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Original Article

REAL TIME COLD CHAIN MONITORING OF SIMULATED VACCINE DISTRIBUTION

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ABSTRACT

Objective: The objective of this study was to monitor the real time cold chain of simulated vaccine distribution using data logger in different environmental temperature and the effect of non-conditioning ice packs on cold chain.

Methods: The six non-conditioning ice packs were packed in foam box with standard procedure. The LogTag temperature recorder was put in packed foam box to simulate the vaccine distribution. The packed foam box was stored in stability chamber in different temperature; 25, 35, and 45 °C. The lowest temperature, freezing time, and cold chain breakdown duration was recorded. Furthermore, the effect of conditioning ice packs on duration of cold chain (2-8 °C) was performed follow the previous experiment but the ice packs were conditioned before use.

Results: The non-conditioning ice pack played a hazardous effect on cold chain, approximately 5-6 hours of freezing of the vaccine was observed. The lowest temperatures were -9.67±4.63, -10.70±4.67, and -15.80±3.70 °C and the cold chain breakdown duration were 72.28±0.70, 47.36±2.55, and 42.33±0.58 hours for environmental temperature of 25, 35, and 45 °C, respectively. For conditioning ice packs, the result showed that the duration of cold chain were 5.22±0.41, 3.83±0.63, and 3.64±0.59 hours for environmental temperature of 25, 35, and 45 °C, respectively.

Conclusion: The non-conditioning ice pack played a negative role on cold chain system. The cold chain breakdown duration was temperature dependent manner; the lower environmental temperature took longer cold chain breakdown duration. For conditioning ice packs, the duration of cold chain depended on environmental temperature. In conclusion, the conditioning of ice packs was very important. Furthermore, the duration of cold chain was vulnerable to determination of the vaccine transportation to maintain vaccine efficacy.

Keywords: Cold chain, Vaccine, Data logger.

INTRODUCTION

Immunization, generally by the administration of vaccine, is a procedure whereby a person is made immune against infectious diseases or illnesses. Vaccines stimulate both local and systemic immune systems to prevent the person resistant to infection. Vaccine is one of the most cost-effective methods for controlling and eradicating life-threatening infectious diseases and is estimated to protect between 2 and 3 million deaths each year [1, 2].

The cold chain is a system of transporting and storing vaccines within a suggested temperature ranged of 2 to 8 °C. This temperature range has been carefully chosen by the World Health Organization as a guide to care for vaccines against loss of vaccine potency due to excessive cold or heat outside the required temperature [3]. This definition includes all of the materials, equipment, and processes used to maintain vaccines in the required temperature range from the time of production until the vaccines are administered to people [4]. Significant changes in the stability profile may occur following introduction of temperature fluctuations during in transportation, handling, or storage conditions [5]. All vaccines are thermolabile and need to be suitably stored and distributed within a well-organized cold chain system [6].

The recommended vaccines require storage temperature of 2 to 8 °C and must not be exposed to freezing temperatures. The potency of vaccines is irreversibly decreased under freezing temperatures and increased risk of vaccine-preventable diseases. Aluminum adjuvant-containing vaccine will be precipitated or bond breaking if it contacts freezing temperature [7]. In 2007, there are systematic review studied the risk of accidental freezing of vaccines during transportation and storage. The results show that the exposures of vaccine to freezing temperatures are 14 to 35% of refrigerators or transport shipments. In addition, this event is less found in developed countries [8]. The vaccines must be avoid freezing temperature including diphtheria toxoid, hepatitis A, hepatitis B, influenza, *Haemophilus in fluenzae*type b (Hib), pertussis, pneumococcal conjugate, polio virus (inactivated), tetanus toxoid, typhoid (inactivated), or combinations containing these vaccines [9, 10].

Thailand climate is a tropical with average temperature about 27 °C. However, the temperature is varied depending on location and season. The temperature on a summer afternoon may be risen to 40 °C or higher is recorded as hot days, especially in April. The Thai Meteorological Department reports the extreme maximum temperature during summer in Thailand among 1951-2012; Uttaradit province has the highest temperature, 44.5 °C in April 1960 [11]. Thus, the distribution of vaccine to the various hospitals or primary care units should be concerned about the delivery process to avoid neither high temperature nor freezing temperature that make cold chain to break down. The objective of this study was to monitor the real time cold chain of simulated vaccine distribution using data logger in different environmental temperature and the effect of non-conditioning ice packs on cold chain.

