UK Health Security Agency

Publications gateway number: GOV-17610

Varicella vaccine (live) Patient Group Direction (PGD)

This PGD is for the administration of varicella vaccine (live) to individuals identified for pre exposure prophylaxis, and where chickenpox is co-circulating with Group A Streptococcus (GAS) infections, for post exposure prophylaxis in non immune children, from 9 months of age and adults in accordance with national guidelines.

This PGD is for use by registered healthcare practitioners identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no:	Varicella vaccine PGD
Version no:	v2.0
Valid from:	5 January 2025
Review date:	5 July 2026
Expiry date:	5 January 2027

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England in line with national recommendations.

Those using this PGD must ensure that it is organisationally authorised and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). **Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

[1] This includes any relevant amendments to legislation.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of the UKHSA PGD templates for authorisation can be found from:

Immunisation patient group direction (PGD) templates

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk

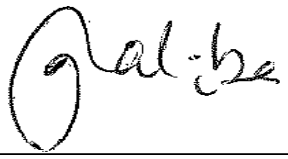
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: your local screening and immunisation team

Change history

Version number	Change details	Date
v1.0	New Varicella vaccine PGD template to support outbreaks where chickenpox is co-circulating with Group A Streptococcus (GAS) / scarlet fever in non immune children from 9 months of age and adults in accordance with national guidelines.	5 January 2023
v2.0	UKHSA Varicella vaccine PGD amended to: • remove the reference to disinfectants from route and method of administration; disinfection of the skin other than with soap and water prior to immunisation is not recommended (as outlined in Chapter 4) • include additional reference to UK guidelines for the management of contacts of invasive group A streptococcus (iGAS) infection in community settings • confirm vaccination is not limited to nursery and preschool settings only, in line with changes to the above guidance • remove contraindication for individuals taking oral salicylates, in line with updated advice in Chapter 34 permitting co-administration with the varicella vaccine • remove advice for a 6 week interval between varicella vaccination and tuberculin testing • remove the exclusion for individuals with a known history of allergy to latex • remove duplication of information common to both Varilrix® and Varivax® • further define exclusions for individuals taking long term moderate or high-dose corticosteroids (in accordance with Annexe 1, guidelines on post exposure prophylaxis (PEP) for varicella or shingles (October 2024)). Vaccination should not be offered until 3 months following course completion • reflect the updated, simplified dosage regime as outlined in Chapter 34. Inclusion of additional age band for individuals aged 13 years and above, with a minimum 6 week interval (previously an interval of 4 to 8 weeks advised for all individuals 12 months and over). Single overarching regime for both pre-exposure and post-exposure indications • change the minimum interval for receiving blood products following vaccination from 14 days to 21 days, in line with recommendations in Chapter 6 • rename the term immune globulin to immunoglobulin • remove reference to VZIG following its discontinuation in the UK (as advised in guidelines on post exposure prophylaxis (PEP) for varicella or shingles (October 2024)) • include advice in cautions section that Varilrix® contains phenylalanine. Assurances that vaccines are still indicated by the PKU medicines advisory body • include contact details of wholesalers for GSK and MSD • include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA vaccination PGD templates • reflect updated guidelines and references	16 December 2024

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist Immunisation Programmes, UKHSA		16 December 2024
Doctor	Dr Vanessa Saliba Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		16 December 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA		16 December 2024

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

Expert Panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Greta Hayward	Consultant Midwife – Immunisation Programmes, UKHSA
Michelle Jones	Principle Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Prof Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Tushar Shah	Lead Pharmacy Adviser, NHSE London

2. 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 the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

NHS England (South East) authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within the NHS England South East Region.
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South East) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
South East Medical Director System improvement and Professional Standard	**Dr Shahed Ahmad**		**18/12/2024**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to your local screening and immunisation team t

