Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys, Brecon, Powys, LD3 0LU

This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB intranet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

Spikevax® Bivalent Original/Omicron dispersion for injection in multi-dose vial (0.10mg/mL)

COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles)

by registered healthcare professionals for

Groups recommended COVID-19 vaccination according to Joint Committee on Vaccination and Immunisation advice

in the area covered by Powys Teaching Health Board

Version number: **PGD 0192B**

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change history

Version number	Change details	Date
PGD 0192	New Spikevax Bivalent COVID-19 vaccine (for booster use only) v1	01/09/2022
PGD 0192A	Updated to reflect guidance received from Chief Pharmaceutical Officer – Ref AE/COVID/BV (16/09/2022) confirming that in some circumstances it is acceptable to withdraw and utilise a sixth dose from a five dose vial.	21/09/2022
PGD 0192B	V1.1 30/09/2022 Updated **Inclusion Criteria** to include people who were previously eligible for a booster who have not had one, except where the offer has explicitly expired (e.g. spring boosters etc). Update **Medicine Details** section to reflect Chief Pharmaceutical Officer letter re. additional dose from vials Updated **Adverse reactions** section to reference specific guidance for immune thrombocytopenia (ITP) in line with UKHSA PGD and Green Book To align with UKHSA, updated **criteria** and **action if excluded sections** to specifically exclude individuals who: • have had full dose within previous 3 months, • have not had full primary COVID-19 vaccine course • have previously experienced episodes of capillary leak syndrome (CLS)	07/10/2022

PGD development

This template is based on the original draft PGD kindly provided by the UK Health Security Agency (UKHSA), and has been reviewed to meet requirements for Wales by Public Health Wales and Welsh Medicines Information Centre. Our thanks to UKHSA for sharing their resource.

Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise this PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

PGD authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	10/17/2022
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	10/10/2022
Senior representative of professional group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: claire roche FC9C4C63FC374A7...	10/11/2022
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	10/19/2022

PGD adoption by the provider

Name	Job title and organisation	Signature	Date

Local enquiries regarding the use of this PGD may be directed to Medicines Management Team, Bronllys, 01874 712641.

Appendix A provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Characteristics of Staff

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	**Practitioners must only work under this PGD where they are competent to do so.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can use them): • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council. Practitioners must also fulfil the Additional requirements, have undertaken the initial training as detailed and be assessed as competent before undertaking administration of Spikevax® Bivalent COVID-19 Vaccine.
Additional requirements	Practitioners must: • be employed by, or providing services on behalf of, Powys Teaching Health Board. • be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SmPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have access to the Patient Group Direction and associated online resources and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs)

Initial Training	• Completed training appropriate to this PGD training as required by local policy and in line with the COVID-19 vaccination training requirements by workforce group • Must have undertaken appropriate training for working under PGDs for supply/administration of medicines. • Recognises the adverse drug reactions associated with Spikevax® Bivalent COVID-19 Vaccine.
• **Competency Assessment**	Individual/s operating under the PGD must be assessed as competent: • in the use of PGDs • to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent, and discuss issues related to immunisation • to undertake immunisation and to discuss issues related to immunisation • in the handling and storage of vaccines, and management of the "cold chain" • in procedures for the use of aseptic technique for drawing up the correct dose • in the administration of intramuscular injection technique • in the recognition and management of anaphylaxis
• **Ongoing Training and competency**	• Annual attendance at appropriate courses to update immunisation and resuscitation skills and the management of anaphylaxis within the community. This should be documented in the healthcare professional's CPD records/ESR record • Aware of any updates made to the products in the Summary of Product Characteristics (SmPC), BNF and Immunisation Against Infectious Disease (the 'Green Book') • Aware of any updates to relevant national and local guidelines • All registered professionals are professionally accountable and must work within their competence. A record of training and competence must be maintained in the individual's personal file

