ICARS Newsletter

Issue 68: 17th December 2021

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*

Immunisation Clinical Advice Response service

From the 14th December 2021, the ICARS service will be available

9-6pm 7 days a week to support the accelerated programme.*

Please continue to send all clinical queries and incidents direct to the South West ICARS inbox.

If your query is urgent, please indicate so in the subject line.

england.swicars@nhs.net

**Note – not 25/26 December*

PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

Contents:

1. THANK YOU: Thank you message from Jennie Hall (National Director of Nursing and Clinical Delivery) and Jonathan Leach (National Medical Director)

As you are now aware, the NHS has now officially delivered over **100 million doses of the COVID-19 vaccine** in just 12 months. This includes 14 million third doses and booster jabs which most importantly have supported the reduction of COVID-19 infections, reduced the need for people to be in hospital and also those sadly dying from COVID-19.

The success of the vaccination programme is due to the focus and commitment, determination and hard work from everyone involved in the programme, including yourselves. We have also seen innovation in practice as you have reached out to support your local communities.

From those in clinical roles but also colleagues working as volunteers, in administration roles, training staff, each of you is playing such a vital role to supporting the vaccination of people coming forward for their jab. It is the combined effort of every member of the team and every team in the vaccination sites that has allowed us to deliver the 100 million doses.

We would just like to say a huge THANK YOU to all the teams for your dedication, going above and beyond over the last 12 months to help protect the population against COVID-19.

As we have marked the anniversary of the first dose on the 8th December, we are now focused on both preparing and delivering the next phase of the COVID-19 vaccination programme where more people are coming forward for boosters in line with the recent clinical guidance and we are vaccinating to boost protection against the virus.

Our task to deliver the next stage will continue to require that focus, commitment, innovation and determination you have already shown, but will ensure that the unvaccinated, older adults and the most at risk receive the protection that the vaccination provides.

Thank you to ALL OF YOU, without whom, this wouldn't be possible.

Jennie Hall & Jonathan Leach

2. NEW: Operational guidance relating to National call: next steps for the NHS Covid-19 Vaccine Deployment

On 13 December we wrote to all systems and vaccination sites with detailed information about the next steps following the Prime Minister's address to the nation on 12 December (see below) regarding the latest situation with regards to the Omicron and other variants. Read a further letter here, noting the particular instructions for LVS sites.

Further to our system letter published on 13 December available here, we are asking you to please implement the following actions to rapidly expand and maximise capacity.

Information for all sites and systems:

- From Wednesday 15 December, eligible people in Cohort 12 will be able to book a booster on NBS at a minimum of 3 months (91 days) since their 2nd dose (in addition to cohorts 1-11). Unvaccinated individuals, those who are from underserved communities, the housebound, care home residents and staff and people who are severely immunosuppressed remain a priority.

- Sites should accommodate wherever possible anyone attending for their primary vaccination course (1st, 2nd or 3rd dose where required) at a walk-in clinic provided they are eligible.

- Today, changes will be made to the Green Book Chapter 14a (available here) which temporarily remove the requirement for patients to wait 15 minutes in some circumstances after receiving an mRNA vaccination. Please see the UK Chief Medical Officers' opinion here. The National Protocol and PGD for Pfizer-BioNTech (Comirnaty ®) and Moderna (Spikevax ®) will be updated and will be available here, most likely by the afternoon of Wednesday 15 December. Sites are asked to implement the change from Thursday 16th December. All vaccination sites should review their through-put models and increase the number of appointments available on NBS or via their LBS.

- All sites on the NBS are asked to immediately upload as much NBS capacity as possible. Sites are required to review their DNA rates and adjust capacity uploaded to the NBS accordingly. This should include capacity on bank holidays.

- Queue management and priority lines: all sites are asked to consider how to best support clinically vulnerable and frontline health and social care workers (HSCW) for example via enabling access to priority queueing for HSCWs who present a valid ID or pregnant women who might struggle to queue for a long time. Sites should make reasonable adjustments for patients, particularly those who are clinically vulnerable, including LD/Autism and SMI, and their carers; including where they are accompanied by a carer.

- All systems are asked to work with local authorities and employers to set up vaccination opportunities in local employer sites, supermarkets, schools and travel hubs, via pop-ups or other temporary arrangements.

- Please see guidance in the system letter on additional support and access to workforce. For LVS sites, earlier this year we provided an additional £20 million to ICS/STPs to support primary care providers to draw down additional clinical and non-clinical staff to support the delivery of the COVID-19 vaccination programme. This support is still available and PCN Groupings and CP-led sites should liaise with their ICS/STP if they wish to access it.

