# Southwest Regional Covid Vaccination Programme
# Frequently asked Questions – April 2023

| Query raised | Answer |
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| Is pregnancy part of the COVID-19 eligibility criteria for the Spring campaign 2023? | Pregnancy without immunosuppression is **not** an indication for a booster during the spring 2023 campaign. From the 30 June 2023 there will be no primary dose availability until the autumn booster campaign (and only if in an eligible cohort). Anyone considering pregnancy or already pregnant but still completely unvaccinated should be encouraged to come forward for their first and second doses ASAP.<br>Additional update information for midwifes in the clinical bulletin 8th March 2023 (available here). |
| What are the recommended COVID-19 vaccines for children aged 5-11 and 12 years old and over? | 5 to 11s: Comirnaty 10 vaccine (paediatric Pfizer)<br>12 and over: Comirnaty Original/Omicron BA.4-5<br>There should be no fractional dosing. |
| JCVI statement suggests that Pfizer (Comirnaty) Moderna (Spikevax) or Sanofi (VidPrevTyn Beta) are all equally suitable vaccine types for adults aged 75 years and over. However, the Green Book Chapter 14a (page 36) suggests differently and that there is a preferred vaccine type in this group which is Sanofi. Is there a requirement that anyone in the older age group above MUST be offered Sanofi vaccine or is its accepted that they can also receive Comirnaty BA.4-5 (Pfizer) where operational restrictions are in place? | As per the JCVI recommendations and Green Book, individuals in the over 75-year-old cohort (residents aged 65 years and over AND residing in a care home for older adults) suitable vaccine choices are:<br><br>VidPrevtyn Beta (0.5mL mixed dose) **OR** Comirnaty Original/Omicron BA.4-5 (0.3mL dose)<br><br>An individual over 75 years of age can be offered either vaccine. Unless there are clinical considerations as to one vaccine being preferred over another, for example, due to intolerance or allergy. |
| Is the preferred choice vaccine in over 75-year-old immunosuppressed (IS) individuals Comirnaty Original/Omicron BA.4-5? | No. As above, both the JCVI recommended vaccine choices in the over 75-year-old group including individuals that are also in an IS group. |
| Can COVID-19 vaccines be co-administrated with Shingles vaccine? | The Green Book has been updated. Based on recent evidence, and as COVID-19 vaccines are considered inactivated, where individuals in an eligible cohort present having recently received one or more inactivated or another live vaccine, COVID-19 vaccination should still be given. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including pneumococcal polysaccharide vaccine and shingles vaccine in those aged over 65 years, pertussis-containing vaccines, and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in school age children) |

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| Do we still need to delay vaccination for individuals with a history of COVID-19 infection? | As per the Green Book (page 43), there is no need to defer immunisation in individuals after recovery from a recent episode of suspected or confirmed COVID-19 infection. If they are considered clinically well, vaccination may go ahead. |
| A copy of the COVID Vaccination manual form (Version 13.0) sent to sites still contains discrepancies in the clinical questions compared to the clinical bulletin and Green Book.<br>Will the form / point of care system be updated prior to the formal launch of the programme? For example, there is no longer a 7-day interval requirement between shingles vaccination and administration of a COVID-19 vaccine. However, the pre-screening question still include a question related to recent shingles vaccination. | The response from the National team:<br>All the screening questions are kept under active review but must be prepared several months prior to the start of any campaign. The change requests to the specification are then conveyed to the Point of Care suppliers in the form of Application Programming Interfaces (APIs) for Vaccination (NHS Digital information via this link) - to which all providers are requested to make the changes. Most have already made the changes; others will be doing so in the next couple of weeks. |
| **Vaccination in Care Homes** | |
