Regional Clinical Advice Response Service 21/05/21

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.

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

Contents:

1. Protect your vaccines to protect your patients!
2. COVID-19 Vaccine Pfizer-Biontech: Change to Shelf Life When Stored in Refrigerators At 2-8C – 20th May
3. COVID-19 Vaccination: Accelerating Second Doses for Priority Cohorts 1-9
4. Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021
5. National Protocol for COVID-19 Vaccine Astrazeneca (Chadox1-S [Recombinant])
6. Dementia Sufferers and Covid-19 Vaccination

Protect your vaccines to protect your patients!

Have you checked your data logger has an SD card?

Have you clearly marked the expiry time for Pfizer vaccine held in your fridges?

Vaccines wasted through mis-ordering, being left out of the cold chain, being allowed to go beyond their use-by dates, and fridge failures cost the NHS thousands of pounds every year.

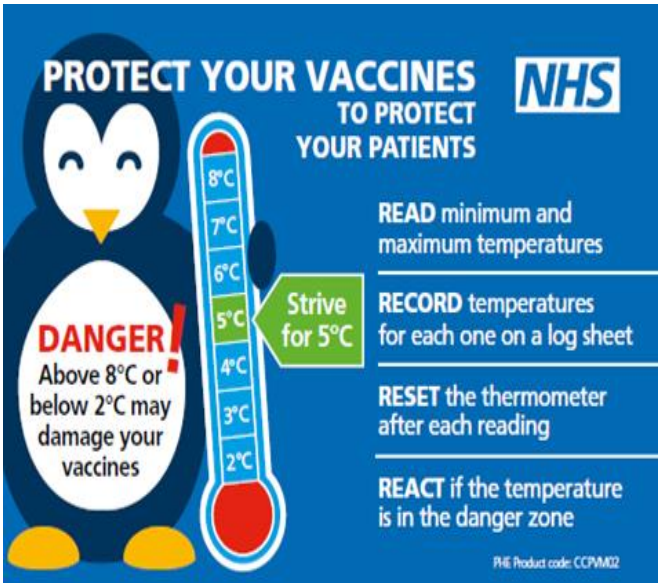
At a time when we are all having to be much more careful with our budgets it is particularly important that we are vigilant around the use of valuable resources.

As a result of recent incidents, we wanted to draw your attention to checking whether the data logger in your fridge has a SD card.

If not, this means that the data can't be readily downloaded, and it negates the reasons a data logger is recommended.

We also recommend that you:

- Check expiry dates (and times) regularly – never use out of date vaccine. It is imperative with the current vaccine stocks, that both expiry times and dates are reviewed
- Keep vaccines in their original packaging in the main part of the fridge, not loose or in drawers
- Don't overstock the fridge – air circulation is important for temperature control
- Keep your fridge door locked at all times when not accessing vaccines
- Use a maximum-minimum thermometer and keep a daily record of the temperatures
- Keep the opening of the fridge door to a minimum
- Have back-up storage for your vaccines in case of power failure
- Position the fridge away from heat sources and mark or tape the fridge plug to avoid it being turned off accidentally



See Chapter 3 of the Green Book for more information

We are aware that many settings are very familiar with best practice and the processes for maintaining cold chain, but in busy times errors can still easily occur.

We recommend all settings take the opportunity to review local procedures and processes and reflect on their practice.

Our case studies below are based on real incidents that have occurred in the last week alone:

1) A cold chain breach occurred when a fridge holding the Pfizer COVID-19 vaccine was noted to have to have reached 8.5 degrees. The setting were not monitoring daily

temperatures on days that they were not vaccinating. This meant that although the increase did not appear excessive, it was not known whether this was accurate or illustrative of the previous 48 hours. There was a data logger in place but unfortunately it did not have a SD card so no information on the fridge temperatures was available at the time the incident was reported. There was a delay whilst an SD card was sourced from the data logger manufacturer and appointments for patients due that day had to be cancelled. The data was retrieved, and a risk assessment completed which enabled use of the vaccine, but due to time elapsed and the short-life of the vaccine some had to be disposed of. Both impacts could have been avoided