Pfizer or Moderna as second dose, where AZ was first dose

By 17 December, NBS will be enabled to allow individuals to book second doses of an alternative mRNA vaccine (Pfizer-BioNTech (Comirnaty ®) or Moderna (Spikevax ®)) when they have received a viral vector-based vaccine (AstraZeneca (Vaxzevria ®)) as first dose. No other changes will be made to the NBS.

The Green book states:

"For individuals who started the schedule (of vaccination) and who attend for vaccination where the same vaccine is not considered suitable or if the first product received is unknown or not available, it is reasonable to offer one dose of the locally available product to complete \the primary course. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again."

JCVI guidance remains that where possible, the first two doses of the primary course of immunisation should be of the same vaccine. However, following appropriate counselling and consent and in accordance with MHRA and JCVI requirements, an alternative authorised vaccine may be offered to complete a course of vaccination when it is considered that there might otherwise be a delay in accessing a second dose (for either patient or operational reasons, including where a patient refuses a particular vaccine or where a site does not have the same vaccine as the first dose available). Patients should be made aware that this may lead to a higher risk of short-term side effects.

All sites should operationalise this guidance including for walk-in clinics.

These individuals will receive specific call/recall communications this week.

Vaccination Centres are asked to:

- Ensure all possible capacity is being utilised, including opening more lanes and PODs, and Extended opening hours, at a minimum to 12 hours a day and to include opening 24/7 wherever possible. Support for security and other support services such as cleaning can be provided. **Hospital Hubs are asked to**
- Consider extending access to local booking systems in order to vaccinate other health and social care workers and unpaid carers in their area
- Consider options to increase capacity to provide extended access at evenings and weekends
- Consider converting HH to HH+ to increase capacity and access to the public
- **Hospital Hub + are asked to** ensure all capacity is utilised, including extending opening hours and increasing the number of lanes.

- **HH/HH+** should offer vaccinations to eligible inpatients and outpatients including those who are clinically extremely vulnerable. **PCNs are asked:** For all General practice teams (not only LVS sites):
- From 13 December, please clinically prioritise your services to free up clinical capacity that is delivering services which can safely be deferred into the new year to focus on the COVID-19 vaccination programme alongside delivering urgent or emergency care.
- Any patient with an *urgent presenting complaint*, or *potentially serious underlying and unmet clinical need*, should be assessed, managed, and referred onwards as appropriate. Any patient with symptoms that are *suspicious of cancer*, or is *concerned that they may have cancer*, should again be assessed, managed, and referred onwards if appropriate. Any routine care that can be safely postponed should be rescheduled until the new year or signposted to NHS 111 online for self-care advice, or to local community pharmacy.
- Further guidance on clinical prioritisation from NHSEI, RCGP and BMA will follow shortly.
- We are working with partners across Government to identify additional areas where we can flex medical certification requirements to release capacity within general practice.
- Please increase your capacity to the same level or above your best day in phases 1 and 2 and consider extending your opening hours. PCN sites are strongly encouraged to open 7 days per week 8am to 8pm as set out in the phase 3 enhanced service specification.
- GP practices signed-up to the Phase 3 ES should prioritise visits to care homes that have not yet received a visit and where requested, arrange a further visit, ensuring that an offer is made to vaccinate staff at the same time. Multiple visits should be undertaken to care homes where necessary to ensure that we are protecting this population. Hospital Hubs have also been asked to offer vaccination to care home staff.
- PCN led sites have been asked to complete booster vaccination of eligible housebound individuals this week. Please complete the survey available on the LVS Foundry workspace here: https://ppds.palantirfoundry.co.uk/workspace/module/view/latest/ri.workshop.main.module.756b0490-bbe5-4be8-a575-d9885f397073) to confirm that you have completed this activity by 12:00 on Friday, 17 December 2021. Those who have not received earlier first or second doses should be prioritised.
    - A £30 supplement has been provided up until 31 December to support vaccination of this cohort.
- For **severely immunosuppressed people**, we ask PCN Groupings signed-up to the Phase 3 ES to continue to offer third primary doses to this cohort from 8 weeks after their second dose. Additionally, from 10 December we

have asked that all PCN groupings signed-up to the Phase 3 ES offer booster vaccination to eligible individuals in this cohort, three months after their third primary dose.

  - Hospital specialist teams have also been asked to vaccinate all eligible inpatients and outpatients. Booster vaccinations should be recorded as 'second boosters' on POC systems.

- If you require additional admin support with call/re-call please liaise with your local commissioner.

  - Although this will take a few days, we can onboard further PCN sites onto the NBS – please contact your local commissioner urgently if you want to be onboarded onto the NBS.

- The Winter Access Fund remains available to support wider primary care capacity but cannot be used to fund vaccination capacity.

