NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Varicella Vaccine (live) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration of Varicella vaccine (live) Version 1 – PHS publication date 1st June 2023		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**

NoS Identifier: NoS/PGD/Varicella/ MGPG1352	**Review Date:** May 2025 **Expiry Date:** May 2025	**Date Approved for NoS:** 18th September 2023

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History for NoS:

NoS PGD that has been adapted and/or superseded	New PGD adapted from Public Health Scotland/Supersedes NoS PGD 1095, Version 1	
Date of change	**Summary of Changes**	**Section heading**
July 2023	Reference to NoS Appendix 1 and 2	Authorisation
July 2023	Wider pre exposure for HC Workers – with specification re age and criteria	Inclusion criteria
July 2023	Statement added about pregnancy should be avoided for one month following the last dose of varicella vaccine	Exclusion criteria
July 2023	Statement added about having received MMR vaccine within the last four weeks	Exclusion criteria
July 2023	SmPC for Varivax states that in those aged 9-12 months the second dose should be a minimum of three months after the first dose added	Is the use out with the SmPC
July 2023	Training requirements for NoS	Continuing education and training
August 2023	Statement added about VZ antibodies and two previous doses of vaccine	Exclusion Criteria
August 2023	Removed statement previously had varicella vaccine	Exclusion Criteria
August 2023	Added unvaccinated HCWs	Indication
September 2023	Added unvaccinated HCWs in pre-exposure and post exposure	Frequency

PHS recent changes

Version	Date	Summary of changes
1.0	1 June 2023	New PGD produced.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Contents Page No

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1).

A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Maggie Watts	Signature		Date Signed	28/08/2023
Pharmacist	Mary McFarlane	Signature		Date Signed	14/09/2023
Nurse	Rhiannon Sharp	Signature		Date Signed	13/09/2023

Approved for use within NoS by:

Nos Group Chair	**Signature**	**Date Signed**
Lesley Coyle		14/09/2023

Authorised and executively signed for use within NHSG by:

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Professor Caroline Hiscox PP: Dr Adam Coldwells, Deputy Chief Executive		18/09/2023

Version 1 effective from 1st of June 2023 review date 31st May 2025

1. Clinical situation

1.1. Indication

Vaccination indicated for non immune children from 9 months of age and adults in accordance with Green Book Chapter 34 and national guidance, **Guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings** for:

- pre-exposure prophylaxis
- post-exposure: in nursery and pre-school settings where chickenpox is co-circulating with Group A Streptococcus (GAS) infection
- and unvaccinated HCWs

1.2. Inclusion criteria

Pre-exposure

- Non immune household contacts of immunocompromised individuals
- All Health Care Workers (HCW) aged 16 years and over who work in primary care or in hospitals and have direct patient contact. Those with a definite history of chickenpox or herpes zoster can be considered protected. Healthcare workers with a negative or uncertain history of chickenpox or herpes zoster should be serologically tested and vaccine offered only to those without VZ antibody. A history of chickenpox is a less reliable predictor of immunity in individuals born and raised overseas and routine testing should be considered and vaccine offered only to those without VZ antibody

Post-exposure

- Evidence suggests that varicella vaccine administered within three days of exposure may be effective in preventing chickenpox (Ferson, 2001). (VARIVAX® is licensed for post-exposure prophylaxis), however regardless of the interval of exposure, vaccination should still be offered to reduce the risk of HCW's transmitting infection to patients in the future.

- Unvaccinated HCW's or those without a clear history of past infection with VZ or with negative VZ antibody should be excluded from work from 7-21 days after first exposure.

A recent survey showed that a history of chickenpox is a less reliable predictor of immunity in individuals born and raised overseas (MacMahon et al., 2004) and routine testing should be considered.

NOTE: Those having direct patient contact include ambulance drivers, cleaners in clinical areas, catering staff, and receptionists as well as medical, nursing, dental and other professional staff whether employed directly or through a sub-contract.

