ICARS Newsletter

Immunisation Clinical Advice & Response Service

Issue 106: 23rd September 2022

PLEASE SHARE THIS NEWSLETTERS WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

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

Please note that this service operates 9am-5pm Monday to Friday

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NEW: Comirnaty® Vaccine Updates

1. **Training has gone live Comirnaty Bivalent**

Training is now live for Comirnaty bivalent, please fine the link is below:

https://portal.e-lfh.org.uk/Component/Details/677490

The Workforce and Training considerations are being updated and will be added to FutureNHS to reflect this.

2. Comirnaty® Bivalent Original / Omicron BA.1 (tozinameran 15 micrograms/ riltozinameran 15 micrograms)

This vaccine will be deployed for use in the programme from 26th September. It is only licensed for **BOOSTER doses** and should not be used as part of a primary course.

There are a few distinct features to be aware of. There is no reference on the packaging to bivalent or the Original / Omicron BA.1 constituents of the vaccines but this is the only bivalent vaccine manufactured by Pfizer that is approved for use in the UK. There is a grey edging to the box and the flip top cap. This product is **ready to use** and does not require diluting. The box and the vial label state in red lettering **DO NOT DILUTE.** The dose volume for Comirnaty® Bivalent is **0.3 mL**.

Pfizer's website has a useful comparison of the different Comirnaty® vaccines currently deployed for use in the programme.

Please be vigilant to the potential for error and ensure you are familiar with the PGD or National Protocol when they are published and are up to date with guidance in the Green Book Chapter 14a and the SPS advice on dealing with multiple vaccines.

Booster vaccine only
Ten vials per box
6 doses per vial
Dose: 0.3 mL IM
DO NOT DILUTE

3. Additional 3 month shelf-life update (12 months to 15 months) for Comirnaty® 30 Concentrate when stored at ultra.

Key Information:

- ***Sites are not required to update any expiry dates on the carton or vials upon receipt of vaccine deliveries.***
- ***It is always the thawed expiry date at 2°C to 8°C as displayed on the post thaw label on the carton that must be adhered to by sites.***
- ***Sites may find that the expiry date on the post thaw carton label is later than the expiry date printed on the vial of vaccine. This will depend on when the vaccine is thawed for delivery.***

- ***The vaccine is safe to use until the expiry date on the post thaw label on the carton.***
- ***Sites must not update the shelf-life of any Comirnaty® 30 Concentrate vaccine already held in fridges on-site.***

A 15-month shelf-life for Comirnaty® 30 Concentrate when stored at ultra-low temperature conditions (-90 °C to -60 °C) has been authorised by the MHRA, this is an update to the previous 12-months frozen shelf-life.

The new (3 month) shelf-life update can also be applied retrospectively to batches, which have been stored appropriately before thawing (see table below). If the update is applicable, it will be applied by our Specialist Pharmaceutical Logistics (SPLs) partners priory to delivery to sites. **Sites do not need to take any further action upon receiving their delivery.**

This shelf-life update will be applied to deliveries from 20 September onwards where applicable.

Full details are in the letter from Pfizer-BioNTech, a copy of which has been sent with this communication and can also be viewed here.

As a result of this latest 3-month frozen shelf-life update, sites **may find** that the thawed expiry date at 2°C to 8°C on the post thaw carton label is later than the expiry date printed on the vial of vaccine; this will depend on when the vaccine is thawed for delivery. Please be assured that the vaccine is safe to use until the expiry date on the post thaw label on the carton.

Example of how the post-thaw expiry date may differ from the vial:

- The post thaw label on the carton could say Exp:19/10/2022, but the vial inside the carton might say Exp:09/2022.

Please note: It is always the thawed expiry date at 2°C to 8°C as displayed on the post thaw label on the carton that must be adhered to when using the vaccine. If this date has passed, the product has expired and must be disposed of immediately in line with your site's expired vaccine disposal procedure.

Sites are not permitted to update the shelf-life of any Comirnaty® 30 Concentrate vaccine already held on-site in fridges. The existing expiry date on the post thaw label on the carton must be followed.

The allowed 1-month storage and transportation at 2°C to 8°C remains the same. **The transportation time has now been extended to 48 hours from the previous 12 hours.** The product must be used within the 15-month extended frozen expiry date.

All vials in cartons with the original Pfizer-BioNTech label with an **expiry date beyond August 2023 will already reflect the 15-month shelf-life** and their shelf-life should not be extended further.