- If a PCN Grouping has not opted in to deliver boosters to cohorts 10-12 please urgently reconsider your participation (in light of the support recently announced temporary contract changes – read here) and notify your local commissioner as soon as possible if you are able to help deliver boosters to this group If a practice has served notice on the phase 3 ES, please advise your local commissioner if anything further could be done to support you to remain in this programme.

- Practices not participating in the programme are asked to urgently support their local vaccination efforts and should liaise with their local commissioner to discuss signing up to the ES or offering workforce to their vaccination site.

- Please read the updated MHRA rules on movement of vaccine – read here. Subject to meeting the conditions outlined, this gives practices within a PCN Grouping the ability to move vaccine to an individual member practice, store it in their fridge and administer opportunistically where this will help increase uptake levels and minimises wastage.

Community Pharmacies are asked to:

- Make use of Flexible Provision to limit Pharmaceutical Services from a site for the purposes of offering Vaccination Services where possible

- All Pharmacy Contractors delivering the COVID-19 vaccination service from a designated site should consider applying to their NHS England Regional commissioner to limit the pharmaceutical services they provide to COVID-19 vaccinations only for a specified time. This is permitted under 27B of the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020.

- Pharmacy Contractors must obtain approval to do this from their NHS England regional Primary Care Commissioning Team at the e-mail address on the NHS England website. To fast track approval of expansions in

capacity, please use the subject header: **Approval Request for Vaccination Site Flexible Provision** and attach the completed Flexible Provision form. More information about this provision can be found in the Guidance on the NHS Regulations 2020 (p33).

- Where a Pharmacy Contractor with a designated site utilises this provision and as a result needs, by exception, to deliver medications that are needed urgently by the patient prior to the Pharmacy Contractor recommencing provision of full Pharmaceutical Services the Pharmacy Contractor can claim £6 (including VAT) per medicine delivery. This delivery service will be included within the next version of the Community Pharmacy Local Enhanced Service COVID-19 vaccination programme: Phase 3 2021/22 (the LES) and will only be available for emergency deliveries made from 15 Dec 2021 to 31 Jan 2022.
- *Requests will be approved subject to the following:* Automatic agreement will be given where the proposal is for 20% or less of the Pharmacy Contractors combined weekly core and supplementary hours and is at times of the day/week that will have the least impact on patients subject to the below requirements being met. More than 20% of their combined weekly core and supplementary hours can be requested but this must be discussed and agreed with the Regional commissioner in advance of the application being made.

1. At least 24 hours' notice to limit Pharmaceutical Services have been given.
2. The application includes details of the COVID-19 designated site being supported (ODS code and site name) and the name (and ODS code) of the alternative Community Pharmacy premises which will provide support to any patients during the hours when the pharmacy premises is open for COVID-19 vaccinations only.
3. Pharmacy contractors must provide clear signposting to patients to alternative provision.
4. Pharmacy contractors must have a process in place to ensure that all patients retain access to their medicines, including provision of an emergency delivery service during hours of limited service delivery as described under the LES where necessary.
5. All workforce released from other pharmaceutical services must be actively involved in the delivery of COVID-19 vaccinations for the full period of time that the premises ceases delivery of other pharmaceutical services.Pharmacy Contractors must make amendments to their Directory of Service (DoS) entry and NHS website profile so that patients can continue to be signposted to appropriate services **SVOCs /RVOCs are not permitted to approve requests to limit Pharmaceutical Services, since this decision must consider alternate access to medicines. Community Pharmacy-led LVS sites that wish to operate a pop-up in a pharmacy or non-registered premises**

- Sites should further consider the use of temporary pop-up clinics. Agreement must be obtained in writing to operate a pop-up clinic as per the Roving and Mobile models Standard Operating Procedure. Community Pharmacy-led sites should seek approval from their Regional Team by e-mail. To aid them in prioritising approval of expansions in capacity, please use the subject header: **Approval Request for Vaccination Site pop-up**

- As a temporary response to the Omicron emergency, LVS sites may wish to consider operating a pop-up in another registered pharmacy. This is a temporary measure that is time-limited to support an urgent response and will not replace the site designation process or lead to the permanent stand-up of sites.

The Contractor operating the designated site remains responsible and accountable at all times for the provision of vaccination services, including meeting all standards in relation to vaccine handling, premises, workforce and training. The vaccination site will be treated in legal and regulatory terms as associated premises of the Contractor for the purposes of delivering COVID-19 vaccines (even if this is another registered premises) and are therefore effectively an extension of the Pharmacy Contactor's business. The GPhC's standard for registered pharmacies must be met at all times, including the completion of a risk assessment for the pop-up clinic, along with actions to be taken to minimise risks to the safe and effective delivery of the vaccination service, and remaining Pharmaceutical Service.

Patients must be made aware of the Contractor responsible for providing COVID-19 vaccinations

Appropriate indemnity and, if appropriate, a written staff-sharing agreement must be in place. Any staff working in a vaccination site must meet the workforce and training requirements for the role that they are fulfilling.