Clinical Condition

Clinical condition or situation to which this PGD applies	Spikevax® Bivalent Original/Omicron COVID-19 Vaccine is indicated as a booster dose for active immunisation to prevent COVID-19 caused by the SARS-CoV-2 virus in individuals 18 years of age and older who have received a primary series and/or a booster with an mRNA vaccine and/or adenoviral vector vaccine, in accordance with official guidance of the national COVID-19 immunisation programme, recommendations given in Chapter 14a of Immunisation Against Infectious Disease (the 'Green Book'), and subsequent official correspondence/publications. **Note**: this PGD covers services providing the national COVID-19 immunisation programme.
Inclusion Criteria	Spikevax® Bivalent Original/Omicron COVID-19 mRNA vaccine should be offered to individuals (aged 18 years and over) in **those groups eligible for a booster dose** as part of the national COVID-19 vaccination programme[1], in accordance with recommendations from the JCVI and Chapter 14a of Immunisation Against Infectious Disease (the 'Green Book') and subsequent guidance/correspondence from Welsh Government[2] [3] Further advice on risk groups, including definitions, are set out in Chapter 14a of Immunisation Against Infectious Disease (Green Book)
Exclusion Criteria	Individuals for whom no valid consent has been received (for further information on consent see Green book chapter on Consent) or a 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained. The Patient Information Leaflet (PIL) for Spikevax® Bivalent Original/Omicron should be available to inform consent. Individuals who:

[1] includes those previously eligible for a booster who have not had one, except where the offer has explicitly expired (e.g. spring boosters etc.)

[2] Welsh Government guidance

[3] Winter respiratory vaccination strategy : Autumn/Winter 2022 to 2023 [HTML] | GOV.WALES

	• are less than 18 years of age
	• have had a previous systemic allergic reaction[4]
	• (including immediate-onset anaphylaxis) to:
	  ○ a previous dose of Spikevax® Bivalent Original/Omicron or
	  ○ any component (excipient) of Spikevax® Bivalent Original/Omicron[5]
	  ○ another mRNA vaccine
	• have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination
	• have previously experienced episodes of capillary leak syndrome (CLS)
	• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).
	• not received the full primary COVID-19 vaccine course
	• have had a full dose of COVID-19 vaccine in the preceding 3 months (see 'Action to be taken if the patient is excluded' section)
	
	See 'Green Book' chapter 14a for latest information/updates
	
	Where there is doubt, rather than withholding vaccination, seek appropriate advice or refer, see below.

Cautions (including any relevant action to be taken)	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 not drive for 15 minutes after vaccination. Special precautions are advised for individuals with a personal history of allergy including a:

[4] There is now evidence that many individuals with initial apparent allergic reaction to an mRNA vaccine can tolerate a second dose of the same vaccine. See Green Book flowchart for further information.

[5] Excipients include polyethylene glycol (PEG), refer to the SPC for a full list of excipients.

- 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 contain PEG (such as depot steroid injection, laxative)
- history of idiopathic anaphylaxis

(also see Green book chapter 14a table 5: 'Management of patients with history of allergy)

Table 5: Management of patients with a history of allergy

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• 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 PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis	• prior anaphylaxis reaction to COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine (for known PEG allergy see text above)
ACTIONS	• proceed with vaccination in any setting • some individuals may be reassured by being observed for 15 minutes (may not be required if previously tolerated the same vaccine) • some patients (e.g. those with mastocytosis) may benefit from pretreatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a person has previously tolerated a dose of the same vaccine, it is safe to administer in any setting. Otherwise - consider giving vaccine and observe for 30 minutes	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to AstraZeneca or Novavax vaccines give alternative vaccine in any setting • consider observation for 30 minutes

