

### **ICARS** Newsletter

Issue 67: 10th 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

PLEASE SHAREWITH ALL RELEVANT STAFF INVOLVED WITH THE VACCINATION PROGRAMME

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

### Contents:

- 1. <u>Update: Comirnaty PGD and national protocol for the COVID-19 vaccination programme in England</u>
- 2. New: JCVI advice in response to the emergence of the B. 1. 1.529 (Omicron) variant: next steps for deployment
- 3. New: Vaccination of adults and children in a single location
- 4. New: Thank you letter for volunteers

- 5. For Action: COVID-19 and seasonal flu vaccination for pregnant women
- 6. Operational: Guidance on the NBS third dose booking pathway for eligible adults who are severely immunosuppressed
- 7. Operational: Anaphylaxis kits
- 8. Operational: Regular checking and resetting data loggers
- 9. Operational: 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
- 10. Operational: C19 Vaccination Record Cards
- 11. Learning: Key Learning re cold chain incidents
- 12. Learning: Case Study 4 incidents of vandalism at an LVS site
- 13. Resource: Escalation form for incidents relating to NBS, Covid Pass and VDRS
- 14. Resource: Combined needles and syringes for the COVID19 vaccine administration

# 1. Update: Comirnaty PGD and national protocol for the COVID-19 vaccination programme in England

For your information, updates to the Comirnaty PGD and national protocol, for the COVID-19 vaccination programme in England, have been published this morning (8th December):

- <a href="https://www.gov.uk/government/publications/national-protocol-for-comirnaty-covid-19-mrna-vaccine">https://www.gov.uk/government/publications/national-protocol-for-comirnaty-covid-19-mrna-vaccine</a>
- https://www.england.nhs.uk/coronavirus/publication/patient-groupdirection-for-comirnaty-pfizer-biontech/

### 2. New: JCVI advice in response to the emergence of the B. 1. 1.529 (Omicron) variant: next steps for deployment

Please see the attached letter regarding next steps for deployment of the Covid-19 vaccination programme., following JCVI announcement (dated 3rd December 2021).

### 3. New: Vaccination of adults and children in a single location

We have received several queries regarding separation of children from adults in vaccination sites. Please note, there is no national mandate for children to be separated from adults in a vaccination site. Adults and children may both be vaccinated within a single location. Sites are required to establish pathways for children to ensure that they are seen by identified staff who are trained and competent in vaccinating children.

### 4. New: Thank you letter for volunteers

Please find a <u>letter from Dr Emily Lawson</u>, National Director and Senior Responsible Officer for the NHS COVID-19 and Flu Vaccine Deployment Programme. In it she reiterates her thanks to volunteers working hard to support the NHS COVID-19 vaccination programme. Please share this letter with your volunteers.

### 5. For Action: COVID-19 and seasonal flu vaccination for pregnant women

We write to ask all healthcare colleagues 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; and to signpost acute physicians to best practice guidance on the management of COVID-19 infection in pregnancy, including medication.

New data published by the UK Health Security Agency (UKHSA) has provided further evidence for the safety of COVID-19 vaccination in pregnancy, with good birth outcomes in vaccinated women who had their babies between January and August this year.

This is in contrast with growing evidence that pregnant women are at increased risk of severe illness from COVID-19 compared with non-pregnant women, particularly in the third trimester. Recent data shows that between July and October, nearly 20% of the most critically ill patients receiving Extracorporeal Membrane Oxygenation (ECMO) support in England were unvaccinated pregnant women. Around one in three women who are hospitalised with the virus need to be delivered preterm to help them recover and one in five of their babies need care in the neonatal unit. The JCVI also recommended that booster vaccinations are offered to all adults from 3 months after their second dose, in order to increase levels of public protection against the Omicron variant.

As COVID-19 infection rates and hospitalisations of pregnant women continue to rise, it is more important than ever that all healthcare workers, including GPs, midwives, obstetricians, pharmacists and others continue to build vaccine confidence and make every contact count across both the flu and COVID-19

vaccination programmes. This means recommending both COVID-19 and flu vaccination and providing evidence-based advice and support to women on the benefits for them and their babies; as well as information on the risks of not being vaccinated. This also means encouraging all double-vaccinated women to take up the offer of a booster as soon as they are called forward.

