****NHS England and NHS Improvement – South West

Integrated South West Public Health Team

**Regional Clinical Advice Response Service 5/02/21**

**For any COVID-19 vaccination related queries or to escalate an incident please contact:** [**england.swcovid19-voc@nhs.net**](mailto:england.swcovid19-voc@nhs.net)

**Learning From Recent Incidents**

**Issue**

COVID vaccination centre reception staff accepted a vaccine delivery from a driver and informed the clinical pharmacists but did not tell them that the vaccine was out of the delivery van in reception. Pharmacists were in the middle of a procedure so were not able to attend immediately to transfer the vaccine and as a result the vaccine was out of the fridge for 8 mins. Risk assessment determined that due to the specific situation at the clinic and the delivery temperature log that the vaccine remained in the cold chain and could be used.

**Learning from the PCN SEA for sharing**

Vaccination centres should ensure that procedures are in place so that staff only allow vaccine to be removed from delivery vehicles when it can be immediately transferred to the centre fridge.

Vaccination centres should ensure that all staff are made aware of the importance of the cold chain to preserve vaccine integrity.

Vaccine centres may wish to consider whether a pharmacist is always available to accept a vaccine delivery.

**COVID-19 Vaccination Programme Information for Healthcare Practitioners: Republished 3 February 2021**

The Information for Healthcare Practitioners has been updated and can be found at the below link:

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/958015/COVID-19_vaccination_programme_guidance_for_healthcare_workers_3_February_2021_v3.2.pdf>

For your information, the updated sections are as follows:

**1. Timing of offer of vaccine to those who are about to receive immunosuppressive therapy and allergy advice sections updated to reflect updated advice in Green Book COVID-19**

**chapter.**

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The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression.

This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID- 19 and from their underlying condition.

Although the immune correlates of protection are currently unknown, post-vaccination testing may be considered. Until further information becomes available, vaccinated patients with immunosuppression should continue to follow advice to reduce the chance of exposure.

**2. Section on surveillance of COVID-19 cases in vaccinated individuals added**

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Surveillance of COVID-19 cases in vaccinated individuals. The PHE Immunisation Department is conducting enhanced surveillance of cases of infection in vaccinated individuals in England, in order to confirm infection, identify risk factors and outcomes, and monitor phenotypic and genetic characteristics of SARSCoV-2 isolates and to compare these cases to those in unvaccinated individuals.

Individuals will mainly be identified by active follow up of a sample of cases identified by linkage between community testing and vaccination data. Clinicians who are seeing patients face to face are also encouraged to report any confirmed cases in partially or fully vaccinated individuals if they tested positive within the preceding 7 days. This provides the best opportunity to get early and complete sampling from these cases.

Further information, criteria for reporting and the reporting COVID-19 vaccination programme: Information for healthcare practitioners 19 form are available at [www.gov.uk/government/publications/covid-19-enhancedsurveillance-of-cases-in-vaccinated-individuals](http://www.gov.uk/government/publications/covid-19-enhancedsurveillance-of-cases-in-vaccinated-individuals)

**Also see RCARS Newsletter dated 28.01.21 for further information**

**3. Revised advice for action to take following inadvertent administration of incomplete dose of vaccine and new advice following administration of vaccine whose potency may have been adversely affected by an inadvertent storage or preparation error added**

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**Inadvertent administration of incomplete dose:**

Inadvertent administration of incomplete dose of vaccine If less than the full dose of COVID-19 vaccine is inadvertently given, for example, if some vaccine leaks out as it is being administered, a full dose should be drawn up and given as soon as possible after the error is realised. If a full dose is not given on the same day as the partial dose, for example if the error is realised after the individual has left the vaccination centre, or if it is suspected but not known for certain whether an individual received a partial dose, a full repeat dose should be offered 48 hours after the possible partial dose was given. The 48 hour wait period is to allow for any reactions experienced following the incomplete dose to resolve before the repeat dose is given. It is recommended that the repeat dose should be given within 7 days of the incomplete dose to minimise the time the individual may be left susceptible to infection. If more than 7 days have elapsed, seek expert advice. If this was the first dose, the ‘second’ dose of the two dose schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose.

**Potency issues due to storage or preparation error**

Administration of a dose of vaccine whose potency may have been adversely affected by an inadvertent storage or preparation error If a dose of COVID-19 vaccine is given following an incident in which the potency may have been affected, for example, a storage or preparation error, and expert advice has recommended that the dose of vaccine should be repeated, this should either be given on the same day as the potentially affected dose was given or, from 48 hours after the potentially affected dose was given. The 48 hour wait period is to allow for any reactions experienced following the potentially affected dose to resolve before the replacement dose is given. It is recommended that the replacement dose should be given within 7 days of the potentially affected dose to minimise the time the individual may be left susceptible to infection. If more than 7 days have elapsed, seek expert advice. If this was the first dose, the ‘second’ dose of the two dose schedule (which will actually be the third dose in this case) should still be given at the recommended interval from the additional dose.

