



ICARS Newsletter

Issue 72: 21st January 2022

Immunisation Clinical Advice Response Service

About this bulletin:

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

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

Please note that ICARS operates from 9am - 5pm Monday to Friday.

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1. NEW: Extending the post-thaw expiry date of specific batches of Comirnaty® (30 microgram/dose) for Adults and Adolescents

Vaccination sites have been advised via [this letter](#) (supported by [this SOP](#)) to extend the post-thaw expiry date of specific batches of unpunctured, undamaged Comirnaty® 30 microgram/dose COVID-19 mRNA vaccine from 31 to 45 days.

The PGD and National Protocol include the following under storage:

Thawed unopened vials have a 1-month shelf-life at 2°C to 8°C

These details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's [SPC](#). The product's [SPC](#) also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.

The Off-label section of the PGD and National Protocol states:

Vaccine should be stored according to the conditions detailed in the storage section. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to [Vaccine Incident Guidance](#). Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this [PGD/protocol].

UKHSA, DHSC and NHSEI have therefore reviewed these documents and have agreed that use of the products following formal notification of post-thaw expiry extension based on company data would be reasonable. This use would be characterised as an off-label use but within the protocol and the PGD.

Immediate actions for sites:

- **Ensure all colleagues working at the vaccination site are aware that the PGD and National Protocol for Comirnaty® 30 microgram/dose COVID-19 mRNA vaccine can be used for administration of vaccine that has had the post-thaw expiry extended in line with the system letter of 17th January 2022.**
- **Ensure all staff know that the consequence of being able to still use the PGD and National Protocol for the extended expiry products is that all**

those who administer now under those legal mechanisms can continue to do so.

- **Ensure all clinical staff consider the off-label use of extended expiry product when carrying out the clinical assessment and consenting process.**

2. NEW: Confirmatory positive samples for COVID-19 infection

Until recently, a positive result from a lateral flow device (LFD) test would need to be followed up with a positive PCR test to confirm COVID-19 infection. Recently UKHSA has announced a temporary change to confirmatory PCR tests. For now, most people who get a positive LFD test will not need to take a PCR test to confirm the result. More details can be found [here](#).

This has an impact on the interpretation of clinical guidance for vaccinations. The [Green Book Chapter 14a](#) advises deferral of vaccination after an individual has had a COVID-19 infection. The timeframe for deferral varies according to age and whether a person is in a risk group. For individuals who were symptomatic, the guidance states that the deferral timeframe should begin from the day that the individual started to experience symptoms of COVID-19. If they were asymptomatic, the deferral timeframe begins from the day that they took a sample for the confirmatory positive test. In the absence of confirmatory PCR tests, during this period of temporary suspension, it is clinically appropriate to interpret that the first positive LFD test for that episode of infection is a confirmatory positive test from which the deferral timeframe begins.

3. UPDATE: Myocarditis/pericarditis UKHSA updated FAQs

UKHSA has updated the healthcare professional myocarditis/pericarditis FAQs, which now include a question relating to strenuous exercise. The Information for healthcare professionals on myocarditis and pericarditis following COVID-19 vaccination is available [here](#).

4. NEW: Vaccination of 5 - 11 year olds and 12-15 year olds and 16 to 17 year olds updates

4a) Operational guidance following JCVI advice on the booster vaccination of eligible 12 to 17-year olds and household contacts of immunosuppressed people

On Saturday 8 January, NHS England and NHS Improvement issued [operational guidance on boosters for eligible 12 to 17 year olds including household contacts of immunosuppressed people](#). The [updated PGD and National Protocol](#) were published on 7 January, and so the guidance outlines that PCN and Hospital Hub/Hospital Hub+ sites can begin to invite and vaccinate eligible groups via local booking systems. Please read the guidance if you have not already done so. The guidance is to be read in conjunction with our [system letter](#) from 23 December 2021 and [JCVI advice](#) from 22 December 2021.

4b) Operational guidance for 5-11-year olds in a risk group and household contacts of immunosuppressed people

[Guidance has been cascaded to the system](#) to support vaccination of at-risk 5-11-year olds. With immediate effect, all GP teams and hospital consultants are asked to start conducting searches of 5-11 year olds in a risk group (as defined in the Green Book) or household contacts of someone who is immunosuppressed who are now eligible for their primary vaccination course.