Work is ongoing regionally with system-level vaccination leads to facilitate access to vaccination antenatally. This includes supporting vaccination sites and maternity services to deliver a range of approaches, such as making vaccinations available in antenatal clinics, pop-up sites, or vaccination teams in other parts of the hospital.

We ask you to support these efforts, by ensuring that your clinical teams are up to date on the advice for this group:

### COVID-19 vaccination

- For the latest bite-sized advice for use with women, please see the <u>UKHSA</u>
   <u>leaflet for all women of childbearing age, pregnant or breastfeeding</u> and the
   RCOG/RCM information leaflet and decision aid.
- Women can receive the vaccine at any point in pregnancy, and are encouraged to do so as soon as possible, to ensure maximum protection in the third trimester.
- Women who already received a first dose of AstraZeneca vaccine and didn't experience any serious side effects, should continue to receive a second dose. Serious side effects from this vaccine are very rare and even less likely in the second dose.
- In line with the <u>JCVI advice of 29 November</u>, double-vaccinated women eligible for a booster will be called forward in order of descending age groups, with priority given to the vaccination of older adults and those in a COVID-19 at-risk group.
- More detailed guidance and evidence on vaccination in pregnancy for clinicians can be found in <u>chapter 14a of the Green Book</u> and <u>on the RCOG</u> <u>website.</u>

### Flu vaccination

- At this time, pregnant women are also being offered seasonal flu vaccination and it is therefore important that, as for COVID -19 vaccination, seasonal flu vaccination is supported and recommended by all healthcare workers over the winter period. TheCOVID-19 vaccines or booster can be given at the same time as the flu vaccine or the whooping cough vaccine.
- Information for healthcare workers on the seasonal flu programme for pregnant women is <a href="here.">here.</a>

While the overall risk of mortality from COVID-19 infection remains low for pregnant women, MBRRACE-UK rapid reviews of maternal deaths in the

pandemic and UKOSS analysis of hospital admissions highlight the importance of timely best-practice management of infection, including correct medical treatment. We would like to draw acute physicians' attention to RCOG/RCM <u>guidance for healthcare professionals</u> caring for pregnant women with COVID-19 in the antenatal, intrapartum and postnatal periods. This includes guidance on what medicines are appropriate for use in pregnancy.

Thank you for your continued efforts. We are grateful for everything you are doing to ensure that women receive the information and support they need to make the right decision for them and their babies.

### 6. Operational: Guidance on the NBS third dose booking pathway for eligible adults who are severely immunosuppressed

Further to our operational guidance from 29 November 2021, the following provides clarification on the updated booking pathway enabling eligible individuals to book their third COVID-19 vaccine dose of the primary course via the National Booking System (NBS).

Eligible individuals aged 18 or above who have a referral/recommendation letter from their GP or hospital consultant can now book a third primary dose appointment via the NBS. Individuals will be required to bring their referral letter from their GP or hospital consultant to their appointment.

Individuals eligible for a third dose as identified in the <u>JCVI advice</u> can book their third primary dose at least 8 weeks following their second COVID-19 vaccine dose unless otherwise advised by their GP/specialist team and outlined in the referral letter. Individuals aged 18 or above booking their third dose via the NBS will be directed to sites with Comirnaty® / Pfizer-BioNTech or Moderna (Spikeva ®) capacity.

For under 18-year-olds, work is ongoing to determine a NBS booking journey. Until this is in place, the NBS is directing those aged under 18 to alternative pathways such as walk-in sites via the national walk-in site finder.

#### Actions required

With immediate effect, all vaccination sites are asked to have local processes
in place to identify severely immunosuppressed individuals presenting for their
third dose COVID-19 vaccine primary course. Local processes such as 'fasttracked' routes are highly recommended to ensure these vulnerable groups
are directed to their vaccination and do not have to wait in queues. All
severely immunosuppressed patients attending with a referral letter from their
GP or specialist stating their eligibility are to be offered a third primary Covid19 vaccine dose.