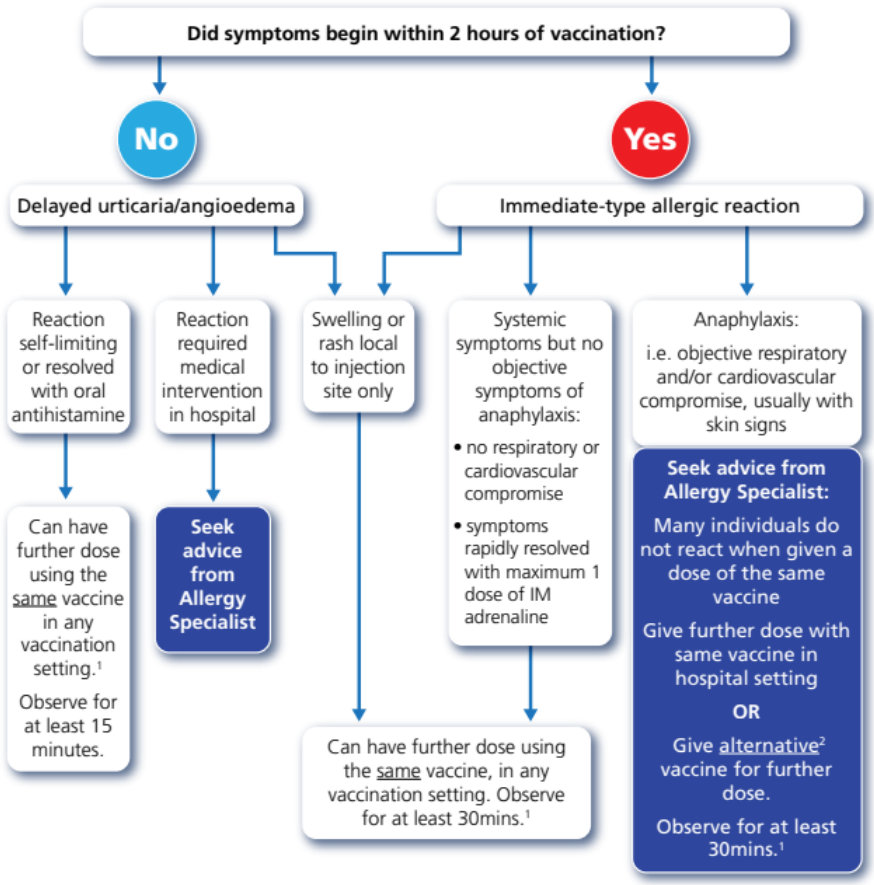
Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal or written post vaccination information and exiting the centre. Facilities for management of anaphylaxis should be available at all vaccination sites (see Green Book chapter 8).

According to the Summary of Product Characteristics (SPC), it is recommended that all recipients of the

	Spikevax® Bivalent Original/Omicron COVID-19 vaccine are kept for observation and monitored for a minimum of 15 minutes. The 15-minute observation period following vaccination with the mRNA COVID-19 vaccines has been removed[6] for individuals aged 12 years and over who have no history of a severe allergic reaction (as outlined in the Green Book advice.) This follows careful review of the safety data by the MHRA and advice from the government's independent Commission on Human Medicines. The observation time however will remain in place for a small proportion of individuals potentially at increased risk of anaphylaxis, such as those with a history of anaphylaxis as per the Green Book advice. Green Book Chapter 14a flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine.

[6] Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine - GOV.UK (www.gov.uk)

Flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine



1 Consider pre-treatment with non-sedating antihistamine, at least 30mins prior to vaccination.

2 If reaction was to AstraZeneca vaccination, complete or boost with an mRNA vaccine. If reaction was to an mRNA vaccine, give the same or alternative mRNA vaccine in hospital setting.

Spikevax® Bivalent Original/Omicron has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned in the SmPC Information may temporarily affect the ability to drive or use machines.

Individuals who have participated in a clinical trial of COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters (or further doses[7]) should be offered vaccination, at least three months after the dose considered as the final primary

[7] Wales DCMO letter re. COVID programme update – available here

	dose or the final revaccination (if the latter is required for certification purposes). 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 on completing vaccination in these individuals is available from UKHSA (formerly PHE): COVID-19 vaccination received overseas. There is no convincing evidence of any 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 but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, although individuals with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. Vaccination should ideally be deferred in those where it is strongly believed or known that the individual had a recent COVID-19 infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, vaccination of adults should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen for that episode in those who are asymptomatic (while symptomatic testing still available), whichever was earlier. This four week interval may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). JCVI currently consider[8] that in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration,