**4. Change from 5 doses in a vial of Pfizer BioNTech vaccine to 6 doses as per updated Regulation 174 Information for UK healthcare professionals on Pfizer/BioNTech COVID-19 vaccine 3 February 2021**

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Each vial contains 0.45 ml of vaccine and should be diluted with 1.8 ml of Sodium Chloride 0.9% Solution for Injection (also referred to as normal saline). Once diluted, each reconstituted vaccine will supply 6 doses of 0.3 ml.

**Using AstraZeneca to Vaccinate Across Multiple Sites - Position Statement for the vaccination of care home residents using COVID-19 Vaccine AstraZeneca (AZ)**

B**ackground**

Standard Operating Procedures (SOPs) developed by the Specialist Pharmacy Service (SPS) have supported the implementation and administration of COVID-19 vaccination across the NHS.

The movement of punctured vials of AstraZeneca COVID-19 vaccine between multiple sites, i.e. end user locations, presents a greater risk of microbiological contamination and proliferation than a single site delivery. The SPS SOPs aim to balance the need to protect vaccine quality, minimise the risk of harm to the patient from accidentally administering contaminated vaccine and minimise vaccine wastage. **SPS advice is that moving a punctured vial of the AstraZeneca COVID-19 vaccine between care homes should only occur in rare circumstances**, for example when it is essential to vaccinate a small number of patients in each of several care homes as part of a “mop up” exercise within a 6 hour period to avoid significant wastage.

**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 care homes consider the likelihood of a higher than average ambient temperature.**

**Recommendation**

When planning a vaccination session for local care homes, the Primary Care Lead Pharmacist and the Lead GP at the PCN Designated Site should undertake an assessment to identify and understand the risk factors associated with the transfer of the vaccine for administration to remaining care home patients. Vaccinators must be made aware of these risk factors and the following risk reduction measures must be considered and be in place.

**Risk reduction measures:**

* **Aseptic technique is of paramount importance.**
* 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.
* Remove vial from a validated cool box immediately before withdrawing the first dose and replace it immediately after withdrawing the last dose to be administered on any one site (care home).
* Swab the entire vial and then the bung, with a 70% alcohol swab after removal from the validated cool box.
* Swab the entire vial with a 70% alcohol swab before replacing it in the validated cool box.
* Check that the validated cool box temperature stays between +2C and +8C at all times.
* If the temperature exceeds 8C discard all punctured vials.
* If failure of aseptic technique is suspected, discard all punctured vials.

To read the statement online published on 1st February 2021, please see below link:

<https://www.england.nhs.uk/coronavirus/publication/position-statement-for-the-vaccination-of-care-home-residents-using-covid-19-vaccine-astrazeneca-az/>

**REMINDER: PROCESS FOR OFFERING VACCINATION TO COHORTS 3 AND 4**

**(NHS 31st January 2021)**

The current deployment approach taken by the NHS is to offer COVID-19 vaccination as set out by the JCVI recommendations, and in sequential order by cohort. In order to support achievement of a vaccination offer **to all individuals within JCVI cohorts 1-4 by 15 February 2021**, and guided by the principles of minimising wastage, reducing inequality of access, and maximising pace, **we have moved to a more flexible approach across cohorts 1-4 only.**

You should continue to prioritise vaccinating people from JCVI priority cohorts 1 (residents in a care home for older adults and their carers) and 2 (all those 80 years of age and over and frontline health and social care workers).

It is then permissible to offer vaccination to cohort 3 (75-79 year olds) and cohort 4 (70-74 year olds and the Clinically Extremely Vulnerable under 70). **Sites should have reserve lists of recipients for every clinic, who can come in at short notice if vaccine is still available.** These reserve lists should be drawn from the ‘next cohort’ on the list – at the moment either cohort 3 or cohort 4.

In line with JCVI guidance and the statement from the Chief Medical Officers on second doses published on 30 December, **vaccine supplied should only be used to deliver first doses of vaccine, with second doses being scheduled for the 12th week.** It is supplied on the basis that it will be used immediately for vaccination of patients and not stored, since weekly deliveries are now being made.

**What does this look like in practice?**

**Minimising wastage**

Vaccine should not be wasted. If there is vaccine supply and deployment capacity, but a degree of uncertainty on whether clinics will be full, further invitations can be made to individuals from across cohorts 1-4 in order to utilise available supply.

**Reducing inequality**

Working closely with local partners, deployment should continue to minimise inequalities between different communities. Please do as much as you can to get vaccination to your highest risk populations, mindful of deprivation, ethnicity and all factors impacting COVID risk. This increased flexibility offers an opportunity to tackle inequity and begin reaching health inclusion groups. Communities with greater levels of vaccine hesitancy or other challenges around engagement and uptake will take longer to reach, so all local areas should ensure engagement is either underway or begins now. Every effort must be made to reach these groups using targeted local outreach and community champions as informed by local Equalities and Health Inequalities Assessments (EHIAs). Please ensure you work with your system partners, especially Local Authorities and Voluntary and Community Sectors in your area to ensure health inclusion. Please help us make sure no one gets left behind, and feed back on how the central team can help support excellent local work to ensure equity in vaccination rates.

**Maximising pace**

Where there is vaccine supply and deployment capacity, this allows a pragmatic operational approach that enables opportunistic vaccination within cohorts 1-4, such as vaccinating partners of similar age from cohorts 3 & 4 who attend together, or those living in multigenerational households.

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