- Eligible individuals presenting for their third dose COVID-19 vaccination must be identified on arrival and directed to the appropriate pathway to receive the correct vaccine dose in line with JCVI guidance.
- Individuals who book a vaccination within a time period that does not align with their referral letter or individuals who attend an NBS appointment without a referral letter from their GP or consultant should be managed according to local arrangements. In the case that a vaccination site cannot offer a third dose vaccine at this moment in time (e.g. if further information is required on the correct interval between the doses), individuals should be advised to contact their GP or consultant. We have provided a template letter to GPs/consultants to support this step. **At arrival**
- The <u>'check a vaccination appointment'</u> app has been updated to identify individuals who have booked a third dose appointment and support front-ofhouse staff/ staff booking-in individuals at arrival. Individuals will be prompted to show their referral letter.
- Q-Flow: For sites who do not use the check-in app, information on the third
  dose booking route can be accessed via Q-flow. Training materials have been
  updated (<a href="here">here</a>) and all staff (including volunteers) are advised to review this
  quidance.

**Point of Care Systems** - To reiterate, as has been common practice since 13th September, third doses should continue to be recorded as "Booster" in Point of Care applications. When administering a Moderna (Spikevax ®) third dose, please ensure it is recorded as a full dose and not a half dose.

Please prioritise these actions. We are grateful for your continuous support.

If you have any questions please contact: england.vaccinecentresgroupsupport@nhs.net

### 7. Operational: Anaphylaxis kits

LVS and Vaccination Centres are requested to check the expiry date of Anaphylaxis.

We are aware that some LVS and VC sites, especially those which have been operational since the beginning of the programme, may now have anaphylaxis kits nearing expiry. As these are critical items, with all active vaccination sites requiring two usable kits at all times, it is very important that new kits are ordered ahead of any potential expiry dates.

### Action for sites:

 All sites are requested to check the expiry status of their anaphylaxis kits, if kits are due to expire before the end of the year (31 December 2021), then please place an order for a new kit as soon as possible via the Unipart Helpdesk.

- Please ensure you confirm your kit(s) expiry date when placing an order, as this will help prioritise the most urgent kits.
- Replacement kits will be issued where possible with your site's next vaccine delivery.
- If demand is high, kits will be issued in priority date order to ensure sites with the earliest expiry dates receive their replenishment first.
- Sites are requested to order as soon as possible to avoid any unwanted delays in delivery, as delivery lead times can exist for these kits.
- We would kindly request that sites do not place orders for replenishment kits at this time, if their existing kits have an expiry date post the 31 December 2021.
- Should a kit be used as part of a medical emergency or a kit has been damaged, then a new kit should be ordered immediately.

### 8. Operational: Regular checking and resetting data loggers

All vaccination sites are requested to ensure they monitor fridge temperature history on a regular basis, to avoid cold chain breaches. This can either be done via the integrated data logger within your fridge or via an independent monitoring unit.

Please note that not all makes and models of fridges have integrated data loggers, as previously advised, on some models sites must undertake their own local checks using an independent monitoring unit and refer to manuals where necessary. On a weekly basis, it is also advisable to fully check data loggers are operating correctly and to reset them, as some data logger units will only hold a set amount of data and once full will stop recording until the unit has been reset.

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

Please ensure you follow all the correct cold chain management processes to eliminate the risk of a cold chain breech happening, in addition to using data loggers. SPS resources about Cold Chain management are available here:

Maintaining the COVID-19 vaccines cold chain — SPS - Specialist Pharmacy Service — The first stop for professional medicines advice.

Part of assurance of the site lead is to ensure that SOPs and processes are followed. Guides for data loggers will vary according to model of data logger, please see the manual supplied with your unit or fridge for full information.

# 9. Operational: 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

We have been made aware that some vaccination sites have been seeking greater clarity on the ongoing maintenance of electronic/electrical equipment provided by the National Covid-19 Vaccination Programme. To assist in answering these queries, we have compiled the following short guide.

If your site is experiencing any other issues with equipment provided by the Programme, which is not covered by the below, please contact the Unipart Customer Service Helpdesk (<u>CS@nhsvaccinesupport.com/0800\_678\_1650</u>) in the first instance.

### Repairs and maintenance of fridges provided by the National Vaccination Programme:

Sites are responsible for arranging for any faults or repairs to fridges, which have been provided by the National Vaccination Programme for the storage of Covid-19 vaccine. It is recommended that sites utilise existing fridge maintenance contracts to get this work carried out. The cost for the repair can be recharged to the National Vaccination Programme, as long as a quote has been obtained prior to the work being commissioned. Standard processes must be followed for recharging costs.