By the end of January, commissioned providers approved to vaccinate children aged 5-11 years old who are in a clinical risk group (as defined in the Green Book) or are household contacts of someone who is immunosuppressed should have started to offer the primary vaccination course (first and second dose).

This guidance is to be read in conjunction with our system letter ([here](#)) from 23 December 2021 and JCVI advice ([here](#)) from 22 December 2021.

4c) Template invitation letters for consultants/GPs 12-15 booster and 5-15 household contacts

Further to our operational guidance from 08 January to vaccination sites, GPs, and hospital specialist teams on the booster dose for eligible 12 to 15 year olds, we have issued template letters to assist clinicians in inviting severely immunosuppressed people aged 12 and over or their responsible adults.

These letters can also be used to invite household contacts aged 12 to 15 of someone who is immunosuppressed and are now eligible for their booster. The template letters have been made available [here](#) and are to confirm eligibility for the booster dose and how they can receive their vaccination.

4d) New resources to support vaccination of at-risk 5-11-year olds

The UK Health Security Agency (UKHSA) has published the following:

- COVID-19 vaccination guide for parents of children 5 to 11 years of age – product code: C21CFE1OEN

- What to expect after your child's COVID-19 vaccination leaflet – product code: C22W511EN

They can be viewed [here](#) and copies can be ordered [here](#) using the product codes above.

4e) Learning from the initial role out of the 12-15 model through SAIS teams

A summary of learning and improvements shared by regions and local SAIS teams including consent examples and learning from incidents is now available and has been updated with additional feedback from the December period. Supporting resources and legal guidance regarding rights of the child can be accessed on Futures [here](#).

5. NEW: Vaccination in pregnancy video from RCGP

The Royal College of GPs has published a new resource for clinicians on vaccination in pregnancy. Written by Dr Jo Parsons a post-doctoral researcher with a PhD in vaccine uptake in pregnancy and Dr Sarah Hillman, a GP and clinical lecturer at the University of Warwick, the [screencast](#) provides information on vaccinations within pregnancy, including the COVID-19 vaccine.

6. NEW: Operational and Administration updates and guidance

6a) NEW: Point of Care system changes – update to security measures

A number of changes are being introduced into the Point of Care systems over the coming weeks.

These changes are outlined below. All vaccination sites must take note of the changes and ensure the necessary preparatory arrangements are in place at each vaccination site. Additional targeted communications will be shared within the Point of Care systems once release dates are confirmed.

These changes will mean ALL users with access to the Point of Care systems will need to have a unique email address recorded within the system to support user authentication and password resets. This email address should be an @nhs.net account and must be unique to the user. It must not be a shared or generic mailbox. The email address provided will not be used for any other purpose other than to support system access.

Removal of 'there and then' password feature in Outcomes4Health (Pinnacle)

The 'there and then' password generation feature in Outcomes4Health (Pinnacle) will be disabled from 18/01/2021.

Creation of accounts

- New user accounts must be unique to the user and created with a valid and uniquely identifiable email address and the user must have access to this email address in order to log into their account. Temporary login credentials are sent to the new staff member via the email address attributed to that user profile on creation.
- Site Administrators should ensure that any new staff member have their Pinnacle user profile created prior to their arrival on-site.
- All Site Administrators within the POC system must have a unique @nhs.net email address. This email address must be a named individual and must not include shared or generic site mailboxes. For more information about NHSmail, please visit: <https://digital.nhs.uk/services/nhsmail>.

New staff members must arrive onsite with their Outcomes4Health (Pinnacle) login credentials to hand or have access to the email address attributed to the account in order to access the Outcomes4Health (Pinnacle) system.

Resetting password by accessing email

Where a user has forgotten their password but is able to access their email, they will be able to request a password reset via email. This can be actioned by the Site Administrator within the Outcomes4Health (Pinnacle) system. More information can be found here: [Outcomes4Health FAQ and Troubleshooting Guide](#).