All pharmacists involved in the service must be able to demonstrate that they have the ability and capacity to provide sufficient supervision of vaccination services.

- The Responsible Pharmacist for the designated site must be able to demonstrate that they have the capacity and ability to oversee all vaccinations services that are operated in associated premises, including if they are an associated premise in another registered pharmacy as well as any other Pharmaceutical Services being offered from the registered premises associated with the designated site.

- A Supervising Pharmacist must be on site at any pop-up clinic, linked to the Responsible Pharmacist for the designated site through a governance framework.

- The Responsible Pharmacist and Superintendent Pharmacist must be able to demonstrate that the Supervising Pharmacist is able to provide sufficient supervision of vaccination services.

- The Responsible Pharmacist must be clear that the GPhC standards are being met at all times and pressure must never be exerted by an employer to take on more responsibility that the Responsible Pharmacist is professionally content with.

Support the wider system in prioritising COVID-19 vaccination uptake and delivery -Community Pharmacy Contractual framework easements for all pharmacy contractors

Recognising the significant contribution of the pharmacy workforce to the COVID-19 vaccination programme in all delivery models, NHSEI and DHSC have agreed with PSNC that there will be an extension to the deadline for meeting the requirements of the Pharmacy Quality Scheme for all contractors wishing to take part in line with the arrangements put in place for 2020-21 (further details will shortly be published as a Drug Tariff determination on the NHSBSA website).

In addition, contractors will not be required to complete the Community Pharmacy Patient Questionnaire for 2021/2022 and the requirements to complete both a national audit and the local multidisciplinary clinical audit will be waived. The three parties will keep the situation under ongoing review. The latest UKHSA information can be found in full here.

Booster vaccination guidance as advised by the Joint Committee on Vaccination and Immunisation (JCVI) can be found in full here.

If you have any questions please contact england.vaccinecentresgroupsupport@nhs.net for Vaccination Centres Support or england.pccovidvaccine@nhs.net for Local Vaccination Centres (Primary Care Networks and Pharmacies).

3. Publication of updated COVID-19 vaccine PGDs and National protocols for the COVID-19 vaccination programme in England.

Following the UK Chief Medical Officers (CMO) report and update to Chapter 14a of the Green Book, the PGDs and national protocols for Comirnaty COVID-19 vaccine and Spikevax COVID-19 (Moderna) vaccine have been updated and republished today.

These documents are to support the delivery of the COVID-19 vaccination programme in England and can be accessed via the following link: https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds)

See below for further information on these updates:

Update on Patient Group Directions (PGDs) and National Protocols for the change to the COVID-19 minimum booster interval

This note should be read in conjunction with the system letter and the operational guidance issued 7 December 2021 and 8 December 2021. Booster doses should now be offered to those in cohorts 1-10 no earlier than 91 days from their second dose vaccination.

- The National Booking System is now available for those in cohorts 1 to 10 to book their booster vaccination appointment from 61 days after their second dose for appointments no earlier than 91 days from their second dose vaccination.
- Updated versions of the Comirnaty ® (Pfizer BioNTech) and Spikevax® (Moderna) PGDs and National Protocols are available here. Sites should immediately review these documents and ensure that staff are authorised to operate under the updated versions, particularly noting that they should be administering a booster from 91 days.
- Booster vaccines can be administered at the minimum three-month (91 day) interval via local bookings and walk ins (including Grab-a-Jab clinics) subject to the site operating under an appropriate legal mechanism.
- Updated patient information is available to order here: www.healthpublications.gov.uk/Home.html

Thank you for your ongoing support to deliver Covid-19 vaccinations throughout the autumn and winter.

If you have any questions please contact england.vaccinecentresgroupsupport@nhs.net for Vaccination Centres Support or england.pccovidvaccine@nhs.net for Local Vaccination Centres (Primary Care Networks and Pharmacies).

UPDATE: Updated Comirnaty® (Pfizer BioNTech) and Spikevax® (Moderna) PGDs and National Protocols

The Comirnaty® (Pfizer BioNTech) and Spikevax® (Moderna) Patient Group Directions (PGDs) and National Protocols have been revised and are available here. The updated documents enable booster doses for eligible cohorts to be administered from three months after completion of the primary course. Each document has a Change History section which summarises the amendments and additions. Vaccinating teams must familiarise themselves with all the revisions throughout the documents and ensure they are authorised and working to the most current version of these legal documents.

We do anticipate that a revised Vaxzevria® (AstraZeneca) PGD and National Protocol will also be made available in due course. Until this is published, vaccinating teams must note that a Patient Specific Direction must be used for

any booster doses of this vaccine which are administered earlier than six months after completion of the primary course.

