



Temperature Monitoring of Vaccines' Storage Compartments in Different Health Centres and Pharmacies at Karachi, Pakistan

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Research Article

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Abstract

Objective: Invasion of illness due to microbes has now becoming a worst situation for health associated professionals. As a fragile product, its storage and handling should be proper as recommended.

Background: For the prevention and cure of diseases, vaccine has now become a popular tool biosafety. The main aim of the present study was to find out vaccines' storage compartment temperature in different private clinics, hospitals, and community pharmacies in Karachi, Pakistan. The desired potency of vaccines is an integral part for vaccination.

Result: During present study, visited 803 different clinics, centers, and pharmacies and found refrigerator and/or freezers only 491 clinics, centers, and pharmacies. In these 491, 107 private clinics, 9 governmental health care centers, 56 hospital, and 319 community pharmacies had been selected randomly because they kept vaccines. Only 77.19% were positively responds to our survey. The present study prevailed overall 38.52% and 7.32%, refrigerators and freezers had recommended temperature respectively in clinics, pharmacies, and health care centers.

Conclusion: It has been found due to lack of knowledge, insufficient training, importance of cold chain, and above all shortage and/or breakdown of power supply have been played an important role. Based on the present study, it has been forcefully recommended there must be local guidelines or at least national guidelines. It has been tried to enhance the importance of cold chain for vaccines, and endeavor to implement the rules.

Keywords: Vaccines, temperature, storage conditions, pharmacy practices

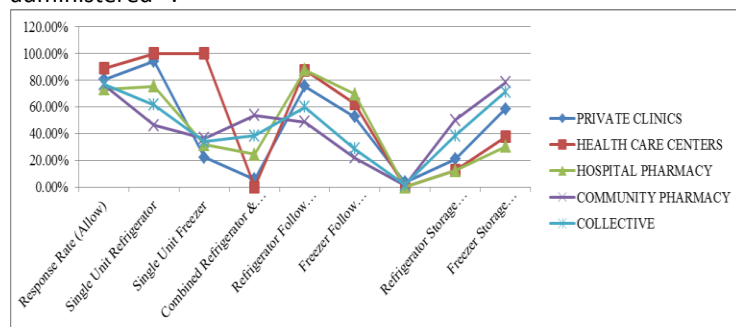
Introduction

Microorganisms are ubiquitous, they are found in food, air, water, soil, pharmaceuticals and even in clean areas in industry¹⁻⁵. The curing and prevention of disease is also a challenging circumstance for health-care professionals. An important factor of biosafety is the continuation of immunity to the individual(s) to inhibit the introduction or increase of disease in the population⁶. The accomplishment of vaccination plan based on to deliver effective vaccine to maximum population⁷. The storage and handling of vaccine should be strictly adhered as recommended by renowned regulatory bodies like Food and Drug Administration (FDA), Centre of Disease Control and Prevention (CDC), Health Canada, World Health Organization (WHO)⁸. The main dilemma of vaccines are biological products, and fragile. They have to be protected from heat and light and should be stored as recommended by manufacturers and national immunization program. Irreversible and permanent loss of vaccine may be caused by exposure of heat and/or light. Usually, the degradation rate of vaccines is directly proportional to the exposure of extreme temperatures. The distribution, transportation, and storage of vaccines should be appropriate from manufacturing until administered to a patient. The influence of vaccine has been lost in extreme heat or cold temperature⁹.

Ambient-temperature, storage of vaccines was used to describe situations in which vaccines were transported or stored without ice, refrigeration, or air conditioning, and thus were exposed to ambient daily temperatures. A temperature-controlled environment used to maintain during storage and distribute vaccines in optimal condition is called the vaccine cold chain. The efficiency of vaccine cold chain has been based on trained personnel; appropriate transportation and storage equipments; efficient management procedures^{10,11}. Vaccine has been degraded with the span of time, but failure to adhere the cold chain requirements may enhance the vaccine degradation. The cost of vaccination has been increased because of revaccination and also lessen the faith of patient on vaccines. Exposure of



vaccine by inappropriate temperature should not be administered¹².



Vaccines may vary in stability with temperature changes. Nearly all the inactivated vaccines has been required refrigerator storage temperatures between 35°F to 46°F (2°C to 8°C), with a desired average temperature of 40°F (5°C). Hepatitis A, hepatitis B, oral polio vaccine (OPV), bacille Calmette-Guerin (BCG) vaccine, measles mumps rubella (MMR) vaccine, pneumococcal vaccine, meningococcal vaccine¹³. Live attenuated vaccines must also be kept at refrigerator temperature like influenza vaccine, rotavirus

refrigerator or freezer compartment. The accuracy of thermometer for observing the temperature of refrigerator and/or freezer should be +/- 1°F (0.5°C). Moreover, digital data loggers may be programmed to record temperatures continuously. CDC has also been suggested to maintain the records for at least 3 years^{16,17}.