| Elderly care homes with younger but vulnerable residents within them. Is there clinical discretion to vaccinate? Particularly where the individual is aged less than 65? | The JCVI recommendation is for all residents in an older adult care home (CQC registration dependent) irrespective of age. The PGD is supportive of vaccinating residents under 65 years of age in older adult care homes.<br><br>For residents under 65 years of age Comirnaty BA.4/5 bivalent vaccine should be the vaccine of choice. |
| Some patients aged 75 and over are resident in care homes not designated for older adults. Do we treat these individuals as housebound for the purposes of vaccination? The assumption is that the presence of a 75-year-old in a, for example, Learning Disability (LD) homes does not mean every resident of that LD home must be vaccinated. | You cannot vaccinate LD care homes / non older adult care homes (NOACH) based on JCVI recommendations, including those with residents aged between 65 -74. Individuals aged 75 and over, or aged 5 years and over who are immunosuppressed (as defined in the "immunosuppression" rows of table 3 and 4 in the Green Book), in LD care homes should be vaccinated on an individual basis. |
| What about assisted/independent living sites for the elderly where each resident has their own private residence? Should every resident of such facilities be vaccinated? | Individuals aged 75 and over, or aged 5 years and over who are immunosuppressed (as defined in the "immunosuppression" rows of table 3 and 4 in the Green Book), should be vaccinated on an individual basis rather than vaccinating the whole setting. |
| What is the advice for residents in care homes who have recently had COVID-19? | As per the Green Book, as above for individuals with a history of COVID-19 infection. |
| What about vaccinating care homes during a COVID-19 outbreak? | As per page 43 of the Green Book. During care home outbreaks, vaccination of residents with confirmed COVID-19 may go ahead, provided residents are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this policy should help to maximise vaccination coverage without the need for multiple visits. |

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| Withdrawal of Evergreen Offer – 30th June 23 | |
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| If the evergreen offer for healthy 5- to 49-year-olds is to be withdrawn on the 30th of June, what happens to those who have only had a primary dose (for example, on the 5th of May 2023). Does this mean they will have no recourse to a second primary dose after the 30th? | If a healthy 5–49-year-old comes forward for a first dose beyond the beginning of May, there will not be sufficient time in the Spring campaign to complete a primary dose schedule. Unless the individual is part of an eligible cohort in the autumn 2023 campaign, then they will not be eligible for completion of the primary dose schedule as part of the seasonal campaign vaccination offer either. Planning assumptions for autumn will continue based on current risk groups but please note the JCVI recommendations for autumn 2023 may change. |
| If an individual that is under 50 years of age received a 1st primary dose immediately prior to the end of June, will there be an opportunity to complete their primary course during the autumn campaign? | As per previous answer for the healthy 5–49-year-olds. |
| The Green book, ch14a, p44 says:<br>"The advice to suspend the routine 15-minute observation period therefore applies to all currently available COVID-19 vaccines, including the bivalent mRNA products and the both the Novavax **and Sanofi Pasteur vaccines**."<br>Sanofi leaflets talk about a 15 min wait. GB pg 44 talks about suspending this for all vaccines. | Yes, advice is to go with the Green Book. No 15-minute wait unless where otherwise indicated e.g., patient with a history of anaphylaxis, or based on clinical advice. |
| **VidPrevtyn Beta ® (manufactured by Sanofi/GSK) vaccine** | |
| **Vaccine Preparation questions:** | |
| Do we need to get the vials out for a minimum of 15mins before mixing? Then put them back into the fridge. What happens if it is left for 20mins, 30mins etc- i.e., what is the range? | The manufacturer has confirmed that the acclimatisation of the vials to room temperature is to support patient comfort. Please see information below regarding in use storage for the mixed vials. |
| Do we need to protect from light during this 15min wait? | During the in-use period the vial may be exposed to room light. Updated SPS shelf life and storage available through this link. In practice, avoid direct UV exposure whilst mixing and drawing up minimising light as practically as possible. If possible, retain in a container which protects the vial from light. Ensure mixed vials are clearly separated from main bulk stock. Local risk assessments and SOPs should be updated. |
