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
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**NEW: Maximising vaccine site throughput**

The emergence of the Omicron variant requires the vaccine programme to massively increase capacity. This is partly being achieved by recruiting more staff and volunteers and opening extra sites. Alongside this, however, we need to review every step in the vaccine pathway to how we can increase productivity and throughput.

Key to this is the use of the National Protocol, a novel legal mechanism developed for the COVID-19 vaccine programme that splits the process of vaccination into four separate stages: clinical assessment, vaccine preparation, vaccine administration and record keeping. Uniquely, each stage can be completed by a different individual and only the first has to be directly delivered by a Registered Healthcare Professional (RHCP).

Studies at sites that have adopted the National Protocol show that splitting activity into component parts speeds up the vaccination process, as well as enabling RHCPs to focus on the activities that only they can do – particularly important when resources are stretched.
The National Protocol is the most flexible model for delivering vaccines and we would like every site to examine how it can be exploited to maximise throughput. To assist in the task, we have produced a new, short slide deck which provides details of how various sites have adapted work processes, team structure and technology to improve productivity.

We encourage you to review these examples, consider which are applicable to your local circumstances and adopt them wherever possible, modifying them as needed.

More information on the legal mechanisms for administration of COVID-19 vaccines, including detailed information on the National Protocol, can be found here. The Specialist Pharmacy Service has also developed a summary of how different legal mechanisms apply to different professional groups.

Information about optimising the workforce can be found here, as well as many useful resources available on the Workforce and Training workspace here. If you have ideas to share, please visit the Improvement Hub and get in touch with the team.

NEW: Next steps for the NHS Covid-19 Vaccine Deployment: maintaining the focus on health inequalities

In the South West we want to make every effort to maintain a focus on protecting our most vulnerable groups during the current phase of the COVID vaccine deployment in response to the Omicron variant.

Across the region there remain 225,000 people who have not received a first dose and 146,000 people who have not received a second dose.

The letter Preparing the NHS for the potential impact of the Omicron variant and other winter pressures asks us to ensure that we:

- Deliver at scale whilst also retaining the focus on vaccination of those at greatest risk, including those who are housebound.
- Continue to maximise uptake of first and second doses including through identifying dedicated resources to work alongside directors of public health locally.
- Healthcare colleagues are asked to make every contact count this winter with people with Severe Mental Illness and Learning Disabilities – to ensure access to COVID-19 and flu vaccination, in the context of stark health inequalities for these patients.
- Healthcare colleagues are asked to make every contact count this winter with pregnant women – and those planning pregnancy – to advise them of the
benefits of COVID-19 and flu vaccination. Please note the following from the Operational Guidance (RVOC6748):

- 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.

- 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 Learning Disabilities or Autism and Severe Mental Illness, 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. Next steps

1. Please ensure that you are referring to the Standard operating procedure: Roving and mobile models in setting up any new pop-up or mobile offers.

2. If you have any workforce capacity issues affecting your ability to offer Evergreen clinics, outreach or pop-up models then please discuss with your workforce lead and for escalation to the regional workforce lead if unresolved.

3. We are sending you a data pack on unvaccinated clusters in your System area. These have been reviewed by System Inequalities Leads at the Inequalities Oversight group today. Please ensure that you have plans in place to ensure that these areas are being targeted with appropriate provision of vaccination sites and targeted comms as appropriate.

4. For further resources to support inequalities work please see

- Our resources page https://www.england.nhs.uk/south/professional/public-health/immunisations/covid-19/


- Campaign resource centre https://coronavirusresources.phe.gov.uk/covid-19-vaccine/resources/

Dr Emma Kain | Screening and Immunisations Lead, Consultant in Public Health
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.

Please note that no changes have been made to the following:

- The minimum interval between first and second doses 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
- The minimum interval between completion of the primary course and the booster dose
  - 91 days remains the minimum interval and doses should not be administered earlier than this
- The deferral time for doses following infection with COVID-19
  - For all adults and 12-17 year olds who are in a risk group, vaccination should be deferred until 4 weeks after onset of COVID-19 symptoms, or 4 weeks after a positive PCR sample if the individual was asymptomatic
  - For 12-17 year olds not in a risk group, vaccination should be deferred until 12 weeks after onset of COVID-19 symptoms, or 12 weeks after a positive PCR sample if the individual was asymptomatic.

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.

NEW: Information regarding vaccinations for children and the 12-15 vaccination offer.