The following cohorts could be considered for vaccination when chickenpox is co-circulating with GAS infections in a nursery or pre-school setting in accordance with national guidance, Guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings:

- non immune children from 9 months of age
- non immune staff working in the nursery or pre-school setting

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- are less than nine months of age
- have a clear history of chickenpox
- have documented VZ antibodies following serological testing or written evidence of having had two doses of varicella containing vaccine
- have active chickenpox infection
- have active untreated tuberculosis

- are immunosuppressed (for full details see Green Book Chapter 34 and Chapter 6)
- have severe humoral or cellular (primary or acquired) or combined immunodeficiency
- have family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient is demonstrated
- present other evidence of lack of cellular immune competence (such as individuals with leukaemias, lymphomas, blood dyscrasias, clinically manifest HIV infection)
- are receiving immunosuppressive therapy including high dose of corticosteroids. Green Book Chapter 34 indicates high dose corticosteroids would include children who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/kg/day for at least one week, or 1mg/kg/day for one month. For adults, an equivalent dose is harder to define but immunosuppression should be considered in those who receive 40mg of prednisolone per day for more than one week
- are receiving salicylate therapy (other than topical treatment for localised conditions) because of the association of Reye's syndrome with salicylates
- have received normal immunoglobulin (HNIG) or Human varicella zoster immunoglobulin (VZIG) or a blood transfusion within the last three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies (see off-label section and Green Book Chapter 34).
- are known to be pregnant. Pregnancy should be avoided for one month following the last dose of varicella vaccine (see Green Book Chapter 34). Women who intend to become pregnant should be advised to delay. For inadvertent vaccination in pregnancy see Green Book Chapter 34.
- have had a confirmed anaphylactic reaction to a previous dose of the vaccine

- have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine. Both vaccines contain neomycin. Varivax® contains gelatine.
- have received MMR vaccine within the last four weeks (varicella and MMR vaccine can be administered on the same day but if these vaccines are not administered on the same day, then a four week minimum interval should be observed between vaccines
- have a history of anaphylactic allergy to latex
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

1.4. Cautions/need for further advice/ circumstances when further advice should be sought from a doctor

The Green Book advises that there are few individuals who cannot receive Varicella vaccine (live). Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

The plunger stopper and tip cap of the syringe may contain latex. For latex allergies other than anaphylactic allergies (such as a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered.

As a precaution if an individual has a history of severe (such as anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. The individual should be referred to a specialist and a PSD should be used. (see Green Book Chapter 6).

Individuals receiving high-dose corticosteroids can receive varicella-containing vaccines after they have stopped corticosteroid therapy for at least 1 month. For individuals who require protection against chickenpox, seek advice from a specialist. A PSD should be used if vaccination is indicated.

Individuals taking oral salicylates or aspirin under medical supervision and require protection, seek advice from a specialist. A PSD should be used if the vaccine is indicated.

Where blood products are given within 14 days of varicella vaccine they may interfere with response to vaccination and re-vaccination should be considered.

Household healthy contacts who get vaccinated against varicella can protect immunocompromised people from being exposed to the disease. If the vaccinated person develops a vaccine-related rash, they should stay away from immunocompromised people who do not have evidence of immunity against varicella until all lesions resolve or no new lesions appear within a period of 24 hours.

Transmission of varicella vaccine virus resulting in varicella infection, including disseminated disease may rarely occur from vaccine recipients (who develop or do not develop a varicella-like rash) to contacts susceptible to varicella. Known susceptible immunosuppressed contacts in the household should:

- be advised to be alert to early signs or symptoms and seek early treatment with antivirals
- avoid contact with post-vaccination rashes on the recipient

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents 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.

1.5. Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

1.6. Action if patient declines

Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Varivax® powder and solvent for suspension for injection in a pre-filled syringe

Varicella (live)

After reconstitution, one dose of 0.5ml contains:

Varicella virus Oka/Merck strain (live, attenuated) ≥1350 PFU (plaque forming units)

or

Varilrix® powder and solvent for solution for injection in a pre-filled syringe

Varicella (live)

After reconstitution, one dose (0.5 ml) contains:

Varicella virus1 Oka strain (live, attenuated) not less than $10^{3.3}$ PFU[2]

2.2. Route of administration

Administer by intramuscular or subcutaneous injection.