| As part of the vaccine preparation stages in the manufacturer instructions mixing stages, step 4 states withdraw 'the entire contents from the adjuvant vial'- no mention of volume. Can we assume this is, volume is 2.5mls. Will a defined volume be included? | This feedback was given previously but the manufacturer Summary of Product Characteristics (SPmC) will not change.<br><br>*The amount of adjuvant provided in the adjuvant vial may vary between 2.85 mL and 3.25 mL. Nonetheless, the complete volume of adjuvant should always be transferred into the antigen vial. The overfill is required by health authorities to guarantee that 10 doses of 0.5 mL vaccine can be delivered.* |

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| How can you help to prevent leakage of vaccine and reduce amount of air when withdrawing doses for administration? | You need to consider vial pressure equalisation.<br><br>During the addition of the adjuvant emulsion to the antigen, always keep the needle tip in the air space of the vial. Equalise the pressure by adding the adjuvant emulsion in gradual steps and allowing air to vent back into the syringe repeatedly until all of the adjuvant emulsion has been added and there is 2.5mL air in the syringe.<br><br>N.B. If using a syringe with an auto retracting needle depressing the plunger fully will cause the needle to retract prematurely. If the above technique is not used the full 2.5mL may therefore not be added to the vial.<br><br>When withdrawing doses please make sure that the stopper is pierced in a different place when withdrawing each dose. Insert the needle vertically (at a 90° angle), do not twist or rotate the needle once inserted.<br><br>*UKHSA have also produced a simple poster with instructions on the preparation and mixing of VidPrevtyn Beta, available here.* |
| What if there is overage or poor technique results in less volume? | Please report any specific clinical incidents during clinic sessions to the ICARS service for further advice: england.swicars@nhs.net |
| Once the vials have been mixed together- if we can get an 11th or 12th dose out can we use it. If we can't get a 10th dose out- should we be worried there wasn't enough adjuvant in the first vial. | Use 10 doses from the vial (as per the product SPmC).<br><br>Any remaining vaccine after the tenth dose should be disposed of as per local protocols.<br><br>Please report any deviations in the expected ten doses to our ICARS service for further advice: england.swicars@nhs.net |
| **The following questions relate specifically to vaccine storage & handling of the mixed vaccine:** | |
| How long can the vaccine be out of the fridge for?<br><br>If we are vaccinating one individual every 5 mins, is it acceptable to have the vaccine out of the fridge for 50mins to work through a vial, or does it need to go back into the fridge between each dose?<br><br>After the vaccine is mixed what is the expiry of the product at room temperature and if kept in the fridge? | The Green Book was updated shortly after publication to add clarity to this point. It states:<br>*VidPrevtyn Beta® should be stored in a refrigerator at 2°C to 8°C. After mixing the SmPC advises returning the product to the fridge, protecting it from light and then discarding after six hours. MHRA review of quality data have shown that the mixed antigen/adjuvant for VidPrevtyn Beta is stable at 23-27°C for several hours. As any risk of microbial growth would be minimal within a few hours of mixing. UKHSA advises that, in the clinic setting, the 10 doses of VidPrevtyn Beta should be used without returning to the fridge as soon as practicably possible,* ***ideally within one clinic session (2-3 hours).*** *In other settings, such as domiciliary vaccination, the product may be returned to the* |

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| | *fridge or cool box between each vaccination but must be discarded after 6 hours.*<br><br>Go with the Green book and SPS advice, which is practical. **VidPrevtyn Beta in use (once the antigen and adjuvant are mixed together) must be discarded within 6 hours**. The SPS SOP available here supports storage at up to 25℃ (based on the MHRA review of quality data). Further information on the vaccine characteristics is available here and local medicines governance processes should be followed. The 6-hour expiry applies to the mixed vaccine in use (if stored at 2-8℃ or room temperature (up to 25C°)). Once mixed the vaccine should be used as soon as practically possible. |