Resetting passwords without accessing email

Where an existing user has forgotten their password and is unable to access their email (except @nhs.net which can be accessed using onsite computers), they must follow the procedure below. Please note that new users will not be able to setup a password via the Vaccine Service Desk.

- To request an urgent password reset, call the Vaccine Service Desk on 0300 200 1000 or email at vaccineservicedesk@england.nhs.uk between 06:00-22:00 every day
- The user must provide contact information including a phone number that they can be contacted with onsite
- The Pinnacle support team will then contact the user using the phone number provided
- The user must verify their identity with the security word attached to their account
- The Pinnacle support team will then verbally provide a new temporary password for the user to access the system. They must then immediately update their password.
- If the user has forgotten their security word they will not be granted a password reset and must gain access to their email account to do so.

Reviewing access to all IT systems

- It is the Site Lead's responsibility to ensure that access is managed appropriately in all IT systems supporting the vaccination programme.
- Access to IT systems must be removed for staff when they leave a site operation or change to a role where access is no longer required.

Out of Hours Access to Point of Care Systems

The Point of Care (POC) system functionality to create or amend vaccination events will be restricted between the hours of 00:00 and 06:00 UK time for all COVID vaccination sites with the only exceptions being Defence Medical Services and Hospital Hubs.

If your site has a Programme requirement to operate for 24 hours a day, then the Site Lead is required to inform the Regional Lead so they can submit a formal Change Request Form with appropriate justification. This request will be processed and approved by the National team before the POC supplier can be instructed to remove the restrictions within their system.

We thank you for your ongoing support to deliver COVID-19 vaccinations throughout the autumn and winter.

For all IT system related support, please contact the Covid Vaccine Service Desk: vaccineservicedesk@england.nhs.uk or 0300 200 1000

6b) Changes to both Pfizer Comirnaty reconstitution and administration needles and syringes

UKHSA informed the Programme of the following:

Combined needle and syringe for the administration of the Pfizer Comirnaty vaccine is changing to a 25g needle

The GBUK Prosum combined needle and syringe used for the administration of the Pfizer Comirnaty vaccine will be switching from the 23g needle currently supplied to the same product but with a 25g needle, in the new year.

The process of preparing to move the product ready for a later switch has started. Unfortunately, some of this has been released earlier than planned so it is possible you may receive the product with the 25g needle with your recent orders. Please continue to use this product and be aware that this will revert back to the 23g needle until all stocks are depleted when a permanent switch to the 25g needle will occur sometime in the next few weeks.

New Comirnaty Pfizer dilution needle/syringe is being phased in for England

New product: BD Discardit Non safety CNS 23g x 25mm, with 2ml syringe.

Previous product: Griffiths and Neilsen Vanishpoint Safety Hypodermic Needle & Syringe 21G Green x 38mm (1.5 inch) with 3ml Concentric Syringe

This product is from the BD Discardit range, which should be familiar to vaccinators since the first dilution syringe issued in the Covid vaccination programme was also BD Discardit - there are two things to note:

- This product's specification (gauge and length) differs from previous products. Both the vaccine manufacturer and UKHSA clinical colleagues have confirmed that this specification is appropriate to use for dilution.
- This product does not incorporate a safety feature. Standard non-safety dilution needles will be supplied for a period of time with the expectation to return to a safety product as soon as practically possible. UKHSA have advised vaccinators should not experience a difference when using the needles and syringes. Preparation and administration of the vaccine should continue using correct existing practice, which remains the same. Please see attachment RVOOC 7215.

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6c) C19 Vaccination Record Cards

The COVID-19 vaccination record cards previously supplied with the vaccine will no longer be offered from ImmForm. All vaccine providers will need to order stock of the record cards directly from the Health Publications website.

The first designs remain suitable for first and second doses and are in stock and will be withdrawn when stocks are exhausted. Please use your current stock in the interim. There is no need to return stock.

