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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

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Updated JCVI advice on vaccination of children and young people

On 22 December, the government accepted updated advice from the Joint Committee on Vaccination and Immunisation (JCVI) on the vaccination of children and young people. Further details on the announcement and next steps can be found in this letter. We will work to put plans in place to deliver these updated recommendations in a safe and effective way.

Clinical Workstream updates

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1. Spikevax (also known as COVID-19 Vaccine Moderna): extension of shelf life from 7 months to 9 months; including retrospective updates for manufactured batches

Moderna Biotech Spain, S.L. in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) has advised the following:

- From 23 December 2021, a new shelf life of 9 months has been approved in the UK for Spikevax (extended from 7 months).
- The Product Information will be updated and the extended shelf life included on the labels for vials manufactured from February 2022 onwards (those with an expiry date of November 2022 onwards).
- This 2-month extension should be applied retroactively to vials manufactured before December 2021 and during the implementation period (any batches with a listed expiration up to August 2022) - see table below for updated expiration dates.
- The storage conditions remain unchanged (–25 °C to –15 °C).
- The statement on storage on dry ice has been removed to allow storage, including during transport of the product, as low as at –50°C. The section has been amended to remove the reference to dry ice and states "Do not store below –50°C".
- Within the 9-month shelf life, unopened vials may be stored refrigerated at 2°C to 8°C, protected from light, for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation. Once thawed, the vaccine should not be re-frozen. This extension of the shelf life by 2 months applies to all vials manufactured with an expiry date printed on the label as of 23 December 2021 onwards, as long as approved storage conditions between –25ºC and –15ºC have been maintained and the applied shelf life was 7 months. Batches of Spikevax vaccine already distributed in the UK and those to be produced and distributed in UK in December 2021 and in January 2022 will continue to be labelled with a 7 months shelf life, as the implementation of the change is ongoing. The extension of expiry dates will therefore apply to vials on the market as described in the table below.

Printed expiry date: December 2021 updated to February 2022

Printed expiry date: January 2022 updated to March 2022

Printed expiry date: February 2022 updated to April 2022

Printed expiry date: March 2022 updated to May 2022

Printed expiry date: April 2022 updated to June 2022

Printed expiry date: May 2022 updated to July 2022

Printed expiry date: June 2022 updated to August 2022

Printed expiry date: July 2022 updated to September 2022

Printed expiry date: August 2022 updated to October 2022

2. Booster timeframe

Booster doses are recommended for all individuals aged 16 years and over and those aged 12 to 15 years if they are in a risk group or living in a household with someone who is immunosuppressed.

JCVI recommended that booster doses should be offered no sooner than three months following completion of the primary course. To support the operational aspects of the programme, including booking of appointment via NBS and sending invitations, this timeframe has been defined as 91 days.

Sites should be aware that there is some operational flexibility to administer a booster dose at a different timeframe if someone presented slightly early via a walk-in site. This lies in the interpretation of 3 months, which is the terminology used with the Green Book, the PGDs and National Protocols. As such, in this scenario a local clinical decision on a case by case basis could be made to support vaccination at a 12-week interval as opposed to a fixed 91 days.

3. Green Book Chapter 14a: Changes in the revised document – December 24th 2021

The Green Book Chapter 14a has been updated. Vaccinating teams must read the Green Book revision to ensure they are familiar with all of changes.

This latest update includes the JCVI advice on boosters for all those aged 16 and 17 years and those aged 12 to 15 years in a risk group or living in a household with an individual who is immunosuppressed. Boosters should be given no sooner than 3 months following completion of the primary course.

Also included is information on the paediatric formulation of the Comirnaty® vaccine 'orange cap' and the recommendation for primary vaccination of those aged 5 to 11 years in a risk group or living in a household with an individual who is immunosuppressed.

There has also been an update to include pregnant women (in all trimesters) as part of the clinical risk group and a reference has been added to guidance on monitoring patients with a history of immune thrombocytopenia.

Read the full update here.

4. Changes to both Pfizer Comirnaty reconstitution and administration needles and syringes

As communicated in a separate cascade last week, UKHSA informed the Programme of the following:

1. 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.

2. New Comirnaty Pfizer dilution needle/syringe is being phased in for England from next week

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. Changes will be made to the relevant SPS SOPs gradually. Some vaccination sites will have received the new syringes and needles before these SOPs are updated but please continue to use the syringes and needles provided by UKHSA, and as always use original stock up first.