[8] COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk)

	deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. The UK regulator will maintain real-time surveillance after authorisation of COVID-19 vaccines in the UK. In response to any safety signals, MHRA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the UK. Supply under this PGD must be in accordance with any such amendments.
Action to be taken if patient is excluded	• In case of postponement due to acute illness, or COVID-19 related, advise when the individual can be vaccinated and ensure another appointment is arranged • For individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine, or any component of the vaccine, advice should be sought from an allergy specialist. • 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, the current advice is that an individual's second or 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. • For individuals with capillary leak syndrome, after specialist advice any doses should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. • Individuals who have not completed their primary course should complete the recommended schedule before receiving the booster. • Where the individuals have had a full dose of COVID-19 vaccine in the preceding 3 months, advise the individual should return at or after 3 month period has passed since their last full vaccine dose. • Seek appropriate advice from a clinical supervisor

	in a vaccination centre or community clinic, the local Health Protection Team, Immunisation Coordinator or the individual's clinician where appropriate. • The risk to the individual of not being immunised must be considered. • Document the reason for exclusion and any action taken in the individual's clinical records in the Welsh Immunisation System (WIS). • In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.
Action to be taken if patient 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. • Advise the individuals/parent/carer about protective effects of the vaccine and the risks of infection and disease complications • Document advice given and decision reached in the Welsh Immunisation System (WIS) • Follow local policy for deferred consent • In a GP practice setting, inform or refer to the GP as appropriate
Arrangements for referral for medical advice	• Refer to GP, immunisation co-ordinator or Consultant in Communicable Disease Control (CCDC) or other healthcare professional for clinical advice as appropriate, rather than withhold immunisation and document any advice received on the Welsh Immunisation System. Local Medicines Information and Advice Services also set up to support. • If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor or appropriate prescriber should be consulted.

Details of the Medicine

Name, form and strength of medicine	Spikevax® Bivalent Original/Omicron 0.10mg/mL dispersion for injection COVID-19 mRNA Vaccine.

	This is a 2.5mL multi-dose vial, which contains minimum 5 doses[9] of 0.5 ml.
	Note: MHRA has agreed[10] a batch specific variation for Spikevax® Original/Omicron 0.10mg/mL dispersion for injection COVID-19 mRNA Vaccine, which is a 5.0mL multi-dose vial containing minimum 10 doses[11] of 0.5mL.
	The vaccine is a white to off white dispersion (pH: 7.0 – 8.0). **One dose** (0.5 mL) contains 25 micrograms of elasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles) and 25 micrograms of imelasomeran, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles). Elasomeran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using cell-free in vitro transcription from the corresponding DNA templates, encoding the viral Spike (S) protein of SARS-CoV-2. Imelasomeran is a single-stranded mRNA, 5'-capped, encoding a full-length, codon-optimised pre-fusion stabilised conformation variant (K983P and V984P) of the SARS-CoV-2 spike (S) glycoprotein (Omicron variant, B.1.1.529). Vial packs may be labelled: Spikevax® Bivalent Original/Omicron 0.10mg/mL dispersion for injection elasomeran/imelasomeran
Legal category	Spikevax® Bivalent Original/Omicron is a Prescription Only Medicine (POM) As with any new medicine in the UK, this product will be closely monitored to allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

[9] Chief Pharmaceutical Officer letter re. potential additional dose from vials, available here
[10] Moderna Direct Healthcare Professional Communication (available via link)
[11] Chief Pharmaceutical Officer letter re. potential additional dose from vials, available here

	As these vaccines are labelled with a black triangle, all adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Yellow Card Scheme.
Indicate any off-label use	The 15-minute observation period following vaccination with Spikevax® Bivalent Original/Omicron Vaccine (or Comirnaty® Bivalent Original/Omicron BA.1) has been removed[12] for individuals aged 12 years and over who have no history of a severe allergic reaction (as outlined in the Greenbook advice.) Also see **Cautions section**. 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. 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.
Preparation (see also storage section)	**See SmPC for detailed product characteristics** Each multi-dose vial is a 2.5 mL dispersion contained within type 1 (or type 1 equivalent glass) with a stopper (chlorobutyl rubber) and a blue flip-off plastic cap with seal (aluminium seal). **Unopened multi-dose vials:** • have a shelf life of 9 months at -50ºC to -15ºC. • may be stored refrigerated at 2°C to 8°C, protected from light, for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation. • The unopened vial may be stored at 8 ºC to 25ºC for up to 24 hours after removal from refrigerated conditions **For punctured multi-dose vials**: • Chemical and physical in-use stability has been demonstrated for 6 hours at 2ºC to 25ºC after