Intramuscular is the preferred route for most individuals as this reduces the likelihood of a local reaction, however the vaccine should be administered subcutaneously to individuals with a bleeding disorder (see Green Book Chapter 4).

In infants it is recommended that all doses of vaccine(s) be given in the anterolateral aspect of the thigh, ideally on their own, so that any local reactions can be monitored more accurately. Vaccine may alternatively be administered in the deltoid muscle region of the upper arm in older subjects (from 1 year of age).

The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

0.5ml

2.4. Frequency

Pre-exposure: Non immune household contacts of immunocompromised patients and unvaccinated HCWs

Children 9 months to 12 months should receive two doses of varicella vaccine. The second dose should be given after a minimum interval of three months.

Children from 12 months of age or older and adults should receive two doses of varicella vaccine, four to eight weeks apart (and certainly not less than four weeks apart).

Post-exposure: Non immune children from 9 months and staff working in nurseries and pre-school settings and unvaccinated HCW

Children from 9 months of age and adults with no clear history of chickenpox could be offered 2 doses of varicella vaccine, four to eight weeks apart.

Early administration of the first dose is important in an outbreak setting. Administration of varicella vaccine within 3 days of exposure may be effective in preventing further spread.

Interchangeability

A single dose of Varilrix® may be administered to those who have already received a single dose of another varicella-containing vaccine. Where Varivax® has been given as a single dose, the course can be completed effectively with another varicella-containing vaccine in accordance with the Green Book Chapter 34 (see Off-label section).

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section

2.8. ▼ black triangle medicines

No.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

Yes.

The SmPCs inform that due to the theoretical risk of transmission of the vaccine viral strain from mother to infant, it is not generally recommended for breast-feeding mothers. Vaccination of exposed women with negative history of varicella or known to be seronegative to varicella should be assessed on an individual basis and should seek advice from a specialist. However, studies have shown that the vaccine virus is not transferred to the infant through breast milk and therefore breast-feeding women can be vaccinated if indicated in accordance with the Green Book Chapter 34.

The SmPC for Varivax states that in those aged 9-12 months the second dose should be a minimum of three months after the first dose. This is superseded by recommendations set out in Guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings, when appropriate.

Varivax® vaccine is not interchangeable with another varicella vaccine as per the SmPC. Although there are no data on interchangeability, it is likely that a course can be completed effectively with a different vaccine in accordance with the Green Book Chapter 34. See Dose and frequency.

Concurrent administration of Varivax® and tetravalent, pentavalent or hexavalent (diphtheria, tetanus, and acellular pertussis [DTaP])-based vaccines has not been evaluated. However, Varivax® can be given if rapid protection is required and it is the only product available in accordance with Green Book Chapter 34 and Chapter 11.

Varivax® SmPC states that the vaccination should be deferred for at least five months following blood or plasma transfusions, or administration of normal human immune globulin or varicella zoster immune globulin (VZIG), however, it can be given after three months in accordance with Green Book Chapter 34.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines or National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

Store at between +2°C to +8°C.

Store in original packaging in order to protect from light.

Do not freeze.

NHS Board guidance on Storage and Handling of vaccines should be observed.

Varilrix®: After reconstitution, it is recommended that the vaccine be injected as soon as possible. The reconstituted vaccine may be kept for up to 90 minutes at room temperature (25°C) and up to 8 hours in the refrigerator (2°C to 8°C). If not used within the recommended in-use storage timeframes and conditions, the reconstituted vaccine must be discarded.

Varivax®: Administer the vaccine immediately after reconstitution, to minimise loss of potency. The in-use stability has been demonstrated for 30 minutes between 20ºC and 25ºC. Discard if reconstituted vaccine is not used within 30 minutes.

