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***Original research article***

# Capability of Refrigerators to Control the Cold Chain Temperature for Vaccine Storage

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## ABSTRACT

Proper refrigeration for vaccine storage at the recommended temperature by manufacturers is vital. Most of vaccines should be kept between +2°C and +8°C. This study aimed to compare the capability of different attributes of refrigerators (types, purposes and years of utilization of refrigerator) in controlling temperature for vaccine storage. Data were collected from 155 health care facilities in Bangkok, Thailand. Computerized temperature data loggers, LogTag TRIX-8, were used to continuously monitor temperature. The result shows that different types of refrigerators had different capability, and the pharmaceutical refrigerator had the highest mean of capability at 96.61%; better than household two-door and one-door refrigerator, while the capability of household two-door and one-door refrigerator was not statistically different. The purpose and years of utilization group did not relate to the capability to control temperature. In conclusion, a pharmaceutical refrigerator is ideally recommended if possible. A household refrigerator with single purpose is acceptably used for vaccine storage. Regular maintenance and calibration will keep those refrigerators for sustainable capability in controlling the temperature. The findings can be useful as guidance for health care staff in decision making to choose the refrigerator as well as maintain it for vaccine storage.

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**Keywords:** Capability of refrigerator; Cold chain; Control temperature; Data logger; Vaccine storage

## 1. Introduction

Vaccines are biological products which are sensitive to both heat and cold, thus they need to be stored within a narrow range of temperatures to maintain their quality. The World Health Organization (WHO) recommends that the vaccines storage condition is between +2°C and +8°C, does not allow for refreezing or storage at room temperature. Exposure to extreme heat, cold, or sunlight at any steps in the cold chain system can damage vaccines, resulting in loss of vaccine potency. Consequently, the vaccine will no longer provide any protection against the diseases [1]. According to the WHO-UNICEF Effective Vaccine Store Management Initiative, some key criteria are all vaccines have been stored within WHO recommended temperature ranges; the capacity of cold storage has been sufficient to meet the demand; the buildings, equipment and transport available to the program have enabled the cold store to function effectively; all buildings, equipment and transport have been correctly maintained [2]. Reliable storage and temperature monitoring equipment is one of the main elements for effective cold chain [3].

A number of studies in several countries including Thailand demonstrated the problems in both storage and transport of cold chain system [4-18]. Techathawat et al. [9] monitored temperature during both storage and transport of vaccines among 48 routes across Thailand and found inappropriate temperatures at all levels (regional, provincial, district, and health center). Pumtong et al. [12] also reported that only 14 out of 590 vaccine shipments (2.4%) in 8 provinces were between +2°C and +8°C throughout the shipments. Nualdaisri et al. [11] monitored the temperature of cold chain system in district (9 hospitals) and sub-district stores (44 health centers) in the south of Thailand. The collected data from the fridges revealed that 60% of them were in a normal range of temperature (+2°C to + 8°C). The range of temperature among health centers was between -7.1°C and +26.7°C. McCollostter and Vallbona [20] conducted the study in the United States to quantify the cold chain failure in the refrigerators and found that almost half maintained a stable temperature (+2°C to +8°C). A failure of the cold storage comes from several reasons, such as wrong storage, storage at the wrong temperature range, broken fridge and old equipment [12, 18]. Both pharmacists and health care officers in Thailand have attempted to develop the methods of packaging and transportation for vaccine delivery in order to assure the quality of vaccine [13-14, 17]. After delivery, all vaccines should be stored in a refrigerator or freezer that is designed specifically for the storage of vaccine. There should be sufficient space around the vaccine packages to allow air circulation, and without them touching the side and back walls of the fridge. According to the Standard Operating Procedure on Vaccine Inventory and Storage 2013 by Department of Disease Control, Thailand [19], a refrigerator for single purpose to keep vaccine is recommended at the warehouse and health care facility where providing vaccination. However, their specifications are different. There must be, at least, one fridge with two-door, opaque door, separate fridge/freezer +2°C to +8°C range, and capacity storage not less than 18 $ft^3$ (590.4 $dm^3$) at the warehouse. For the health care facilities, the fridge should be either one-door or two-door, opaque door, separate fridge/freezer +2°C to +8°C range, and capacity storage not less than 5 $ft^3$ (140.1 $dm^3$).