Updated expiry dates are shown below:

Printed Expiry Date		**Updated Expiry Date**

July 2022	→	January 2023
August 2022	→	February 2023
September 2022	→	March 2023
October 2022	→	April 2023
November 2022	→	May 2023
December 2022	→	June 2023

Footnote: All dates refer to the end of the calendar month.

This update supersedes the previous frozen shelf-life increase approved 29 April 2022 for Comirnaty® 30 Concentrate stock held at ultra-low temperature storage conditions (-90 °C to -60 °C), which changed the shelf-life at that time from 9 months to 12 months.

4. **PGD and National Protocol for Comirnaty® Original/Omicron BA.1 Bivalent COVID-19 mRNA vaccine**

   A new Patient Group Direction (PGD) and National Protocol for Comirnaty Original/Omicron BA.1 Bivalent vaccine have been published. Vaccinating teams should read the new documents, familiarise themselves with the contents, and complete the authorisation process, ready to use them.

NEW: Nuvaxovid and Specialist Vaccination Clinics

Nuvaxovid® was licensed for use earlier this year. The JCVI has recommended in exceptional circumstances Nuvaxovid® may be used off label as a booster dose where no clinically suitable alternative vaccine is available.

Nuvaxovid® will be deployed for use in complex clinics from 28th September where advanced resuscitation skills and equipment are available. Individuals with contraindications or previous anaphylactic reactions to COVID-19 vaccines or their components, particularly Polyethylene Glycol (PEG), will be referred for specialist clinical assessment. Nuvaxovid® will be one of the options available within the complex clinics and will be limited to those where exceptional clinical need has been identified. It is not being offered as a choice. Regional teams will be able to advise as to the location and referral processes for these clinics

All vaccine services should be assessing people for their history of anaphylactic reactions and using Table 5 –"Management of patients with a history of allergy" and the flow chart for managing patients who have had allergic reactions to a previous dose of COVID-19 vaccine in the Green Book Chapter 14a.

NEW: Spikevax® Zero (0) / Omicron (O) Bivalent COVID-19 Vaccine Administration and Dosing Errors

1. Spikevax® Zero (0) / Omicron (O) Bivalent COVID-19 vaccine administration errors

Foundry data shows several instances where Spikevax® Zero (0)/Omicron (O) has been recorded as being given as a dose for a primary course of immunisation for COVID-19.

This bivalent vaccine is only licensed for **BOOSTER doses** and must not be used for primary courses. Investigation of records on point of care systems show that, in many cases, this appears to be a data error and further investigation continues.

However, where a genuine administration error has occurred, and an individual has received a 0.5ml dose of Spikevax Zero(0)/Omicron(O) as a primary dose, this is considered equivalent to a half dose (50 micrograms) of the monovalent product and this does not need repeating.

The remaining doses of their primary course should be completed with a product licensed for this purpose (Spikevax Original or Comirnaty 30 Concentrate). If their next scheduled dose is a booster this should be given after a minimum interval of 3 months.

2. Spikevax® Zero (0) / Omicron (O) Bivalent COVID-19 vaccine dosing errors

There have also been several incident reports of Spikevax® Zero(0)/Omicron(O) being given as an incorrect dose volume. There is only ONE correct dose of Spikevax® Zero (0)/Omicron (O): **0.5 mL**

If an incorrect dose is administered, where the dose volume given in error is lower than the licensed dose, UKHSA have indicated that **no revaccination is required**. Incidents should be reported and managed in line with local procedures.

Please be vigilant to the potential for error and ensure you are familiar with the PGD or National Protocol and are up to date with guidance in the Green Book Chapter 14a and the SPS advice on dealing with multiple vaccines.

Booster vaccine only
Ten vials per box
5 doses per vial
Dose: 0.5 mL IM

NEW: Updates on Combined Needle and Syringe products

1. Spikevax® Bivalent Needles and Syringe

We have been in discussions with UKHSA, which procure and supply combined needles and syringes (CNS) to the vaccine programme, regarding the reported difficulties with the use of the new Owen Mumford Unifine 25G x 25mm, 1ml CNS being supplied for the administration of Spikevax® Bivalent.

UKHSA has confirmed that they are actively engaging with the supplier regarding these concerns. A decision has been taken by UKHSA to switch the current CNS associated with Spikevax® Bivalent vaccine from the Owen Mumford Unifine 25G x 25mm, 1ml safety CNS to the established GBUK Prosum 25G x 25mm, 1ml CNS. The GBUK Prosum 25G x 25mm CNS with 0.1ml graduations is a non-safety product and is the same product that has been used for the Comirnaty® 30 vaccine from the start of the programme; the only difference being a 25G needle instead of a 23G one.