The PGD and National Protocol for the Regulation 174 Pfizer BioNTech COVID-19 Vaccine has not been revised. There is very little remaining stock of this product in the system. Sites who do have stock of this product must ensure that they use the correct legal mechanism for administration of vaccine doses. They must also maintain good stock management, including, where appropriate, utilisation of this product before any Comirnaty® supplies are used.

UPDATE: Green Book Chapter 14a: Changes in the revised document - November 30th 2021

The Green Book Chapter 14a has been updated in line with JCVI recommendations. Below are the key additions. It is advised that you also read the green book revisions to ensure you are aware of all changes.

- Details about new variants of SARS-CoV-2.
- Information about trials and approvals of Comirnaty® (Pfizer BioNTech) use in children aged 5-11 years. Please note, there have been no recommendations to support vaccination of this cohort in the UK.
- Confirmation that JCVI have recommended a second dose of vaccine for individuals aged 12-15 years who are not in a risk group. Please note that this recommendation has not gone live in the Programme yet.
- Statement about intervals between first and second dose for those individuals under the age of 18 years who are not in a risk group, suggesting that the interval may be shortened to 8 weeks from 12 during periods of high incidence or concern regarding vaccine effectiveness. Please note, no change has been made to the dosing interval at this time for 12-17 year olds not in a risk group. The interval remains at 12 weeks. Any change will be announced and communicated from the Programme if the circumstances suggest this is necessary.
- Additional information regarding individuals eligible for a third primary dose. For those individuals aged 16 years and above who had severe immunosuppression in proximity to their first or second dose and have therefore received or are due to receive a third primary dose, a further reinforcing dose is recommended. This booster (fourth) dose can be administered from three months after completion of the primary course, in line with clinical advice on optimal timing.
- Confirmation that the JCVI have recommended the acceleration of the booster programme in order of age and risk status. This includes the opening of the booster offer to all adults over the age of 18 in a phased manner. Please note

that the Programme will announce and communicate the phased opening to different cohorts. It is imperative that those aged 50 and over and those individuals in risk groups (aged 16 years and above) continue to be prioritised for booster vaccinations.

- Confirmation that for those eligible for a booster dose, the time interval is now from three months after completion of the primary course. Please see more information regarding the current legal mechanisms to facilitate this in item three of this Bulletin.
- Clarification that both Comirnaty® (Pfizer BioNTech) or Spikevax® (Moderna) (0.25ml dose) should be offered as the preferred vaccines for booster doses as they have both been shown to give a good immune response to those already primed. For individuals aged 16-17 years who are eligible for a booster dose, Comirnaty® (Pfizer BioNTech) is the recommended vaccine. In limited circumstances Vaxzevria® (AstraZeneca) may be used for individuals who cannot receive mRNA vaccines.

4. NEW: System and Operational letters following recent JCVI advice on boosters and second doses for cohorts 11, 12 and severely immunosuppressed people.

On 3 December, Amanda Pritchard, Dr Emily Lawson, Dr Nikki Kanani and Ed Waller wrote to systems and vaccination sites on the next steps following the JCVI advice of 29 November, on booster doses for cohorts 11 and 12 (18-39 year olds), second doses for 12-15 year olds and booster (4th) doses for severely immunosuppressed people. You can read the letter here. An operational note was also issued 7 December and can be viewed here.

On 10 December, we issued an Operational Note providing guidance on the booster dose offer for severely immunosuppressed individuals, which can be accessed here .

5. NEW: Information on the temporary suspension of the observation period following vaccination with COVID-19 vaccines.

***Julie Yates, Lead for Screening and Immunisation statement**:*

As you are aware the PGD and NP have been updated to confirm suspension of the 15-minute wait following vaccination during this phase of accelerated roll out of the booster programme. Please note that these changes do not mean that the wait is removed for everyone who has had a vaccine of either Pfizer or Moderna.

The Green Book has been updated to provide further guidance on this and a flyer has been produced nationally to advise patients of this change, the situations where a wait is still required and what to look out for post vaccination.

Please note the guidance reinforces the following:-

- If anyone has a history of an allergy they must wait on site for 15 minutes
- Everyone having the vaccination must not drive for 15 minutes
- For housebound and domicillary they must have a responsible adult with them for 15 minutes following the vaccination Please can you ensure that patients are made aware of these changes and ensure the 15 minute wait continues to be implemented where it is still required.

UKHSA Statement: 16th December 2021

The Green book on immunisation chapter 14a has been updated to include information on the 15 minute wait after mRNA vaccines and advice on heterologous primary courses.

Please read the chapter here and bookmark it in your browser:

https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

Waiting after your COVID-19 vaccination flyer

We have produced a guide for all recipients of the vaccines. Please read the attached guide which explains the change to the post vaccination observation period.

