Gibraltar Health Authority

PATIENT GROUP DIRECTION

Issued under Part 2 of the Medicines (Prescription Only) Regulations, 1987 by the Director of Public Health with the consent of the Minister

for

COVID-19 mRNA Vaccine (Spikevax (XBB.1.5)

LEGAL STATEMENT			
Protocol Issuer	Director of Public Health Gibraltar Health Authority (GHA) St. Bernard's Hospital Gibraltar Contact Telephone: +(350) 20079160		
Date effective	13th October 2023		
Date of expiry	13th October 2025		
Staff characteristics	See below (section 1)		
Professional Authorisation		SIGNATURE	DATE
Lead Doctor	Dr Helen Carter Director of Public Health[1]		
In Consultation with		SIGNATURE	DATE
Lead Pharmacist	Ms Melanie Gordon Chief Pharmacist		
Lead Nurse	Ms Sandra Gracia Director of Nursing		
Legal Authorisation		SIGNATURE	DATE
With the consent of Minister	The Honourable Minister for[2] Health Vasquez MP		
This PGD has been taken for peer review at the Gibraltar Health Authority Immunisation Committee. This PGD has been peer reviewed by the GHA immunisation committee. It has been ratified by the GHA Executive Team.			

[1] A Patient Group Direction issued shall only have effect if it is signed by the Director of Public Health with the consent of the Minister.
[2] See footnote 1.
Authors: Mr I Bramble, enrolled nurse and Dr Helen Carter, Director of Public Health, Ms Melanie Gordon Chief Pharmacist
Date written 12th October 2023

1. Characteristics of staff

Qualifications and professional registration	Registered professional with one of the following bodies: • nurses or midwives currently registered with the Gibraltar Nursing Registration Board (GNRB) • practitioners currently registered with the Gibraltar Medical Registration Board (GMRB) • Anyone deemed by the Director of Public Health to be competent who meets the additional requirements below.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the SPC, and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must have undertaken training appropriate to this PGD as required by local policy and SOPs • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016) and to discuss issues related to vaccination. For further information on consent see Chapter 2 of 'The Green Book'. Further information for consent can be found on the GHA website Public Health webpage under immunisations • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose • must be competent in the intramuscular injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and COVID-19 vaccination programme: Information for healthcare practitioners • must have been signed off as competent using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months) or have used the tool for self-assessment if experienced vaccinator (vaccinated within past 12 months)

Additional requirements (continued)	• should fulfil any additional requirements defined by GHA policy Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the GHA, UKHSA and/or NHS England and NHS Improvement and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	COVID-19 vaccination is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus Gibraltar is guided by the NHS vaccine program, as described in the Green Book (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of Immunisation Against Infectious Disease: the 'Green Book') Gibraltar has revised the schedule of the NHS to meet the local requirements based upon the advice from the Director of Public Health taking into account the local epidemiology and population health needs. Apart from the different cohorts offered the vaccine this program is given in accordance with the NHS national COVID-19 vaccination programme This PGD has been developed in October 2023 to meet the recommendation for a single COVID-19 vaccine booster to eligible cohorts of the population. These are different to the cohorts that the NHS are vaccinating as described in criteria for inclusion. This PGD will cover future COVID-19 booster dose programs confirmed through written instructions by the Director of Public Health for this COVID-19 vaccine type until the expiry date of the PGD. A single booster dose will be given to those who have had 1 or more previous COVID-19 containing vaccines. A second dose will be given, at least 3 months apart, to those who are eligible who have not received any previous COVID-19 containing vaccines.

Criteria for inclusion	COVID-19 vaccination should be offered to individuals aged 18 years and over in accordance with the recommendations in Chapter 14a. **Individuals who have not already received a dose during the current seasonal campaign,** who are**:** • aged 50 years and over • aged 18 to 50 years old with a long term health condition as guided by the criteria contained in Table 3 of Chapter 14a. • aged 18 years or older who has significant close contact with someone who has a long term health condition • health and social care workers • pregnant individuals • individuals over 18 years old living in long stay residential setting such as ERS and prison If an individual has not received a COVID-19 containing vaccine previously and they are in one of the eligible cohorts listed above they should have a second dose of the vaccine at least 3 months after the first dose. Different vaccine types may be utilised for a second dose depending upon stock availability. Other groups may be included into the recommended cohort(s) for vaccination, if the Director of Public Health issues a written instruction during an emergency and a surge vaccine response is required.