Supplies of the GBUK Prosum CNS are being sent out with deliveries of Spikevax® Bivalent from w/c 20 September.

This switch is **a precautionary measure** to allow time for a number of issues identified by the NHS to be fully investigated and at this time there is no recall associated with the Owen Mumford Unifine 25G x 25mm, 1ml safety CNS product.

If sites have volumes of Owen Mumford Unifine 25G x 25mm, 1ml CNS and have not experienced issues, **then these can continue to be used**, however if there are concerns sites can still use existing stock of either BD Flu+ 23G x 25mm, 1ml CNS or GBUK Prosum 23G x 25mm, 1ml CNS until the alternative product is received.

If your site does encounter any difficulties with using the Owen Mumford CNS, please ensure it is reported as soon as possible. The process for doing this is as follows:

- Escalate all incidents/problems via the SVOC/RVOC/NVOC escalation route, including batch number information and the number of incidents your site has experienced. This information will then be forwarded to UKHSA and be used as part of the investigation
- Complete the MHRA yellow card process

Education and training materials produced by the supplier of the Owen Mumford product, including a video and poster, are available here. A note has been added to the video to reflect the general usage instructions: “The purpose of this video is to demonstrate the features of the needle/syringe. It is not intended as a training resource regarding other aspects of practice and, where those shown differ from national/ local guidance, current recommendations should be followed”.

2. Nuvaxovid®: Confirmation of administration needle and syringes to be used for Nuvaxovid®

The CNS supplied for the administration of Nuvaxovid® will be the GBUK Prosum 25G x 25mm CNS with 0.1ml graduations and is a non-safety CNS.

This is the same product used for the Comirnaty® 30 vaccine from the start of the programme, with the only difference being a 25G needle instead of 23G.

The GBUK Prosum CNS comes in packs of 100 and will be sent on a one for one basis alongside vaccine deliveries.

For individuals with morbid obesity (M/O), the PROSUM, GBUK 23G x 38mm needle and syringe, will be supplied as the M/O needle for the administration of Nuvaxovid® (note: this is the same CNS as used for Spikevax® Bivalent).

3. Comirnaty® Bivalent

The CNS being supplied with Comirnaty® Bivalent is a new safety retractable needle. Details of the training resources are available in the September 14 Clinical Bulletin

UPDATE: Owen Mumford Unifine Safety Retractable Needle

Following some feedback from sites about the pliability of the new Owen Mumford Unifine 25G x 25mm, 1ml CNS being supplied for the administration of Spikevax® Bivalent, we have been in discussions with the UK Health Security Agency (UKHSA), which procure and supply combined needles and syringes (CNS) to the vaccine programme. UKHSA are actively engaging with the supplier.

No manufacturing issue has been identified with the needle and there is no product recall. **As a precautionary measure, to allow time to review feedback given by the NHS,** UKHSA has decided to switch from the Owen Mumford Unifine 25G x 25mm, 1ml safety CNS to the established GBUK Prosum 25G x 25mm, 1ml CNS. This product, that is well known to the programme, will be delivered alongside Spikevax® Bivalent from Sunday 18th September onwards.

The new CNS product is a GBUK Prosum 25G x 25mm CNS with 0.1ml graduations and is a non-safety product. This is the same line used for the Comirnaty® 30 vaccine programme from the start with the only difference being a 25G needle instead of a 23G one.

All sites will be proactively supported with a supply of one of the above CNS products aligned to their next delivery day, to ensure there is no disruption to vaccinations in the case of difficulties with the Owen Mumford CNS.

It's important to note that if sites have volumes of Owen Mumford Unifine 25G x 25mm, 1ml CNS and have not experienced issues **then these can continue to be used**, however if there are concerns sites could use either BD Flu+ 23G x 25mm, 1ml CNS or GBUK Prosum 23G x 25mm, 1ml CNS until the alternative product is received.

If your site does encounter any difficulties with using the Owen Mumford CNS, please ensure it is reported as soon as possible. The process for doing this is as follows:

- Escalate all incidents/problems via the SVOC/RVOC/NVOC escalation route, including batch number information and the number of incidents your site has experienced. This information will then be forwarded to UKHSA and be used as part of the investigation.
- Complete the MHRA yellow card process.

Resources demonstrating the features of the Owen Mumford product, including a video and poster, are available here.

Please be assured that the vaccine programme will continue to work closely with UKHSA, as they monitor the situation.

NEW: Updates for 119

1. Housebound queries from 119

With the launch of the Autumn Programme, we are seeing a sharp increase in the number of housebound 119 queries.