[12] Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine - GOV.UK (www.gov.uk)

	initial puncture (within the allowed use period of 30 days at 2ºC to 8ºC and 24 hours at 8 ºC to 25ºC). **Spikevax Bivalent vials are multi-dose;** • The vaccine should be prepared and administered by a trained healthcare professional using aseptic techniques to ensure sterility of the dispersion. • The vaccine comes ready to use once thawed. • Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal. • Pierce the stopper preferably at a different site each time. • Withdraw each dose of vaccine from the vial using a new sterile needle and syringe for each injection. **The dose in the syringe should be used immediately**. • An additional overfill is included in each vial and where low dead space needles and syringes are used, it may be possible to withdraw a total of 6 doses from a single vial. Do not pool excess vaccine from multiple vials. • Thawed vials and filled syringes can be handled in room light conditions.
Route / Method of Administration	**Administer by:** • Intramuscular injection, preferably into deltoid region of the upper arm. • Individuals who have minimal muscle mass in the deltoid area of the upper arm, or a particular reason to avoid immunisation in the deltoid muscle, can be given their vaccine in the vastus lateralis muscle in the thigh if necessary • Do NOT inject the vaccine intravascularly, subcutaneously or intradermally. **Administration:** • Inspect visually prior to administration and ensure appearance is consistent with the description in the product literature and respective vaccine dose. • A separate needle and syringe should be used for each individual. • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with 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/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/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 is below the upper level of the therapeutic range, can receive intramuscular vaccination. A 25mm needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes (ACIP 2019). The individual/parent/carer should be informed about the risk of haematoma from the injection. • The site at which each vaccine was given should be noted in the individual's records. • The vaccine SmPC provides further guidance/infographic on administration.
Dose and frequency	Spikevax® Bivalent Original/Omicron dispersion for injection is indicated as a booster dose for active immunisation. JCVI is recommending that the booster vaccines (reinforcing doses) will now be given to all adults (aged 18 and over) no sooner than three months after the primary course. **Booster dose** For individuals 18 years of age and older, a booster dose of Spikevax bivalent Original / Omicron (0.5 mL, containing 50 micrograms mRNA) should be given intramuscularly to adults at least 3 months after completion of a primary series or booster with a COVID-19 mRNA vaccine or adenoviral vector vaccine.
Supplies	• The Welsh Government and NHS Wales has procured a central supply of Spikevax® Bivalent Original/Omicron Vaccine in response to the COVID-19 pandemic and will issue guidance on how this can be accessed. • Vaccines for use for the national immunisation programme are provided free of charge.

	• Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's Regulatory approval (SPC), and "Vaccine Incident guidance: responding to vaccine errors" and UKHSA's COVID-19 vaccination: Information for healthcare practitioners. • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Storage and transportation section below).
Storage and transportation	• Store in original packaging to protect from light. • For storage conditions after thawing and first opening, see section **Preparation section** above. • 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. Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage (see All Wales Advisory document on Ordering Storage and Handling of Vaccines and Green Book Chapter 3). Refer to local Medicines Information Service for advice. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to Immunisation co-ordinator, and via Datix reporting system • Refer to "Vaccine Incident guidance: responding to vaccine errors" and UKHSA's COVID-19 vaccination: Information for healthcare practitioners. • Distribution and transportation procedures must be strictly adhered to. Any cold chain failures must be documented and reported to the Health Board and Immunisation Co-ordinator
Disposal	• Any unused product or waste material should be disposed of in accordance with local requirements • Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local

	authority regulations and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste
Drug Interactions	• No interaction studies have been performed. Concomitant administration of Spikevax (original) or Spikevax bivalent Original / Omicron with other vaccines has not been studied. • 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 inactivated 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 side effects more difficult • Green Book chapter notes a UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. In contrast, a study of co-administration of Novavax COVID-19 vaccine with inactivated influenza, did show some attenuation of the antibody response to COVID-19. Although the clinical significance of this is unclear, administration of Novavax COVID-19 vaccine should be separated from administration of influenza vaccine by at least 7 days. • With the exception of this, as COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine), where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most 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 in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). In addition to influenza and Novavax vaccine, the other current exception is the shingles vaccines, where a seven day interval should ideally be observed. This is based on 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. • A UK study of co-administration of Vaxzevria® (Astra Zeneca) and Comirnaty® (BioNTech) COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. • Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.
Identification and management of adverse reactions	The most frequently reported adverse reactions were injection site pain (92%), fatigue (70%), headache (65%), myalgia (62%), arthralgia (46%) chills (46%), nausea/vomiting (23%), axillary swelling/tenderness (19.8%), fever (15.5%), injection site swelling (14.7%) and redness (10%). Adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of reactogenicity events was associated with greater age. Overall, there was a higher incidence of some adverse reactions in younger age groups: the incidence of axillary swelling/tenderness, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting and fever was higher in adults aged 18 to < 65 years than in those aged 65 years and above. Local and systemic adverse reactions were more frequently reported after the second dose than after the first