Key learning:

- Ensure daily monitoring occurs on all days vaccine is held in the fridge
- check that your data logger has an SD card and be prepared to download when you report a cold chain incident

2) A setting had Pfizer vaccine delivered on a Monday but continued to vaccinate with this supply through to Saturday before the time since delivery was recognised. Although the vaccine had been kept within the fridge at 2-8 degrees, the vaccine was administered to a large number of patients after the recommended120 hours expiry time. Following careful investigation and expert clinical advice the vaccine was, on this occasion, confirmed as being stable and no harm occurred. However, this avoidable situation could have resulted in the need to re-vaccinate all of these individuals.

Key learning:

- When taking the Pfizer vaccine out to reconstitute or administer, check the expiry time for the batch has not exceeded 120 hours
- Ensure named individuals are identified each day to be responsible for stock monitoring and cold chain management
- Keep clear records and have visible aide memoires as needed to ensure expiry times are not exceeded

If you experience a cold chain or any other clinical incident report it promptly to CARS england.swcovid19-cars@nhs.net and we will support your investigation and any mutual aid required for vaccine supply.

COVID-19 Vaccine Pfizer-Biontech: Change To Shelf Life When Stored In Refrigerators At 2-8C – 20th May

You may be aware that the MHRA has now amended the Conditions of Authorisation for the COVID-19 mRNA Vaccine BNT162b2 (the "Pfizer-BioNTech vaccine")

This amendment permits the storage of the thawed unopened vial in a 2-8C refrigerator for up to one month (31 days). Please see the announcement and details below.

The updated documents: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

MHRA statement: https://www.gov.uk/government/news/pfizerbiontech-covid-19-vaccine-shelf-life-extended-from-5-to-31-days-says-mhra

The advice from the MHRA is:

Please note that this extension applies to all existing batches currently in circulation with the UK. Any boxes already labelled with 120 hours post ULT should either be used within that original expiry or provisions made for the expiration date extension under suitable controls. The controls anticipated would be 'in-line' with the approach to the controls required for the application of the thaw labels when first applied

To note an email cascade of a formal letter from Keith Ridge and Emily Lawson (attached and below) is being sent via SPOC

Also to note that SPS SOPs for handling the Pfizer vaccine have been updated and will be published this evening May 20th 2021. They include a new, temporary SOP which can be used as a guide to relabelling existing stocks in centres that thaw the vaccines until they have new thaw labels which are expected to be available early in the week beginning May 24th 2021. Once they have their new thaw labels sites should destroy the old 5-day thaw labels.

Please also note that the changes announced today relate only to the extended post-thaw shelf life of the undiluted vaccine when stored at 2-8C in the fridge before use. All existing restrictions on in-use shelf life of the diluted vaccine remain in place, and existing restrictions on movement/transport times and methods for undiluted and diluted vaccine, remain unchanged.

Letter:

Dear Colleague

Earlier today, and following an assessment of additional data supplied by Pfizer/BioNTech, the Medicines and Healthcare products Regulatory Agency (MHRA) has amended the Conditions of Authorisation of the COVID-19 mRNA Vaccine BNT162b2 (commonly known as "COVID-19 Vaccine Pfizer-BioNTech") under Regulation 174 of the Human Medicines Regulation 2012.

This change extends the approved storage period of the unopened, thawed vial at 2-8°C (i.e. cold chain conditions) from five days to **one month** (31 days). The full details of the revised Conditions of Authorisation can be found here.

This is a welcome move which brings additional flexibility to our vaccination programme. Vaccination administration sites will now have a longer period of time over which to use this vaccine, supporting efforts to open up booking slots, minimise waste and ensure that cohort penetration is achieved. It will become easier to align vaccine clinics with the delivery and availability of this vaccine. Planning for 'roving' or 'pop-up' vaccination services will also be made easier by this amendment. In turn, we expect that the need for administration sites to engage in 'Mutual Aid' will significantly diminish.