1. **Original design, product code:** [COV2020311 1 = Pack of 50 COVID-19 Vaccination record card - 2 doses](#)
2. Hope design record card Product code: [COV2020311V3 COVID-19 vaccination record card \(pack of 50\)](#)
3. The NEW third dose/booster record card is designed so that providers can record the number of the dose on the left hand side of the card. This makes it suitable for a third dose or booster as appropriate. It can be ordered now be ordered from the [Health Publications website](#) using the product code: **COV2021311**
 - If you have already registered on Health Publications, you can immediately place your orders for delivery next week. If you have not registered it only takes a few minutes to register here: <https://www.healthpublications.gov.uk/Home.html>
 - Please do not register as an individual as this restricts you to 5 copies/units. Register as a vaccine provider, NHS, etc. Please search on the website using

the enter the product code in the search window as the fastest way to find what you need.

- If you require more than 500 units (so that would be 500 x pack of 50 Total 25,000) you will need to call 0300 123 1002 to place your order.

6d) Infection Prevention Control (IPC) update

The COVID-19 Booster programme was asked to upscale at pace and has done so very effectively over the recent holiday period. There remains a continued need to emphasise and prioritise core IPC practices.

[IPC guidance](#), which is referenced in all operational frameworks, has now been updated with the overriding message being to ask teams to remain focused on the key IPC messages contained within it. View the 16 December IPC update [here](#).

6e) El Dawlia ico Med - Sterile Hypodermic Syringe. 2ml syringe with 21G x 1.5” Safety Needle (Lots 2105 and 2106)

The UK Health and Security Agency (UKHSA) has advised that all sites with any residual stocks of the El Dawlia ico Med - Sterile Hypodermic Syringe with Combined Safety Needle, which was subject to a voluntary manufacturer recall (22 October 2021), should now dispose of these needles locally following appropriate procedures. There will be no further collection of this product arranged – please see attachment RVOC 7317.

6f) Combined needles and syringes for the COVID19 vaccine administration

If a site experiences an issue with any combined needles and syringes associated with the COVID19 vaccine programme they should be reported as follows:

- Notify COVID19PHEsupplies@phe.gov.uk so an investigation can be opened with manufacturer
- Raise a Yellow card to MHRA
- If appropriate notify NVOC via the SVOC/RVOC route.

6g) Guidance on waste management for local vaccination services (LVS) sites

There is updated guidance on waste management for local vaccination services (LVS) providing advice on how sites can help reduce pressures on clinical waste providers and minimise disruption on LVS. This includes:

1. Following guidance on correct waste management
2. Maximising the capacity of the waste containers
3. Maximising onsite / contingency storage capacity
4. Checking who you need to contact for queries relating to clinical waste
5. We've set up a contingency service for the supply of sharps containers.

The guidance can be found [here](#) via FutureNHS.

6h) Guide for LVS and Vaccination Centres on managing the ongoing maintenance of fridges and other electrical items provided by the National Covid-19 Vaccination Programme

National guide attached on the ongoing maintenance of electronic/electrical equipment provided by the National COVID-19 Vaccination Programme.

7. NEW: First anniversary of Covid-19 vaccinations delivered in community pharmacy sites

A huge thank you goes to everyone across all delivery models who has gone above and beyond, and worked so hard over Christmas and New Year. A special thank you goes to community pharmacy colleagues, as yesterday marked the one year anniversary of the first sites going live – watch Dr Emily Lawson DBE's video [here](#)

Dr Emily Lawson DBE, vaccination lead for the NHS in England, said:

“Since community pharmacies began vaccinating a year ago, they have delivered an incredible 22 million vaccines including around a third of all booster jabs as they stepped up to join the national effort to tackle Omicron.

“I would like to pay tribute to the outstanding work of the 1,500 community pharmacy teams who have played such a vital role in the most successful vaccination programme in NHS history – pharmacists play a unique role at the heart of communities and have been pivotal in getting jabs to the most vulnerable on their doorsteps.”

8. NEW & REMINDERS: Workforce Support and Learning

8a) Key Learning re cold chain incidents

With the vaccination programme operating at such a high level all settings should remain familiar with best practise and the processes for maintaining the cold chain.

Key points to consider include:

- ensure daily monitoring occurs on all days vaccine is held in the fridge
- check that your data logger has an SD card, or equivalent functionality, and be prepared to download data when you report a cold chain incident
- 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 ICARS england.swicars@nhs.net and they will support your investigation and any mutual aid required for vaccine supply.