In developing countries, ambient temperature has been elevated, for the transportation and storage of vaccines, cold chain has been on high priority¹⁸. The toxiods of diphtheria, and tetanus were stable for months while pertussis vaccine was stable for two weeks at 22°C–25°C. At the same temperature, OPV was lost 50% of its potency after 20 days and freeze dried measles vaccine and hepatitis B were preserved acceptable potency for one month. The chances of loss of potency have been increased significantly by frozen of DTP and hepatitis B vaccines.

Table 1: Observation/Information of Storage of Vaccines

OBSERVATION/INFORMATION	PRIVATE CLINICS	HEALTH CARE CENTERS	HOSPITAL PHARMACY	COMMUNITY PHARMACY	COLLECTIVE
Response Rate (Allow)	86/107 (80.37%)	8/9 (88.89%)	41/56 (73.21%)	244/319 (76.49%)	379/491 (77.19%)
Single Unit Refrigerator	81/86 (94.19%)	8/8 (100%)	31/41 (75.61%)	113/244 (46.31%)	233/379 (61.48%)
Single Unit Freezer	19/86 (22.1%)	8/8 (100%)	13/41 (31.71%)	89/244 (36.46%)	129/379 (34.04%)
Combined Refrigerator & Freezer	5/86 (5.81%)	0/8 (0%)	10/41 (24.39%)	131/244 (53.69%)	146/379 (38.52%)
Refrigerator Follow Recommended Temperature	65/86 (75.58%)	7/8 (87.5%)	36/41 (87.8%)	119/244 (48.77%)	227/379 (59.89%)
Freezer Follow Recommended Temperature	10/24 (52.63%)	5/8 (62.5%)	16/23 (69.57%)	48/220 (21.82%)	79/275 (28.73%)
Refrigerator Storage Temperatures Less Than 2°C	3/86 (3.49%)	0/8 (0%)	0/41 (0%)	3/244 (1.23%)	6/379 (1.58%)
Refrigerator Storage Temperatures More Than 8°C	18/86 (20.93%)	1/8 (12.5%)	5/41 (12.2%)	122/244 (50%)	146/379 (38.52%)
Freezer Storage Temperatures More Than -15°C (-14°C to +2°C)	14/24 (58.33%)	3/8 (37.5%)	7/23 (30.43%)	172/220 (78.18%)	196/275 (71.27%)

vaccine, typhoid vaccine, and yellow fever vaccine. MMRV, varicella, zoster should be kept freezer storage temperatures between -58°F to +5°F (-50°C to -15°C). Most live virus vaccines tolerate freezing temperatures, but deteriorate rapidly after they are removed from storage. Reconstituted lyophilized (freeze-dried) MMR may be frozen or refrigerated. Diluents for reconstituted vaccines should not be frozen and kept in refrigerator or room temperature. The particular diluents of lyophilized vaccines should be used for the same vaccines¹⁴. However, CDC has been recommended use of manufacturer-supplied prefilled syringes for large immunization events and storage. Vaccine has exposed to improper temperatures that is unintentionally administered generally should be repeated¹⁵.

The temperature of the storage compartment can be monitored by thermometer. CDC forcefully recommended the usage of certified calibrated thermometers in the center of