Nevertheless, it is important to be fully aware that no other Conditions of Authorisation for COVID-19 Vaccine Pfizer-BioNTech relevant to the handling of the vaccine itself have changed and that this vaccine remains inherently fragile. It must be treated with care and in particular, it is important that any transportation and preparation of the vaccine always takes

place within the permitted parameters and in accordance with the Standard Operating Procedures developed by the NHS Specialist Pharmacy Service. These Standard Operating Procedures are in the process of being updated with the amendment to the storage condition and this update will be completed shortly.

Operationally, the responsible NHS Hospital Chief Pharmacist, CCG Lead Pharmacist or Superintendent Pharmacist (as applicable), should engage with healthcare professionals operating on site now to make them aware of this development and to ensure that the implications for vaccine supplies already in their possession are carefully understood. Local procedures should be updated in line with the latest NHS Specialist Pharmacy Service guidance as soon as possible.

It remains important that vaccination administration sites continue to vaccinate all patients within eligible cohorts at pace, ensuring that residual on-site stock holdings remain low at all times.



Emily Lawson
SRO Vaccine Deployment
Chief Commercial Officer
NHS England and NHS Improvement



Dr Keith Ridge CBE
Chief Pharmaceutical Officer for England
NHS England and NHS Improvement

COVID-19 Vaccination: Accelerating Second Doses for Priority Cohorts 1-9

Read the full letter online at the link below:

Coronavirus » COVID-19 vaccination: accelerating second doses for priority cohorts 1-9 (england.nhs.uk)

Dear Colleague

Yesterday evening, in response to advice from the independent JCVI, the Government set out further action aimed at tackling rising cases of the COVID-19 B1.617.2 variant.

The updated instruction states that:

“Appointments for a second dose of a vaccine will be brought forward from 12 to 8 weeks for the remaining people in the top nine priority groups who have yet to receive their second dose. This is to ensure people across the UK have the strongest possible protection from the virus at an earlier opportunity.

The move follows updated advice from the independent experts at the Joint Committee on Vaccination and Immunisation (JCVI), which has considered the latest available evidence on the variant and has recommended reducing the dosing interval to help protect the nation from the variant.

People should continue to attend their second dose appointments and nobody needs to contact the NHS. The NHS will let those who should bring their appointment forward know, when they are able to do so.

Those aged under 50 will continue to get their first dose, with their second dose at 12 weeks,

as has been the deployment strategy so far."

The full press release can be found here: Most vulnerable offered second dose of COVID-19 vaccine earlier to help protect against variants - GOV.UK (www.gov.uk)

ACTIONS NOW REQUIRED

Therefore, we are writing to ask you to take the following actions.

Second doses for cohorts 1-9

The immediate priority for all delivery models is to ensure that there is sufficient capacity for those who need to book a first dose or re-book a second dose appointment.

For those in cohorts 1-9 who have already received a first dose of a vaccination and have an appointment booked for a second dose in the next 10 days (up to and including 24 May) **no action is required and appointments should continue as scheduled**.

For those in cohorts 1-9 who have their second dose appointment scheduled on or after 25 May **the following action now needs to be taken:**

- For vaccination centres and community pharmacy-led LVS: every effort needs to be made to ensure any additional capacity for first and second doses is uploaded to the National Booking System (NBS). The NHS will contact individuals directly within priority cohorts 1-9 with an appointment on or after 25 May (where that is more than 8 weeks after their first dose) who have booked via the NBS to encourage them to rebook an earlier appointment.
- For PCN-led Local Vaccination Services: all second dose appointments for those in cohorts 1-9 scheduled on or after 25 May (where that is more than 8 weeks after their first dose) should be brought forward. Plans to do this should include working with your ICS to bring in additional workforce to run additional clinics. In addition to using the stock already in the network, revised second dose supply delivery schedules will be communicated shortly in the usual way. If PCN sites have exhausted all opportunities to bring forward second doses and still have insufficient capacity to bring forward second dose AstraZeneca clinics, they may wish to redirect patients to book via the NBS. Additional financial support, as well as supporting communications materials, will be made available to primary care network-led LVS to cover the administration costs of this activity. Further information will be shared with practices shortly.
- For Hospital Hubs: all second dose appointments for those in cohorts 1- 9 scheduled on or after 25 May (where that is more than 8 weeks after their first dose) should be brought forward.