NEW: Second phase for children and young people aged 12 to 15

This letter sets out the next steps on second dose vaccination for healthy 12- to 15-year-olds

NEW: Second dose out-of-school COVID-19 vaccination offer to children and young people aged 12-15 years

As per the system letter on 13 December (here)
Children who are not in a risk-group will be offered a second dose vaccine from Monday 20th December. Children will be able to receive their vaccine in school via SAIS providers from 10th January or at vaccination sites out of school.

Recent infection with COVID-19 would require deferral of vaccination as follows:

- For 12-15 year olds in a risk group, vaccination should be deferred until 4 weeks following the start of symptoms, or the day of a positive PCR sample for asymptomatic individuals.
- For 12-15 year olds not a risk group, vaccination should be deferred until 12 weeks following the start of symptoms, or the day of a positive PCR sample for asymptomatic individuals.

Pfizer-BioNTech (Comirnaty ®) is the recommended vaccine and the PGD and National Protocol support vaccination of this cohort.

**LEARNING: Consent rights of the child**

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

**REVISION: Children Self Assessment Checklist B**

A small revision has been made to [Children Self Assessment Checklist B](#). Endnotes have been added that summarise the clarifications made to the checklists since publication.

An additional standard has also been introduced regarding the information requirements when re-consenting parents of this age group:

"If re-consenting parents/child who already engaged with the programme (such as previously consented for a 1st dose) then any additional information can be provided at any point, providing it is prior to vaccination and the parent/child has the time to consider the information".

**NEW: Operational guidance on the booster vaccine for severely immunosuppressed individuals**

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

Press notice: [Press notice: JCVI issues advice on third vaccination for severely immunosuppressed](#)
NEW: Operational guidance: provision of walk-ins for severely immunosuppressed people who present for a third primary COVID-19 vaccine dose without a GP or specialist referral letter or a booster with a referral letter from the GP or specialist

From 17 December:

Any walk-in clinic will be required to provide a third primary dose and booster dose for severely immunosuppressed people attending with a GP or specialist referral letter. A GP or specialist referral letter confirming third primary dose eligibility is sufficient evidence to confirm eligibility for a booster, however, clinical assessment is required to ensure optimal timing.

Sites who have indicated 'third dose availability' under their profile on the walk-in vaccination site finder will be required to provide a third primary dose to eligible severely immunosuppressed people who present relevant medical evidence (see below). The clinician on site will be required to conduct a clinical assessment to confirm third dose eligibility based on the medical evidence provided.

This note set out operational guidance to support the above.

Note: For this group the booster will be a fourth dose following completion of their primary course of vaccination that comprises three doses.

Update walk-in coronavirus (COVID-19) vaccination site finder website

From 17 December, the walk-in coronavirus (COVID-19) vaccination site finder will be updated to:

- allow people who believe they may be eligible for a third primary dose and have relevant medical evidence (but without a GP or specialist referral letter) to walk-in to clinics that have flagged 'third dose availability' on their site profile on the walk-in vaccination site finder to receiver their third primary dose. 'Third dose availability' on a site profile indicates a clinician is on site to undertake this assessment.

- allow severely immunosuppressed with a referral letter for the third primary dose to any walk-in site providing boosters to receive their booster. An assessment should be undertaken by a clinician on site to ensure that this is optimally timed as per the Green Book.

Clinical assessment – third primary dose

- JCVI have updated advice[1]: Whilst access for eligible severely immunosuppressed people to a third primary dose previously required the involvement of their GP or Specialist in identifying the appropriate clinical timing, the updated advice enables vaccination sites to offer a third primary dose subject to the
availability of a competent clinician who can assess if the person is eligible based on medical evidence provided.

- The Patient Group Direction and National Protocol for Pfizer-BioNTech (Comirnaty®) and Moderna (Spikevax ®) COVID-19 vaccine have been updated (available [here](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) to enable the administration of a third primary dose without a referral letter subject to a clinical assessment being undertaken by a competent clinician. The third primary dose can be given at eight weeks post the second dose (or later).

- The clinical framework ([here](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) for assessing patients presenting for additional COVID-19 vaccine doses due to severe immunosuppression has been developed to support clinicians on site to offer third primary doses for eligible individuals presenting with medical evidence (but without a referral letter).

- Medical evidence confirming eligibility for a third primary dose includes:
  - The referral letter from the person’s GP or specialist confirming eligibility and timing of a third primary dose.
  - A hospital letter that describes the person’s condition at the time of the first and/or second dose
  - Evidence of prescribed medication at the time of the first or second dose, either in a hospital letter that describes the medication being prescribed, a prescription copy or a medication box with the patient’s name and a date on it. The clinical assessment framework ([here](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) provides an overview of typical medication.