An accessible version of this leaflet should be given to every person being vaccinated with a copy of What to expect after your COVID-19 vaccination leaflet, a record card, the vaccine PIL* and a sticker.

*Link to Yellow card scheme website where you can view all the vaccine patient information leaflet latest versions.

English versions are available to order now. Please order paper copies of the flyer now using the product code: **C21AAEN** from the Health Publications website:
https://www.healthpublications.gov.uk/EditArticleContents.html?sp=l2518&sp=Sen_US

And you can view/bookmark the page to see the HTML and pdf versions:

https://www.gov.uk/government/publications/covid-19-vaccination-observation-period

Translations and accessible versions will be available to order shortly from Health Publications.

COVID-19 vaccination programme collection

Please bookmark this in your browser.
https://www.gov.uk/government/collections/covid-19-vaccination-programme

The COVID-19 vaccination training guidance and slide set have also been updated: Please see at link above.

All programme publications are subject to regular revisions, so please link to our pages, do not republish. If you link, when we update the page, the link remains live and useful.

Many thanks,

Immunisation and countermeasures department

UK Health Security Agency

Immunisation@phe.gov.uk

Suspension of the 15-minute wait for vaccination with mRNA vaccine for COVID-19: UK CMOs' opinion

Published 14th December:
https://www.gov.uk/government/publications/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion

The Chief Medical Officers (CMOs) of the UK and lead Deputy Chief Medical Officers (DCMOs) for vaccines have considered whether, in the light of the very considerable need to speed up vaccination and boosting in response to Omicron variant, the 15-minute wait for some mRNA COVID-19 vaccines should be suspended.

Their view, having considered the views of the COVID-19 Vaccine Benefit-Risk Expert Working Group (EWG), NHS planners and others is that with the low rates of anaphylaxis, in the context of the considerable need for people to be boosted or vaccinated, the 15-minute wait after a vaccination with mRNA vaccine will cause more harm than it can avert because it will significantly reduce the number of people who can be vaccinated over a short period of time. The 15-minute wait should therefore be suspended for first, second and homologous or heterologous boost vaccinations with mRNA vaccine given the current situation, with this operationalised in line with the needs in each of the 4 nations.

The long-term decisions on the 15-minute wait, when the current need for extreme speed of vaccination and boosting is over, should rest with the Commission on Human Medicines (CHM), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Joint Committee on Vaccination and Immunisation (JCVI). If Ministers agree then this should be a temporary

measure on the grounds of public health need to protect as many citizens as possible over a short period of time. How the 15-minute suspension is operationally implemented should be determined by each nation.

The CMOs recognise that this will lead to a marginal increase in risk for a very small number of people, but substantially fewer than would be harmed by a slower vaccine rollout in the current public health emergency leading to some citizens not getting boosted or vaccinated prior to exposure to Omicron. This includes a consideration that any prior vaccination and particularly boosting is likely to lessen the likelihood of severe disease arising from Omicron variant infection.

Those with a history of allergic reactions should be managed in line with Green Book advice and everyone who is vaccinated should be given verbal and written advice on allergic reactions including what actions to take if they become unwell.

The background to this decision is laid out below.

We will copy this to the Chair of CHM and JCVI for information.

Background

The current threat and response

Omicron is spreading extremely rapidly, with a doubling time of 2 to 3 days. If this is maintained, it will spread extremely rapidly through the population. Even if less severe than Delta, with the very high numbers involved modelling from several groups show this will cause substantial mortality, severe illness and pressure on the NHS. This constitutes a national health emergency.

While some protection by any level of vaccination against severe disease is likely, data to date show that 2 doses of any available vaccine is not sufficient to prevent symptomatic disease.

There is therefore a need to boost as much of the population as possible before the peak of the Omicron wave or provide first vaccination to those with no prior protection. It is likely that this will significantly reduce the number of people becoming ill, hospitalised and dying. Given the speed of the current wave this will need to be undertaken very rapidly.

The mRNA vaccines have shown better ability to boost and are therefore the basis for the current booster campaign. In the CovBoost study antibody responses to mRNA vaccine boost were also much quicker than for other vaccine modalities (typically 7 to 10 days).

Basis of the 15-minute wait

All currently deployed vaccines have proven safe with low rates of severe side effects. As with all vaccines occasional cases of anaphylaxis have been reported, and the rates are slightly higher (but still very low) in the case of mRNA vaccines from Pfizer/BioNTech and Moderna but still overall very rare. For mRNA vaccines there have been 2 fatal Yellow Card reports of anaphylaxis linked to primary

course vaccination and no deaths from anaphylaxis linked to booster vaccination reported in the UK to date.