Early indications show that a number of housebound queries are coming from the same Systems and PCNs as in the Spring Booster, which from the supporting data may help in the focus of attention

If you have any queries regarding this information, do let us know. We look forward to discussing further in our calls next week.

****PLEASE NOTE: The following slides have been altered from the RVOC9199 distribution to be appropriate for this ICARS newsletter distribution****

HouseBound 119 Queries SW - 13 Sep

2. Updates for 119

It needs to be ensured that 119 are using the correct contact and address details when directing eligible members of the public and Health & Social Care Workers to an appropriate vaccination facility. There is now a new 119 tool and guidance which the call handlers should be following.

Call handlers offer assistance with booking onto the National Booking System (NBS) and provide information as it is shown to them. They will only offer sites available, and provide information showing, on the NBS at the time of the call. They are accessing the same booking system the citizens/ public can access themselves online.

If any location should not be showing available, or has incorrect information, the vaccination change team will need to be contacted to have the site removed or details changed for what the site offers. The document attached to the original cascade (Vaccination Change Request Form.docx) should be used to provide details of any site removals or updates and these should be sent to the following vaccinationschange@nhs.net as directed at the bottom of the form.

Should you receive any reports from sites stating that patients have been incorrectly directed by 119 and the above steps have already been followed please complete the escalation form (20211208_Vaccination Booking Service Escalation Guidance V7 (final).docx) attached to this message and submit to RVOC on england.swcovid19-voc1@nhs.net

We appreciate it can be very challenging to obtain specific call details, however to obtain aid from 119 in these matters these details are essential as, if this information is provided, 119 are able to track the call and listen to what is said and if any unsanctioned practices are found they can be discontinued.

20211208_VACCINATION BOOKING SER

Vaccination Change Request For

NEW: IT Updates

1. Pinnacle Coadministration Support

If you are use Pinnacle (Outcomes4Health) to record vaccination events and would like to learn how to quickly record both a Flu and COVID vaccination for the same patient, please read the attached guide.

InterimCo-adminDataEntrySolution[84].

2. Update to Primis Information

It seems that sites are unable to download the tools to support PRIMIS search. We have confirmation that any person that wishes to download the tools from Nottingham University online resource area must first complete this short form to gain access to them. This is especially relevant to access TPP Booster RPT, in meantime, please see the below attached TTP rpt (see PRMIS COVID 19 Spring Booster.rtp) with the instructions on how to download and open the TPP searches are available on the same page.

- Once you have opened the Spring Booster resource area, click on the TPP Download now button
- Click on the Download in the top toolbar. Once you have downloaded the file called TPP Spring Booster.rpt which i have attached (see PRMIS COVID 19 Spring Booster.rtp)) you just need to import it into SystmOne – you do not need to open the report just download.
- Go to **Clinical Reporting** and then click on the **Import** button and navigate to where the file has saved (for some, this was automatically in the **Downloads** folder). Once the Spring Booster search is visible in SystmOne, you can run it and view the patient names in the response files.


For TPP users (1).pdf


PRIMIS COVID19 Spring Booster (3).rp

NEW: Webinars and Workshops

1. **Rapid Insights Workshop: South West Leadership and Culture for the Covid-19 Vaccination Programme. 12th Oct 9:30-11:00**

Following the success of the four rapid insight events, the South West NHS England team and the South West AHSN are running a 5th Rapid Insights Workshop: South West **Leadership and Culture for the Covid-19 Vaccination Programme** on the 12th Oct 9:30-11:00. This is a fantastic opportunity to share learning from the Vaccination Programme we know people have worked so hard to support.

Previous Rapid Insights sessions have generated lots of useful reflections and learning and we are keen to understand through this session the role that Leadership and Culture has played in the Covid-19 Vaccination Programme to date.

We would like 5-6 programme leaders from across each system to join and contribute to the workshop discussion. We will explore key learnings from the Vaccination Programme including:

1. Exploring successes
2. Reviewing challenges
3. Considering the key leadership and culture factors that should be considered in any large-scale vaccination service for the future

An invite, further details and link will follow shortly but, in the meantime, please consider who you would like to attend from your system and hold the date

2. **Vaccination programme shared learning community webinar**

The next learning community webinar will be held on Wednesday 5 October, 2pm-3pm "I'm interested in Quality Improvement. How do I get started?". Details on registration for the event will be available shortly on the Improvement Hub.

Recordings of the previous learning community webinars are available to view, along with all supporting resources on the Improvement Hub. If you have a suggestion for a future webinar subject, please email c6.cag@nhs.net