- In the clinical assessment, a competent clinician needs to confirm if an individual meets the criteria for a third primary dose using the green book information (Chapter 14a, see Box: Criteria for a Third Primary Dose of COVID-19 Vaccine’ [https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) and through obtaining further clinical information such as medication being taken. A clinical framework has been developed to support clinicians in their clinical assessment and inform the development of the pathway. The framework is available here: [Resources for immunosuppressed people - CommsLink - FutureNHS Collaboration Platform](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)

- A clinical escalation process is required to the senior clinician on site in the case that the treating registered health care professional is not competent to assess eligibility based on the medical evidence provided.

- Where an assessment is made that an individual is eligible for a third dose, the authorising clinician should briefly record the rationale in the PoC System and administer the vaccine under the appropriate legal mechanism. NOTE: a third primary dose is a full dose of Pfizer-BioNTech (Comirnaty®) or a full dose of Moderna (Spikevax ®). For those aged 12 to 17 years, the Comirnaty (Pfizer-BioNTech) vaccine is preferred. The third primary dose of Spikevax (Moderna) for patients with immunosuppression is different from the booster dose that is a half dose of Spikevax (Moderna).
· In the event that the clinical assessment does not confirm or cannot determine an individual's eligibility for a third primary dose, please advise the individual to contact their GP or specialist to confirm whether they are part of the severely immunosuppressed group and eligible for additional doses. The clinical assessment framework (here) contains a template letter from the vaccination site to the GP or specialist (Appendix F) to support this step.

· The individual whose eligibility for a third primary dose cannot be determined on site may be eligible for a booster as an eligible member of a currently open JCVI cohort. This should be assessed before they leave the site, and an appropriate vaccine given.

· The decision and rationale to not provide a third primary dose is to be recorded in the Point of Care (PoC) System.

**Clinical assessment - individuals presenting for their booster dose with a referral letter confirming third primary dose eligibility:**

- A GP or specialist referral letter confirming third primary dose eligibility is sufficient evidence to confirm eligibility for a booster (fourth dose), however, clinical assessment is required to ensure optimal timing.

- The information of the referral letter together with the clinical framework for assessing patients presenting for additional COVID-19 vaccine doses due to immunosuppression (here) should support clinicians in their clinical assessment to determine optimal timing of a booster.

- A clinical escalation to the senior clinician on site should be considered in the case that the treating registered health care professional is not competent to assess the optimal timing based on the referral letter.

- If the senior clinician on site cannot determine the optimal timing based on the information in the GP or specialist referral letter, please advise the individual to contact their GP or specialist with guidance that further detail is required to administer the booster in the appropriate interval.

**IMMEDIATE ACTIONS**

**Site requirements**

· With immediate effect, sites offering walk-in clinics are asked to review their profile on the website to find a walk-in coronavirus (COVID-19) vaccination clinic and update, where appropriate, third primary dose availability. This indicates a clinician is on site to undertake the required assessment on third dose eligibility and the clinical assessment on timing of the booster for individuals presenting with a letter from their GP or specialist outlining eligibility and timing for the third primary dose.

· The administration of the third primary dose and booster must be undertaken in accordance with the requirements of the PSD, PGD or national protocol legal prescribing tools. For the booster the third dose referral letter is sufficient evidence to meet requirements under the NP and PGD.
On-site processes

The following steps will need to be in place with immediate effect:

• Queue management: all sites are asked to consider how to best support clinically vulnerable such as severely immunosuppressed people for example via enabling access to a priority or fast-track lane.

• At arrival/check-in:

  • For the third primary dose, if the individual has a GP or specialist referral letter, this is sufficient evidence to administer this dose. If the individual presents with relevant medical evidence (but without a referral letter), they should be directed to be seen by a competent clinician who can assess eligibility for a third primary dose.

  • For the booster dose, if the individual presents a referral letter confirming third primary dose eligibility, this is sufficient evidence to confirm eligibility for booster (fourth dose), however, a clinical assessment is still required to ensure optimal timing.

• Clinical assessment step: as outlined above and supported by the clinical assessment framework.