We extract below some of the key points from the COVID-19 vaccine benefit-risk expert working group (EWG) analysis on booster vaccination:

a. Anaphylaxis following mRNA COVID-19 vaccination is a very rare but a potentially life-threatening event.

b. The EWG has previously stated that occurrence of anaphylaxis, where the first 2 doses of the same vaccine have been previously administered with no allergic reaction, would be extremely unlikely and agreed that the 15-minute observation time can be waived for homologous boosters (where the booster is the same vaccine as the first 2 doses) where no allergic reaction occurred on the first 2 doses.

c. The overall reporting rate of anaphylaxis with booster doses (0.26 per 100,000) was below that of reporting for the first 2 doses, with Moderna (1.47 per 100,000) and Pfizer (1.23 per 100,000). There had been 28 reports of anaphylaxis events with Pfizer booster doses (12 on a homologous i.e. Pfizer boosters, after Pfizer first/second dose; and 16 on heterologous schedule (i.e. Pfizer booster after AZ or Moderna or where primary dose was unspecified first and second doses).

d. Five of the 28 anaphylaxis Pfizer reports met the case definition criteria for anaphylaxis; of which 4 were heterologous, the fifth case was homologous, but the patient had received concurrent flu vaccine which is a potential co-suspect in the case. There were 9 reports of anaphylaxis events with Moderna booster doses, all reports on a heterologous schedule.

e. Within the 15-minute waiting time 17 events were reported and outside the 15-minute waiting time, 14 events were reported, but within the same day. The exact timings were not always specified, for instance – several said'<1 day' or 'after a few minutes' or 'outside the vaccination centre'. Six reports indicated an onset time of 5 minutes or less from vaccination.

f. There were no fatal reports, however 18 of the reports stated adrenaline was administered and 8 were hospitalised. It was noted that several had pre-existing allergies to a variety of allergens.

Reports with the Yellow Card database are under constant review and subject to change. This can include of receipt of additional information on reports, including additional reactions or details which may lead to identification of duplicated information. As such numbers of events may fluctuate.

The CMOs take these data as read. They demonstrate a real, but very rare, absolute risk with 2 reports of fatalities. It is not clear whether the 15-minute wait contributed to the non-fatal outcomes. The 15-minute wait was observed in the reports with fatal outcomes.

The risks of the 15-minute wait in the current situation

Initial analysis from NHS England from England, which is likely to be similar to other nations, implies that under the conditions of a system working at full capacity (as is needed now) the 15-minute wait reduces throughput by 23%. This leads to over 500,000 people not getting a vaccine in the initial period who would otherwise have done so.

Even allowing for the relatively crude initial calculations here, the absolute number of people put at risk because they cannot get vaccinated due to the 15-minute wait (in the high tens of thousands or higher) is much greater than the more precisely calculated number who get anaphylaxis.

Since the mortality rate for COVID-19 is non-trivial (although not yet calculated for Omicron) the probability of harm through delay is, in the view of the CMOs substantially in excess of the probability of benefit from maintaining 15-minute waits under the current situation.

The CHM has also agreed that the 15-minute observation period for primary course, third doses and booster doses of mRNA vaccines could be waived on a temporary basis during the emergency response to the Omicron variant. They will keep this under close review.

6. UPDATE: Cohort eligibility and operational status

This resource has been updated, summarising which cohorts are eligible for vaccination, under what parameters, and how they can access the offer. At the time of review, the programme has not yet implemented all of the JCVI recommendations made on 29th November 2021, although the document has been updated to identify these.

We recommend that teams avoid printing the document as it will become out of date rapidly. You are advised to save the hyperlink where the revised version will be uploaded weekly.

Following updated guidance from the Joint Committee on Vaccination and Immunisation (JCVI), our system letter issued on 3 December and operational guidance on 7 and 8 December, the National Booking Service (NBS) has now been updated to allow booking for booster appointments to take place from 3 months after the second dose for eligible groups.

People in Cohorts 1 to 10 can now pre-book their booster appointments from 2 months (61 days) after their second dose, for appointments to take place from 3 months (91 days).

The walk-in vaccination site finder on the NHS website has also been updated to reflect that people in these cohorts can walk in to have their vaccination from 3 months (91 days) after their second dose.

NBS Update:

Please note that regional colleagues will be able to request onboarding to the National Booking Service (NBS) for sites via the Change Control process. The full message published on 10 December can be viewed here on FutureNHS.

7. NEW: Support to increase the roll out of boosters

The COVID-19 Vaccine Equalities Connect and Exchange Hub is a great resource to make sure that the vaccine is accessible to our patient, public and underserved communities by bringing together learning from vaccination teams across England to support positive practice in improving uptake. The Hub has a huge range of case studies, webinar recording and evidence papers showcasing how vaccination uptake has been improved in local areas. The Hub provides practical tips to support uptake across communities that have been hesitant in taking up the vaccine offer including people from Black and south Asian background, people experiencing homelessness and traveller communities. There are also dedicated spaces focusing on Pregnancy and increasing uptake within some cohort 6 populations.

