

SOP for monitoring the total transportation time of thawed undiluted / unpunctured Comirnaty 30 microgram for adults and adolescents and Spikevax (Original and Bivalent) COVID-19 vaccines

The current version of this SOP and other related documents can be found on the following website – please check this website to ensure you are using the most up to date version –
<https://www.lancsmmg.nhs.uk/lancashire-and-south-cumbria-resources/lsc-covid-19-vaccination-programme/>

1. Introduction

- 1.1. This SOP must be used in conjunction with the following Specialist Pharmacy Service (SPS) SOPs:
 - <https://www.sps.nhs.uk/articles/ordering-receipt-and-storage-of-covid-19-vaccines/>
 - <https://www.sps.nhs.uk/articles/transporting-covid-19-vaccines/>
- 1.2. Comirnaty 10 microgram for children 5 to 11 years and Comirnaty Bivalent have no restriction on their transportation within their shelf life at 2-8⁰C and are therefore **not covered** by this SOP.
- 1.3. This SOP is for the transportation of thawed, undiluted vaccine.
- 1.4. The SPC for Comirnaty 30 microgram allows for 48 hours transportation once thawed. The SPCs for Spikevax Original and Spikevax Bivalent allow for 12 hours transportation once thawed. There are no restrictions on the number of journeys.
- 1.5. Where the vaccine was originally received frozen at a Hospital Hub, there is no need for consideration of the journey from the wholesaler and a label is only required if the vaccine is going to be transported once thawed.
- 1.6. Where the vaccine was originally received thawed, the time of the journey from the wholesaler to the designated site must be considered. This delivery time needs to be taken into consideration to ensure the MHRA Conditions of Authorisation are followed with respect to allowed journey time.
- 1.7. If the delivery time of thawed vaccine from the wholesaler is unknown, sites should assume a delivery time of 6 hours (but see section 3.1.4 below for further details about ascertaining accurate delivery time). Therefore, there would be another 42 hours of journey time remaining for Comirnaty 30 microgram and 6 hours of journey time remaining for Spikevax Original and Spikevax Bivalent.

2. Purpose

- 2.1. This SOP describes the process for monitoring the total transportation time of thawed undiluted Comirnaty 30 microgram, Spikevax Original and Spikevax Bivalent COVID-19 vaccines to ensure that the total time does not exceed the allowed time and to ensure maintenance of the vaccine integrity.
- 2.2. The cold chain must be maintained during transport and the vaccine must be packed and handled with care to avoid excessive movement or shaking.

3. Procedure

3.1. Receipt of thawed vaccine – first movement from the wholesaler

- 3.1.1. Note: no record is required when receiving frozen vaccine as the transportation restrictions are only applicable to thawed vaccine.
- 3.1.2. When receiving thawed vaccine, SPS SOP HCV1 in the link above must be followed.
- 3.1.3. Note and endorse the delivery note with the time of receipt in the 24-hour clock format.
- 3.1.4. A pre-printed transportation label (supplied from SVOC for use in Lancashire and South Cumbria) must be attached to the vaccine box. In the case of the larger pizza boxes the label must be attached to the top right-hand corner on the front of the box; for the smaller mini boxes it must be attached to the inside of the box lid. The following must be recorded on the label:
 - The number of the journey (in this case 1)

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- The date
- The start time of the journey when it left the wholesalers - see below
- The end time of the journey i.e. the time received
- The transit time of the journey, for example

Start of Journey from Wholesaler: 08.15

Delivery time at Designated Site: 12.30

Transit time: 12.30 minus 08.15 = 4 hours 15 minutes

The commitment with wholesalers is to tell sites if their delivery journey has been over 6 hours. Where possible, sites should enquire on receipt of delivery the time the delivery left the wholesaler or obtain this information from the delivery note. If not told or unknown, sites should assume they have 42 hours for Comirnaty 30 microgram or 6 hours for Spikevax Original and Spikevax Bivalent in hand for onward distribution and have records and processes to manage and monitor compliance. This section (3.1.4.) replaces section 4.2.2. in SPS SOP HCV1.