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. Characteristics of staff

Qualifications and professional registration	All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with Health and Care Professions Council (HCPC) Check section 2 (Limitations to authorisation) to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for healthcare professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease (the Green Book), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the cold chain • must be competent in the recognition and management of anaphylaxis • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHSE and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for non immune children from 9 months of age and adults in accordance with national guidance, guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings, and UK guidelines for the management of contacts of invasive group A streptococcus (iGAS) infection in community settings and Green Book Chapter 34 for: • pre exposure prophylaxis • post exposure: in nursery and pre-school settings where chickenpox is co-circulating with Group A Streptococcus (GAS) infection
Criteria for inclusion	**Pre-exposure** • non immune household contacts of immunocompromised individuals **Post-exposure** The following cohorts should be offered vaccination when chickenpox is co-circulating with GAS infections in a nursery, pre-school or similar congregated setting in accordance with national guidance, guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings and UK guidelines for the management of contacts of invasive group A streptococcus (iGAS) infection in community settings: • non immune children from 9 months of age • non immune staff working in the relevant setting
Criteria for exclusion[2] (continued over page)	Individuals for whom no valid consent has been received (or for whom a best-interests decision in accordance with the Mental Capacity Act 2005, has not be obtained). For further information on consent, see Chapter 2 of the Green Book. Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are less than 9 months of age • have a clear history of chickenpox • have previously completed a course of 2 doses of varicella vaccine • have active chickenpox infection • have active untreated tuberculosis • are immunosuppressed, for example (for full details, see Chapter 6) - severe humoral or cellular (primary or acquired) or combined immunodeficiency - present other evidence of lack of cellular immune competence (such as individuals with leukaemias, lymphomas, blood dyscrasias, or is an individual living with AIDS or HIV infection) - are receiving immunosuppressive therapy, including high-dose corticosteroids. This includes long-term moderate to high dose corticosteroids for more than 10 days in the last month or long-term moderate dose corticosteroids in the last 3 months (see Annexe 1, immunosuppression definitions, guidelines on post-exposure prophylaxis (PEP) for varicella or shingles • have received normal immunoglobulin (IVIG) in the last 3 months • are pregnant • have had a confirmed anaphylactic reaction to a previous dose of the vaccine

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

Criteria for exclusion (continued)	• have had a confirmed anaphylactic reaction to any constituent or excipient of the vaccine. Both vaccines contain neomycin. Varivax® contains gelatine. See respective SPCs for full excipient lists • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) All healthcare workers (HCWs) for occupational health reasons are excluded from this PGD. If HCWs require vaccination, they need to be vaccinated using a PSD or Written Instruction in accordance with their organisation's policy and procedures.
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). 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. Where blood products are given within 21 days following varicella vaccination, they may interfere with the immune response and revaccination should be considered. If revaccination is deemed appropriate, this PGD does not provide cover for additional doses and a PSD should be used. When a vaccinated individual develops a vaccine-related rash, they should stay away from immunocompromised people who do not have evidence of immunity against varicella, until all lesions have crusted over. Transmission of varicella vaccine virus from vaccine recipients to susceptible close contacts has occasionally been documented, but the risk is low. Lesions should be covered to further reduce the risk of transmission. Transmission in the absence of a post-vaccination rash has not been documented. 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 that have developed on the original recipient Varilrix® contains a source of phenylalanine. Though phenylalanine may be harmful to individuals with phenylketonuria (PKU), the individual, parent or carer will be well versed as to the amounts of phenylalanine tolerable in their diet. The National Society for Phenylketonuria (NSPKU) advise the amount of phenylalanine contained in vaccines is negligible and therefore strongly advise individuals with PKU to take up the offer of immunisation.
Action to be taken if the individual is excluded (continued over page)	Individuals who have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. Individuals who are pregnant should be advised to return for immunisation after pregnancy. For inadvertent vaccination in pregnancy, see Chapter 34. Individuals receiving corticosteroids may be considered for varicella-containing vaccines following course completion, with a recommended interval of 3 months in line with Chapter 6.

