Adapting Existing Cooling Containers to Meet Cold Chain Requirements: Insights from Huachiew Chalermprakiet University COVID-19 Vaccination Center

การประยุกต์ใช้กล่องเก็บความเย็นที่มี ให้ตรงตามข้อกำหนดของห่วงโซ่ความเย็น: กรณีศึกษาจากศูนย์วัคซีนโควิด-19 มหาวิทยาลัยหัวเฉียวเฉลิมพระเกียรติ

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Abstract

Subsequently, the global pandemic of COVID-19 broke out in 2019, and the COVID-19 vaccine had to be distributed urgently with slightly limited stability data and storage conditions. The cold chains for daily use of inactivated and non-replicating viral COVID-19 vaccines at the Huachiew Chalermprakiet University (HCU) Vaccination Center were developed and validated. The vaccine storage container was studied and validated adapting existing cooling containers. Storage cold boxes made from plastic/foam with different dimensions for use with ice/ gel packs for the storage of COVID-19 vaccines were optimized for suitable conditions. For the results, it was found that plastic boxes for daily storage vaccine No. 1 (4,209 in^3) and No. 2 (2,035 in^3) with ice packs 5-6 kg and 2.5-3 kg, respectively, could maintain temperature between 2-8 °C for 8 hours. The prepared vaccine in pre-drawn syringes was stored in a foam box as in a temperature-controlled container No.3 (3,520 in^3) with 4 kg of ice pack, which could maintain temperature at 4-6 °C for 7 hours. When using the foam boxes for transferring the pre-drawn vaccines to the vaccination station, it was found that temperature-controlled containers No. 4 (541 in^3) and No. 5 (877 in^3) with three different conditions of using cooling materials were able to store the pre-drawn vaccines with a temperature between 7-13 °C for 7 hours. All of the results in this study showed the appropriate temperature in vaccine storage containers that meet the cold chain requirement for storage of COVID-19 vaccines.

Keywords: COVID-19, cold chains, inactivated COVID-19 vaccine, non-replicating viral COVID-19 vaccine

บทคัดย่อ

การแพร่ระบาดของโควิด-19 เริ่มต้นในปี พ.ศ. 2562 ส่งผลให้จำเป็นต้องมีการกระจายวัคซีน โควิด-19 อย่างเร่งด่วน ในขณะที่ข้อมูลความคงตัวและการเก็บรักษาวัคซีนยังมีจำกัด จึงมีการพัฒนาและตรวจสอบความถูกต้องของห่วงโซ่ความเย็นสำหรับเก็บรักษาวัคซีนโควิด-19 ชนิดเชื้อตายและชนิดเชื้อเป็นที่ไม่สามารถแบ่งตัวได้ในการใช้งานประจำวันที่ศูนย์ฉีดวัคซีนโควิด-19 มหาวิทยาลัยหัวเฉียวเฉลิมพระเกียรติ โดยศึกษาและตรวจสอบความถูกต้องในการดัดแปลงบรรจุภัณฑ์เก็บความเย็นที่มีอยู่เพื่อใช้ในการเก็บรักษาวัคซีน โดยหาสภาวะเหมาะสมในการใช้ถุงน้ำแข็งหรือถุงเจลที่บรรจุลงในกล่องที่ทำจากพลาสติกหรือโฟมซึ่งมีขนาดแตกต่างกัน จากผลการศึกษาพบว่า กล่องพลาสติกเก็บวัคซีนประจำวันหมายเลข 1 (ปริมาตร 4,209 ลูกบาศก์นิ้ว) และหมายเลข 2 (ปริมาตร 2,035 ลูกบาศก์นิ้ว) บรรจุถุงน้ำแข็งปริมาณ 5-6 กิโลกรัม และ 2.5-3 กิโลกรัม ตามลำดับ สามารถรักษาอุณหภูมิได้ระหว่าง 2-8 องศาเซลเซียส เป็นเวลา 8 ชั่วโมง สำหรับวัคซีนที่เตรียมในกระบอกฉีดยาพร้อมฉีดจะถูกเก็บในกล่องโฟมควบคุมอุณหภูมิหมายเลข 3 (ปริมาตร 3,520 ลูกบาศก์นิ้ว) บรรจุถุงน้ำแข็งปริมาณ 4 กิโลกรัม จะสามารถคงอุณหภูมิระหว่าง 4-6 องศาเซลเซียส เป็นเวลา 7 ชั่วโมง ส่วนการใช้กล่องโฟมสำหรับการส่งต่อวัคซีนพร้อมฉีดไปยังจุดฉีดวัคซีน พบว่ากล่องควบคุมอุณหภูมิหมายเลข 4 (ปริมาตร 541 ลูกบาศก์นิ้ว) และหมายเลข 5 (ปริมาตร 877 ลูกบาศก์นิ้ว) ที่ทำการศึกษาถึงการใช้วัสดุทำความเย็นที่แตกต่างกัน 3 สภาวะทดสอบ พบว่าสามารถควบคุมอุณหภูมิของวัคซีนที่เตรียมพร้อมฉีด อยู่ระหว่าง 7-13 องศาเซลเซียส เป็นเวลา 7 ชั่วโมง จากผลการศึกษาแสดงให้เห็นว่าบรรจุภัณฑ์เก็บความเย็นที่ใช้เก็บรักษาวัคซีนโควิด-19 ที่ทำการศึกษาทั้งหมด สามารถควบคุมอุณหภูมิได้อย่างถูกต้องเหมาะสมตามข้อกำหนดของห่วงโซ่ความเย็น

