# Position Statement: Reducing microbial risk when transporting COVID-19 vaccines in pop up, roving, and mobile models.

**Background**
The Standard Operating Procedure (SOP) from NHS England and Improvement on 'Roving and mobile vaccination models' and those developed by the Specialist Pharmacy Service (SPS) on transporting COVID-19 vaccines from 'Primary Care Network (PCN) designated sites to end user locations' describe how to operate vaccination models which enable administration of vaccines at identified locations outside of vaccination 'base' sites, such as at a patient's residence (Care Homes and houses).

The movement of punctured vials of COVID-19 vaccines between multiple sites (i.e. end user locations) presents a greater risk of microbiological contamination and proliferation than a single site delivery. There is a need to consider the protection of vaccine quality and minimise the risk of harm to the patient from accidentally administering contaminated vaccine.

Moving a punctured vial of a COVID-19 vaccine should not be routine. Movement of punctured vials should only occur in specific circumstances, where an assessment of the risk of microbial contamination and proliferation versus risk of wastage and loss of opportunities to administer vaccines at end user sites has been considered by the PCN Clinical Director.

**Recommendation**
When planning a vaccination session, the Lead Pharmacist and Lead GP at the PCN designated site should undertake an assessment to identify the risk factors associated with the transfer of vaccine, including punctured vials, and ensure that mitigations are put in place. The risk factors associated with the transfer of vials must also be identified, understood and mitigated by vaccinators. The risk reduction measures detailed below must be in place.

**Risk Assessment**
The risk of patient harm through administration of a contaminated dose of vaccine is related to a combination of the following:

- there being no antimicrobial preservative contained within the multidose vial
- vaccinator aseptic technique
- the environment within which the dose is prepared
- the number of punctures to the vial; the more punctures the greater the chance of contamination
- the higher the ambient temperature and the longer the interval between first puncture and subsequent doses, the greater the risk of a harmful level of contamination. In a residential premises, consider the likelihood of a higher than average ambient temperature.

**Risk reduction measures**:

- **Aseptic technique is of paramount importance**
- Once punctured, the 6-hour expiry must be recorded on the vial
- Minimise the time between the first and last puncture within the maximum 6-hour period
- Ensure the vial is transported and stored within a validated cool box for the 6-hour period and that agitation of the vials during this period is minimised
- Remove the vial from a validated cool box immediately before withdrawing the first dose
- Swab the entire vial with a single use 70% alcohol swab after removal from the validated cool box and then use a fresh single use 70% alcohol swab to swab the bung
- Swab the bung with a single use 70% alcohol swab prior to every dose withdrawn and leave to dry for 30 seconds
- Swab the bung and then the entire vial with a single use 70% alcohol swab before replacing it in the validated cool box

- Place the vial in the validated cool box immediately after withdrawing the last dose to be administered on that site
- Where diluted (punctured) and undiluted vials are held in the validated cool box concurrently, it is essential that they are stored and transported in a segregated way to avoid the risk of confusion
- The validated cool box should only be decontaminated when leaving the home if there is contamination or if a resident has a known infectious pathogen.
- Check that the validated cool box temperature remains between $+2^0$C and $+8^0$C at all times
- If the validated cool box temperature exceeds $+8^0$C, discard all punctured vials
- If failure of aseptic technique is suspected, discard all punctured vials
- If the visual inspection of the vial suggests that the integrity of the product has been compromised, discard the vial.