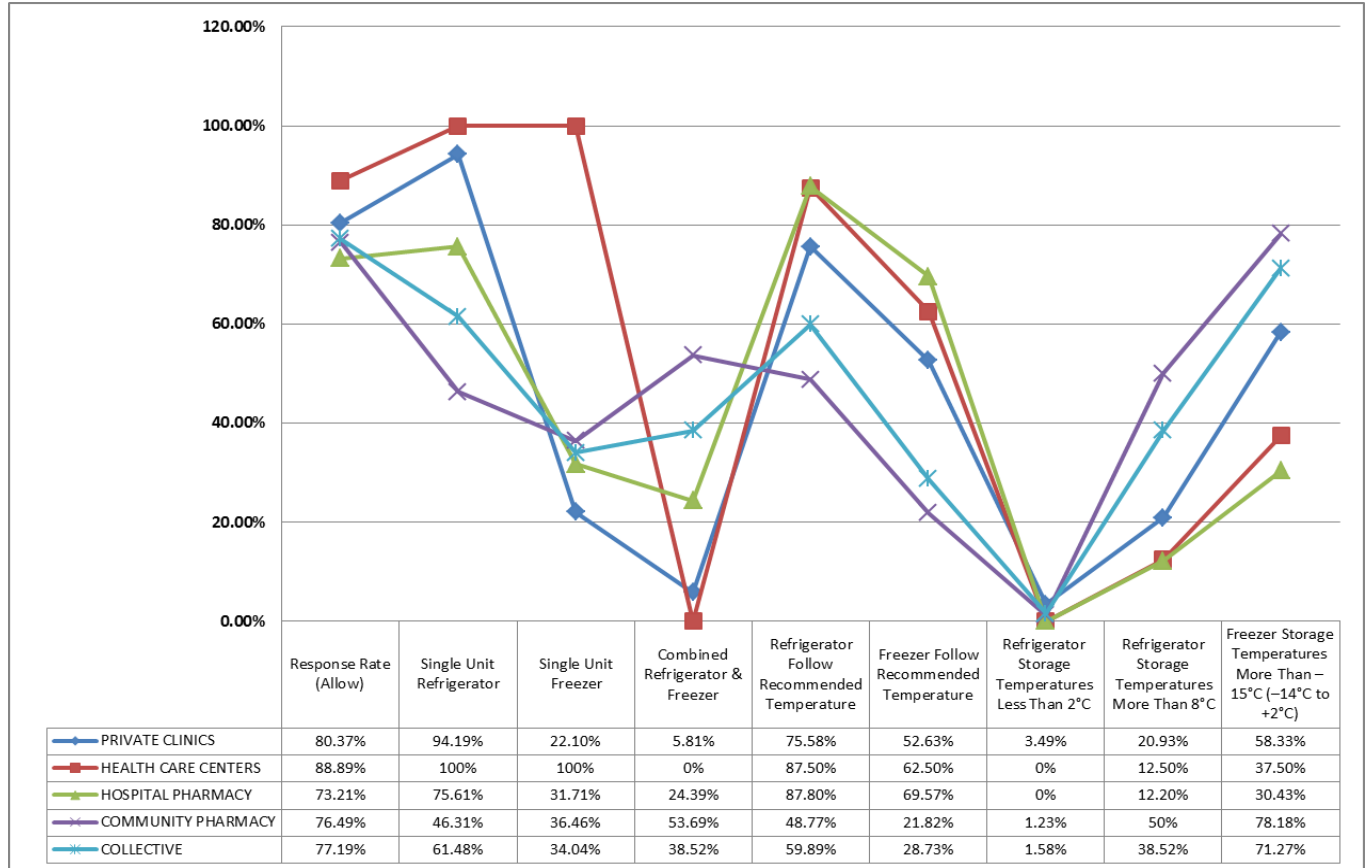
Material and Method

The main aim of the study is to find out the prevalence of storage condition and temperature of marketed vaccines in different private clinics, hospitals, and community pharmacies in Karachi, Pakistan. Our study has been conducted from November 2012 to July 2013. During present study, we had visited 803 different clinics, centres, and pharmacies and found refrigerator and/or freezers only 491 clinics, centres, and pharmacies. In these 491, 107 private clinics, 9 governmental health care centres, 56 hospital, and 319 community pharmacies had been selected randomly because they kept vaccines. During our visit to clinics and pharmacies, digital thermometer (Digi-thermo, Model 15-077-8B, Control Company, Friendswood, TX) has been used



for the measurements of refrigerator and freezer temperatures. For the stabilization of thermometer reading, its metal tipped probe was left 20 min in the centre shelf of storage compartments. The temperature of the refrigerator and/or freezer has been shown on Table 1 and Fig. 1. The handling and knowledge of respondents regarding vaccines by the respondents will be discussed in future.

Fig. 1: Storage of Vaccines in Clinics, Health Care Centres & Pharmacies



The change in the recommended storage temperature decreased the potency which may effect on the efficacy of vaccines. Vaccines were degraded with the span of time, lost their potency. The augmentation in the loss of potency of vaccines, by change in storage condition as recommended. The most suitable temperature for the storage of vaccine is 5°C. The range of recommended

Results

The overall response rate was only 379/491 (77.19%), majority of the respondents were afraid of the misdemeanor because of lack of drug rules implementation in their clinics and pharmacies. During our survey 379 out of 491 has been provided a positive response, 80.37%, 88.89%, 73.21% and 76.49% randomly selected private clinics, governmental health care centers, hospital pharmacies and community pharmacies respectively, cooperated and provided us the information and also grant us permission to visit their vaccine storage refrigerator and/or freezer. We noted vaccine storage areas, 61.48%, and 34.04% were single unit refrigerator and freezer respectively, while only 38.52% were combined refrigerator and freezers. Overall 59.89% refrigerators and 28.73% freezers in clinics, pharmacies and health care centers had the recommended temperature [refrigerator storage temperatures between 35°F to 46°F (2°C to 8°C); freezer temperature between -58°and +5°F (-50°C to -15°C)].