# <u>Annual servicing and calibration of fridges provided by the National Vaccination Programme:</u>

All fridges used for the storage of vaccines should have an annual service and calibration carried out. Sites are responsible for arranging servicing and calibration work on the fridges provide to store Covid-19 vaccine and should ensure this work is done around the 12-month anniversary of the product being delivered. This work can be charged back to the National Vaccination Programme as per standard process.

# <u>Fridges/independent data loggers units requiring renewal of remote data logging software:</u>

The National Vaccination Programme has not provided any fridges or independent data logger units, which required separate remote data logging software. Any sites with fridges or independent data logger units, which now

require a new software licence will need to purchase this software licence direct. This cost cannot be charged back to the National Vaccination Programme, as the original equipment was not purchased by the Programme.

### Fridge faults affecting vaccine supply for all models of delivery:

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

- report to ICARS team <u>england.swicars@nhs.net</u> copying in england.swcovid19-voc@nhs.net
- report the fridge to Unipart so a replacement can be ordered Unipart Customer Service Desk - <u>CS@nhsvaccinesupport.com</u> 0800 678 1650 | 0700-1900 Mon- Sun
- report via the Foundry system/one care with batch numbers.

#### The relevant SOP is

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

### Fridge manuals and advice:

- For fridges supplied by the national team, PDF manuals can be provided by contacting Unipart Customer Service Desk <u>CS@nhsvaccinesupport.com</u> 0800 678 1650 | 0700-1900 Mon- Sun
- Unipart Helpdesk can also provide fridge technical support phone numbers if sites request.

For fridges/freezers arriving damaged on delivery please follow the advice on this link <u>Latest Info - COVID-19 Vaccination Programme - FutureNHS Collaboration</u> Platform

### AED Servicing:

All AEDs provided by the National Vaccination Programme are guaranteed for 5 years, there is no requirement for sites to have these devices serviced on an annual basis.

### AL40 Cool boxes - with digital temperature display on the top of the unit:

We have had some reports of the digital temperature display on AL40 cool boxes failing. Any sites experiencing this issue, should use an independent data logger unit instead to monitor the temperature of the interior of the cool box. The loss of the digital display does not impact the functionality of the cool box and it can continue to be used with the addition of a data logger. New data loggers can be ordered from the Unipart Customer Service Helpdesk

### 10. Operational: C19 Vaccination Record Cards

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

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

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

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

### 11. Learning: Key Learning re cold chain incidents

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

Key points to consider include:

- ensure daily monitoring occurs on all days vaccine is held in the fridge
- check that your data logger has an SD card, or equivalent functionality, and be prepared to download data when you report a cold chain incident
- ensure named individuals are identified each day to be responsible for stock monitoring and cold chain management

- keep clear records and have visible aide memoires as needed to ensure expiry times are not exceeded.
- If you experience a cold chain or any other clinical incident report it promptly to ICARS <a href="mailto:england.swicars@nhs.net">england.swicars@nhs.net</a> and they will support your investigation and any mutual aid required for vaccine supply.

### 12. Learning: Case Study - 4 incidents of vandalism at an LVS site

Please find below a case study of a recent series of security incidents, including key learnings, for reference in handling future security incidents.

This case study and other useful security information for sites is available on FutureNHS here.

### Situation

Local Vaccination Site (LVS) was subject to several acts of vandalism over a four-week period. Despite reporting each incident to the local Police, the acts of vandalism continued. Contacting the Police in person was very difficult as several attempts to report the incidents by telephone resulted in the caller waiting over 45 minutes for a response. Eventually the only means of reporting the crimes was via on-line reporting. This generated a response, after a few days, which stated that as there was no evidence or witnesses to the crimes the Police would not be investigating further.

Shortly after the fourth attack on the LVS a local School Immunisation Team office and a local school was targeted with three bomb hoaxes. This led to an evacuation of the school, Police involvement and local media interest.

The following day a 66-year-old local male was arrested and charged with the 3 bomb hoax offences and the four acts of criminal damage at the Local Vaccination Site.

### **Background**

The small, rural Local Vaccination site had been targeted over a four-week period to escalating levels of vandalism and criminal damage. Initially paint had been used to daub anti-vaccination messages on the marquee outside the LVS which was being used as a rain shelter for patients. These messages were either removed by staff/volunteers or replaced by the marquee company. This incident was reported on-line to Police as well as the local Clinical Commissioning Group (CCG) and the System Vaccination Operation Centre (SVOC).