• Recording of additional COVID-19 vaccine doses: For severely immunosuppressed individuals, the third primary dose is to be recorded as a booster dose, and the booster dose is to be recorded as a 'second' booster in the PoC system. The decision to administer a third dose or booster dose has to be recorded in the POC by the authorising clinician. PCN and Community Pharmacy-led sites should select the ‘other residential settings’ setting to ensure additional supplementary payments can be applied.

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).

GUIDANCE: Information for healthcare professionals on Guillain-Barré Syndrome (GBS) following COVID-19 vaccination

Please see updated guidance on GBS:

It is very important that all suspected cases are reported to the MHRA using the COVID-19 Yellow Card scheme.

Should someone who has had GBS unrelated to COVID-19 vaccination have their COVID-19 vaccination?

Yes, they should be vaccinated as recommended for their age and risk group, including booster doses.
A causal link between COVID-19 vaccination and GBS has not been proven and there is no evidence of a higher rate of reporting of GBS following COVID-19 vaccination in individuals who have previously had GBS. Hence, the balance of risk benefit is in favour of completing the recommended COVID-19 vaccination schedule. See the Green Book for further information.

**If someone has had GBS after a COVID-19 vaccination, should they have subsequent doses?**

If GBS develops in an individual after a dose of either the Pfizer/BioNTech or Moderna vaccine, they should complete the vaccination schedule with the same vaccine once fully recovered. The balance of risk benefit remains in favour of completing a full COVID-19 vaccine schedule and there is an increased rate of known side-effects if mixed schedules are used. If the next dose is a booster dose, then the Pfizer/BioNTech vaccine is recommended.

If GBS develops within 6 weeks of receiving the AZ vaccine, then on a precautionary basis Pfizer/BioNTech should be given for any subsequent doses. Please see the Green Book for further information.


**UPDATE: Facilitating Vaccination in Pregnancy: Guidance for LVS**

In view of growing evidence that pregnant women are at increased risk of serious illness from COVID-19, the Joint Committee on Vaccination and Immunisation (JCVI) has called for pregnant women to get vaccinated as soon as possible, and to be considered a clinical risk group (JCVI Priority Group 6) by the Vaccination Programme.

We ask sites to ensure that any women who are pregnant or breastfeeding are able to receive vaccination, if they have made a choice to receive it. Refreshed guidance on offering vaccination in pregnancy will be issued to LVS in the new year, in view of the JCVI’s statement.

Sites are also asked to consider operational guidance on queue management and priority lines, issued on 14 December:

"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."

**UPDATES: Operational updates and reminders**

**NEW: Vaccine movement**
Given the rapid escalation of the COVID-19 vaccine booster programme, it is likely that some sites will request mutual aid to meet exceptional patient demand. There are a number of flexibilities currently in place that can support the timely access to vaccine, supported by guidance to support good professional decision-making.

The Mutual Aid policy allows movement of sufficient vaccines between end users, in quantities sufficient to meet demand. Existing information supports doing this safely and should be followed i.e. whilst protecting vaccine from physical shock in transit and assuring the cold chain (Specialist Pharmacy Service vaccine supply information).

It is for pharmacy professionals at a system level to determine what’s best to do, pharmaceutically, for patients, taking into account the context at any given time. In the current circumstances, speed of accessing effective vaccines is clearly very important, but bear in mind we are dealing with vaccines that are inherently fragile in nature.

Vaccines should always be moved in original cartons because individual vials of Comirnaty® (Pfizer BioNTech), Spikevax® (Moderna) aren’t labelled with the post-thaw expiry date (SPS guidance).

The Mutual Aid policy also permits movement under NHS England and NHS Improvement direction; NHS Regions are therefore able to support systems that require assistance to access supplies for those sites where they are required.

Message on behalf of Catriona Khetyar, Regional Chief Pharmacist:

The national HSA and 3PL distribution capacity is overwhelmed and cannot get enough vaccine to the right places to meet demand due to having not enough refrigerated vehicles. Unfortunately their solution to this is ask for local redistribution of vaccine from VCs and HHs which have been given large allocations to draw down. The MHRA have stated that under the current circumstances they will not challenge the drawing down of vaccine for the specific purpose of sending it to another site, regardless of whether there is a WDA.

However conditions of transfer still need to be met and the mutual aid process still needs to be followed to provide pharmacist assurance of this and track the location of vaccine.

Where the systems and regions do not have the capacity to physically move the stock, the national team are arranging military support at the regional team’s request. The military teams will transport in non-refrigerated vans using cool boxes.