MATERIALS AND METHODS

Effect of non-conditioning ice packs on the lowest temperature, freezing time, and cold chain breakdown duration

The six of 19.3 cm × 23.0 cm × 4.5 cm (width × length × thickness) ice packs were frozen at -20 °C for 48 hours before use and then immediately packed into the 25.0 cm × 34.5 cm × 28.7 cm (width × length × height) with 2.7 cm thick wall foam box follow standard procedure without the conditioning of ice packs. The LogTag temperature recorder (Log Tag Trix-8, Biogenetech co., Ltd., New Zealand) was put in zip bag and then put in plastic box. After that, the packed Log Tag temperature recorder was put into the center of prepared foam box and sealed with adhesive tape. This packing procedure was simulated the routine vaccine delivery. The foam box was stored in stability chamber (Memmert, Germany) in different temperature; 25, 35, and 45 °C. The temperature recorder was set up to read every 5 minutes and the data were immediately collected after the start button was pressed. The lowest temperature was recorded. Furthermore, duration from first reading to the time that

temperature reached 0 °C was recorded as freezing time (hours). Duration from first reading to the time that temperature reached 2 °C was recorded as cold chain breakdown duration (hours). Each test was performed in triplicate.

Determination of the duration of cold chain

This method was set up the same as previous method. However, before pack the ice packs into the foam box, the frozen ice packs were kept in ambient temperature until the drop and dissolved ice occurred called conditioning ice packs.

The different environmental temperatures; 25, 35, and 45 °C were compared. The temperature recorder was set up to read every 5 minutes and the data were immediately collected after the start button was pressed. Duration of cold chain in hours was recorded.. Each test was performed in triplicate.

RESULTS AND DISCUSSION

The appropriate temperature for vaccine delivery or transporting should be in the ranged of 2 to 8 °C [3]. The conditioning of ice packs for delivery the vaccine is very important to maintain the cold chain. However, the ice packs that were packed into the foam box without conditioning are usually observed, especially in non-trained personnel or in urgent situation. Furthermore, the non-conditioning ice packs may cause accidental freezing of vaccine and cold chain breakdown. The vaccine that contacts the freezing temperature for a long time causes the vaccine potency decreased [7]. In this study, we observed that the non-conditioning ice pack that immediately packing into foam box play a hazardous effect on cold chain. Freezing of the vaccine was observed, approximately 5-6 hours and the observed lowest temperature were -9.67±4.63, -10.70±4.67, and -15.80±3.70 °C for environmental temperature of 25, 35, and 45 °C, respectively. This phenomenon could destroy the potency of the vaccine was especially important for adjuvant-containing vaccine, since it dissociated the antigen from the adjuvant alum interfering with the immunogenicity of the vaccine [7]. Furthermore, cold chain breakdown duration, the duration that temperature out of 2 to 8 °C, the very long time of cold chain breakdown was occurred. The cold chain breakdown duration were 72.28±0.70, 47.36±2.55, and 42.33±0.58 hours for environmental temperature of 25, 35, and 45 °C, respectively. The phenomena were temperature dependent manner, the lower environmental temperature caused more cold chain breakdown duration (Table 1).

Table 1: The lowest temperature, freezing time and cold chain breakdown duration at various environmental temperatures

Environmental temperature (°C)	The lowest temperature (°C)	The freezing time (h)	Cold chain breakdown duration (h)
25	-9.67±4.63	5.78±1.71	72.28±0.70
35	-10.70±4.67	4.81±1.41	47.36±2.55
45	-15.80±3.70	5.92±0.30	42.33±0.58

Data represent as mean±SD (n=3)