Previous descriptive studies investigated the number, age, type, brand and model of refrigerators used in the health care facilities [13-14, 20]. Some monitored the temperature in the refrigerator compartments [11, 21]. However, none of the reviewed studies on the association between the capability to control temper-

ature of refrigerators and their attributes was found. This research aimed to compare the capability of refrigerators to control temperature for cold chain vaccine storage between household and pharmaceutical refrigerators, purposes of refrigerator as single purpose for vaccine storage and multipurpose use, and among years of utilization.

## 2. Materials and Methods

This study was a cross-sectional analytical research.

### 2.1 Study population and sampling

Sample size determination

$$[22]\ n = \frac{NZ^2pq}{d^2(N-1) + Z^2pq}$$

p = 0.6, q = 0.4, d = 0.05, Z = 1.96, N = 255

The sample size was 150 plus 20%, just in case the health facilities would not be willing to participate in the study. So, the total was 180. A stratified random sampling and quota sampling were used (table 1). One hundred fifty-five out of 180 were willing to participate in the study. Each health facility kept vaccine in one refrigerator. Thus, that refrigerator was used for collecting data. (Table 1)

**Table 1**. Characteristics of health care facilities participated.

| Type of health care facilities | Total | No of sample |
|---|---|---|
| Public hospital | 22 | 14 |
| Public health center | 68 | 35 |
| Private hospital | 18 | 12 |
| Private primary care clinic | 147 | 94 |
| **Total** | **255** | **155** |

### 2.2 Data collection

Data were collected between September and November, 2012. A computerized temperature data logger was placed at the center of refrigerator compartment and continuously monitoring every 5 minutes for at least 7 days in each health care facility. Total 34 data loggers were used to collect the temperature among 155 health care facilities. These data loggers generated the reference temperature in each refrigerator. The accuracy of the computerized temperature data logger, LogTag TRIX-8, is ± 0.5°C (resolution = 0.1°C and measurement range between -40 to +85°C).

### 2.3 Data analysis

Dependent variable was the temperature recorded by data logger. There were three independent variables:

types of refrigerators recorded from observation (4 types; pharmaceutical refrigerator, household one-door, household two-door, and others)

years of utilization of refrigerators recorded from the health facility document (2 groups; 0-5 years, and more than 5 years)

purposes of refrigerators recorded from observation (2 groups; single-purpose and multipurpose)

Percentage of capability to control cold chain temperature was calculated as:

$$= \left(\frac{\text{no. of recorded temperatures within 2 to 8°C)}}{\text{no. of total recorded temperatures during the observation}}\right) \times 100$$

The 'capability to control' is the capability of the refrigerator to keep the temperature between +2 to +8 °C. In this study, the data logger was placed in the refrigerator compartment for 7 days, recorded every 5 minutes, so totally there were 2,016 records per site. Therefore, 100%'capability to control' means all 2,016 records were between +2 to +8 °C.

The collected data were calculated and analyzed by Microsoft Office Excel 2007 and SPSS program version 18.0. Descriptive statistics (frequency, percent-tage, mean and standard deviation) and inferential statistics (independent samples t-test and the one-way analysis of variance) were used in data analysis. A level of significance sets at 0.05.

The study was considered for exemption by Faculty of Dentistry/ Faculty

of Pharmacy, Mahidol University, Institutional Review Board.

## 3. Results and Discussions

Three attributes were studied to compare the capability to control cold chain temperature between +2 to +8°C: types of refrigerators, purposes of refrigerators, and years of utilization of refrigerators.

### 3.1 Types of refrigerators and the capability to control cold chain temperature between +2 and +8°C

The refrigerators used for vaccine storage among health care facilities in Bangkok were grouped into 4 types; pharmaceutical refrigerator, household two-door, household one-door, and others (minibar and cold room). It was found that refrigerator types of household two-door, household one-door, and pharmaceutical fridge were used at 61.29%, 27.0%, and 8.38% respectively. The capability to control temperature within the range +2 to +8 °C of each refrigerator type shows in table 2. Approximately 23% of pharma-ceutical fridges could maintain the temperature between +2 and +8°C at all time (100%), while 69.23% could do at 99-70% of time observed. Only one refrigerator worked less than 70% and none were less than 20%, while 14.74% two-door and 21.43% one-door type worked properly less than 20% (Table 2). The mean of the percentage of the capability to control temperature of each refrigerator type were calculated and compared. The result shows that different types of refrigerators had different capability ($p$ = 0.037) (Table 3). A difference was found between pharmaceutical refrigerator and household one-door ($p$ = 0.028) (Table 4).

