and management inside EPI refrigerator at health facilities

 participated in the study

\*Statistically significant at 0.05 level of significance

care centers while 34 out of 40 visited private health facilities were updating the recoding. 14 out of 40 private centers had alternative supply of electricity whereas no government health care center had any alternative supply of electricity (p=0.000). Overall average score of vaccine stock management was  $4.35(\pm 0.73)$  which was varying between 2 to 5. Score for governmental PHC centers was 4.6 and private PHC was 4.1 which was significantly different (p=0.002). Fig. 2 presented the comparison between government and private primary health care clinics average score for each evaluated area.

## 4. DISCUSSION

It has been demonstrated that immunization prot ects patients or individuals from disease through vaccination [24]. Not much literature was identified nationally about Evaluation of the Cold Chain Expanded Program on Immunization Health Care facilities in Saudi Arabia, however, one study reported availability of cold chain tools

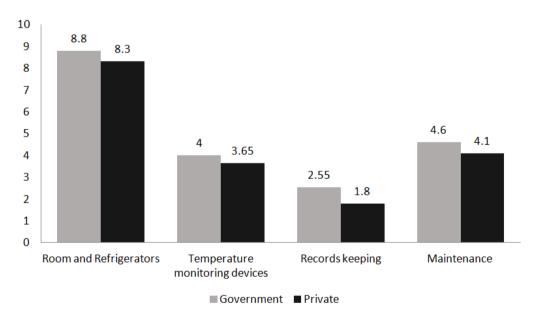
and an assessment of health workers practice in Dammam [25]. The results revealed that Governmental health care centers in this study were found better in terms of availability of separate vaccination room, more space to store the vaccines. availability of temperature monitoring devices and regular monitoring of the temperature and wider range of vaccines in comparison to private health care centers. Furthermore, the average score obtained by government health care centers for each evaluated section was found to be significantly higher than that obtained by private health care centers.

The findings from the current study revealed that all governmental health facilities had separate room for vaccine. Additionally, present study found that GHF had better vaccine monitoring and storage capacity compared to private centers. These results were go with the hand to hand by Mugharbel KM et al study, where results reported that all GHF clinics stored vaccines in a

Category	Sec	P-value	
	Government No. (%)	Private No. (%)	
Number of persons assigne	d for EPI cold chain mainter	nance	
None	0	0	0.000*
One or more	40(100)	40(100)	
Manual for cold chain availa	ble		
Yes	24(60)	0	0.000*
No	16(40)	40(100)	
Vaccine stock register availa	able		
Yes	40(100)	24(60)	0.000*
No	0	16(40)	
Vaccine expiry record availa	ible		
Yes	40(100)	36(90)	0.116
No	0	4(10)	
Records updated			
Yes	40(100)	34(94.4)	0.221
No	0	6(5.6)	
Alternative electric supply			
Yes	0	14(35)	0.000*
No	40(100)	26(65)	
Section score			
Average (SD)	4.6(±0.49)	4.1(±0.84)	0.002*

# Table 4. Vaccine stock management and its operations status in comparison with health facilities participated in study

Statistically significant at 0.05 level of significance



#### Fig. 2. Average score for each evaluated area between government and private clinics

single refrigerator/freezer unit, while Private HC used small personal units contrary to MOH or WHO criteria [25,26]. Although our study findings were better than earlier study by Bogale HA et al in Ethiopia in which 60 health institutions were included, among those over 86% of the facilities did not have separate room for vaccination and to store vaccines, only 46(76.7%) had functional

refrigerators [27]. Preserving a desired temperature in countries such as Saudi Arabia, where temperatures are typically very high for the majority of the year, is a difficult task. In this study score of room and refrigerator assessment for the Government health care facility was 8.8(0.82), which is lower than private health facility 8.3(1.86).

Similarly, the score of temperature monitoring devices found better in Government health care facility in comparsition to private. The current study found very lowest score for the vaccines status and management 54.25(4.9) for government facilities and 24.6(7.4) for private health care facilities (Range 0- 113). Additionally, average score obtained for each evaluated domains of the questionnaires by government health care centers was found significantly higher than private health care centers (p=0.000).

The current findings revealed that monitoring of the temperature in the governmental primary health care clinics are faar better in comparison to private primary health care clinics in the current study. Although these results were similar to previous study by Mugharbel et al, who found that the availability of temperature monitoring devices and storage facilities were better in governmental health facilities compare to private. Furthermore, they also reported that temperature monitoring cards were more up to date in governmental facilities compared to private [25]. In addition, earlier studies conducted in various countries, evidenced that maintaining equipment temperature within the WHO-defined range is not always adhered to [28,29]. As a result, the availability of appropriate refrigerating devices is insufficient, but their continuous monitoring is a major concern.