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.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

Varilrix® SPC states that a history of contact dermatitis to neomycin is not a contraindication.

Varilrix® contains 331 micrograms of phenylalanine per dose. Phenylalanine may be harmful for individuals with phenylketonuria (PKU).

Varilrix® can be concomitantly administered with the following monovalent or combination vaccines:

- measles-mumps-rubella vaccine (MMR)
- diphtheria-tetanus-acellular pertussis vaccine (DTaP)
- reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTap)
- *Haemophilus influenzae* type b vaccine (Hib), inactivated polio vaccine (IPV)
- hepatitis B vaccine (HBV)
- hexavalent vaccine (DTaP-HBV-IPV/Hib)
- hepatitis A vaccine (HAV), meningococcal serogroup B vaccine (Bexsero®)
- meningococcal serogroup C conjugate vaccine (MenC)
- meningococcal serogroups A, C, W and Y conjugate vaccine (MenACWY)

- pneumococcal conjugate vaccine (PCV)

Varivax® can be concomitantly administered with the following vaccines:

- MMR vaccine
- *Haemophilus influenzae* type b conjugate vaccine
- hepatitis B vaccine, diphtheria/tetanus/whole-cell pertussis vaccine
- oral polio virus vaccine.

Doses of inactivated vaccines can also be given at any interval before, after, or at the same time as a live vaccine and vice versa.

If MMR vaccine is not given at the same time as varicella vaccine then a four week minimum interval should be observed between the administration of these vaccines (see Green Book Chapter 11) as the measles vaccine may lead to short-term suppression of the cellular immune response.

When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Limited protection against varicella may be obtained by vaccination up to three days after exposure to chickenpox.

As with any vaccine, a protective immune response may not be elicited in all vaccinated individuals.

As for other varicella vaccines, cases of varicella disease have been shown to occur in persons who have previously received varicella vaccines. These breakthrough cases are usually mild, with a fewer number of lesions and less fever as compared to cases in unvaccinated individuals.

Individuals with lower levels of immunosuppression that do not contraindicate this vaccination may not respond as well as immunocompetent subjects; therefore, some of these individuals may acquire varicella in case of contact, despite appropriate vaccine administration. These individuals should be monitored carefully for signs of varicella.

Pregnancy should be avoided for one month following the last dose of varicella vaccine (see Green Book Chapter 34). Women who intend to become pregnant should be advised to delay. For inadvertent vaccination in pregnancy see Chapter 34.

The presence in the household of a non-immune pregnant household contact is not a contraindication to vaccinating a healthy child or adult in the same household with varicella vaccine. The benefit of reducing the exposure of non-immune pregnant women to varicella by vaccinating healthy contacts outweighs any theoretical risks of transmission of vaccine virus to these women.

People receiving high-dose corticosteroids can receive varicella-containing vaccines after they have stopped corticosteroid therapy for at least one month.

If tuberculin testing (Mantoux test) has to be done it should be carried out before or simultaneously with vaccination since it has been reported that live viral vaccines may cause a temporary depression of tuberculin skin sensitivity. As this effect may last up to a maximum of 6 weeks, tuberculin testing should ideally not be performed within that period after vaccination to avoid false negative results.

Administration of varicella zoster virus antibody-containing blood products, including VZIG or other immune globulin preparations, within one month following a dose of varicella vaccine may reduce the immune response to the vaccine and hence reduce its protective efficacy. Therefore, administration of any of these products should be avoided within one month after a dose of varicella vaccine. Where an individual requires protection against chickenpox, consult an appropriate specialist regarding the individual's immune status and suitability for receiving live varicella vaccine. Administration may be indicated in some cases – a PSD will be required

Vaccination should be deferred for at least three months following blood or plasma transfusions, or administration of normal human immune globulin or varicella zoster immune globulin (VZIG) because of the likelihood of vaccine failure due to passively acquired varicella antibodies.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Very common adverse reactions include fever, pain, redness, tenderness, soreness and swelling. A higher incidence of pain, erythema and injection site swelling after the second dose was observed as compared to the first dose.