Criteria for exclusion[3]	Individuals for whom valid consent, or a 'best-interests' decision in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, has not been obtained (for further information on consent see Chapter 2 of the Green Book) and the GHA website. Several UKHSA resources are available to inform consent (see Written information to be given to individual or carer section). Individuals who: • are under 18 years of age • do not meet any of the criteria for inclusion, irrespective of prior vaccination status or previous vaccine eligibility • have received a dose of COVID-19 vaccine in the last 3 months • are suffering from an acute febrile illness: the presence of a minor infection is not a contraindication for vaccination See special cautions section for individuals with a past history of because the following indications may not be an absolute criteria for exclusion: • known to be severely allergic to the vaccine or to any component or residue[4] from the manufacturing process in the vaccine

[4] Refer to the product SPC for a full list of excipients.

	• have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of an allergic reaction (see off-label use section below and Chapter 14a). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post-vaccination information and exiting the premises • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutesafter vaccination. Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5. Special precautions, such as those outlined in Chapter 14a (flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine) are advised for individuals with a personal history of allergy including a: • prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to have a polyethylene glycol (PEG) component (such as depot steroid injections, laxative) • history of idiopathic anaphylaxis Individuals with undiagnosed PEG allergy often have a history of immediate-onset unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Such individuals should not be vaccinated with Comirnaty® or Spikevax® mRNA vaccines except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously (for further information see Chapter 14a). It may therefore be considered as an alternative, depending upon stock availability, for individuals aged 18 years and over where an mRNA COVID-19 is not considered to be clinically suitable, including in severely immunosuppressed individuals. Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in Chapter 14a in relation to the administration of subsequent doses.

Cautions including any relevant action to be taken (continued)	Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals. No specific management is required for individuals with a family history of allergies. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. The individual or carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barré Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk-benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, where GBS occurred within 6 weeks of an Astra Zeneca vaccine, mRNA COVID-19 vaccines are preferred for subsequent doses. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in individuals with a history of ITP receiving any COVID-19 vaccine and

	recommends a platelet count check 2 to 5 days after the vaccine is given (British Society for Haematology-COVID-19). **Past history of COVID-19 infection** There are no safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected, asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, though those with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. As clinical deterioration can occur up to 2 weeks after infection, vaccination should be deferred until clinical recovery. During care home outbreaks, vaccination of residents with confirmed COVID-19 can proceed, provided that individuals are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this approach facilitates vaccination without the need for multiple visits. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.
Action to be taken if the patient is excluded **Action to be taken if the patient is excluded** (continued)	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient-specific basis, under a PSD. The reason for exclusion must be documented in the patient notes. Considerations for individuals who are to be excluded: • Individuals who have had an immediate-onset anaphylaxis to a previous dose of COVID-19 vaccine, or any component of the vaccine, advice should be sought from an allergy specialist. Refer to the full list of excipients in the relevant SPC (see References section). Any subsequent dose should be provided by an appropriate prescriber or on a patient-specific basis, under a PSD. • Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are

	being investigated, subsequent doses should be deferred pending further investigation. Following investigation, any subsequent dose should be provided by an appropriate prescriber or on a patient-specific basis, under a PSD. • Individuals who have never received a dose of COVID-19 vaccine and do not meet inclusion criteria in this PGD, or who were previously eligible for a booster during previous campaigns but not the present one, should be reassured that the evidence does not currently support a need to vaccinate them. If new evidence means that they are considered to be at high risk during a future campaign, they will then be invited for vaccination. • Individuals who have had a COVID-19 vaccine in the preceding 3 months • In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged.

Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of 'The Green Book' and the GHA website on the Public Health Immunisation webpage. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.
Arrangements for referral for medical advice	As per local GHA policy

3. Description of treatment

Name, strength & formulation of drug	Spikevax® XBB.1.5 (0.1mg/ml dispersion for injection). One dose (0.5ml) contains: 50 micrograms of andusomeran (embedded in SM-102 lipid nanoparticles)
Legal category	Prescription Only Medicine (POM)
Black triangle	Yes. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this produces
Off-label use **Off-label use** (continued)	**Allergy** According to the respective SPCs, it is recommended that all recipients of vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the previous Omicron COVID-19 variant, the UK Chief Medical Officers (CMO) recommended suspension of this 15 minute requirement. This temporary suspension, in individuals without a history of allergy, has also been agreed by the Commission on Human Medicines. However, vaccinated individuals should be informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Individuals with a personal history of allergy, should be managed in line with Chapter 14a Table 5. No specific management is required for individuals with a family history of allergies. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card Scheme is strongly encouraged. **All Yellow Card reports must be also sent to the Director of Public Health and if a suspected severe reaction requiring hospitalisation then the Director of Public Health must be contacted immediately through GHA hospital switchboard.**

Storage	Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by NHS operational guidance or standard operating procedure. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Route / method of administration	The details SPC is contained in the appendix to this PGD Verify the vial bears the correct name. Each vial contains 5 doses of 0.5ml Thawed vials and filled syringes may be handled in room light conditions. After removing the flip-off cap, using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. **Do not shake or dilute** – the vial should be gently swirled after thawing and before each administration. Prior to injection, inspect each dose to confirm the vaccine is white to off-white in colour in both vial and syringe. The vaccine may contain white or translucent product-related particles. Withdraw 0.5ml of Spikevax XBB.1.5. using a 1mL syringe with integrated 23g or finer x 25mm needle. The dose should be used immediately. Once the vial is punctured, the vial should be discarded after 6 hours. During the in-use period, when doses are being withdrawn from the vial and administered, the vial may remain at room temperature (up to 25°C). This may include the time it takes to move short distances between patients e.g. in a care home, or the time between patients in a clinic.

	Record the date and time the vial is to be discarded onto the vial label. An additional overfill is included in each vial to ensure 5 doses of 0.5ml can be delivered. Any remaining should be discarded in line with local procedures. Where possible, the stopper should be pierced at a different site each time, to minimise the chances of dislodging a fragment of the bung.

Dose and frequency of administration	Vaccination should be offered as a single dose to eligible cohorts who have previously received at least one dose of a COVID-19 containing vaccine. For individuals who have never received a COVID-19 containing vaccine and are in an eligible cohort for the booster program they should be offered a second dose after 3 months depending upon vaccine supply being available. A different make of vaccine can be offered as a second dose depending upon supply availability.
Duration of treatment	See Dose and frequency of administration above
Quantity to be supplied / administered	One dose 0.5ml given intramuscularly
Supplies	GHA clinics should order/receive COVID-19 vaccines from the SBH Pharmacy dept. The Pharmacy dept will source the vaccine via the national appointed supply route for the GHA. To ensure continuity in supply, the MHRA has agreed for these batches to be supplied to market via a Batch Specific Variation and therefore they are approved to be used as licensed product. The leaflet supplied with the batches is approved, therefore please ensure that this Spikevax® XBB 1.5 Patient Information Leaflet (PIL) is provided to vaccine recipients. Copies of the PIL and SPC are also available by scanning the QR code on the carton or on the Gov.UK website.

Storage

Spikevax XBB.1.5 (0.1mg/ml) are stored frozen between -50ºC to -15ºC.

Thawed vaccines to be stored at 2-8°C and should not be re-frozen.
Store in original packaging to protect from light if not in use.

Manufacturer storage details relate to storage requirements and available stability data at thetime of product authorisation. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The SPC also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.

In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.

Spikevax® XBB.1.5 (0.1mg/ml)	Up to 12 hours at 2°C to 8°C (within the 30 day* post-thaw expiry)	30 days* at 2°C to 8°C	Up to 6 hours at 2°C to 25°C	Up to 24 hours at 8°C to 25°C

Where Spikevax® XBB.1.5 (0.1mg/ml) has been stored at -50°C to -15°C for between 9 to 12 months, the unopened vial must be used within a maximum of 14 days and not exceeding a total storage time of 12 months, provided once thawed, the vial is protected from light and stored at 2°C to 8°C throughout.

Specific directions pertinent to each vaccine are outlined below

Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection

Thawed vial
Thawed unopened vials must be stored at 2°C to 8°C for no more than 30 days. Vials kept in a frozen state for between 9 and 12 months will be given a 14 day thaw expiry, which will be indicated on the outer packaging.