In this study governmental primary health care clinics was in compliance with the WHO guidelines of cold chain managements, which was comparable to previous studies by Mugharbel et al; while Khan et al reported that differences in the cold chain management federal and district levels [30]. The previous study found Federal and provincial EPI stores had demonstrated better compliance to the standard cold chain practices with an average of 91 % compliance. However, cold chain practices in place at district and sub districts levels EPI stores were observed to be on average 77% and 63 % compliant to the standard guidelines.

In this study the temperature of the refrigerators placed in private health facilities was higher than governmental facilities (p=0.000). Also, upper limit of the class interval obtained from primary health facilities indicated the temperature breach in some of the private clinics. According to WHO guidelines temperature should be maintain between 2 to 8 oC (REF 1). Some studies indicated that temperature breach may affect the safety and efficacy of the vaccines [30-35]. Only 40% of the centers included in the study were measuring temperature twice a day. Previous study from India reported that 60% of centers were implemented regular twice daily temperature monitoring, which was comparable to our findings [36].

Although this study has several limitations. Firstly, the Brand of the temperature monitoring devices was not included in the data, therefore, the sensitivity and accuracy of the devices vary from brand to brand. Secondly, the temperature of the refrigerator was only noted at the time of data collection, if history was taken than variation in the temperature over the period of time would give a different picture. Thirdly the staff knowledge about vaccine handling and management of temperature was not included in the questionnaire.

#### 5. CONCLUSION

Our study highlights the cold chain management programs in private and government facilities in capital of Saudi Arabia. More importantly governmental PHC centers in the current settings comply with the standards to the guidelines, provided by Saudi Ministry of Health and WHO, was observed, in comparison to private PHC centers. Study findings highlighted the need of the training of the staff that would help to improve handling of the immunization room, the monitoring system and keeping the record. In addition, regular visits of ministry of health personnel would help to improve the adherence auidelines regarding of the cold chain management by the primary health care clinics.

#### DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

## CONSENT

Written consent was obtained from participants for participation in this study.

#### ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

#### **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

## RFEFRENCES

- WHO. Immunization, Vaccines and Biologicals: The Expanded Programme on Immunization. WHO. Available:https://www.who.int/immunization /programmes\_systems/supply\_chain/benef its\_of\_immunization/en/ [Accessed 25th October 2020].
- USCIS. Chapter 9 Vaccination Requirement. U.S. citizenship and Immigration Services. Available: https://www.uscis.gov/policymanual/volume-8-part-b-chapter-9 [Accessed 25th October 2020].
- Rodrigue J, Notteboom T. The Cold Chain and its Logistics. The Geography of Transport Systems. Available:https://transportgeography.org/?p age\_id=6585 [Accessed 25th October 2020].
- WHO. Immunization in Practice: A Practical Guide for Health Staff. China: WHO; 2015.
- Kaushik A. Quick Review Series for B.Sc. Nursing: 2nd Year E-Book. India: Elsevier; 2018.
- UNICEF. Procurement Guidelines: Temperature Monitoring Devices. UNICEF supply division. Available:https://www.unicef.org/supply/me dia/4391/file/E006-temperature-monitoringdevices-procurement-guidelines.pdf [Accessed 25th October 2020].
- Organization WH. Global programme for vaccine and immunization:expanded programme on immunization: safe vaccine handling: cold chain and immunizations. Geneva: World Health Organization; 1998;8–21.
- Shah J, Agarwal M, Patel J, Trivedi A. Quality assessment of immunization services: a cross sectional study at UHCs of Ahmedabad municipal corporation. Int J Health Sci Res. 2015;5(7):21–5.

- 9. Hanjeet KLM, Sinniah M, Schnur A. Evaluation of cold chain monitoring in Kelantan, Malaysia. Bulletin of the World Health Organization. 1996;74(4):391-397
- Galazka A, Milstien J, Zaffran M. Thermostability of vaccines: global programme for vaccines and immunization. Geneva: World Health Organization; 1998.
- 11. World Health Organization. Department of Immunization, Biologicals. Immunization in practice: A practical guide for health staff. World Health Organization; 2015.
- Silva E. Development and strategies of the Colombian vaccination program. Clin Infect Dis. 1989;11(Supplement\_3):S505–S6.
- 13. Manual for vaccination room staff ministry of health Kingdom of Saudi Arabia 1426.
- Getting started with VVMs: Questions and Answers on field operations Technical Session on Vaccine Vial Monitors. WHO/ 2002/ Geneva
- 15. Safe vaccine handling, cold chain and Immunizations, a manual for the Newly Independent

States. WHO/EPI/LHIS/98.02.