The COVID-19 Vaccination Programme FutureNHS site, set up to help health care professionals deliver their local vaccination programme, provides invaluable material which will help you to move the Booster offer on at pace. The Evaluation Hub of the site includes the November Knowledge Synthesis Report highlighting impact stories, evaluation findings, lessons learned, best practice examples and case studies from vaccination sites across the country. Additionally you can also share your work via this mapping form - share and tell us your impact story to be included on the Evaluation Hub. Additional Improvement resources are available here.

8. UPDATE: Onward transfers of COVID-19 mRNA vaccine following those to an individual practice within a Primary Care Network grouping

Colleagues should note that national guidance supports the transfer of vaccine to an individual practice within a PCN grouping, but it does not support subsequent transfers of that vaccine on to other premises such as a care home or a pop-up site. We appreciate the impact of this on your ability to vaccinate quickly and effectively and so we have asked for clarity on the basis for this guidance. We have agreed within the South West region to support subsequent transfers from an individual GP practice for vaccination of care home patients or housebound patients subject to appropriate governance and cold chain management.

Note that both thawed Comirnaty vaccine (Pfizer), and thawed Spikevax vaccine (Moderna) should spend no more than 12 hours being transported within the one-month shelf life.

The vaccine stock transferred between sites should align with those numbers of patients booked for vaccination, and so there should be no vaccine stock returned other than in exceptional circumstances in line with the guidance in the Roving and mobile models SOP.

9. REMINDER: Vaccination of high-risk children aged 12-15 years of age

Reports have been received from a number of sources that many at risk 12-15-year-old children (ie. those with underlying health conditions), including those with a learning disability, autism or both, are being turned away when their parents or carers are seeking to book a COVID vaccination via their GP at a PCN Grouping led site on their behalf.

This has meant that families have not been able to get their child vaccinated which has been distressing for all concerned and may impact on attendance and ease of delivery of subsequent doses required. In order to ensure at risk children aged 12-15 years old are able to receive their vaccinations and so support vaccination uptake improvement for this cohort of children, please can all staff be reminded that at risk children aged 12-15 years old are eligible for vaccination at PCN-led sites and additional reasonable adjustments may need to be accommodated. They should not be redirected to school aged immunisation services, unless the young person and their family agree.

Many thanks for your help in advance.

10. UPDATE: Clinical Safety Checklist

The safety checklist has been updated to reflect recent changes to the vaccine programme in response to the identification of the Omicron variant. It is designed to be used at all sites at the start of each vaccine session. We will continue to keep it updated on (at least) a monthly basis so please continue to send us any comments or suggestions for improvement.

11. SUPPLY: AstraZeneca vaccine availability

There are a number of individuals who have had only one dose of COVID-19 vaccine AstraZeneca (ChAdOx1-S recombinant). To facilitate completion of their primary course, sites are asked to make appointments available for individuals to book through the National Booking System and via local booking arrangements.

AstraZeneca vaccine is available to order through the Foundry platform and sites should contact their System leads if they need support in accessing stock.

12. UPDATE: Operational guidance for care homes

We have updated the Non-older adult care home COVID-19 Vaccination operational support pack and the Older adult care homes: operational support pack, following the JCVI's statement on boosters published on 29 November 2021 and subsequent updates to The Green Book, Chapter 14a and our letter dated 3rd December 2021 to system leaders regarding the next steps in deployment.

13. NEW: Advisory re Coolmed annual medical fridge/freezer service

We understand some LVS sites may have received an email from a company called Coolmed on 9 December stating that it had been tasked by the NHS to arrange your site's annual medical fridge/freezer service for units received as part of the National Covid-19 Vaccination Programme in 2020/2021.

We can confirm that this is a genuine email, however, it does contain an inaccuracy, in that Coolmed has not been tasked by the NHS to arrange this work. Sites are responsible for organising annual servicing and calibration work on these units and can choose their own supplier to carry this out, as per the communication issued by the National Programme on 7 December entitled 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

14. NEW: One-year anniversary of the COVID-19 vaccination programme

8 December 2021 marks the anniversary of the first COVID-19 vaccination and coincidentally, is the day on which we hit the milestone of 100 million vaccinations having been administered in England.

In a 2-minute video tweet, Dr Emily Lawson, Senior Responsible Officer, Vaccine Deployment, reflects on a year of the NHS COVID-19 vaccination programme, the most successful in health service history, designed and delivered by NHS colleagues. You can watch the video here.

Sajid Javid, Secretary of State for Health and Social Care, has written to all primary care staff to thank you for all the work you have done and are still doing on the COVID-19 vaccination programme. You can read the letter here.