คำสำคัญ: โควิด-19 ห่วงโซ่ความเย็น วัคซีนโควิด-19 ชนิดเชื้อตาย วัคซีนโควิด-19 ชนิดเชื้อเป็นที่ไม่สามารถแบ่งตัวได้

Introduction

Since the COVID-19 pandemic attacked globally in early 2020, scientists have been trying to study the nature of this new coronavirus with the hope that humans will overcome the war with this microscopic enemy as soon as possible. One of the greatest hopes of people in every country is the COVID-19 vaccine. News of the race in vaccine development from many pharmaceutical companies strongly attracts people's attention throughout the year. The lengthy process of vaccine development, which usually takes ten to fifteen years or longer, has shortened and expedited, and the conventional sequential processes have adapted to a parallel manner due to the emergency need to fight for the life of the global population. [1]

Finally, on December 8, 2020, Comirnaty, the mRNA-based COVID-19 vaccine by Pfizer and BioNTech, was first given to a 90-year-old lady at a local hospital in Coventry, United Kingdom. [2] Shortly after that day, the vaccine Comirnaty (BNT162b2), which proved to be effective and safe, received emergency authorization from the US Food and Drug Administration (FDA) for those aged ≥16 years on December 11, 2020, and the European Medicine Agency (EMA) on December 21, 2020, for use in the USA and Europe following by the approval for Moderna's vaccine (mRNA-1273) for those aged ≥18 years in the same month. [1,3] The COVID-19 viral vector vaccine, AZD 1222 of Oxford/AstraZeneca, was authorized to be used in people aged≥18 years by EMA with conditional marketing authorization as the third COVID-19 vaccine in January 2021 [4] and followed by the approval of viral vector Ad26.COV2.S from Janssen/Johnson and Johnson in late February/early March 2021. [5,6] In other regions of the world, one of the first registered COVID-19 vaccines for use in any country was Sputnik V or Gam-COVID-Vac from Gamaleya Research Institute, which the Russian Ministry of Health approved in August 2020 [7] with only early-stage trials in 76 subjects; in China, CoronaVac (Sinovac), an inactivated whole-virus vaccine was approved in July 2020 for emergency use. [8] Though Sputnik V and CoronaVac were approved without safety or efficacy data from the Phase III trial at first [9,10], by 2022, Sputnik V had been approved in 70 countries, while CoronaVac received an emergency use license by WHO in June 2021. [11]

The cold chain and logistics management are crucial to preserve the quality of the COVID-19 vaccine from manufacturing through transportation and storage till reaching the target population. Both of inactivated and non-replicating viral vaccine must be maintained in the cold chain with a standard range of 2-8 °C. The recommended storage condition for pre-drawn non-replicating viral vaccine, is between 2-25 °C. Therefore, cold chains require suitable infrastructures and equipment and have high maintenance costs. Effective cold chain management and adequate monitoring need precise coordination across processes to ensure vaccine quality through real-time temperature monitoring and traceable records. [12] In Thailand, hospital pharmacists are health care personnel responsible for managing the cold chain for vaccines in the drug system. According to the data provided by WHO, the CoronaVac vaccine should be stored in the original carton to avoid exposure to direct sunlight and ultraviolet light in a refrigerator at 2 °C to 8 °C. It must not be stored in a freezer. The unopened vials in a refrigerator between 2 °C to 8 °C have a 12-month shelf-life or until the expiry date as stated on the label. [13] The storage of AstraZeneca's COVID-19 vaccine is in the same condition as the CoronaVac vaccine. However, since each vial of

AstraZeneca's vaccine contains ten doses of vaccine, after the vial is punctured, it can be stored in the refrigerator for only up to 6 hours, and the remaining vaccine must be discarded. (14)

Thailand received the first 200,000 doses of CoronaVac from China on February 28, 2021. Four days after that, it was given to medical staff as a priority group at Bamrasnaradura Infectious Diseases Institute for the first time in Thailand. (15) Once the COVID-19 vaccine is available in Thailand, the speed of vaccination is one of the strategies to reduce the severity of COVID-19 symptoms and decrease the transmission rate. By the farsightedness vision of Huachiew Chalermprakiet University's president, HCU, in cooperation with local government hospitals and the Poh Teck Tung Foundation, had accepted the task to be one of the COVID-19 vaccination centers in Samutprakarn province, Thailand. Within a few days of preparation, the volunteers from various faculties and the administration were ready to serve the community at the HCU Vaccination Center on June 9, 2021. The vaccine service started from CoronaVac, followed by a non-replicating viral COVID-19 vaccine from AstraZeneca once available in the country. From June 9 to July 23, 2021, the total number of people who received the COVID-19 vaccine from the HCU Vaccination Center was 9,275. Alongside our colleagues, lecturers and staff of the Faculty of Pharmaceutical Sciences are responsible for many tasks in the HCU Vaccination Center, including planning workflow, medical screening, educating people in waiting areas, vaccine preparation, vaccine storage and handling, post-vaccine observation, vaccine administration tracking, and reporting. For COVID-19 vaccine storage and transport, we, as pharmacists, had to utilize the cold chain equipment that we had on hand, such as a commercial-grade refrigerator, various-sized cold boxes, gel packs, ice packs, and data loggers to get the most efficient cold chain that reached temperature ranges.

Objective

This study aims to develop the cold chain for daily storage of inactivated and non-replicating viral COVID-19 vaccines at the HCU Vaccination Center.

Research hypothesis

Ice packs and/ or gel packs in cold chain packaging provide a uniform and desired temperature range for storage of inactivated and non-replicating viral COVID-19 vaccines.

Conceptual framework

The cold chain was developed and validated for daily storage of inactivated and non-replicating viral COVID-19 vaccines at the HCU Vaccination Center.

Methods

The cold chain for daily storage of inactivated and non-replicating viral COVID-19 vaccines was developed and validated urgently to preserve the quality of the vaccine used at the HCU vaccination center. Ice packs were prepared by packing 0.5 and 1.5 kg of crushed ice into the zip lock bag and freezing them in the freezer (Forma ULT freezer, Thermo Scientific, USA) at the temperature of -80 °C for 24 hours to get the stable shape of the ice packs. Then, the ice packs were moved to store in the freezer at -20 °C (SF-C697ST, Sanyo, Japan). Gel packs were stored in the freezer at -20 °C for 24 hours before use (Figure 1). The ice packs must be defrosted for ~30 minutes, while the gel packs were defrosted for 1 hour before incubation.

Figure 1 Ice and gel packs in the freezer (-20 °C).

On the early morning of each service day, the specific number of vaccines predicted to be used within the day were removed from the refrigerator and stored in either temperature-controlled containers No. 1 or 2. The temperature inside temperature-controlled boxes No. 1 and 2 were kept at 2-8 °C. The number of ice packs in these two boxes (Table 1) was modified from the logistical conditions. [16] These two cold boxes were kept in a temperature-controlled room below 25 °C during working hours, not more than 8 hours a day. The ice/gel packs were placed at the bottom and four sides of the cold box, as shown in Figure 2A. The cardboard was placed on the top of the ice/gel packs as the insulation layer to prevent direct contact between the ice/gel packs and the vaccine boxes. The calibrated data logger (RC-5, Elitech Technology, USA) was fixed in the middle of the cardboard to monitor the temperature inside each cold box[17]. The pre-drawn vaccines were stored in cold box No. 3 and kept in a temperature-controlled room that maintained temperature of not more than 25 °C. Therefore, the amount of the ice pack (Table 1) for this cold box was validated in the air-conditioned room. The temperature inside this cold box was monitored by the data logger, which was placed in the middle of the cold box.

Since the vaccination station was located in an unairconditioned area, the pre-drawn vaccines had to be placed in the aluminum tray inside the small cold box before being transferred to the vaccination station. Therefore, the pre-drawn vaccines were kept in cold boxes No. 4 and 5 (Figure 2B), which maintained the temperature inside the box in the range of 2-25 °C as a recommended storage condition. [18] Consequently, these two cold boxes were incubated with three conditions (Table 1) for 1 hour in the air-conditioned room; then, the cold boxes were placed at the vaccination spot to simulate the working situation. The data loggers were placed in the middle of the aluminum tray (Figure 2B) to monitor the temperature inside the cold boxes, and another one of the data loggers was used to monitor the ambient temperature at that time. One-Way ANOVA with 95% Confidence interval was used to investigate the difference in temperature inside each cold box among different ambient temperatures.

Table 1 Size of the cold box No.1-5, condition, and function of the box.

Cold box No.	Size (volume)	Condition	Function of the box
No.1 (Plastic box)	11.5" x 12" x 30.5" (4,209 in^3)	Ice pack 5-6 kg (1.5 kg x 2) + (0.5 kg x 6)	Store the vaccine in a temperature-controlled room to use within a day.
No.2 (Plastic box)	18.5" x 11" x 10" (2,035 in^3)	Ice pack 2.5-3 kg (1.5 kg x 1) + (0.5 kg x 3)	Store the vaccine in a temperature-controlled room to use within a day.
No.3 (Foam box)	16" x 10" x 22" (3,520 in^3)	Ice pack 4 kg (0.5 kg x 2) + (1.5 kg x2)	Store the pre-drawn vaccine in a temperature-controlled room.
No.4 (Foam box)	13.2" x 8.2" x 5" (541 in^3)	(A) Ice pack 2 kg (0.5 kg x 4) (B) Ice pack 1 kg (0.5 kg x 2) + Gel pack 1 kg (1 kg x 1) (C) Gel pack 2 kg (1 kg x 2)	Store the pre-drawn vaccine and bring it to the vaccination spot in ambient conditions.
No.5 (Foam box)	16" x 8.7" x 6.3" (877 in^3)	(A) Ice pack 2 kg (0.5 kg x 4) (B) Ice pack 1 kg (0.5 kg x 2) + Gel pack 1 kg (1 kg x 1) (C) Gel pack 2 kg (1 kg x 2)	Store the pre-drawn vaccine and bring it to the vaccination spot in ambient conditions.

A B

Figure 2 Cold box No.1 for daily use in the vaccine preparation room with a temperature below 25 °C (A). Cold box No.5 for carrying the pre-drawn vaccines to the vaccination spot at the unairconditioned area (B).

Results

Since cold boxes No. 1 and 2 were used daily to store the vaccine in the temperature-controlled room, ice packs 5-6 kg and 2.5-3 kg were sufficient to produce 2-8 °C for cold boxes No. 1 and 2, respectively. Cold box No. 1 was usually used daily as it could store up to 5 boxes (box size: 15.6 x 9.5 x 4.4 cm) of the CoronaVac vaccine and up to 10 boxes (box size: 7 x 3.5 x 3.5 cm) of the AstraZeneca's vaccine when the vaccine boxes were placed in a single layer without stacking.

Cold box No. 3 had to be packed with ice packs and incubated for 2 hours to reach a stable storage temperature in the range of 2-8 °C before use. The result showed that cold box No. 3 with 4 kg of ice packs could be used to control the storage temperature within 4-6 °C for 7 hours. It was used for storing the pre-drawn vaccine up to 40 doses and kept in the temperature-controlled room before the vaccine was distributed to the vaccination spot (Figure 3).

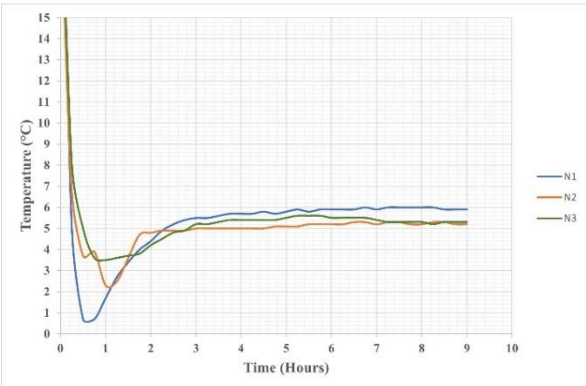
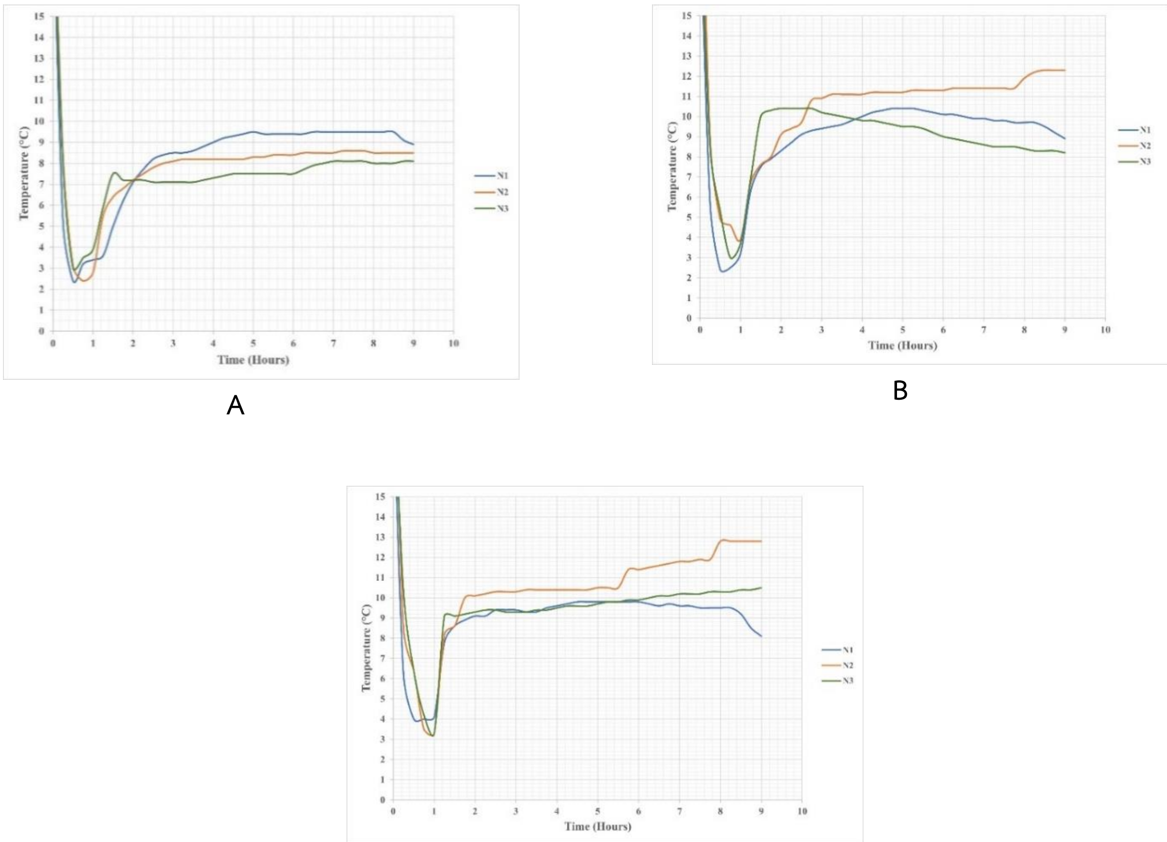


Figure 3 Controlled temperature in cold box No.3 (N = 3 in different three days at a temperature not above 25 °C).

Cold box No. 4 was incubated with three conditions: A contained 2 kg of ice packs, B comprised 1 kg of ice pack and 1 kg of gel pack, and C consisted of 2 kg of gel packs. The temperature of these three conditions gradually increased more than 2 ℃ and became stable after 2 hours of incubation, as demonstrated in Figure 4. The result showed that all three conditions (A, B and C) could hold the temperature between 7-9 ℃, 8-12 ℃ and 9-13 ℃, respectively, to store the 10 doses of pre-drawn vaccine for 7 hours. This study was simulated for routine use by placing cold box No. 4 in an ambient temperature at the vaccination spot for a difference of 3 days. The internal temperature in each cold box of all condition (A, B and C) was found to be different (with $p < .05$), affected by the different ambient temperatures (26-31℃) of each day. However, the temperature inside the cold box remained within the recommended vaccine storage temperature (2-25 ℃).



A

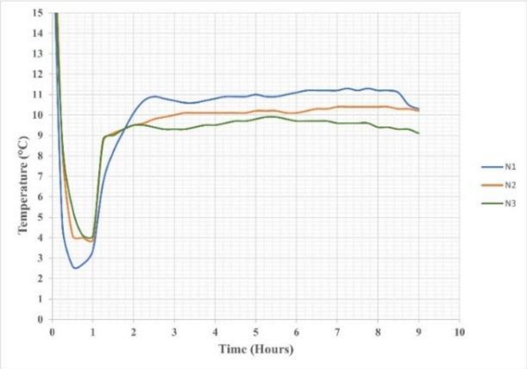
B

C

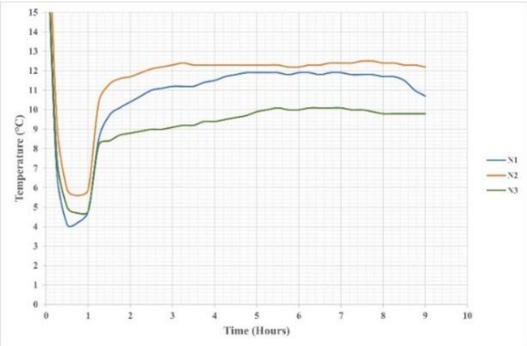
Figure 4 Controlled temperature in cold box No. 4 with difference conditions; A, B and C. N = 3 in different three days at the ambient temperature.

Cold box No. 5 preserved up to 10 doses of pre-drawn vaccines was incubated and studied for three conditions (A, B and C) as same as cold box No. 4. The results, as demonstrated in Figure 5, showed that all three conditions (A, B and C) were able to hold the temperature within the range of recommendation vaccine storage temperature (2 - 25 ℃) between 9-11 ℃, 9-12 ℃ and 10-13 ℃ for 7 hours, respectively. The internal temperature in each cold box of all condition

(A, B and C) was found to be different (with $p < .05$), affected by the different ambient temperatures (26-31°C) of each day. All of the internal temperatures of each cold box (cold boxes No. 1-5) were shown in Table 2, including the storage hold time investigated in this study.



A



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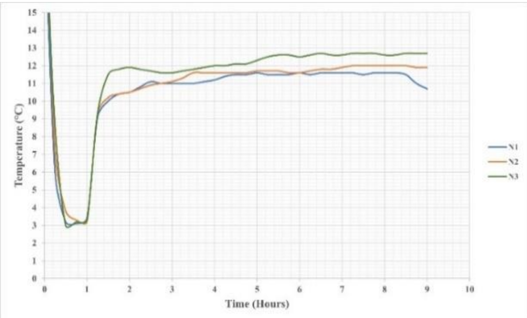

C

Figure 5 Controlled temperature in cold box No. 5 with difference conditions; A, B and C. N = 3 in different three days at the ambient temperature.

Table 2 Internal temperature and storage hold time of each cold box.

Cold box No.	Internal temperature (°C)	Storage hold time
No.1	2-8 °C	8 hours
No.2	2-8 °C	8 hours
No.3	4-6 °C	7 hours
No.4		
- Condition A	7-9 °C	7 hours
- Condition B	8-12 °C	7 hours
- Condition C	9-13 °C	7 hours
No.5		
- Condition A	9-11 °C	7 hours
- Condition B	9-12 °C	7 hours
- Condition C	10-13 °C	7 hours

HCU vaccination center used this developed cold box condition for storing vaccines and distributed the pre-drawn vaccines to the vaccination station. To ensure that all the vaccination vaccines are always kept in recommended storage condition, the internal temperature of each cold box was continuously monitored throughout the working period. The internal temperature of cold boxes No. 4 and 5, which were sent to the vaccination spot, increased by ~5 °C after 4 hours of use due to the opening frequency. Hence, one of the freshly defrosted ice packs or gel packs was replaced after 4 hours of using cold boxes No. 4 and 5 to keep the desired temperature.

Conclusion and discussion

Cold chain containers for storing inactivated and non-replicating viral COVID-19 vaccines at the HCU vaccination center were urgently developed and validated. Ice/ gel packs operate based on the principle of thermodynamics. The heat can be removed from a low temperature inside cold boxes and released to a high-temperature environment outside the cold boxes. Optimizing a thermodynamic system used in the cold chain is the key to maintaining the inside temperature of the cold boxes, as the content of ice/gel packs used in the containers was in different sizes.

Cold boxes No. 1 and 2 with ice packs 5-6 kg and 2.5-3 kg, respectively, can maintain the internal temperature within the range of 2-8 °C for storing unprepared vaccines to use within a day. Cold box No.3 with 4 kg of ice pack could store the pre-drawn vaccines at 4-6 °C for 7 hours when placed in the temperature control room. Cold boxes No. 4 and 5 for pre-drawn vaccines that studied for three conditions (A, B and C) with a suitable amount of ice/gel pack in each cold box due to the difference transition from a solid (frozen ice/gel) to liquid (melted ice/gel) state, all of the cold boxes showed the effectiveness for maintained the stable controlled temperature for 7 hours that able to store the pre-drawn vaccines with a temperature below 25 °C at vaccination spots. The internal temperature of cold boxes can be easily affected by the environmental temperature during the working period. It was observed that the internal temperature in each cold box under all conditions was significantly different ($p < .05$). Therefore, it is essential to monitor the internal temperature of each cold box to ensure that it remains within the desired range. This experimental study demonstrates the use of different cooling materials, namely ice packs and gel packs to ensure proper storage conditions for vaccines maintained within the correct temperature range.

This study demonstrated that designing and qualifying a cold chain storage system must be validated. The size of containers, type of cooling materials (ice/gel pack) and amount of cooling materials must be developed to ensure the suitable storage condition of COVID-19 vaccines.

Limitation

The result of this study was used as a guideline for setting the cold chain storage conditions to meet the requirements of COVID-19 vaccines. In cases where different container sizes, types of cooling materials (ice/gel packs), and amounts of cooling materials are used, the condition must be developed and validated.

Suggestions

Since the ice packs used as cooling materials in cold boxes are plastic zip-lock bags, continuous use may lead to partial loss of their contents as the ice melts over time. Therefore, after more than ten usage cycles, it is recommended to inspect the weight of each ice pack. If any pack has lost more than 10% of its target weight (i.e., 0.45 kg for a 0.5 kg ice pack or 1.35 kg for a 1.5 kg ice pack), it should be discarded.

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