The second attack again involved the use of paint but also escalated to sharp bladed instruments being used to slash the sides and roof of the marquee resulting in severe damage. Again, this was reported to the Police via the on-line reporting process, the local Clinical Commissioning Group (CCG) and the System

Vaccination Operation Centre (SVOC). The site manager also contacted the local media who visited and produced a news story which was printed nationally and shown on local television. The site manger requested Closed Circuit Television (CCTV) and night security patrols from the CCG. This was approved and provided by the CCG over the following days. COVIC-UKCVS highlighted the incidents to the National Police Coordination Centre to ascertain what the Policing response had been.

Approximately a week after the second attack a third incident occurred which again resulted in severe damage to the marquee. Unfortunately, the CCTV that had been fitted did not cover the area damaged and no offenders were caught on camera. As a result of this 3rd incident a meeting was arranged by the NHS National Vaccinations Operations Centre (NVOC) with the site manager, the local SVOC, local CCG, Regional Vaccination Operation Centre (RVOC) the NHS Vaccination Security Lead and the United Kingdom Covid Vaccination Security Team (UKCVS) resulting in several recommendations, these included:

- Additional funds to be made available for comprehensive CCTV coverage of the premises.
- Additional funding for night-time security patrol to be sourced from the local Acute hospital contractor.
- Car park lighting to be upgraded
- Internal lighting timer switches to be fitted
- UKCVS to approach the National Police Co-ordination Command (NPoCC) to request they approach the local Police for an update on Police actions.

Nine days later a fourth overnight attack on the practice occurred resulting in similar damage as the second and third incidents. This time the CCTV cameras picked up a good image of a male involved in the incident. This incident was reported to the Police who attended site and collected the CCTV image of the offender. The next day a local High School was subject to two bomb hoaxes resulting in the evacuation of the school. At a similar time to the school hoaxes, a local private Schools Immunisation Provider was also subject to a bomb hoax at their local office. Both incidents resulted in major Police involvement and media coverage. The following day a local 66-year-old male was arrested and charged with the 3 bomb hoax offences and the 4 criminal damage offence at the LVS.

#### Conclusion

As a result of close working between the site manager, the local SVOC, RVOC, CCG and Local Resilience Forum (via the CCG) the LVS was provided with the support and resources to enable an upgrade in security measures at the site which ultimately provided evidence which assisted in the arrest and charging of the offender.

The difficulty in getting an adequate response from the Police was addressed by COVIC-UKCVS, who liaised with NPoCC. NPoCC's subsequent approach to the Local Police Forces Senior Management Team led the Force producing a Policing plan which resulted in improved prioritising and communication with the LVS.

### Key learnings

On review of the above case, the following key lesson have been identified, to help improve the response to future security incidents of this nature.

- Sites should continue to raise any and all security incidents, so that patterns
  can be identified and evidenced to support follow up action.
- Close working relationships between sites, local police (as required), and local vaccination teams should be leveraged to identify sites requiring support and advise them what support is available (e.g. additional funding for CCTV, night security, and improved lighting).

### 13. Resource: Escalation form for incidents relating to NBS, Covid Pass and VDRS

Please see attached updated escalation forms and guidance that have been created for incidents affecting individuals relating to:

- National Vaccination Booking Service
- NHS Covid Pass
- VDRS

The escalation form has been developed by the service centre to ensure that all the relevant information is obtained prior to commencing an investigation. It will assist in minimising email traffic between our service desks.

In addition to the escalation form, the incident reporting guidance will aid in completing the form; this will avoid incomplete forms being submitted.

We can confirm that once a form has been completed it should be sent direct to the relevant service centre at <a href="mailto:scas.phers-servicecentre@nhs.net">scas.phers-servicecentre@nhs.net</a>. Any forms received that are incomplete will be returned to the requestor for correction before any action is taken.

However please note that any general queries relating to these services should continue to be escalated via the SVOC/RVOC/NVOC routes.

### 14. Resource: Combined needles and syringes for the COVID19 vaccine administration

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

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

### LVS sites requiring a collection of the El Dawlia ico Med:

Please see attached RVOC 6280 Cascade for action required by LVS sites requiring a collection of the El Dawlia ico Med - Sterile Hypodermic Syringe. 2ml syringe with 21G x 1.5" Safety Needle following medical recall.