1. **Purpose**

This SOP describes the process for

* removing vaccine vials from the refrigerator and preparing them for transport
* transcribing the post-thaw expiry dates onto vial transport container
* preparing a cool box for use
* transporting the cool box to end user locations
* receipt of vaccines at end-user locations

1. **Scope**

The scope of this SOP is the use of cool boxes to transport COVID-19 vaccines to end user locations (e.g. care homes and other domiciliary settings). Vaccine should be ordered and delivered wherever possible to the location where it is to be used.

Excluded from scope are:

* returning un-used sealed vials to original dispatching site. This may be necessary in exceptional circumstances only. Refer to NHSE Standard Operating Procedure: roving and mobile models: [Coronavirus » Standard operating procedure: roving and mobile models (england.nhs.uk)](https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-roving-and-mobile-models/).
* movement of punctured vials. NHSE has published a position statement which provides further information on the microbial contamination risks associated with moving punctured vials, and identifies potential risk reduction measures. <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/09/position-statement-reducing-microbial-risk-when-transporting-covid-19-vaccines-v1.1.pdf>
* Transport of vials for Mutual Aid. <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/01/C1424-mutual-aid-and-the-transfer-of-covid-19-vaccines-between-nhs-vaccination-sites-v2.pdf>

If any of the three scenarios above are approved, the transport principles described in this SOP will remain generally applicable. If Spikevax vials are to be transported again, the total permitted transport time, including that already used by the Specialist Pharmaceutical Logistics (SPL) providers, must not be exceeded (Section 5.2.2).

1. **Responsibility**

All steps undertaken in section 5.2 are classed as assembly of medicines and must be undertaken by or under the supervision of a doctor, registered nurse, or pharmacist under Regulation 3A of Human Medicines (Coronavirus) (Further Amendments) Regulations 2020. These listed healthcare professionals can work under this regulation to label coronavirus vaccine as long as they are acting in the course of their professional duties for the purpose of the supply of the vaccine.

Suitably trained staff are responsible for following all steps in this procedure.

1. **Equipment required**

* Medical grade cool box that has been validated for the required time from packing to receipt at the end user location
* Thermometer (if required and not integral to cool box)
* Cool packs, chilled or frozen according to the manufacturer’s instructions
* Information about loading the cool box (e.g. cool box manufacturer’s instructions for packing)
* Packaging materials e.g. bubble wrap, foam, cardboard supports
* Container for small number of vaccines e.g. box or self-sealing bag
* Blank label

1. **Procedure**
   1. **Prepare the cool box**
      1. Place the required number of pre-chilled cool packs in the cool box according to the manufacturer’s instructions.
      2. Close the lid of the cool box and position it as close as possible to the fridge.
      3. If a thermometer is in use, wait until the cool box temperature has dropped to between 2OC and 8OC.
   2. **Select, label and pack the vaccine**

N.B. During the process, take care to minimise exposure of the vaccine to room temperature. Work swiftly and keep fridge door openings to a minimum.

* + 1. Select the minimum number of vials required for the planned session. This may be
* one or more vials.
* a full carton, where smaller cartons are available.
  + 1. If individual vials are selected
       - place them in a suitable container. If a rigid box is used, use packing materials to prevent excessive movement of the vials within the box.
       - label the container with:
* name of vaccine
* number of vials
* post-thaw expiry date (from outer carton from which the vials have been removed)
* For Spikevax only, journey time remaining. This will normally be 16 hours (of the total 30 allowed). However, if the carton states that the vaccine has already been transported for more than 14 hours, the journey time remaining should be calculated as 30 hours minus the journey time already used.
  + 1. Pack the labelled container into the cool box in such a way that it remains upright and minimises the movement of the vials. If frozen ice packs are recommended by the manufacturer, use packing material e.g. bubble wrap to ensure that the frozen ice pack does not come into direct contact with the vaccines.
  1. **Transport vaccine to end user location**
     1. Pack the cool box into the vehicle in such a way so that it remains upright and stable throughout the journey.
     2. Travel to the end user location.
     3. On arrival check that
        + the journey time was less than the time for which the cool box is validated (if applicable)
        + the temperature inside box is between 2 and 8OC (if thermometer in use)
        + for Spikevax vaccines only, that the journey time was less than the remaining journey time written on the vaccine container.

If not, the vaccine should be quarantined in the refrigerator and advice sought from [insert job title of appropriate senior member of staff].

* + 1. Use the vaccine immediately on arrival, or place it into the refrigerator and use as soon as possible.

1. **Document history**

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| --- | --- | --- | --- |
| **Date** | **Version** | **Section** | **Details** |
| 18/08/2022 | 1.0 | All | This is the first version published. Adapted from and consolidates PVH7, PVH10, AVH7 and MVH7 |
| 07/09/2022 | 1.1 | Table 1 | Added timings for Comirnaty Bivalent Vaccine |
| 27/03/2023 | 1.2 | Section 5 | Removed references to tracking journey times, as this is not required for vaccines used during spring 2023 campaign. Added reference to recording the batch number of the VidPrevtyn Beta outer (co-pack) carton. |
| 04/05/23 | 1.3 | Section 5 | Added in reference to tracking journey time for Spikevax. |
| 30/10/23 | 1.4 | Section 5.2.2 | Total permitted journey time for Spikevax amended to 30 hours in accordance with communication from Moderna <https://www.medicines.org.uk/emc/product/15085/dhpcs#about-medicine> |
| 21/11/23 | 1.5 | Section 6. Document History | The above journey time change communication has now been added to the SPC. |
| 05/04/23 | 1.6 | 5.2.2 | Amended reference to assumed transport time for Spikevax vaccines and removed reference to VidPrevtyn. |