	dose. If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol-containing products) may be used. Spikevax bivalent Original / Omicron had a reactogenicity profile similar to that of Spikevax (original) given as a second booster dose. A detailed list of adverse reactions is available in the vaccine's SmPC. There is an increased risk for myocarditis and pericarditis following vaccination with Spikevax (original) or Spikevax bivalent Original / Omicron. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second dose, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. If an individual develops myocarditis or pericarditis following the first COVID-19 vaccination they 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, the current advice is that an individual's second or subsequent doses should be deferred pending further investigation and careful consideration of the risks and benefits. For those that experience myocarditis or pericarditis within two weeks of the first dose of an mRNA vaccine, testing for N antibody may indicate prior exposure to COVID-19. These individuals are likely to be well protected and therefore the benefit from a second dose is likely to be more limited. Where N antibody is negative or in other circumstances where a further dose is considered necessary, for example in those higher risk of the complications of COVID-19 infection, a second or booster dose of Pfizer vaccine can be considered once the patient has fully recovered. Emerging evidence suggests that an interval of at least 12 weeks should be observed from the previous dose and Comirnaty® (Pfizer) is preferred over Spikevax® (Moderna) due to a slightly higher rate

	of myocarditis reported after the latter vaccine; Vaxzevria® (AstraZeneca) should not be offered to those who have previously received an mRNA vaccine given the more serious nature of thrombosis and thrombocytopaenia syndrome. Similar considerations apply to individuals who experience myocarditis after the second dose, where boosting with Pfizer may be considered for those at higher risk of the complications of COVID-19 infection. Also see information and guidance from UKHSA: • Information for healthcare professionals on myocarditis and pericarditis following COVID-19 vaccination . • Myocarditis and pericarditis after COVID-19 vaccination: guidance for healthcare professionals Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should also be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. A very small number of cases of Guillain-Barre Syndrome (GBS) have been reported after Moderna's Spikevax® vaccination but these reports have not reached the number expected to occur by chance in the immunised population. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca Vaxzevria® vaccine, for any future doses Comirnaty® or Spikevax® COVID-19 vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. Extremely rare reports of capillary leak syndrome (CLS) have been reported after Moderna vaccines in individuals with a prior history of this condition. Individuals with a history of capillary leak syndrome, should be carefully counselled about the risks and benefits of vaccination and advice from a specialist should be sought. Healthcare professionals should be aware of signs and symptoms of CLS to promptly recognise and treat the condition. In individuals with a medical history of CLS, planning of vaccination

	should be made in collaboration with appropriate medical experts. Bell's palsy was reported by three participants in the vaccine group and one participant in the placebo group. As is the case for the Pfizer vaccine, this will be monitored closely. There were no cases of severe COVID-19 disease in the vaccine group, and thus no signal for enhanced disease. Previous immune thrombocytopenia (ITP) is not a contra-indication for vaccination but platelet monitoring is advised for individuals with a history of ITP who receive AstraZeneca (Vaxzevria®) vaccine. Although evidence suggests a raised risk of ITP after the AstraZeneca vaccine, ITP has also been reported with other COVID-19 vaccines. Guidance produced by the UK ITP Forum Working Party therefore 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 2-5 days after the vaccine (British Society for Haematology-COVID-19). Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected. Feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be given if necessary to relieve any of these symptoms. The most commonly reported COVID-19 symptoms are: a high temperature, a new, continuous cough, or a loss or change to sense of smell or taste. The COVID-19 vaccine will not interfere with testing for COVID-19 infection. As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111. Individuals should be provided with the advice within the leaflet What to expect after your COVID-19 vaccination.

