Regional Clinical Advice Response Service 07/05/21

Clinical Advice Response Service – how to contact us from May 2021

From the 3rd May 2021 please can all clinical queries and incidents in the COVID vaccine programme be sent directly to the clinical advice response service to the email below. This change is in line with the changes NHSEI have made to the incident response level.

england.swcovid19-cars@nhs.net

For any COVID-19 vaccination related queries or to escalate an incident please contact: england.swcovid19-cars@nhs.net

Please note that going forward and in line with the RVOC and NVOC, RCARS will now operate between the hours of 8am and 6pm over the weekend.

Contents:
To access each of the items in the contents below, please press ctrl and click on the relevant link.

1. BD Venflons - Update
3. Vaccine Update: Issue 319
4. Look After Your Vaccines – Cold Chain Incidents

BD Venflons - Update

BD Venflons that have been identified for immediate withdrawal following the issue of the FSN on 4 May 21, can still be used to support patient care, where alternative stock is not available and while replacement stock is procured from the NHS Supply Chain, so that patient care can be maintained, noting that the clinical advice on the use of these not embargoed products are fully complied with (contained in the Advisory FSN published on 1 Mar 21, which was circulated to all Systems and Providers on 4 May 21 by the ROC).

Please note that this document was republished on 30.04.21 and can be found at the below link:

COVID-19 vaccination: information for healthcare practitioners - GOV.UK (www.gov.uk)

Updates were made to the following sections and should be reviewed by all healthcare professionals involved in the vaccination programme:

- **Pregnancy section updated:**

  Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group.

  There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA where around 90,000 pregnant women have been vaccinated, mainly with these 2 vaccines, with no safety signals being raised so far. There have been no specific safety concerns from any brand of COVID-19 vaccine in relation to pregnancy but more research is needed and there is more safety data available for the Pfizer BioNTech and Moderna vaccines which is why these 2 vaccines are currently the preferred vaccines to offer to pregnant women. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy.

  Routine questioning about last menstrual period and/or pregnancy testing is not required before offering COVID-19 vaccine. Women who are planning pregnancy or in the immediate postpartum can be vaccinated with a suitable product for their age and clinical risk group.

  If a woman finds out she is pregnant after she has started a course of COVID-19 vaccine, she may complete vaccination during pregnancy using the same vaccine product (unless contraindicated). Alternatively, vaccination should be offered as soon as possible after pregnancy.

  Termination of pregnancy following inadvertent immunisation should not be recommended. Surveillance of inadvertent administration of COVID-19 vaccines in pregnancy is being conducted for the UK by the PHE Immunisation Department. If a pregnant woman is inadvertently given COVID-19 vaccine, this should be reported to PHE. Women who are inadvertently vaccinated in early pregnancy should be offered the second dose of the same product.

- **New contraindications for COVID-19 vaccine AstraZeneca added:**

  COVID-19 vaccine contraindications COVID-19 vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

  - a previous dose of the same COVID-19 vaccine
  - any components (excipient) of the vaccine
COVID-19 Vaccine AstraZeneca should not be given to those with a history of a previous episode of heparin-induced thrombocytopaenia and thrombosis (HITT or HIT type 2) or to those who experience a clotting episode with concomitant thrombocytopaenia following the first dose of AstraZeneca vaccine.

The COVID-19 chapter of the Green Book provides full details about the contraindications and precautions to COVID-19 vaccine. Everyone involved in the COVID-19 vaccination programme should ensure they have read the latest online version of this Green Book chapter so that they are familiar with all the contraindications and precautions to the COVID-19 vaccines. Where there is any doubt as to whether the vaccine can be given, appropriate advice should be sought from the relevant specialist, or from the local immunisation team or health protection team.

**Thrombosis and thrombocytopenia**

Following widespread use of the AstraZeneca vaccine, a very rare specific type of blood clot in the brain known as cerebral venous sinus thrombosis (CVST) occurring together with low levels of platelets (thrombocytopena) following vaccination with the AstraZeneca COVID-19 vaccine has been reported and investigated. The subsequent new contraindications and precautions to this vaccine, including changes to age group recommendations are detailed in the COVID-19 chapter of the Green Book. Further detailed information is also available in the Information for healthcare professionals on blood clotting following COVID-19 vaccination document and a COVID-19 vaccination and blood clotting leaflet is available for patients.

- **Advice about which vaccines to give those vaccinated abroad added:**

  **Individuals who received COVID vaccination overseas**

  If a person has received a first dose of COVID-19 vaccine overseas that is also available in the UK, they should receive the same vaccine for their second dose provided they meet UK eligibility criteria (as per the JCVI guidance). If the vaccine they received for their first dose is not available in the UK, the most similar alternative should be offered (see Appendix 1).

  The various groups of vaccines are:

  - **Adenovirus (ChAdOx) vector:** AstraZeneca, Covishield
  - **mRNA:** Pfizer, Moderna
  - **whole inactivated Coronavirus:** Sinopharm, Sinovac, Covaxin

  The other adenovirus-based vaccines (Jansen, Sputnik, CanSinoBio) use different vectors and so are not immunologically the same as either the AstraZeneca or Covishield adenovirus vector vaccines. However, as they, and the Novavax vaccine, are all based on spike protein, the vaccine course can be completed with any of the locally available vaccines.
**Look After Your Vaccines – Cold Chain Incidents**

Please take a few minutes over the next week to check that all the staff involved with monitoring the vaccine fridge temperatures in the setting in which you give vaccines know how to accurately record the current, minimum and maximum temperatures and know how to RE-SET the fridge thermometer after each reading.

The PHE national immunisation team has been involved in advising on several cold chain incidents already this year and one of the main issues has been the absence of re-setting. Pages of temperature recordings for some of these incidents have been provided, all with identical minimum or maximum readings, often out of range for days or weeks with no action taken.

Readings of current, minimum or maximum temperature should ideally be taken and recorded at the beginning and end of each day and immediate action should be taken if any of these are found to be outside the recommended +2°C to +8°C temperature range.

Please help prevent vaccine wastage and maintain vaccine potency and patient confidence by ensuring everyone involved has access to your local cold chain protocol, that all know how to find and use the RE-SET button appropriately and that all staff know what action they need to take if any of the current, minimum or maximum temperatures are outside of the recommended range.

To help staff prevent wastage, please order a free [keep your vaccine healthy cold chain fridge magnet](https://www.gov.uk) and [keep your vaccines healthy poster](https://www.gov.uk).

**Cold-chain incidents and vaccine storage temperature deviations reported to SW RCARS:**

SW RCARS has been notified of 37 cold chain and vaccine storage temperature deviation incidents since the vaccine rollout began.

The implications of cold chain incidents and temperature excursions can be considerable with costly wastages, cancelled clinics and interruption to the vaccine rollout. For example, RCARS was informed that a fridge failure at one GP Practice resulted in cancelled vaccination clinics later that week.

It is paramount that RCARS is alerted to cold-chain breaches as soon as possible and that any faulty fridges are reported so that replacements can be ordered to prevent repeats of the incident in the future.

In the event of cold-chain failures it is also important that replacement vaccine stock is requested rapidly to enable all planned vaccination clinics to take place throughout the week.
Obtaining additional vaccine stock through Mutual Aid is one way that shortages caused by cold-chain incidents can be addressed to avoid disruption to the programme. As soon as a cold chain breach is established, providers must ascertain the number of replacement vaccine vials required and the date they must be obtained by.

All COVID-19 vaccination queries and incidents should be directed to: england.swcovid19-cars@nhs.net