### 3.2 Purposes of refrigerators and the capability to control cold chain temperature between +2 and +8 °C

It was found that 86.45% of the refrigerators were used for multipurpose or stored both vaccines and medicines, and 13.55% used for vaccine storage only or single purpose. Regarding the capability to control temperature, 28.57% of single purpose and 20.15% of multipurpose refrigerators could control the temperature at all time (100%), 15.67% of multipurpose refrigerators could control the temperature less than 20% (Table 5).

When compared the mean of the percentage of the capability to control temperature by independent samples t-test, there was no statistically significant difference ($p$ = 0.051) (Table 6).

### 3.3 Years of utilization of refrigerators and the capability to control cold chain temperature between +2 and +8 °C

It was found that 69.03% of the refrigerators were used by 0-5 years, but only 21.5% could control the temperature at all time (100%), while 17.76% could control the temperature less than 20% (Table 7).

When the years of utilization of refrigerators were grouped as 0-5 years and over 5 years, and then compared the mean of the percentage of the capability to control temperature, there was no statistically significant difference ($p$ = 0.187). Thus, the refrigerator age did not relate to the ability to control temperature (Table 8).

**Table 2.** The capability to control cold chain temperature between 2-8°C among types of refrigerators.

| Types of refrigerators | Number (%) | Capability to control cold chain between 2-8°C | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100% | | 99-70% | | 69-20% | | <20% | |
| | | n | % | n | % | n | % | n | % |
| Pharmaceutical refrigerator | 13 (8.38) | 3 | 23.08 | 9 | 69.23 | 1 | 7.69 | 0 | 0.00 |
| Household two-door | 95 (61.29) | 20 | 21.05 | 44 | 46.32 | 17 | 17.89 | 14 | 14.74 |
| Household one-door | 42 (27.09) | 8 | 19.05 | 16 | 38.10 | 9 | 21.43 | 9 | 21.43 |
| Others (Cold room, small refrigerator) | 5 (3.22) | 2 | 40.00 | 2 | 40.00 | 1 | 20.00 | 0 | 0.00 |

**Table 3**. Means Comparison of the capability to control cold chain temperature between 2-8°C among types of refrigerators.

| Types of refrigerators | n | Mean of capability to control cold chain between 2-8°C ± SD | *p-value* |
|---|---|---|---|
| Pharmaceutical refrigerator | 13 | 96.61±8.27 | 0.037* |
| Household two-door | 95 | 73.91±35.88 | |
| Household one-door | 42 | 67.37±35.88 | |

ANOVA, *$p < 0.05$

**Table 4.** A post-hoc comparison of the capability to control cold chain temperature between 2-8°C between each pair of refrigerator type.

| Types of refrigerators | *p-value* |
|---|---|
| Pharmaceutical fridge - Household two-door | 0.081 |
| Pharmaceutical fridge - Household one-door | 0.028* |
| . Household two-door - Household one-door | 0.581 |

*$p < 0.05$

**Table 5.** The capability to control cold chain temperature between 2-8°C among purposes of refrigerators.

| Purposes of refrigerator | Number (%) | Capability to control cold chain between 2-8°C | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100% | | 99-70% | | 69-20% | | <20% | |
| | | n | % | n | % | n | % | n | % |
| Single purpose for vaccines | 21 (13.55) | 6 | 28.57 | 11 | 52.38 | 2 | 9.52 | 2 | 9.52 |
| Multipurpose for vaccines and drugs | 134 (86.45) | 27 | 20.15 | 60 | 44.78 | 26 | 19.40 | 21 | 15.67 |

**Table 6.** Means Comparison of the capability to control cold chain temperature between 2-8°C among purposes of refrigerators.

| Purposes of refrigerators | n | Mean of capability to control cold chain between 2-8°C ±SD | *p-value* |
|---|---|---|---|
| Single purpose for vaccines | 21 | 86.70 ± 28.24 | 0.051 |
| Multipurpose for vaccines and drugs | 134 | 72.65 ± 36.45 | |

Independent t-test, $p < 0.05$

**Table 7.** The capability to control cold chain temperature between 2-8°C among years of utilization of refrigerators.

| Years of utilization of refrigerators | Number (%) | Capability to control cold chain between 2-8°C | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 100% | | 99-70% | | 69-20% | | <20% | |
| | | n | % | n | % | n | % | n | % |
| 0 – 5 years | 107 (69.03) | 23 | 21.50 | 46 | 42.99 | 19 | 17.76 | 19 | 17.76 |
| More than 5 years | 48 (30.97) | 10 | 20.83 | 25 | 52.08 | 9 | 18.75 | 4 | 8.33 |