| Do we need to protect the mixed vaccine from light whilst drawing up each dose? | See section above regarding protection from light during vaccine preparation. |
| Is there any limit around travel time for the vaccine? | The updated *SPS SOP HCV-6 Use of cool boxes to transport Covid 19 vaccines V1.2* [28thMarch] supports considerations for the Spring 2023 vaccines and no longer stipulates tracking journey times. A copy is available here. |
| Can VidPrevtyn Beta be used to vaccinate housebound patients over 75 years of age? | The manufacturer does not specify any restriction on transport of the vaccine. However, the vaccines contain no preservative, and the method of puncture cannot preclude the risk of microbial contamination, so **SPS advises transport of mixed vials is not routine**. Movement of vaccines should be reviewed locally. Additional information on the vaccine characteristics is available here. |
| **Dosing Intervals** | |
| The SPmC for VidPrevtyn Beta (Sanofi) states that there must be a 4-month gap after a previous mRNA vaccine. How does this align if we are to follow the 3-month gap after Autumn 22 booster which it is anticipated the PGD/Protocol will advise, or will we have to use a PSD if we give Sanofi at 3 months? | The PGD support a 3 month interval and off label use required for pragmatic delivery. |
| **Squalene** | |
| Now that it has been decided that we will need to gain informed consent in light of the squalene and fish related elements in Sanofi, is there a wider consideration during Ramadan - i.e., will those fasting need to consider the implications of this? Squalene is present in many other medicines, specifically the adjuvanted flu vaccines in common use amongst this cohort, and there has been no need to seek related informed consent for the flu programme. | One of the COVID 19 vaccines in the Spring campaign (VidPrevtyn Beta, manufactured by Sanofi/GSK) contains squalene, a naturally occurring oil product, derived from sharks. There are no additional 'fish related elements' in the vaccine. Further information on the use of human and animals products in vaccines is available through the attached guide (here).<br>As COVID-19 vaccines are intramuscular, some Muslim scholars believe that they do not invalidate fasts. This is from the British Islamic medical association: https://mcb.org.uk/wp-content/uploads/2023/02/2023-MCB-Ramadan-Health-Factsheet-Template.pdf. Additional |

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| | supporting materials are also available from the UKHSA publications link here.<br>However, we are aware that other Muslim scholars believe fasts may be invalidated by receiving the (Sanofi/GSK) vaccine that contains animal ingredients, due to potential nutritional value of the oil. You may therefore wish to seek further advice from your local Imam or request to receive one of the other vaccines that does not contain shark-derived oil. |
| **Primary Doses** | |
| The Green Book has been updated to recommend that a full booster dose of the bivalent mRNA vaccines can be offered when someone attends for primary vaccination. Sites should therefore use Comirnaty Original/Omicron BA.4-5 vaccine for their primary dose appointments in those aged 12 years and over. This includes the third primary dose for those who were severely immunosuppressed at the time of their first or second dose. For the children's programme (5–11-year-olds) the preferred vaccine for the UK Programme is still the paediatric, Comirnaty 10 micrograms dose concentrate vaccine. | |
| The UKHSA poster does not show a primary course for adults, will this information by updated?<br><br>A copy of the "Which COVID-19 vaccine" poster is now available through this link. | Exclusion of the primary course information from the UKHSA publication is because it isn't yet licensed. Only licensed vaccines are added to the UKHSA guide however, "off label" use is supported by JCVI recommendations and included in the Green Book. |
| **Heterologous Schedules** | |
| Where individuals have received an updated bivalent vaccine off label as part of a primary course, it is recommended to complete the course with a vaccine that is currently licensed for primary doses. This heterologous dosing of primary course will have no effect on any COVID-19 Vaccine Pass. Sites should not refuse to complete or restart a patient's primary course because they have been given a vaccine off-label previously as part of the primary course.<br>Further information available in the UKHSA published Guide for Healthcare Professionals. | |