Action to be taken if the individual is excluded (continued)	For individuals prescribed other immunosuppressive treatments, see Annexe 1 of guidelines on post exposure prophylaxis (PEP) for varicella or shingles (October 2024), or Chapter 6 for guidance on the advised minimum intervals. In individuals who have received immunoglobulins or a blood transfusion, vaccination should be delayed for at least 3 months because of the likelihood of vaccine failure due to passively acquired varicella antibodies (see off-label use section and Chapter 6). **Immunosuppression and HIV infection** Varicella vaccine is contraindicated in immunosuppressed individuals. For individuals who require protection against chickenpox, seek advice from a specialist. A PSD should be used if vaccination is indicated. Further guidance is provided by the British HIV Association (BHIVA): use of vaccines in HIV-positive adults (2015). Children's HIV Association of UK and Ireland (CHIVA) immunisation guidelines presently advise against immunising household contacts of severely immunosuppressed individuals. In accordance with Chapter 6, vaccination of household contacts (as per criteria for inclusion) is recommended, as it reduces the risk of exposure to chickenpox for all household members. Active untreated tuberculosis is listed as a contraindication to vaccination in the Varivax® but not Varilrix® SPC. It is pragmatic that any individual with active tuberculosis should avoid GP surgeries or other healthcare facilities until anti-tuberculosis treatment has been commenced and the individual is deemed to be non-infectious. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the individual or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications of disease. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	As per local policy

5. Description of treatment

Name, strength and formulation of drug	**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) **Varilrix® powder and solvent for solution for injection in a pre-filled syringe** Varicella (live) After reconstitution, one dose (0.5 mL) contains: Varicella virus Oka strain (live, attenuated) not less than $10^{3.3}$ PFU
Legal category	Prescription only medicine (POM)
Black triangle▼	No
Off-label use	The SPCs inform that due to the theoretical risk of transmission of the vaccine viral strain from mother to infant, the varicella vaccines are not generally recommended for breast-feeding mothers. However, studies have shown that the vaccine virus is not transferred to the infant through breast milk and therefore breastfeeding women can be vaccinated if indicated in accordance with Chapter 34. Though Varivax® is not licensed for administration with any other varicella vaccine brands, in accordance with Chapter 34, different varicella vaccines can be used to complete a course. See dose and frequency of administration. 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 it is the only product available, in accordance with Chapter 11 and Chapter 34. The Varivax® SPC states that the vaccination should be deferred for at least 5 months following blood or plasma transfusions, or administration of normal human immunoglobulin (IVIG). In accordance with Chapter 6 (deferral of vaccination following immunoglobulin treatment), this interval may be reduced to 3 months for either of the varicella vaccines. The SPCs for both vaccines recommend that salicylates are avoided for 6 weeks following varicella vaccination. Individuals may continue with their salicylate treatment before and after varicella vaccination in accordance with Chapter 34. Different dosage regimes and/or age brackets are recommended in the Varivax® and Varilrix® SPCs, when compared to recommendations in Chapter 34. Doses should be given under this PGD in accordance with the appropriate schedule as outlined in the dose and frequency of administration section. The vaccine should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to Vaccine Incident Guidance. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this PGD. (continued over page)

Off-label use (continued)	Where a vaccine is recommended off-label as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but outside of product licence.
Route and method of administration	Varicella vaccines are given as a 0.5ml dose by intramuscular injection or subcutaneous injection. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in the Green Book Chapter 4. In infants, it is recommended that all doses of vaccine(s) be given into the anterolateral aspect of the thigh, ideally on their own, so that any local reactions can be monitored more accurately. The deltoid muscle of the upper arm may be used in individuals over one year of age. Where 2 or more injections need to be administered at the same time, they should be given at separate sites, preferably into a different limb. If more than one injection is to be given into 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. The vaccine should be visually inspected for foreign particulate matter and other variation of expected appearance prior to preparation and administration. Should either occur, do not administer the dose and discard the vaccine in accordance with local procedures. The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe. **Varivax®** Before reconstitution, the vial contains a white to off-white powder and the pre-filled syringe contains a clear, colourless liquid solvent. The reconstituted vaccine is a clear, colourless to pale yellow liquid. **Varilrix®** Before reconstitution, the powder is slightly cream to yellowish or pinkish coloured cake and the solvent is a clear colourless liquid. The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe or ampoule of solvent to the vial containing the powder. The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine.