- 16. Grasso M, Ripabelli G, sam- marco ML, Selvaggi M. Guidelines for Maintaining and Managing the Vaccine Cold Chain. CDC. 2003;52(42):1023–5.
- 17. NPCS Board of Consultants & Engineers. The Complete Book on Cold Storage, Cold Chain & Warehouse (with Controlled Atmosphere Storage & Rural Godowns). India: NPCS; 2019.
- World Health Organization regional office for the Eastern Mediterranean Alexandria, Egypt 1996. Report on the thirteenth intercountry meeting of national managers of the expanded program on immunization. Doha, Qatar ;1996. WHO EM/EPI/118-E/L
- 19. Jahan S, Al-Saigul AM. Primary health care research in Saudi Arabia: A quantitative analysis. Int J Health Sci (Qassim). 2017;11(2):9-15.
- 20. NPCS Board of Consultants & Engineers. The Complete Book on Cold Storage, Cold Chain & Warehouse (with Controlled Atmosphere Storage & Rural Godowns). India: NPCS; 2019.
- 21. Logistics Skill Council (LSC). Cold Chain Manager - Logistics Sector Skill Council. National Skill Development Corporation (NSDC).

Available:https://lsc-

india.com/uploads/nos/ColdChainManager. pdf [Accessed 25th October 20.

- 22. World Health Organization. Safe vaccine handling, cold chain and immunization. Geneva: WHO. 1998.
- 23. Vaccines and biology, Guide line for establishing or improving primary and intermediate vaccine stores. WHO/V&B/02.34.
- 24. Centers of disease control and prevention. vaccines and immunization. Available:https://www.cdc.gov/vaccines/va c-gen/imz-basics.htm. Last accessed on 8/2/2021.
- Mugharbel KM, Al Wakeel SM. Evaluation of the availability of cold chain tools and an assessment of health workers practice in dammam. J Family Community Med. 2009;16(3):83-8. PMID: 23012197; PMCID: PMC3377047.
- 26. Safe vaccine handling, cold chain and immunization. WHO/EPI/LHIS/98.02. [Goo gle Scholar.
- Bogale HA, Amhare AF, Bogale AA. Assessment of factors affecting vaccine cold chain management practice in public health institutions in east Gojam zone of Amhara region. BMC public health. 2019;19(1):1-6.
- Falcón VC, Porras YV, Altamirano CM, Kartoglu U. A vaccine cold chain temperature monitoring study in the United Mexican States. Vaccine. 2020;38(33):5202-11.
- 29. Kartoglu U, Mistien J. Tools and approaches to ensure quality of vaccines throughout the cold chain. Expert Rev Vaccines. 2015;13(7):843–54. Available:https://doi.org/10.1586/14760584 .2014.923761
- Khan A, uz ZAMAN S, Afzaal H, Tariq MH, Khan TM, Bukhsh A. Expanded Program on Immunization (EPI) cold chain practices assessment in Pakistan. Lat. Am. J. Pharm. 2017;36(6):1241-4.

- Wirkas T, Toiklik S, Miller N. A vaccine cold chain freezing study in PNG highlights technology needs for hot climate countries ISSN. 0264–410X. Vaccine. 2007;25(4):691–7. Available:https://doi.org/10.1016/j.vaccine. 2006.08.028.
- 32. Sow C, Schlumberger M, Mireux F, Ouedraogo SM, Betsem E, et al. Challenges of cold chain quality for routine EPI in south-west Burkina-Faso: An assessment using automated temperature recording devices. Vaccine 2018;36(26):3747–55. Available:https://doi.org/10.1016/j.vaccine.

2018.05.062.

 Murhekar MV, Dutta S, Kapoor AN, Bitragunta S, Dodum R, et al. Frequent exposure to suboptimal temperatures in vaccine cold chain system in India: results of temperature monitoring in 10 states. Bull World Health Organ 2013;91(12):906– 13.

Available:https://doi.org/10.2471/BLT.13.1 19974.

- 34. Techathawat S, Varinsathien P, Rasdjarmrearnsook A, Tharmaphornpilas P. Exposure to heat and freezing in the vaccine cold chain in Thiland. Vaccine 2007;25(7):1328–33. Available:https://doi.org/10.1016/j.vaccine. 2006.09.092.
- Yauba S, Joelle S, Jude N, Tracy BO, Marie K, et al. Temperature monitoring in the vaccine cold chain in Cameroon. J Vaccines Vaccin 2018;9(1):384. Available:https:// doi.org/10.4172/2157-7560.1000384.
- 36. Mallik S, Mandal PK, Chatterjee C, Ghosh P, Manna N, Chakrabarty D, et al. Assessing cold chain status in a metro city of India: an intervention study. AfrHealth Sci. 2011;11:128–33.

© 2021 Alqahtani et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

> Peer-review history: The peer review history for this paper can be accessed here: https://www.sdiarticle4.com/review-history/73028