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Managing Covid Vaccines During Hot Weather Standard Operating Procedure.

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Version Control:

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1	Initial Issue	

Engagement & Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
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Circulated to the following for Consultation

Date	Role / Designation
21/05/2023	Senior Clinical Lead Vaccination/Immunisation
21/05/2024	Vaccination Centre Clinical Lead Nurses

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1 Introduction

Vaccines must be stored and used within temperatures specified by the manufacturer and MHRA-authorized conditions of use, to ensure their safety, quality and efficacy.

Heat speeds up the decline in potency of most vaccines, therefore vaccine effectiveness cannot be guaranteed unless they have been stored at the correct temperature.

With increasing temperatures during summer, it is important to think about COVID-19 vaccines to ensure their continued safety, quality and efficacy.

During the summer, there is an increased risk of temperatures in ambient areas rising above 25°C (this is the maximum permissible storage temperature for all the COVID-19 vaccines authorised in the UK, with the exception of Spikevax XBB; +30 °C). See specific product information for further details¹²³⁴.

Increasing ambient temperatures during the summer is particularly likely in venues that are susceptible to significant fluctuations in temperature such as vehicles and some local community facilities.

This process is following compliance with good practice guidance.

2. Objective

- To provide assurance of maintenance of the cold chain to ensure vaccine efficacy.
- To ensure ambient temperature is monitored regularly during periods of warm weather, where the temperature is likely to exceed 25 °C.
- To ensure that a rise in ambient temperature is identified quickly, and that corrective action is taken.
- To ensure that actions are taken to reduce the risk to vaccine during periods of warm weather.

¹ [Spikevax XBB.1.5 0.1 mg/mL dispersion for injection \(MDV\) - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

² [Comirnaty 30 micrograms/dose concentrate for dispersion for injection 12+ years COVID-19 mRNA Vaccine - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

³ [Comirnaty 10 micrograms/dose concentrate for dispersion for injection Children 5 to 11 years COVID-19 mRNA Vaccine - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

⁴ [Comirnaty 3 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

3. Definitions

- **PTHB** – Powys Teaching Health Board
- **GPhC** – The General Pharmaceutical Council are the regulatory body for pharmacists, pharmacy technicians and pharmacies in Great Britain.
- **Cold chain** – is the system of transporting and storing medicines within the recommended temperature range of +2°C to +8°C from the place of manufacturer to the point of administration to a patient.
- **Temperature deviation/excursion** – any incident where the recorded Refrigerator/Labcold™ portable vaccine carrier temperature is outside of the recommended range of +2°C to +8°C.
- **Vaccine** – a suspension of attenuated or killed microorganisms (viruses, bacteria or rickettsia) or of antigenic proteins derived from them, administered for prevention, amelioration or treatment of infectious disease.

4. Role / Responsibilities

4.1 Senior Pharmacy Technician, Vaccination/Immunisation, Therapies & Pharmacy Stores

The senior pharmacy technician for immunisation / vaccination is responsible for:

- Ensuring that Vaccination Centre (VC) pharmacy support staff are trained and competent to perform the duties required of them in accordance to GPhC standards [Standards | General Pharmaceutical Council \(pharmacyregulation.org\)](https://www.pharmacyregulation.org)
- Arranging regular review to monitor compliance with this procedure.
- Providing advice and support on how to respond to ambient temperature fluctuations in vaccination centres, during transportation of vaccine and in outreach settings.

4.2 Senior Clinical Lead for Immunisation/Vaccination /Clinical Lead for Vaccination Centres / Lead Nurses

The senior clinical lead for immunisation / vaccination (in collaboration with the senior pharmacy technician for immunisation/vaccination) are responsible for:

- Ensuring that staff for whom they have responsibility within the VCs are trained and competent to perform pharmacy support duties in accordance with GPhC standards [Standards | General Pharmaceutical Council \(pharmacyregulation.org\)](https://www.pharmacyregulation.org).
- Ensuring that they understand how to respond to fluctuations in ambient temperature in vaccination centres, during transportation of vaccine and in outreach settings.
- Reacting to pharmaceutical incidents.

4.4 Other Staff

All VC pharmacy support staff are responsible for:

- Undertaking cold chain training, Good Distribution Practice (GDP) training, adhering to this SOP, maintaining competence, and appropriately reporting and reacting to pharmaceutical incidents. Evidence of competencies must be made available on request from the Medicines Management Team.
- Ensuring that they understand how to respond to fluctuations in ambient temperature in vaccination centres, during transportation of vaccine and at outreach settings.