Maximum uptake

Vaccination uptake rates in England remain high, with all priority cohorts showing well over 90% nationally. For second doses uptake is also high with over 9 in 10 for those aged 70 years and over. We continue to deliver on the NHS's 'evergreen' vaccination offer for anyone in eligible cohorts who have yet to take up the opportunity, especially those in cohorts 1-9.

We ask that all vaccination services, supported by their system partners including local3 authorities and voluntary and community sector organisations, continue to do everything they can to ensure maximum uptake. This includes scaling up existing activity such as longer opening hours, vaccine buses, roving and street teams. Previous JCVI advice states:

"In individuals aged 18 to 49 years there is an increased risk of hospitalisation in males, those from certain ethnic minority backgrounds, those with a body-mass index (BMI) of 30 or more (obese or morbidly obese), and those experiencing socio-economic deprivation.

JCVI strongly advises that individuals in these groups promptly take up the offer of vaccination when they are offered, and that deployment teams should utilise their understanding of local health systems and demographics, combined with clear communications and outreach activity, to promote vaccination in these groups."

Full JCVI guidance can be found here JCVI final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 - GOV.UK (www.gov.uk)

Therefore, systems are encouraged to refer to practical guidance for implementing a range of interventions to ensure equitable and COVID-secure access to COVID-19 vaccination and improve uptake. This can be found here: Coronavirus » Maximising vaccine uptake in underserved communities: a framework for systems, sites and local authorities leading vaccination delivery (england.nhs.uk)

Thank you for your continued leadership on this vital programme.



Emily Lawson
SRO Vaccine Deployment
Chief Commercial Officer
NHS England and NHS Improvement



Dr Nikki Kanani
Medical Director for Primary Care



Eleanor Kelly
LA CEO advisor

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021

News 07/05/2021

This month EMA's safety committee (PRAC) reviewed a number of safety signals related to COVID-19 vaccines. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.

PRAC concludes review of signal of facial swelling with COVID-19 vaccine Comirnaty (currently known as COVID-19 mRNA Vaccine BNT162b2 or Pfizer Biontech)

PRAC has recommended a change to Comirnaty's product information. After reviewing all the available evidence, including cases reported to the European database for suspected side effects (EudraVigilance) and data from the scientific literature, PRAC considered that there is at least a reasonable possibility of a causal association between the vaccine and the reported cases of facial swelling in people with a history of injections with dermal fillers (soft, gel-like substances injected under the skin). Therefore, PRAC concluded that facial swelling in people with a history of injections with dermal fillers should be included as a side effect in section 4.8 of the summary of product characteristics (SmPC) and in section 4 of the patient information leaflet (PIL) for Comirnaty. The benefit-risk balance of the vaccine remains unchanged.

Link to the article: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-3-6-may-2021

National Protocol for COVID-19 Vaccine Astrazeneca (Chadox1-S [Recombinant])

The National Protocol for COVID-19 vaccine AstraZeneca and COVID-19 vaccine AstraZeneca Patient Group Direction have now been updated (V04.00) and are available via the following link:

https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds)

Dementia Sufferers and Covid-19 Vaccination

The article at the link below, highlights the recent novel judgement that a dementia sufferer who has had long term opposition to vaccines should not receive the vaccine.

Please follow clink to read the article:

https://www.mentalcapacitylawandpolicy.org.uk/covid-19-vaccination-best-interests-is-not-code-for-mandatory-vaccination-and-a-reminder-you-cant-fail-a-capacity-assessment/

The decision in the case covered here involving *SS v LB Richmond on Thames and SWL CCG* [2021] EWCOP 31 is different to others that have been reported to date (such as *E (Vaccine)* [2020] EWCOP 14, because it was clear that the objection to the vaccine came from the person themselves, not from family members.

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