(continued over page)

Route and method of administration (continued)	The vaccine SPCs provides further guidance on preparation and administration.
Dose and frequency of administration	Single 0.5ml dose per administration. **Infants 9 to 12 months of age**: 2 doses of varicella vaccine, with a minimum interval of 3 months between doses. **Children from 12 months of age to 12 years of age**: 2 doses of varicella vaccine, with a minimum interval of 4 weeks between doses. **Individuals from 13 years of age and over:** 2 doses of varicella vaccine, with the second dose at least 6 weeks after the first dose, but in no circumstances less than 4 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** Both Varilrix® and Varivax® are interchangeable with other varicella-containing vaccines in accordance with Chapter 34 (see off-label use section).
Duration of treatment	See dose and frequency of administration section above.
Quantity to be supplied and administered	Single 0.5ml dose per administration.
Supplies	Vaccines may be procured directly from the manufacturers or their wholesalers: • Varilrix® – manufactured by GlaxoSmithKline. Available from AAH Pharmaceuticals (Tel: 0344 56 8899), www.vaccines.co.uk • Varivax® – manufactured by MSD. Available from Alliance Healthcare (Tel: 0330 100 0448), www.myahportal.co.uk Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage (continued over page)	Store at +2°C to +8°C, in the vaccine's original packaging in order to protect from light. Do not freeze. From a microbiological point of view, vaccines should be used as soon as practicably possibly following reconstitution, to minimise loss of potency. **Varilrix®** 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®** In-use stability has been demonstrated for 30 minutes between 20°C and 25°C. Discard if reconstituted vaccine is not used within 30 minutes.

Storage (continued)	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 on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant sharps box, according to local waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.
Drug interactions	The vaccine must not be mixed with any other vaccine or other medicinal product in the same syringe. Concurrent administration of Varivax® and tetravalent, pentavalent or hexavalent (diphtheria, tetanus, and acellular pertussis [DTaP])-based vaccines has not been evaluated. Varilrix® is preferred but Varivax® can be given if rapid protection is required and it is the only product available (see off-label use section). Administration of blood products that may contain varicella zoster virus antibodies, such as IVIG 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 If MMR vaccine is not given at the same time as varicella vaccine, a 4 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. If these vaccines are administered on the same day, the vaccines should be given at a separate sites, preferably into a different limb. The varicella vaccine may be given at any time before or after any inactivated or any other live vaccine, in accordance with Chapter 11 and Chapter 34. A detailed list of drug interactions associated with the varicella vaccines are available from the product SPCs.

Identification and management of adverse reactions	Common or very common adverse reactions observed in individuals of all ages include fever, pain, injection-site erythema, tenderness, soreness and swelling. A higher incidence of injection-site pain, erythema and swelling has been observed after the second dose compared to the first. Common adverse reactions in individuals aged up to 12 years of age include upper respiratory infection and irritability. Up to 10% of adults and 5% of children develop a vaccine-associated rash, up to a month following immunisation. The rash should be tested to determine whether it is due to the vaccine virus or coincidental wild-type chickenpox (see Chapter 34 for further information). The vaccine virus may rarely be transmitted to contacts of immunocompetent vaccinees. Transmission in the absence of a post-vaccination rash has not been documented. A detailed list of adverse reactions associated with the varicella vaccines is available from the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.
Written information to be given to individual, parent or carer	Offer the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. The following leaflet is available for parents, carers and individuals. • Scarlet fever: symptoms, diagnosis and treatment For further verbal advice, refer to the advice and follow up treatment section below. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC
Advice and follow up treatment	Whilst MMR and varicella vaccines can be given at the same time, scheduled doses of MMR should not be given early. If the vaccines are given separately, allow a 4 week gap. Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. When applicable, advise the individual, parent or carer when the subsequent vaccine dose is due. When administration is postponed, advise the individual, parent or carer when to return for vaccination.