5. Process

5.1 Ambient Temperature Monitoring

Monitoring of temperatures in ambient preparation and administration areas is required i.e., any area where the vaccine is held after removal from cold storage (+2°C – +8°C).

Frequent measurements should be taken with a calibrated digital thermometer (up to three times a day in hot weather – see appendix A - Ambient Temperature Monitoring Log).

The higher the temperature the more frequent the monitoring needs to be:

If the temperature is greater than 22°C in the work area, monitoring should be hourly (see appendix A, Ambient Temperature Monitoring Log).

- Action must be taken to prevent temperatures exceeding 25°C NB. Spikevax XBB vaccine can be stored up to 30°C.
- If temperatures reach 25°C additional steps (see below) will need to be taken to protect the vaccines NB. Spikevax XBB vaccine can be stored up to 30°C.

Where possible, additional mechanical controls (e.g., portable air conditioning) should be used, either on a temporary or permanent basis, to maintain temperatures within the required range.

5.2 Additional Steps

Vaccination Centres

In extreme circumstances and if temperatures are unable to be maintained below 25°C, contact Senior Pharmacy Technician for Vaccination/Immunisation. NB. Spikevax XBB vaccine can be stored up to 30°C.

In this instance it may be necessary to provide the vaccinator with a tray containing a cool pack. Each VC will have a fridge in which cool packs are stored and can be used for this purpose. Contact the pharmacy stores team if extra cool packs are required (for an average clinic of 240 appointments approximately 50 small cool packs will be required).

A tray containing the vaccine must be placed on top of the cool pack tray. This should keep the temperature of the vaccine sufficiently cool and below 25 C.

A new cool pack and tray should be provided each time a vaccinator requests a vaccine.

The cool pack previously used should be cleaned with a Clenil wipe and placed back into the fridge. The time that the cool pack will be ready for next use must be indicated (24-hours after placing in the fridge).

An informal assessment of risk must be undertaken frequently as conditions change. Assessments should take place at the start of, periodically during, and after each vaccination session.

Outreach Clinics

- The use of Labcold™ Portable Vaccine Carriers at outreach clinics will ensure that the vaccine is stored between +2°C - +8°C.
- When transporting vaccine in Labcold™ Portable Vaccine Carriers ensure that the unit fan is not obstructed and where possible that the vehicle air conditioning/cold air fan is used whilst travelling. This will put less pressure on the unit to maintain a stable temperature.
- Where possible, travel with a colleague to outreach clinics, so that the temperature display on the vaccine carrier can be monitored.
- Ambient temperature monitoring of the outreach venue must take place as per section 5.1
- Depending on the size of the clinic, a number of cool packs may be transferred to the outreach venue using large vaccine porters for use as above for VCs.
- Cool packs must be cleaned and transferred to the VC fridge on return, with the time of next use indicated.
- Data loggers must be downloaded at the end of the day, the data analysed and the results saved in the scanned folder file, access here: [Data Logger Downloads](#)

6 Risk Management

The following actions should be considered to reduce risks to the vaccine:

Optimise workflow and work area:

- Pharmacy must manage workflows from storage to preparation and administration, to minimise the time the vaccine is outside cold storage and exposed to elevated temperatures. Remove only one vial at a time from the fridge/Labcold™ portable vaccine carrier.
- Be aware that methods to improve comfort for staff by increasing air movement (e.g. use of fans and opening windows) do not normally lower air temperature, unless they move air from a cooler area to a warmer area.
- Consider restricting the number of people working or waiting in the vaccine preparation area, and removing non-essential electrical equipment, as this may reduce the temperature slightly.
- Minimise the time the fridge door/Labcold™ portable vaccine carrier is open. Repeatedly opening the refrigerator/ Labcold™ portable vaccine carrier will allow warm air to enter. Make

sure fridge doors/ Labcold™ portable vaccine carrier lids are securely closed as soon as possible after opening.

Store punctured vials appropriately:

- Minimise the period of exposure of punctured vials to elevated ambient temperatures.

You should also consider the following:

- Return punctured vials to the fridge when not being used. i.e., during breaks and quiet periods – do not store in the medicine cupboard. Store the punctured vial upright in the plastic tray and indicate which vaccinator the vaccine belongs to i.e. place a post it note in the tray.

6. Monitoring Compliance / Audit / Review

Compliance with this SOP will be audited during annual pharmacy audits.

This SOP will be reviewed every three years or earlier should changes to legislation or to practice indicate otherwise.

7. References

PTHB MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines [Medicines Management - SOPs - All Documents \(sharepoint.com\)](#)

Electronic Medicines Compendium (EMC) for Summary of Product Characteristics <https://www.medicines.org.uk/emc/> (accessed 16/05/2024)

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