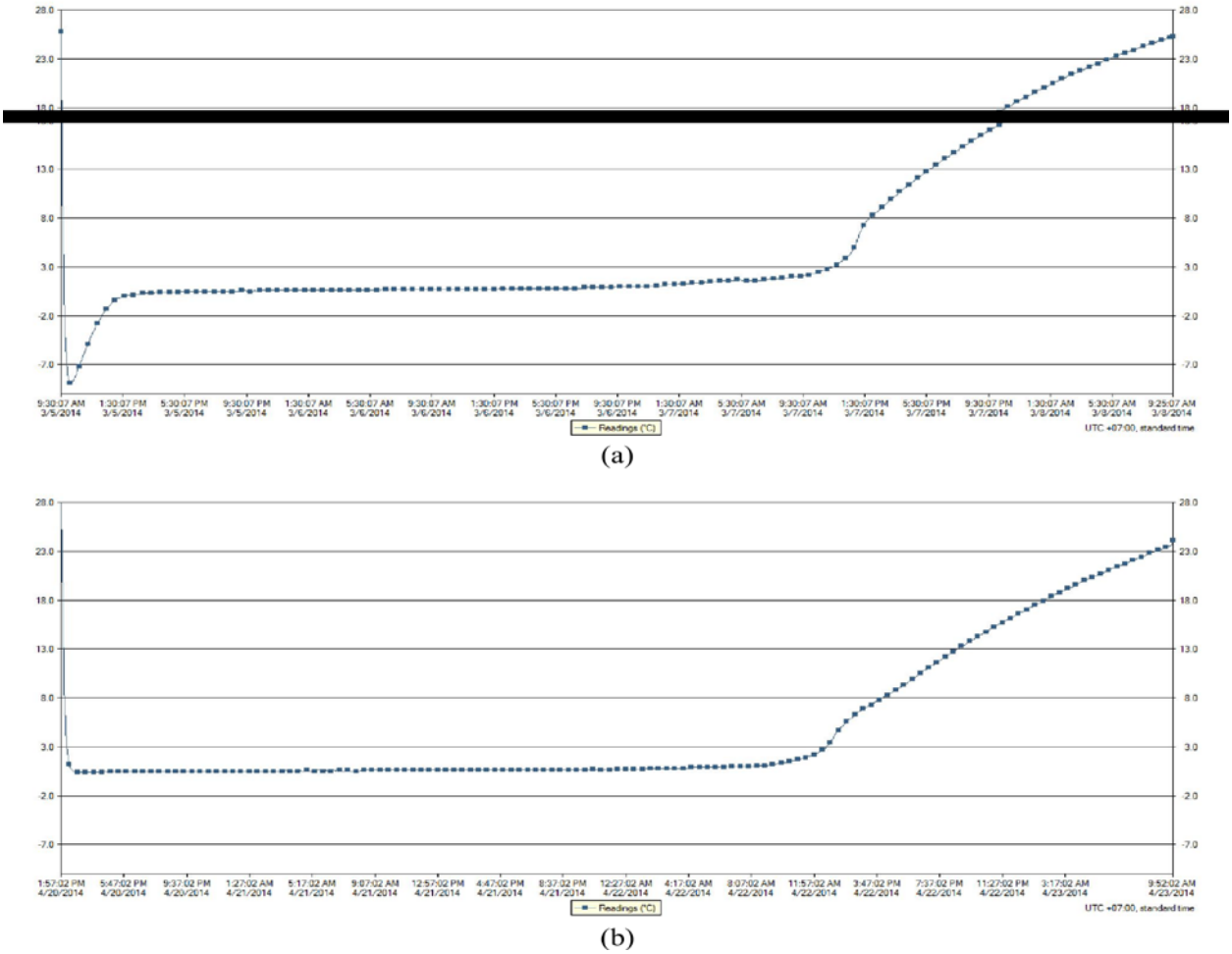

Fig. 1: Pattern of temperature change during real time monitoring at 35 °C (a) non-conditioning and (b) conditioning

This result showed that the conditioning of ice packs before packing into foam box for vaccine transportation was very important to prevent the cold chain breakdown and freezing of the vaccine during vaccine transportation. The Bureau of Communicable Diseases. Department of Disease Control, Ministry of Public Health of Thailand set up the standard of cold chain management system. This manual suggested that the ice pack should be conditioning before use by keeping it at ambient temperature until the drop and dissolved ice occurred [12]. The pattern of temperature change during real time monitoring at 35 °C showed in Figure 1a,b. The same patterns of temperature change were found in the other two environmental temperatures (data not shown). The pattern of temperature change of system that packing with non-conditioning ice packs had 3 stages.

The first stage, the temperature decreased to the lowest temperature after that the temperature was increased (lower than 0 °C), the second stage, the temperature constant for a long time (higher than 0 °C), and the last stage, the temperature gradually increased until the end of experiment (Figure 1a). But, the pattern of temperature change of system that packing with conditioning ice packs had only 2 stages. The first stage, the temperature constant for a long time (higher than 0 °C), and the second stage, the temperature gradually increased until the end of experiment (Figure 1b). However, the less conditioning time, the temperatures lower than 0 °C still occurred. Our colleague observed the temperature of system packing with non-conditioning and conditioning ice pack had the same temperature among the temperature in the constant stage, approximately 0.4-0.6 °C. This result revealed that conditioning of ice packs cannot avoid the cold chain breakdown because it out of the ranged of 2-8 °C, but it could avoid the freezing of vaccine. The conditioning time should be further optimized to make the system maintain the temperature at 2 °C to avoid cold chain breakdown.