Within this period, up to 12 hours may be used for transportation. The 30 (or 14) day shelf life should not exceed the manufacturer printed expiry date (EXP) on the outer carton.

Prior to use, the unopened vial can be stored for up to 24 hours at 8°C to 25°C

Once thawed at 2°C to 8°C, vials must not be refrozen.

Punctured vial
After initial puncture, the shelf life of the punctured vial is 6 hours at 8°C to 25°C, within a 24 hour expiry if stored unopened between 8°C to 25°C and not exceeding the 30 day or 14 day (thawed) shelf life. From a microbiological point of view, the product should be used as soon as practicably possible. In-use storage times and conditions are the responsibility of the user.

Disposal	Follow local clinical waste policy and GHA/NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local GHA arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. A further re-enforcing dose may be required if the patient is severely immune-supressed at the time of vaccination. These patients should be identified by the clinical team responsible for their care and the requirement for an additional dose of vaccine discussed with the Director of Public Health. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. A seven-day interval should ideally be observed between COVID-19 vaccination and shingles vaccination. This is based on a pre-cautionary approach for the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine.
Identification & management of adverse reactions	The most frequently reported adverse reactions are injection-site pain, swelling or redness, fatigue, headache, myalgia, chills,arthralgia, pyrexia, nausea, diarrhoea and vomiting. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Uncommon side effects include enlarged lymph nodes, feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak, decreased appetite, excessive sweating and night sweats. Very rare cases of myocarditis and pericarditis have been observed following vaccination with Spikevax®. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should be

	instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as acute and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals shouldconsult guidance and/or specialists to diagnose and treat this condition. Heavy menstrual bleeding has been reported after COVID-19 vaccination. In most cases, this is temporary and self-limiting. Individuals should be provided with the advice within the leaflet What to expect after your COVID-19 vaccination which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. A detailed list of adverse reactions is available in the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product. **All Yellow Card reports must be also sent to the Director of Public Health and if a suspected severe reaction requiring hospitalisation of a patient then the Director of Public Health must be contacted immediately through GHA hospital switchboard.** Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.
Written information to be given to patient or carer	Ensure the individual should be offered appropriate written information such as the: • Patient information leaflet for Spikevax XBB.1.5 (0.1mg/ml) • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding • COVID-19 vaccination: a guide to booster vaccination • Waiting after COVID-19 vaccination Further information is available on the GHA website-Public Health-immunisations webpage

Patient advice / follow up treatment	There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label use section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see leaflets What to expect after your COVID-19 vaccination and Waiting after COVID-19 vaccination) Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Inform the individual/carer of possible side effects and their management. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine.
Special considerations / additional information	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. **Pregnancy** There is no known risk associated with being given a non-live vaccine during pregnancy (see Chapter 14a). In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended for COVID-19 vaccination. Because of wider experience with mRNA vaccines, these are the preferred vaccines to offer

	to pregnant women. Evidence for use of VidPrevtyn Beta® in pregnancy is presently limited and therefore should only be considered where the potential benefit is thought to outweigh the potential risk to the mother and fetus **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19. **Previous incomplete vaccination** Vaccination can be resumed provided a minimum interval of 3 months has been observed and the individual continues to be eligible for the current seasonal campaign. There is no need to administer extra doses to compensate for previously missed booster doses, even if the individual was previously eligible. **Co-administration with other vaccines** Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, 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 an individual presents requiring 2 or more vaccines. It is generally better for vaccination to proceed to prevent any further delay in protection and avoid the risk of the individual 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 influenza, and pneumococcal polysaccharide vaccines in those aged over 65 years and pertussis-containing and influenza vaccines in pregnancy. A pre-cautionary approach continues with not co-administering with shingles vaccine as per previous advice section for drug interactions. **Individuals vaccinated abroad** Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice may be found in COVID-19 vaccination programme: information for healthcare practitioners. **Immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement

Special considerations / additional information (continued)	corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. **Individuals with severe immunosuppression** The need for additional doses for individuals who have severe immunosuppression (as defined by Box 1: Criteria for additional doses of COVID-19 vaccine in those aged 12 years and above, Chapter 14a) should be at the discretion of the individual's specialist and discussed with the Director of Public Health. A minimum 3 month interval between doses is recommended. However, for individuals about to receive planned treatment, a minimum interval of 3 weeks between COVID-19 doses may be followed, to enable the vaccine to be given whilst the individual's immune system is better able to respond. Ideally, vaccination should take place 2 weeks before immunosuppressive treatment commences, or until 2 weeks after the period of immunosuppression, in addition to time needed for clearance of the therapeutic agent. If not possible, consideration could be given to vaccination during a treatment holiday or when the degree of immunosuppression is at a minimum. Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment. More information on optimal timing of doses for this group may be found in Chapter 14a. Such individuals should receive a dose under a PSD. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations, including COVID-19 (see Chapter 7 of the Green Book). This is not covered by this PGD and should be provided on a PSD

Records	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD All records should be clear, legible and contemporaneous. As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.

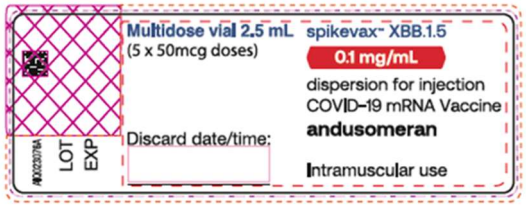
Key references	**Information Specific to this Medicine** • Summary of Product Characteristics, Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection, last updated 18 September 2023 • COVID-19 vaccination programme. Updated 3 March 2022. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Published 4 October 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme https://www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Updated 16 March 2021 https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners *4 (publishing.service.gov.uk) • Patient Information Leaflet (PIL) **General** • Lasting Powers of Attorney and Capacity Act 2018 and the Mental Health Act 2016 https://www.gibraltarlaws.gov.gi • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.

Key references	https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made • UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

1.1. Preparation of Spikevax (XBB.1.5) vaccine for Administration

1. Purpose

This SOP describes the process for preparation of ready to administer syringes of Spikevax XBB.1.5 (0.1mg/mL) dispersion for injection COVID-19mRNA Vaccine andusomeran (**Spikevax (XBB.1.5))** prior to immediate administration.
Different strengths / formulations of Spikevax vaccine are available. Ensure the correct procedure is selected for the strength / formulation required. This SOP is for use with Spikevax Bivalent (original/omicron) with the label formats:



2. Scope

This procedure covers the process from the removal of vials of thawed vaccine from the outer carton in the refrigerator, or removal of individual vials from a cool box, up until the point of administration. This includes assigning an expiry date and time after the first dose withdrawal and the preparation of syringes for administration.

This procedure may be adapted to suit either of the following models:

- One person to both draw up individual doses into syringes and administer the vaccine.
- One person to draw up individual doses into syringes and pass the syringe to a vaccinator. This model requires additional local risk assessment, and the introduction of local controls to reduce the risk of needle stick injuries on transfer between individuals

3. Responsibility

Staff performing any stage of the preparation of the vaccine are responsible for following this procedure.
The responsible Pharmacist must ensure that appropriate and formal authorisation for vaccine administration is in place such as a Patient Group Direction (PGD), National Protocol, Patient Specific Direction (PSD) or other appropriate legal mechanism. In addition, the responsible Pharmacist must ensure that the staff groups who are undertaking the processes are those defined as eligible to do so.

4. Procedure

4.1. Prepare the workstation for use:

- ensure the preparation workstation is clear and free from any other vials of vaccine.
- ensure a yellow lidded sharps bin with sufficient free capacity and an indelible pen are available
- clean workstation with a disinfectant wipe and discard into a clinical waste bin.

4.2. *[Insert statement on local practice for wearing of aprons and other PPE / sanitising hands / donning gloves for preparing injectable medicines]*

4.3. When ready to begin preparation select one vial of **Spikevax (XBB.1.5)** vaccine.

4.3.1. If working with vials stored in a refrigerator:

- If there is more than one batch of vaccine vials, use the one with the shortest expiry
- Check the post thaw expiry on the carton has not been exceeded.
- Remove a single vial and close the carton.

N.B It is permissible to remove multiple vials from the refrigerator if local systems are in place to ensure segregation of punctured and unpunctured vials.