Common adverse reactions include rash, maculopapular rash, varicella-like rash (generalised median 5 lesions or injection site median 2 lesions), upper respiratory infection and irritability.

Based on isolated case reports from post-marketing surveillance, the vaccine virus may rarely be transmitted to contacts of vaccinees who develop or do not develop a varicella-like rash.

There are limited data from clinical trials available in individuals at high risk of severe varicella. However, vaccine-associated reactions (mainly papulo-vesicular eruptions and pyrexia) are usually mild. As in healthy subjects, erythema, swelling and pain at the site of injection are mild and transient.

The following serious adverse events temporally associated with the vaccination were reported in individuals 12 months to 12 years of age given Varivax® : diarrhoea, febrile seizure, fever, post-infectious arthritis, vomiting.

Complications of varicella from vaccine strain, including herpes zoster and disseminated disease such as aseptic meningitis and encephalitis, have been reported in immunocompromised or immunocompetent individuals. For full details/information on possible side effects, refer to the marketing authorisation holder’s SmPC.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

In the event of severe adverse reaction individual should be advised to seek medical advice.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme yellowcard.mhra.gov.uk

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Give advice regarding normal reaction to the injection e.g. sore arm is possible.
- Give advice on the management if individual becomes feverish.
- Advise individual when subsequent doses are due when applicable.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Advise that pregnancy should be avoided for one month following the last dose of varicella vaccine (see Green Book Chapter 34). Women who intend to become pregnant should be advised to delay.
- Advise that they may experience a local rash around the site of injection or a more generalised rash in the month after vaccination. Individuals should seek

medical advice should they develop a rash post vaccination and should also avoid any contact with immunocompromised individuals until they have received medical advice. For Healthcare workers advise they should report to their occupational health department for assessment before commencing work.

- If the individual is due for MMR vaccine (the first dose is usually given at age one year and the second dose is given at 3 years 4 months) it can be given at the same as varicella vaccine. However, if both the vaccines are not given simultaneously then MMR will need to be postponed until four weeks after the varicella vaccine.

- Inform individual/parent/carer of possible side effects and their management.

- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: yellowcard.mhra.gov.uk

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS board policy.

Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.

Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.

3.5. Follow up

As above.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM

adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

The following are to be available at sites where the vaccine is to be administered:

- Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit)
- An acceptable level of privacy to respect individual's right to confidentiality and safety
- Basic airway resuscitation equipment (e.g. bag valve mask)
- Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection
- Access to a working telephone
- Another competent adult, who can summon urgent emergency support if required should ideally be present
- Access to medical support (this may be via the telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- A copy of this PGD in print or electronically

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- 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.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.

- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

- Have undertaken NoS PGD module training on TURAS Learn
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken immunisation training where available
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

Note: All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified

these should be discussed with those responsible for authorisation to act under the PGD.

5. Audit trail

Record the following information:

- that valid informed consent was given.
- name of individual, address, date of birth and GP with whom the individual is registered if possible.
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine.
- name and brand of vaccine.
- date of administration.
- dose, form and route of administration of vaccine.
- batch number.
- where possible expiry date.
- anatomical site of vaccination.
- advice given, including advice given if excluded or declines immunisation.
- details of any adverse drug reactions and actions taken.
- administered under PGD.

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- Immunisation against Infectious Disease [Green Book]
- Immunisation against Infectious Disease [Green Book] chapter 34
- Current edition of British National Formulary (BNF) and BNF for children
- Marketing authorisation holder's Summary of Product Characteristics
- All relevant Scottish Government advice including the relevant CMO letter(s)
- Professional Guidance on the Administration of Medicines in Healthcare Settings 2019
- Professional Guidance on the Safe and Secure Handling of Medicines

7. Version history

Version	Date	Summary of changes
1.0	1 June 2023	New PGD produced.

Appendix 1 - Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Varicella Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 1

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2 - Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Varicella Vaccine By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date