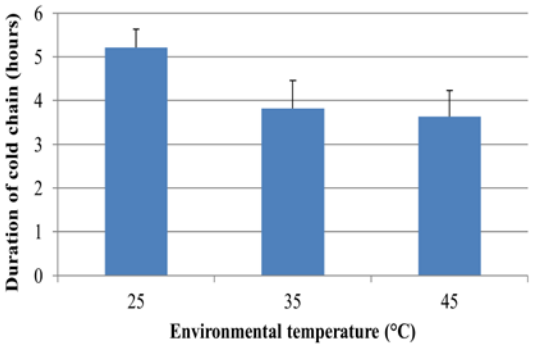

Fig. 2: Duration of cold chain at various temperatures (conditioning ice packs)

Duration of cold chain determination is necessary because it will indicate the maximum duration that is transport vaccine. The longer duration of cold chain system had more time of the transportation. In the other hand, the shorter duration of cold chain, the less time for transportation. This study varied the three environmental temperatures to determine the cold chain duration. The result showed that the duration of cold chain were 5.22±0.41, 3.83±0.63, and 3.64±0.59 hours for 25, 35, and 45 °C, respectively (Figure 2).

When the temperature of vaccine delivery was 25 °C, the transportation of vaccine should be already finished within approximately 5 hours. Conversely, if the temperature of vaccine delivery was reached 35 or 45 °C (transportation with vehicles that without the controlling of temperature), the transportation of vaccine should have finished within approximately 4 hours. However, the application of these results cannot be extrapolated to the other size of foam box, size of ice packs, and packing procedure.

CONCLUSION

The non-conditioning ice pack play a negative role on cold chain system, the freezing was observed for more than 5 hours for all environmental temperature. The cold chain breakdown duration was temperature dependent manner; the lower environmental temperature caused higher cold chain breakdown duration. For conditioning ice packs, the durations of cold chain were approximately 5, 4, and 4 hours for environmental temperature of 25, 35, and 45 °C, respectively. These results were valuable for transportation of vaccine in specific foam box, prevention of a cold chain breakdown resulting to maintain the vaccine potency.

REFERENCES

1. World Health Organization. Immunization [internet]. [cited 2014 Jan 13]. Available from: http://www.who.int/topics/immunization/en/
2. Armstrong EP. Economic benefits and costs associated with target vaccinations. Journal of managed care pharmacy : JMCP 2007;13(7 Suppl B):S12-5.
3. Australian Department of Health. Vaccine cold chain guidelines [internet]. [cited 2014 Jan 12]. Available from: http://www.health.wa.gov.au/CircularsNew/attachments/623.pdf
4. Ontario. Vaccine storage and handling guidelines [internet]. [cited Jan 12]. Available from: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/guidance/guide_vaccine_storage.pdf2014.
5. World Health Organization. Stability of vaccines [internet]. [cited 2014 Jan 12]. Available from: http://www.who.int/biologicals/vaccines/stability_of_vaccines_ref_mats/en/index.html.
6. World Health Organization. Vaccine cold-chain management [internet]. [cited 2014 January 12]. Available from: http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/vaccines-and-immunization/learn-more-about-vaccines/vaccine-quality-and-safety/vaccine-cold-chain-management.
7. The United States Centers for Disease Control and Prevention. Guidelines for maintaining and managing the vaccine cold chain [internet]. [cited 2014 Jan 12]. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5242a6.htm.
8. Matthias DM, Robertson J, Garrison MM, Newland S, Nelson C. Freezing temperatures in the vaccine cold chain: a systematic literature review. Vaccine 2007;25(20):3980-6.
9. Chen D, Tyagi A, Carpenter J, Perkins S, Sylvester D, Guy M, et al. Characterization of the freeze sensitivity of a hepatitis B vaccine. Human vaccines 2009;5(1):26-32.
10. World Health Organization. Aide-memoire for prevention of freeze damage to vaccines [internet]. [cited 2014 Jan 12]. Available from: http://whqlibdoc.who.int/hq/2007/WHO_IVB_07.09_eng.pdf.
11. Thai Meteorological Department. Extreme maximum temperature during summer in Thailand [internet]. [cited 2014 Jan 12]. Available from:http:/www.tmd.go.th/programs/uploads/tempstat/max_stat_latest_en.pdf.
12. The Bureau of Communicable Diseases, Department of Disease Control, Ministry of Public Health of Thailand. Working standard of immunization internet cited Apr 28 Available from thaigcdddcmophgothknowledgesdownload136 2014.