**Table 8.** Comparison means of the capability to control cold chain temperature between 2-8°C among years of utilization of refrigerators.

| Ages of refrigerator | n | Mean of capability to control cold chain between 2-8°C ± SD | *p-value* |
|---|---|---|---|
| 0-5years | 107 | 72.18±37.39 | 0.187 |
| More than 5 years | 48 | 79.86 ±31.31 | |

Independent t-test, $p < 0.05$

## 4. Discussion

Analysis of temperature monitoring for vaccine storage in this research is different from other previous researches which reported the ranges of temperature in the refrigerators [11-17]. The capability of refrigerators to control temperature is another perspective to assess and compare the quality of the refrigerators among different attributes.

Refrigerators typically used for vaccine storage are available in different types (pharmaceutical, household one-door and two-door). According to the Vaccine Storage & Handling Toolkit 2016 by Centers for Disease Control and Prevention (CDC), a pharmaceutical refrigerator is recommended for storage of vaccines. If the pharmaceutical refrigerator is not available, a stand-alone freezer and a stand-alone refrigerator is acceptable. In case of using a household fridge with a combination refrigerator/freezer unit, only the refrigerator compartment is used for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. Thus, there should be a separate stand-alone freezer to store frozen vaccines [3]. In Thailand, both pharmaceutical and household fridges are acceptably used for vaccine storage in the health care settings. This study found that only 8.38% of refrigerators were pharmaceutical grade, and more than 90% were household refrigerators either one-door or two-door type. Previous research showed that 42% - 75% of health centers and hospitals used household fridges with one-door [11-12, 14]. The reasons to explain this fact are a limited budget and the small quantity of vaccines in the facilities. The results showed that the efficacy to control the temperature between +2 and +8 °C by pharmaceutical refrigerators are better than household

refrigerators, whereas two-door and one-door refrigerators have the same capability. So, it can be concluded that whenever possible the pharmaceutical refrigerators should be used to store vaccine for better cold chain management.

A refrigerator, as a single purpose, for vaccine only is recommended as shown in the SOP on Vaccine Inventory and Storage 2013 [19]. However, most of the refrigerators at the sample sites stored not only vaccines but also other cold medicines. The frequency of opening the doors was higher than those storing only vaccines. This behavior tends to deteriorate the capability of the refrigerators to control temperature, which suggests that the single purpose refrigerator (vaccine only) can control the temperature better than the multipurpose refrigerator. Points of recording by data logger might be out of the range (2-8°C) in some events, such as door opening for a long time, power outages, or having some accidents. In such cases, when data logger alerted or alarmed, health care staff might take correction actions, and then the temperature of refrigerator could be resilient. This can cause the refrigerators have the capability to control temperature between 2-8°C less than 100%. According to this research, years of utilization of refrigerator, whether more or less than 5 years old, do not relate to the capability to control temperature for cold chain. This is contrast to the study by Nualdaisri [11]. Some of new refrigerators cannot control the temperature as expectation. This finding implied that if old refrigerators had good maintenance, they still worked well, since 100% capability to control temperature could be found among refrigerators older than 5 years. The maintenance system plays an important role to keep all types and all ages of refrigerators for proper working condition. Monitoring equipments, such as a digital data logger, could help continuously monitor temperature of refrigerator. This could provide detailed information on all temperatures recorded at preset intervals. The current standard of twice-daily readings from thermometers may not be adequate to maintain proper vaccine storage. Therefore, the use of the digital data loggers should be used in the household fridges.

Findings from this study could be useful for health organizations, such as Department of Disease Control, Provincial Public Health Office, and hospitals, as guidance in order to consider the type, purpose and years of utilization of refrigerators in that they should suggest the health facilities for vaccine storage. Generalization should be made cautiously as this study conducted in Bangkok.

## 5. Conclusion

This research proposed a new indicator, capability to control temperature, as a mean to compare the quality of refrigerators. Good vaccine storage practice is essential. This study would assist the health care facilities to the find proper type of refrigerator suitable for vaccine storage. A pharmaceutical refrigerator is ideally recommended if possible. A household refrigerator with single purpose is acceptably used for vaccine storage. Regular maintenance and calibration will keep those refrigerators for sustainable capability in controlling the temperature. Furthermore, a temperature monitoring device, such as digital data logger, is suggested for a household refrigerator.

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