5. Safe handling of dry ice in Hospital Hub and Vaccination Centre settings

The large increase in vaccine volumes currently being delivered to hospital hubs and vaccination centres has introduced an increased risk of carbon dioxide asphyxiation.

Staff working in Hospital Hubs and Vaccination Centres who handle vaccines at these ultra-low temperatures are reminded that vaccines delivered packed in dry ice (solid carbon dioxide) shippers should be unpacked immediately, and the dry ice removed to a well ventilated area to enable it to turn to gas (sublime) safely; this may take up to 24 hours. Any delay could lead to the build-up of unacceptable and potentially dangerous levels of carbon dioxide in an enclosed room.

You can find helpful guidance in the Specialist Pharmacy Service SOPs for Comirnaty and Spikevax vaccines and by following this link https://www.sps.nhs.uk/wp-content/uploads/2020/10/Handling-Dry-Ice-and-Vapour-Phase-Nitrogen-Shippers.pdf

6. Temporary suspension of the 15-minute observation period following vaccination with COVID-19 mRNA vaccine

Full details of the temporary suspension of the 15-minute observation following COVID-19 mRNA vaccination in some patients were included in the Clinical Bulletin published on December 16th.

All sites should ensure staff (including volunteers) are aware of the following:

- **Vaccination sites should retain an observation and monitoring area.**
- This temporary suspension only applies to individuals who do not have a personal history of allergy. Table 5 from the Green Book Chapter 14a regarding the 'Management of patients with a history of allergy' includes recommendations for observation following vaccination of this group.
- A 15-minute observation period is also recommended for those individuals who had non-allergic reactions such as vasovagal episodes, non-urticarial skin reaction or non-specific symptoms following previous vaccine doses.
- Following vaccination with any of the COVID-19 vaccines, all individuals should be observed for any immediate reactions whilst they are receiving information and, where applicable, leaving the site. If at any point during this time an individual appears unwell or there are concerns about potential adverse effects, they should be advised to remain on site for a period of observation and monitoring.
- **Due to the risk of fainting and other side effects, all individuals who are vaccinated should be strongly advised not to drive for at least 15 minutes after receiving their vaccine.**
- Individuals should be made aware of the signs and symptoms of anaphylaxis and the information leaflet 'Waiting after your COVID-19 vaccination' can be used alongside verbal counselling to reiterate these points. Individuals should be informed about how to access immediate healthcare advice in the event of displaying symptoms.

7. Supporting individuals to receive their booster vaccinations - posters

A series of posters, available in English and translated into 20 additional languages, has been produced for colleagues to download and display in local vaccination sites. Additional translated versions will be added early in the New Year. They provide information to support people to receive their booster vaccinations and are available on NHS Futures here within the Clinical workstream publications section.

8. Updates from other areas of the programme

- Latest LVS Updates
- Latest Vaccination Centre Updates
- Equalities Connect and Exchange Hub: Weekly Update
- Workforce and Training update

Training resource for COVID vaccinators: Intramuscular injection technique

Please see this useful resource to add to your training materials for new and existing vaccinators to help ensure correct injection technique.

Incorrect administration, particularly injecting too high on the arm, can result in shoulder injury and a number of such incidents have been reported to the regional clinical team recently.

This video by Sophie McCracken, paramedic clinical advisor, shows how to correctly administer intramuscular injections, including the process of 'landmarking' to ensure the correct site on the deltoid muscle is used:

https://www.youtube.com/watch?v=306tmWDKbT0

Update on LVS Vaccine Deliveries

On Friday 31 December, Dr Nikita Kanani wrote to all Local Vaccination Sites (PCN and Community Pharmacies) regarding vaccine orders being reduced to either zero or minimal levels this week (w.c 3 January). Following a further review of stock levels, the decision has now been made to stop all scheduled deliveries of vaccine from Thursday 6 January for all LVS sites. This decision has been made to mitigate the risk of vaccine expiry, as there is already a large volume of vaccine in fridges, and we have multiple sites flagging their excess stock to ICS/Regional teams to support with mutual aid.

Taking this action will give us all the greatest opportunity to utilise the vaccine stock, which is already out in the system and remove the real risk of wastage as we move through January. Nationally, we currently have sufficient stock in the network to cover all demand for at least the next three weeks.

We know that not all this stock is in the right place and nationally we are working with Regional and ICS teams to ensure stock is rebalanced as appropriate. Any site requiring additional stock, should contact their System to access mutual aid from another site.

Deliveries for week commencing 10 January will be reviewed as we proceed through this week and a further communication regarding this will be issued later this week