8b) Regular checking and resetting data loggers

All vaccination sites are requested to ensure they monitor fridge temperature history on a regular basis, to avoid cold chain breaches. This can either be done via the integrated data logger within your fridge or via an independent monitoring unit. Please note that not all makes and models of fridges have integrated data loggers, as previously advised, on some models sites must undertake their own local checks using an independent monitoring unit and refer to manuals where necessary.

On a weekly basis, it is also advisable to fully check data loggers are operating correctly and to reset them, as some data logger units will only hold a set amount of data and once full will stop recording until the unit has been reset.

Vaccination sites requiring data loggers can order these from the Customer Service Unipart helpdesk. The manuals for all fridges, which have been supplied by the national programme, can be obtained from the Unipart desk or from the NHS Futures Supply and Delivery Hub.

Please ensure you follow all the correct cold chain management processes to eliminate the risk of a cold chain breach happening, in addition to using data loggers. SPS resources about Cold Chain management are available here [Maintaining the COVID-19 vaccines cold chain – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#). Part of assurance of the site lead is to ensure that SOPs and processes are followed. Guides for data loggers will vary according to model of data logger, please see the manual supplied with your unit or fridge for full information.

8c) Fridge faults affecting vaccine supply for all models of delivery

Where a fridge fault affects vaccine supply site should follow these steps.

- report to ICARS team england.swicars@nhs.net copying in england.swcovid19-voc@nhs.net

- report the fridge to Unipart so a replacement can be ordered Unipart Customer Service Desk - CS@nhsvaccinesupport.com 0800 678 1650 | 0700-1900 Mon- Sun
- report via the Foundry system/one care with batch numbers.

The relevant SOP is

at <https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/>

8d) Case studies

Two new case studies are available on the Improvement Hub:

- Using a whole system approach to increase uptake using a population health management data set. Please see the full case study [here](#).
- How a PCN identified and vaccinated people who are severely immunocompromised. Please see the full case study [here](#).

The COVID-19 Vaccination Programme [Improvement Hub](#) has published a number of case studies to share learning and improvement work across the programme. Please email, c6.cag@nhs.net, if you have an improvement or shared learning case study to share.

8e) Useful links and contacts

NHS Futures Platform

Please note that you can view the delivery schedules in the Supply & Delivery Hub area on the NHS Futures platform. To register, please follow this link [FutureNHS Collaboration Platform - FutureNHS Collaboration Platform](#).

National Supplementary Inventory List

- National equipment and consumables provision and supply [Coronavirus » Equipment and consumables provision and supply \(england.nhs.uk\)](#)

Appendix 1a – Supply inventory list items, delivery routes, and volumes by model (PDF) [Coronavirus » Appendix 1a – Supply inventory list items, delivery routes, and volumes by model \(PDF\) \(england.nhs.uk\)](#)

NHS England and Improvement Guidance for Clinicians and NHS Managers Coronavirus (england.nhs.uk)

Mutual aid and the transfer of COVID-19 vaccines between Hospital Hubs, Vaccination Centres and Local Vaccination Services

[Coronavirus » Mutual aid and the transfer of COVID-19 vaccines between Hospital Hubs, Vaccination Centres and Local Vaccination Services \(england.nhs.uk\)](#)

Standard Operating Procedures, Specialist Pharmacy Service

<https://www.sps.nhs.uk/home/publications/standard-operating-procedures/>

Useful Contact details:

- **Consumables - ALL supply of consumables (i.e. non vaccine) for ALL SITES** contact **Unipart** - CS@nhsvaccinesupport.com 0800 678 1650 | 0700-1900 Mon- Sun
- **Vaccine or associated products** being issued by PHE: COVID19PHEsupplies@phe.gov.uk
- **ImmForm** ordering: Helpdesk@immform.org.uk
- **Deliveries of ordered vaccine:** NHS.VaccineSupport@movianto.com Tel 01234 587199 (*need ImmForm account number & postcode*)
- **Covid Vaccs Help Desk:** vaccineservicedesk@england.nhs.uk 0300 200 1000 | 0600 – 2200 everyday (inc. bank holidays)
- **All IT and data queries** should be going through vaccineservicedesk@england.nhs.uk as the single point of contact