3.2. First movement of the thawed vaccine where the vaccine was originally received frozen i.e. from a Hospital Hub

3.2.1. The first time the thawed vaccine is to be moved the donor must attach a pre-printed transportation label (supplied from SVOC for use in Lancashire and South Cumbria) to the vaccine box. In the case of the larger pizza boxes the label must be attached to the top right-hand corner on the front of the box; for the smaller mini boxes it must be attached to the inside of the box lid. The following must be recorded on the label:

- The number of the journey (in this case 1)
- The date of the journey
- The start time of the journey

3.2.2. When the vaccine is then received at the receiver site, the receiver must record the following on the transportation label:

- The time the vaccine is received
- The transit time of the journey, for example

Start of Journey from donor: 08.15

Time of arrival at receiver site: 12.30

Transit time: 12.30 minus 08.15 = 4 hours 15 minutes

3.3. Subsequent transportations of the vaccine; i.e. second journey or above

3.3.1. The donor site must record on the pre-printed transportation label the following:

- The number of the journey
- The date
- The start time of the journey

3.3.2. When the vaccine is then received at the receiver site, the receiver must record the following on the transportation label:

- The time the vaccine is received

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- The transit time of the journey, for example
Start of Journey from donor: 08.15
Time of arrival at receiver site: 12.30
Transit time: 12.30 minus 08.15 = 4 hours 15 minutes
 - The total accumulated transit time
- 3.3.3. Transportation must not occur if the total accumulated transportation time is expected to exceed the allowed limits outlined above. It is important that the system understands how much transport time is left on each box of vaccine. This information will be used when seeking approval for Mutual Aid; see 3.5 below.
- 3.3.4. If, due to unforeseen circumstances, vaccine is received which has a total accumulated transit time in excess of the allowed limits, the vaccine must not be used and should be quarantined in a fridge. Further advice should be sought from SVOC pharmacy.

3.4. Movement of a small number of vials to a roving/outreach/pop up site or home

- 3.4.1. Refer to the [NHSEI SOP for roving and mobile models](#).
- 3.4.2. Transportation of a small number of vials must be considered within the allowed transportation limits.
- 3.4.3. SPS SOP HCV6 linked above must be followed.
- 3.4.4. The container used must be labelled with:
- contents
 - expiry date / time
 - allowed remaining transportation time

3.5. Requests for Mutual Aid

- 3.5.1. When completing a Mutual Aid request form for Comirnaty 30 micrograms, Spikevax Original or Spikevax Bivalent COVID-19 vaccines (which can be found on the [Lancashire & South Cumbria Medicines Management Group website](#)), the following additional information must be recorded on the Mutual Aid request form, as taken from the information on the transportation label:
- Total number of journeys, as thawed vaccine, so far
 - Total accumulated transportation time
 - Estimated transportation time of the journey for the request

3.6. Transfer of the vaccine

- 3.6.1. The integrity of the vaccine must be maintained. The vaccine must be handled with care and not be subjected to excessive movement or shaking. It must be packed in the transportation cool boxes to avoid movement.
- 3.6.2. The vaccine must be transported with maintenance of the cold chain in validated cool boxes and oversight of the lead pharmacist from each site. The SPS SOPs above provide further information and their website contains additional information on [cold chain management](#).

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3.7. Example of pre-printed label

| Journey number | Date of journey | Start time | End time | Transit time | Accumulated transit time |
|-----------------------|------------------------|-------------------|-----------------|--------------------------|---------------------------------|
| <i>1</i> | <i>16/09/21</i> | <i>8:15</i> | <i>12:30</i> | <i>4 hrs 15 min</i> | <i>4 hrs 15 mins</i> |
| <i>2</i> | <i>20/09/21</i> | <i>14:00</i> | <i>15:30</i> | <i>1 hour 30 min</i> | <i>5 hrs 45 mins</i> |
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