Reporting procedure for adverse reactions	• As a new vaccine product, MHRA have a specific interest in the reporting of adverse drug reactions for this product, see https://coronavirus-yellowcard.mhra.gov.uk/
	• Healthcare professionals should report any suspected adverse reactions via the Coronavirus Yellow Card reporting site https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store and include the vaccine brand and batch/Lot number if available
	• Guidance on the yellow card system is available at the back of the BNF or via the App
	• The Green Book Chapter 14a and Chapter 8 provide further details regarding reporting reactions. Allergic reactions that do not include the clinical features of anaphylactoid or anaphylactic reactions should be reported as 'allergic reaction'.
	• If an immediate adverse event occurs during the post-immunisation observation period, document in the individual's record in WIS.
	• Explain patients can self report any suspected adverse reactions directly to the MHRA.
	• In the event of an unexpected adverse drug reaction:
	  • if necessary seek appropriate emergency advice and assistance
	  • document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber
	  • complete incident procedure if adverse reaction is severe (refer to local organisational policy)

Written and verbal information to be given to the patient or carer	• Full explanation of risks and benefits to the patient / parent / guardian in order to obtain informed consent • Offer Patient information (PIL) supplied with the vaccine pack • Inform individual / carer of possible side effects and their management such as in the leaflet 'What to expect after your vaccination'.

	• Provide patient with vaccine record card completed with vaccine name, batch number and date given and post immunisation advice. • The individual / carer should be advised to seek medical advice in the event of an adverse reaction. • Written or verbal advice on allergic reactions including what actions to take if they become unwell should be given to patients. • Immunisation may not result in protection in all individuals. Government recommended COVID-19 measures should still be followed. • When administration is postponed advise the individual/carer when to return for vaccination. • Advise when subsequent doses are due if appropriate.
Follow- up advice to be given to the patient or carer	Vaccinated individuals should be informed about 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. Patients with a personal history of allergy should be managed as in **Cautions section** (Green Book table 5). No specific management is required for patients with a family history of allergies. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should not drive for 15 minutes after vaccination. The 15-minute observation period following vaccination with the mRNA COVID-19 vaccines has been removed[13] for individuals aged 12 years and over who have no history of a severe allergic reaction (as outlined in the Greenbook advice.) Also see **Cautions section**. Written or verbal advice on allergic reactions including what actions to take if they become unwell should be given to patients. Immunisation may not result in protection in all individuals. Government recommended COVID-19 measures should still be followed.

[13] Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine - GOV.UK (www.gov.uk)

Special considerations /additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. **Pregnancy**. There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy. Since inactivated vaccines cannot replicate, they cannot cause infection in either the mother or the fetus. As with most pharmaceutical products, specific clinical trials of COVID-19 vaccine in pregnancy have not been carried out. Observational data have not shown an increase in adverse pregnancy outcomes. Spikevax bivalent Original / Omicron can be used during pregnancy. JCVI has advised that pregnant women are more at risk of severe COVID-19 disease, and are reminding pregnant women to have their COVID-19 vaccines as soon as possible. They should not delay vaccination until after they have given birth. Data published by the UK Health Security Agency (UKHSA) provides further evidence that COVID vaccines are safe for pregnant women. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far. These vaccines are therefore the preferred vaccines to offer to pregnant women. 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. (see Green Book chapter 14a) Surveillance of inadvertent administration in pregnancy is being conducted for the UK by the Health Security Agency (UKHSA) Immunisation Department, to whom such cases should be reported UK Vaccine in

	Pregnancy (VIP) surveillance programme('inadvertent' means these women would not have been aware they were pregnant at the time of vaccination). **Breast-feeding.** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women should be offered any suitable COVID-19 vaccine. Spikevax bivalent Original / Omicron can be used during breastfeeding. **Fertility.** Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. **Immunosuppression.** Individuals with immunosuppression may not make a full immune response to vaccination. Individuals who are about to receive planned immunosuppressive interventions can be offered vaccination ideally two weeks before therapy commences. **Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. Evidence from trials of co-administration suggest that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects at the second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency[14]. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not considered suitable, or if the first product received is unknown or not available, it is reasonable to offer one dose of the locally available product to complete the primary course. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again.