Discussion and Conclusion

temperature of vaccine storage is $\pm 3^{\circ}\text{C}$ (2°C to 8°C). Inactivated virus, pre-filled syringes, viral envelope proteins, toxoids should be kept in refrigerators^{19,20}. Moreover, the recommended temperature of freezer is -50°C to -15°C, live attenuated vaccines are usually suggested to be store in freezers. If the vaccines have not stored at recommended temperature either too cold or hot, the degradation of vaccines has been enhanced²¹.

The present study has shown out of 491 only 379 provided us the positive response and information regarding their storage compartments. It has been collectively found 61.48% single unit refrigerators, 34.04% freezer as single unit, and 38.52% combined refrigerators and freezers. It has been preferred to be stored vaccine in single unit compartment (refrigerator or freezer) instead of combined unit (refrigerator and freezer) as Kimmel²² was also pointed out. All health care centers have both single unit storage compartments and 94.19% and 75.61% single unit refrigerators were found in private clinics and hospital pharmacies respectively. No combined



refrigerator has been found in governmental health care centers, 24.39% found in hospital pharmacy, while 53.69% combined refrigerator and freezers were mainly found in community pharmacy because of cost effectiveness.

Several workers have been proved the loss in the potency of vaccine in extreme cold or hot temperature as compared to their suggested storage temperature²³⁻²⁶. It has been a disgraceful condition ~ 60% refrigerators have controlled temperature, and 28.73% freezers only follow the recommended temperature for vaccines. Approximately 87% health care centers and hospital pharmacies and 75.58% private clinics have recommended temperature for vaccine storage in refrigerators. The half reduction in potency of diphtheria, tetanus and pertussis vaccine (DTP) at temperature 53-55°C after 4 to 8 days, after 80 to 90 days at 45°C, at 35-37°C for 10 to 13 months, and 5 to 7 years at 20-25°C. Similarly, mumps vaccines half potency remained at 45°C, 37°C, and, 23°C for 5, 13, 71 days respectively¹⁰. Measles has been retained minimum potency for more than 2 years at 2 to 8°C²⁷.

The freezer collectively has shown only 28.73% recommended temperature, while 69.57% and 62.5% freezers in hospital pharmacy and health care centers and 52.63% of private clinics freezers have been provided the recommended temperature. It is an alarming circumstance that not only in Karachi but also in Pakistan as reported by several workers²⁸⁻³⁰ that more than 50% community pharmacy respondents were unaware about the cold storage temperature. In the present study, respondents were unaware and did not know about the recommended temperature of vaccines. It has been known DTP vaccines has been kept at -20°C for 15 days 50% potency has been lost¹⁰. In case with BCG vaccine, 80% of potency at 13-15°C at the end of nine months (Bunch, 1981). As we have found around 70% refrigerators were less than 10 years old, and ~ 55% respondents have knowledge about the lyo-degradation of vaccines. 1.58% refrigerators' temperature was less than 2°C, 38.52% refrigerators were more than 8°C in the mean while 71.27% freezers have more than -15°C (-14°C to +2°C). In MMR, the rubella component seems to be more stable than the other components of combined virus vaccines. It can be stored either in freezer or in refrigerator³¹. The main reasons for the increased in temperature of refrigerators and freezers only 12.4% have power substitution for vaccine storage compartments and electricity load shedding and power blackouts have become severe in Pakistan in recent years^{32,33}.

The desired potency of vaccines is an integral part for vaccination. The potency of respective vaccines varies significantly by change in the recommended storage temperature. By the change in potency, vaccines may not be produced the desired preventative assurance. Thus, all vaccine coordinators should have strictly followed the proper storage temperature as recommended by manufacturers and national/local immunization programmes. The problems can be minimized by proper guidelines for the storage and handling; training of staff; and implementations of rules to follow guidelines strictly. An upsetting condition has been

raised on the handling errors of the storage of vaccine. The handling errors and suggestions will be discussed in next part.

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AUTHORS' CONTRIBUTIONS

Authors contributed equally to all aspects of the study.

PEER REVIEW

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests.