衞生防護中心
Centre for Health Protection

Vaccine storage requirement (Clinic and outreach setting)

Briefing for VSS doctors

July 2024

衞生署
Department of Health

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- Vaccine storage requirement under VSS
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Background

- Storage and handling errors reduce vaccine potency, affect immune response and poor protection against disease
- The impact of thermal damage (exposure to temperatures outside +2°C to +8°C) varies for each vaccine.
- If the cold chain is not properly maintained, vaccine potency may be lost, resulting in an unusable vaccine.

Background

- Purpose-built vaccine refrigerators (PBVR) are specifically designed to store vaccines and should be used for all vaccine storage
- Provide a stable, uniform and controlled temperature throughout the unit

Reference:

https://www.health.gov.au/sites/default/files/documents/2020/04/national-vaccine-storage-guidelines-strive-for-5.pdf

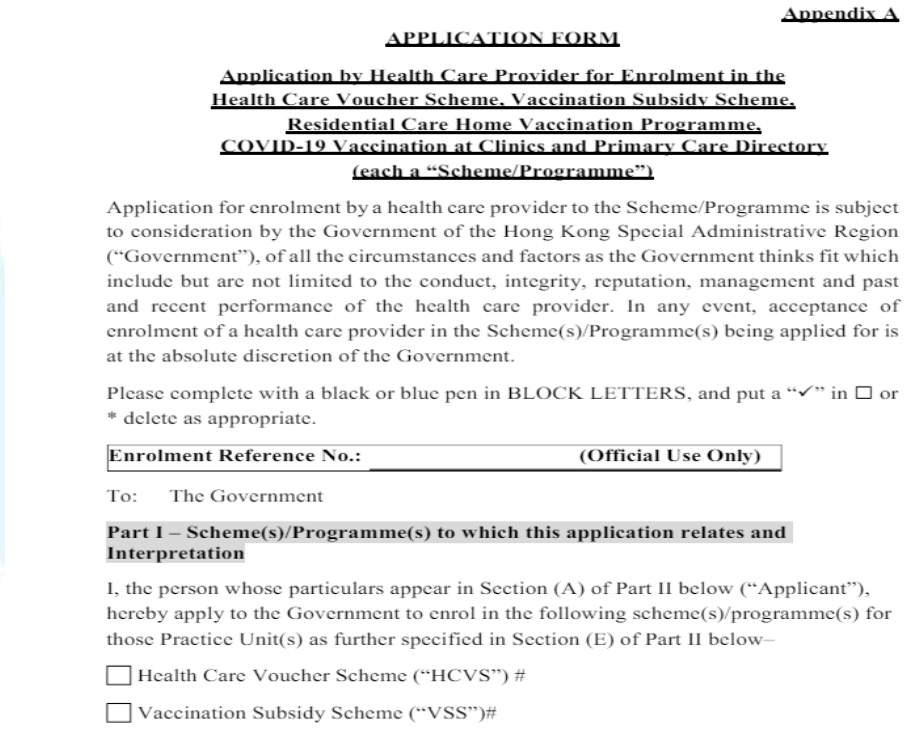
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/223753/Green_Book_Chapter_3_v3_0W.pdf

https://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/reference/vaccine%20_storage_handling_guidelines_en.pdf

Vaccine storage requirement under VSS

- From 2023/24 season, Doctors enrolled in VSS have to use Purpose-built vaccine refrigerators (PBVR) for vaccine storage.



Appendix A

APPLICATION FORM

Application by Health Care Provider for Enrolment in the Health Care Voucher Scheme, Vaccination Subsidy Scheme, Residential Care Home Vaccination Programme, COVID-19 Vaccination at Clinics and Primary Care Directory (each a "Scheme/Programme")

Application for enrolment by a health care provider to the Scheme/Programme is subject to consideration by the Government of the Hong Kong Special Administrative Region ("Government"), of all the circumstances and factors as the Government thinks fit which include but are not limited to the conduct, integrity, reputation, management and past and recent performance of the health care provider. In any event, acceptance of enrolment of a health care provider in the Scheme(s)/Programme(s) being applied for is at the absolute discretion of the Government.

Please complete with a black or blue pen in BLOCK LETTERS, and put a "✓" in ☐ or * delete as appropriate.

Enrolment Reference No.: _____ **(Official Use Only)**

To: The Government

Part I – Scheme(s)/Programme(s) to which this application relates and Interpretation

I, the person whose particulars appear in Section (A) of Part II below ("Applicant"), hereby apply to the Government to enrol in the following scheme(s)/programme(s) for those Practice Unit(s) as further specified in Section (E) of Part II below–

☐ Health Care Voucher Scheme ("HCVS") #

☐ Vaccination Subsidy Scheme ("VSS")#

For VSS Applicants only
Appendix A(i)

Application by Health Care Provider for Enrolment in the Vaccination Subsidy Scheme (VSS)

Record of the Vaccine Storage Refrigerator

Doctors enrolled in VSS have to use Purpose-built vaccine refrigerators (PBVR) for vaccine storage by 2023/24 vaccination season. For further details regarding vaccine storage under VSS, please refer to Chapter 6 of the VSS Doctor's Guide – Requirements on vaccine storage and handling under VSS (https://www.chp.gov.hk/files/pdf/vssdg_ch6_vaccine_storage_and_handling.pdf).

For record and follow-up purpose, please complete this form, supplemented with:-

(1) One photo of the interior of the refrigerator **currently** used for vaccine storage at your clinic; and
(2) One photo of the temperature monitoring device AND temperature record

Should you have any enquiries **regarding PBVR**, please contact Ms. TAM at 3975 4848 or Ms. CHAN at 3975 4846. For **other VSS matters**, please contact our staff at 2125 2299 or 3975 4806

(1) Photo of the interior of the refrigerator and Max-min thermometer

Fridge Brand Name: _____ Fridge Model No.: _____

Doctor's Name: _____ Practice Name and No.: _____

SPID: _____ Contact Phone number: _____

Signature: _____ Date: _____

(2) Photo or copy of the temperature record kept in the clinic

貯存疫苗的雪櫃溫度檢查表 **An Example only**

1. 所有疫苗(季節性流感疫苗及肺炎球菌疫苗)，須保存於攝氏 +2℃ 至 +8℃ 雪櫃內備用。
2. 須每日檢查 三次 （上午、中午及下午 各一次） 雪櫃內的 現時溫度、雪櫃最高及最低溫度，並記錄在本表格上。請於每次記錄雪櫃溫度後，重置最高最底溫度計。
3. 請保留此記錄至少一年，以便有需要時作參考。

**註: 如雪櫃溫度 低於攝氏+2 度 或 高於攝氏+8 度
1. 請暫勿使用受影響的疫苗，並應將疫苗立即存放於攝氏+2 度至+8 度的雪櫃。
2. 請通知診所醫生及向疫苗供應商查詢
3. 在' 溫度超溫事故報告表' 填寫有關事故並傳真至項目管理及疫苗計劃科

日期	檢查雪櫃時間	雪櫃內溫度			記錄人員			備註
		現時	最高	最低	姓名	職位	簽署	
15-08-2022	09:00	5.3	6	4.1				
15-08-2022	13:00	5.4	6	4.1				
15-08-2022	17:00	5.4	6	4.1				

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aspire to be an internationally renowned public health authority

Vaccine storage requirement under VSS

- All doctors under VSS:
  - Select and use the PBVR to store vaccines.
  - Do not use a domestic fridge for vaccine storage
  - Monitor vaccine temperature continuously
  - Written protocols for Vaccine Handling and Management of Cold chain breach

2023/24 Vaccination Subsidy Scheme Doctors' Guide

22 November 2023

Please check the VSS Doctors' Guide regularly for the most current version

https://www.chp.gov.hk/files/pdf/vssdg_ch6_vaccine_storage_and_handling.pdf

Purpose Build Vaccine Refrigerator

- PBVR-also referred to as pharmacy or laboratory refrigerators
- The PBVR should have the following **features**:
  - Microprocessor-based temperature control system
  - Narrow tolerances with internal temperatures, providing appropriate temperature regulation
  - Forced air circulation system to main promoting stable and uniform temperature
  - Digital temperature monitoring system with an alarm
    - High /Low Temperature audible alarms
    - Power failure

Purpose Build Vaccine Refrigerator

- **Other features**
  - A display with current, max. and min. temperature providing a convenient means to monitor the temperature and to facilitate manual recording
  - Open door sensor/alarm which alerts the user that the fridge door is not properly closed
  - Locking mechanisms that restrict access

Purpose Build Vaccine Refrigerator

- Different sizes of PBVR

Non-compliance refrigerators

- Bar refrigerators, Commercial display refrigerators and Domestic fridge (should not be used)
- Missing fans or advanced control mechanisms to maintain temperature uniformity

Wine Cooler

Display Cabinet

Domestic fridge

Vaccine storage and handling in clinic

- Keep vaccines in their original packaging
- Check the packaging and product insert for the storage condition
- Place vaccines in the center of the refrigerator, and position away from walls and doors.
- Maintain a vaccine stock record, perform a weekly or monthly inventory checks (quantities and packing)
- Remove any expired vaccines

Vaccine storage and handling in clinic

- Connect vaccine refrigerators to a dedicated electric circuit
- Label “Do Not Unplug” sign next to the electrical outlets
- Regular maintenance and cleaning
- Set up back-up plan in case of a power failure or PBVR out of service
- Quarantine all affected vaccines from other vaccines (but maintain in the cold chain)

Temperature monitoring

Max-min monitor (in-built)	Data logger (in-built)
Displaying the current, max. and min. temperature	Displaying current temperature, provided most accurate storage temperature information
• Records high and low temperature fluctuation over a period (after the reset to the record time) • Manually record the readings	• Programmed by the user to measure and record temperatures (at least every **30** minutes) • Downloaded at least weekly (or more often if required)

Temperature monitoring device (External)

- External temperature data logger / digital max-min thermometer to monitor the vaccine temperature if applicable
- Regular thermometers should **not** be used because they only show the temperature **at the exact time**

Temperature record

- The 1-year-record can provide a comprehensive vaccine storage temperature readings that could facilitate the the manufacturers to assess the stability and effectiveness of the multiple excursion vaccines
- The “Temperature Chart” should be posted at visible location such as the refrigerator door

Emergency action

- Restore proper storage conditions
- Do not discard the vaccine before discussing the circumstances with the vaccine manufacturers
- Do not use the affected vaccines until manufacturer has confirmed the vaccine is acceptable for use
- Disposal the vaccines according to local regulations

VSS Outreach (Non-Clinic)

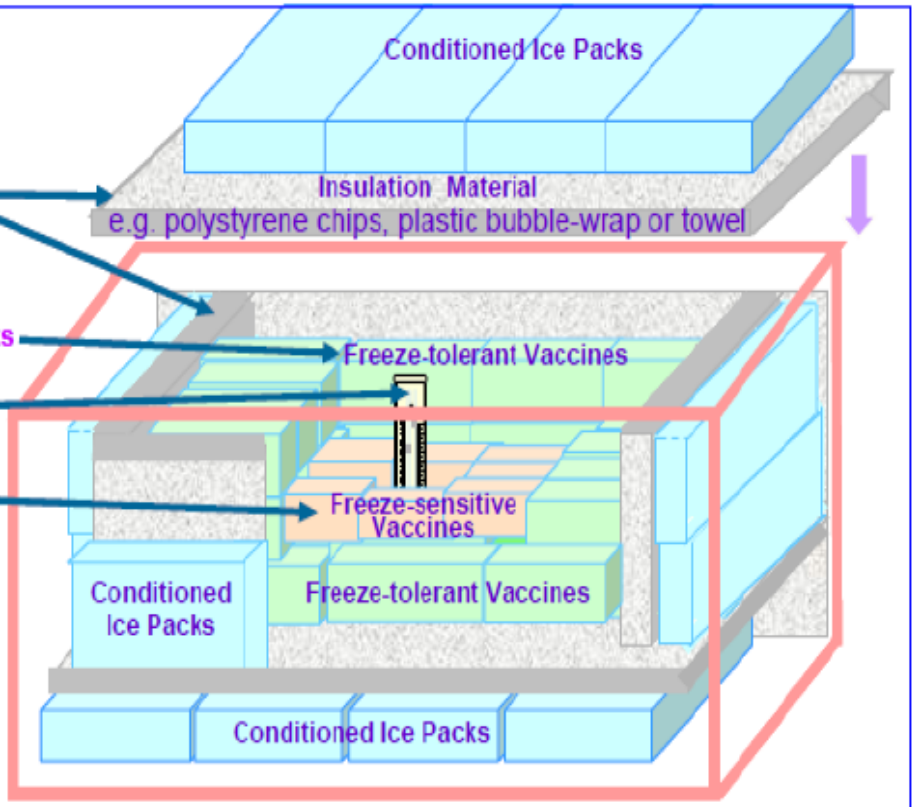
- Prepare the vaccine order and arrange vaccine delivery in advance
- Consider the cold chain (within 2 to 8˚C) maintenance and duration of outreach activity
- Proper monitoring of the temperature throughout the activity

VSS Outreach (Non-Clinic)

- Appropriate equipment should be used for vaccine transport and on-site storage.
- These includes:
  - Cold boxes
  - Ice packs
  - Temperature data loggers / maximum-minimum thermometers
  - Insulating materials (e.g. bubble wrap, corrugated cardboard)
- The setup should be tested for insulation time and temperature stability before it is used.
- Place the device temperature probe in the center of vaccines

Principles for Packing A Cold Box

- Adequate insulating material between conditioned ice packs & vaccines to prevent freezing
- Freeze-tolerant vaccines closer to ice packs
- Max./min. thermometer in the centre of vaccines
- Freeze-sensitive vaccines in the centre



N.B.

- ✧ Conditioned ice packs are frozen ice packs having been exposed to room temperature for 15 minutes to 1 hour, depending on the room temperature, until water drops appearing on the exterior surface and movements of water being heard when the ice packs are shaken
- ✧ If the ice box is small, put ice packs on top and bottom only
- ✧ If heat and freeze indicators are available, use them in ice box when transporting vaccines

Points to note

- Vaccine storage: **PBVR**
  - Keep vaccines / pharmaceutical products only
  - Continuous monitoring the storage temperature
  - Keep temperature record
  - Regular maintenance and cleaning
  - Plan for emergency situation
- Inspection findings from previous outreach activities:
  - Max-min thermometer without reset
  - Temperature probe misplaced

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THANK YOU

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Department of Health