[14] https://www.ema.europa.eu/en/news/ema-ecdc-recommendations-heterologous-vaccination-courses-against-covid-19]

Records to be kept	• patient inclusion or exclusion from PGD • date and time of administration • patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD • that patient consent to treatment was obtained. • details of medicine, such as name (and brand, where applicable), form, strength, dose, frequency, quantity, route and site (if by injection) of administration • batch number and expiry date of vaccine • a statement that administration is by using a PGD including the PGD version number. • name and signature of the health professional administering the medicine • relevant information that was provided to the patient or their carer (including side effects and advice given if excluded or declines) • details of any adverse drug reaction and actions taken • referral arrangements (if any) To facilitate the traceability of the vaccine, the name and the batch number of the administered product should be clearly recorded for each recipient. **Points to note:** Records should be signed and dated (or password-controlled immunisers record on e-records) All records should be clear, legible and contemporaneous. The Welsh Immunisation System (WIS) must be used to capture all COVID-19 vaccination data. As with any new medicine in the UK, this product will be closely monitored to allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Appendices

Appendix A : Key references

- Consent: WHC (2008)010, WHC (2008) 036, WHC (2008) 037, and the 'Green Book' (2021)
- Current edition of BNF and British National Formulary for Children (BNF-C). Available from: https://bnf.nice.org.uk/and https://bnfc.nice.org.uk/
- Immunisation Against Infectious Disease: The 'Green Book' Online version. Available from: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- eMC (electronic Medicines Compendium). Available from: http://www.medicines.org.uk/EMC/about.aspx
- Joint Committee on Vaccination and Immunisation statements for 22/23 booster and new variant vaccines: Joint Committee on Vaccination and Immunisation (JCVI) updated statement on the COVID-19 vaccination programme for autumn 2022 - GOV.UK (www.gov.uk)
- Joint Committee on Vaccination and Immunisation (JCVI) statement on COVID-19 vaccinations in 2022 (21 February 2022); Joint Committee on Vaccination and Immunisation (JCVI) statement on COVID-19 vaccinations in 2022: 21 February 2022 - GOV.UK (www.gov.uk)
- National Minimum Standards and core curriculum for Immunisation Training for Registered Healthcare Practitioners Public Health England, Revised February 2018. Available from: https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- Nursing and Midwifery Council. The Code; Professional standards of practice and behaviour for nurses, midwives and nursing associates (2015). Available at: http://www.nmc.org.uk/standards/code/
- Royal Pharmaceutical Society. Professional Guidance on the Administration of Medicines in Healthcare Settings. Available at: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567
- Resource: UKHSA Vaccination of individuals with uncertain or incomplete immunisation status Available at: https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status
- Resuscitation Council (UK) Resuscitation Council Guidelines (2015) https://www.resus.org.uk/library/2015-resuscitation-guidelines and Emergency treatment of anaphylactic reactions (2008): http://www.resus.org.uk/pages/reaction.pdf
- Resuscitation Council UK. Anaphylaxis guidance for vaccination settings (2020). Available at https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings

- Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine. Available at: Regulatory approval of Spikevax bivalent Original/Omicron booster vaccine - GOV.UK (www.gov.uk)

- Safe management of healthcare waste (WHTM 07-01) 2013. Available from: Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.

- Vaccine Incident guidance: responding to vaccine errors. Available at: https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

  Welsh Government, Coronavirus Guidance: Available at: https://gov.wales/coronavirus

Appendix B: Healthcare Professionals Agreement to Practice

Patient Group Direction for the Administration of:
Spikevax® Bivalent Original/Omicron COVID-19 Vaccine

Patient Group Directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this "Agreement to Practice" you are indicating that you agree to its contents and that you will work within it.

Note to Authorising Managers:
Managers should only authorise staff who have received the required training and have been assessed as competent to work to this PGD. Authorised staff should be provided with a copy of the clinical content of the PGD and a photocopy of this agreement confirming their authorisation. The authorising manager should retain the original signed copy within the practice / clinic / directorate and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

Name and address of Practice / Clinic / Directorate:

I confirm that I have read and understood the content of this PGD and agree to administer this vaccine only in accordance with this PGD.

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