4.3.2. If working with vials from a cool box at 2-8°C:

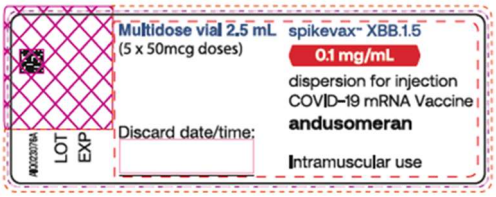
- Check the vial is within the post-thaw expiry date by checking the label on the vial transport container. Refer to SOP HCV 6: Use of cool boxes to transport Covid-19 vaccines to end user locations
- Remove a single vial and close the lid of the cool box.

4.3.3. Assemble the following materials required to prepare syringes:

- **Spikevax (XBB.1.5)** vial X 1
- 1mL syringe with integrated 23g (or finer) x 25mm needle X 5
- Sterile single use 70% alcohol swab x 5

4.3.4.

Check the identity of the vial. This procedure is intended for use with the **Spikevax (XBB.1.5)** vaccine. Check label on the vial selected matches the image below:

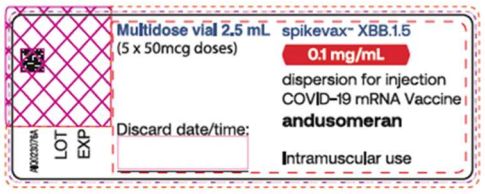


4.3.5. Swirl the vial by gently rotating in a circular motion several times. Do not shake.

4.3.6. Remove the dust cover

4.4. Prepare the syringe(s)

4.4.1. Check the label again to ensure the label on the vial selected matches the image below:



4.4.2. Inspect the vial visually for foreign particulate matter and/or discoloration prior to administration. If foreign particulate matter or discolouration are present, the vaccine should not be administered.

N.B. **Spikevax (XBB.1.5)** is a white to off-white dispersion. It may contain white or translucent product-related particulates

4.4.3. Cleanse the vial stopper with a single use 70% alcohol swab, and discard swab in a clinical waste bin.

4.4.4. Using aseptic technique, draw up **0.5mL** of the vaccine using a new 1mL syringe with integrated 23g or finer x 25mm needle.

N.B.

- A 21g or finer x 38mm needle and 1mL syringe should be used for administering the vaccine to morbidly obese patients.
- If using a syringe with an auto retracting needle depressing the plunger will cause the needle to retract prematurely.

4.4.5. Adjust to remove air bubbles with the needle still in the vial to avoid loss of vaccine.

4.4.6. Check volume withdrawn is **0.5mL. [May require independent 2nd]**

4.4.7. Visually inspect the syringes for foreign particulate matter and leaks. Discard if these are observed.

4.4.8. The newly filled syringe must be used for immediate administration. **[Local risk assessment may be required to manage risk of needle stick injury when handling unsheathed needles]**

4.4.9. Document the expiry date and time on the vial. This is 6 hours after first puncture (use 24-hour format, e.g. 14:00).
N.B. from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible.

4.4.10. Repeat steps 4.4.1 to 4.4.8 a further four times to produce a total of five syringes from each vial. Each time the vial bung is punctured, this should be in a different location to previous points of puncture on the bung.

If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

4.4.11. Once empty, or no longer needed, immediately discard the used vaccine vial into a yellow lidded sharps bin.

N.B. Vials should not be stored between sessions:

- During the in-use period, when doses are being withdrawn from the vial and administered, the vial may remain at room temperature (up to 25°C). This may include the time it takes to move short distances between patients e.g. in a care home, or the time between patients in a clinic.
- The punctured vaccine vial is physio-chemically stable for 6 hours. However, from a microbiological point of view, the method of puncture does not preclude the risk of microbial contamination, so the vaccine should be used as soon as practically possible.

4.5. Dispose of outer cartons by defacing using permanent black marker pens, and placing in the general waste stream. Note: the packaging can be flattened easily. For mass vaccination centres packaging must be stored in a secure container(s) and shredded on-site.

5. References

Spikevax (XBB.1.5) 0.1 mg/mL dispersion for injection

6. Supporting documents

SOP HCV 6: Use of cool boxes to transport Covid-19 vaccines to end user locations.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the **GHA** for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.