Special considerations and additional information	Varilrix® SPC states that a history of contact dermatitis to neomycin is not a contraindication. 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 tuberculin testing (Mantoux test) is required for an individual vaccinated with varicella vaccines, clinicians interpreting the results of tuberculin skin tests should be made aware of recently administered live injectable vaccines. Apart from live measles-containing vaccines, there is an absence of evidence on interference from other live vaccines with tuberculin testing (WHO). Testing may ideally be deferred for 4 weeks, to avoid the theoretical risk of false negative results. 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. Some of these individuals may acquire varicella following contact, despite appropriate vaccine administration. These individuals should be monitored carefully for signs of varicella. **Pregnancy and women of childbearing age** Pregnancy should be avoided for one month following vaccination (see Chapter 34). Women who intend to become pregnant should be advised to delay conception until then. 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. Refer to monitoring advice in Cautions. For further information, see the product information in the respective SPC.
Records (continued over page)	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken

Records (continued)	• supplied via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting, appropriate health records should be kept and the individual's GP informed. When the vaccine is administered to individuals aged under 19, notify the local Child Health Information Systems team (CHIS) using the appropriate documentation or pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**Varicella vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 6, Chapter 11 and Chapter 34 (last updated 30 September 2024) www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics: Varilrix,® last updated 15 October 2021 https://www.medicines.org.uk/emc/product/1676/smpc • Summary of Product Characteristics: Varivax,® last updated 18 January 2024 www.medicines.org.uk/emc/product/5582/smpc • UK guidelines for the management of contacts of invasive group A streptococcus (iGAS) infection in community settings, last updated 7 March 2023 https://www.gov.uk/government/publications/invasive-group-a-streptococcal-disease-managing-community-contacts • Guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings, last updated 3 April 2023 www.gov.uk/government/publications/scarlet-fever-managing-outbreaks-in-schools-and-nurseries • Scarlet fever: symptoms, diagnosis and treatment, last updated 29 March 2019 Scarlet fever: symptoms, diagnosis and treatment • Guidelines on post exposure prophylaxis (PEP) for varicella or shingles (October 2024) www.gov.uk/government/publications/post-exposure-prophylaxis-for-chickenpox-and-shingles/guidelines-on-post-exposure-prophylaxis-pep-for-varicella-or-shingles-january-2023 • NICE CKS, last updated September 2024 Scarlet fever | Health topics A to Z | CKS | NICE • The National Society for Phenylketonuria (NSPKU) Medical Advisory Panel: Vaccines and PKU, issued 2 October 2024 https://nspku.org/download/vaccines-and-pku/ • Personal communication – GSK Medical Info UK, received 29 November 2024 • Personal communication – MSD Medical Information Department, received 28 November 2024 • The World Health Organisation (WHO) Vaccine safety and false contraindications to vaccination. Training manual (2017). Accessed online at https://iris.who.int/bitstream/handle/10665/350968/WHO-EURO-2017-4683-44446-62833-eng.pdf?sequence=1 **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste. Updated 7 March 2023. www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published 7 February 2018 www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners

(continued over page)

Key references (continued)	• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions, last updated 27 March 2017 www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance, last updated 7 July 2022 www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Varicella vaccine (live) PGD v2.0 Valid from: 5 January 2025 Expiry: 5 January 2027

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it.

PGDs 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 professional code of conduct.

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

Authorising manager

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

Note to authorising manager

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

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.