There are all sorts of issues with this, including having sufficient storage for the volume of vaccine, having sufficient manpower to pack vaccine safely and complete MA forms, having confidence in the transport, having enough cool boxes….. To help with maintaining vaccine integrity SPS have very rapidly come up with a quick guide for transferring Pfizer or Moderna vaccine in thawed or thawing state – see attached
PDF ’Transporting Comirnaty and Spikevax Vaccines’ – the main concern being keeping thawed and frozen vaccine separate.

The regional chief pharmacists have escalated our concerns about this process, both for vaccine integrity and capacity in local services, and we have been assured that it will only be used for a week.

REMINDER: Handling requirements for dry ice

As there is a huge demand for vaccine right now there is a great deal of it moving around the system. In some cases there multiple shippers containing dry ice being delivered and it is really important for sites to unpack it immediately and then put the dry ice to sublime in a well ventilated area. Any delay could lead to a room being filled with CO2.

I am aware of a near miss where there was a delay between receipt and unpacking in which asphyxiation was thankfully averted.

All sites handling dry ice should have undertaken their risk assessment and be aware of this. SOP’s (VH2 and VH3) are clear and should be followed:

- **Unpacking and storing frozen COVID-19 Vaccine Pfizer-BioNTech in ultra-low temperature freezers in Trusts – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice**
- **Receiving of frozen COVID-19 Vaccine Pfizer-BioNTech in ultra-low temperature freezers in Trusts – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice**

UPDATE: Infection Prevention Control (IPC) update

As the COVID-19 Booster programme has been asked to upscale at pace, with the subsequent increase in vaccination activity, there is a continued need to emphasise and prioritise IPC practices. The overriding message is to ask teams to remain focused on the key IPC messages that have been developed that will support teams in delivering this considerable increase is vaccination delivery.

The following resources may be helpful:

- **IPC guidance** which is referenced in all operational frameworks.
- Encouraging everyone to follow good practice in COVID-19 infection prevention and control is key to keeping healthcare settings as safe as possible. When discussing locally ‘what should we be doing?’, the Every Action Counts website offers easily accessible advice and guidance on supporting good practice in infection prevention and control behaviours. An Every Action Counts toolkit is also available.
A helpful summary for relevant safety resources is available here. For anyone wishing to access more detailed or more specific information the clinical workstream have produced a summary of resources available on NHS Futures here.

**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 so please continue to send us any comments or suggestions for improvement.

**GUIDANCE: Managing challenging behaviours at vaccination sites guide for Site Managers**

The Vaccination Centres Team have developed a short pack with safety awareness steps to take by staff and volunteers should they come across challenging behaviours. Individuals may become challenging for a number of reasons such as fear of needles, anxious about being in public having isolated, worried about protecting loved ones or fear they might catch the virus etc. Site Managers can help staff and volunteers to de-escalate challenging behaviours by using team stand-up meetings to remind everyone to listen with empathy to bring calm to a situation and a safe outcome.

Please use the pack to outline to staff and volunteers how they can help manage challenging behaviours and display the posters included at your sites. Site Managers can use the pack as a complementary set of resources should local staff/volunteer safety and wellbeing policies and communications be in place.

*Increased attendance at vaccination sites numbers may result in queues. Please note the guidance/advice that is available on the NHS Futures site on security arrangements at vaccination sites. Here is a short reminder about steps that should be taken in relation to queues:*

- Have a plan to manage queues, including giving information to those queuing
- Avoid having queues near to main roads or other physical hazards
- Keep local police and other authorities informed of your opening times and expected numbers
Ensure your team know what to do if there is an incident, and that all incidents are reported

SUPPORT: Resources for support

SUPPORT: Vaccination Service Desk information on FutureNHS

The Vaccination Service Desk has an area on FutureNHS designed to support front-line staff and members report tech and data issues for:
- Pinnacle
- Vaccination records
- National Immunisation Vaccination System (NIVS)
- Foundry
- National Booking System or Q-Flow
- MYS
- Other tech and data queries.

Please encourage staff to visit this page and select the nature of their query to view the information required by the Vaccination Service Desk team. Send this to us via email at vaccineservicedesk@england.nhs.uk.

Using these templates will ensure that your issues or queries are dealt with efficiently

SUPPORT: Supply and Delivery Hub

Supply and Delivery Hub helps you access key information in a timely way and help support you to deliver your local vaccination service. Here you will find the latest delivery information (vaccine and vaccine consumables as well as non-vaccine consumables, equipment and PPE), alongside the latest supply chain and customer service FAQs and other helpful information.