UK Health Security Agency

Publications gateway number: GOV-13985

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 the administration of varicella vaccine (live) by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference no:	Varicella PGD
Version no:	v1.00
Valid from:	5 January 2023
Review date:	30 June 2024
Expiry date:	5 January 2025

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisations 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'. Only sections 2 and 7 can be amended within the designated editable fields provided.

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.

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:

www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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:

[1] This includes any relevant amendments to legislation.

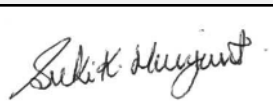
For East Anglia email: England.eaimms@nhs.net
For Essex email: England.essexatimms@nhs.net

For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net

Change History

Version number	Change details	Date
V1.00	New Varicella vaccine PGD template to support outbreaks where chickenpox is co-circulating with scarlet fever in non immune children from 9 months of age and adults in accordance with national guidelines.	5 January 2023

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

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		5 January 2023
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		5 January 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		5 January 2023

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England (NHSE)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE South West
Lesley McFarlane	Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA
Gill Marsh	Principal Screening and Immunisation Manager, NHSE North West
Tushar Shah	Lead Pharmacy Advisor, NHSE London

2. Organisational authorisations

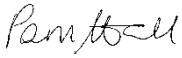
The PGD is not legally valid until it has had the relevant organisational authorisation.

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 East of England 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 East of England commissioned immunisation services or NHS Trust providing immunisation services covering Norfolk, Suffolk, Cambridgeshire, Peterborough, Essex, Southend-on-Sea, Thurrock, Bedfordshire, Hertfordshire, Luton and Milton Keynes local authorities, and Health and Justice facilities where NHS England East of England is the commissioner.
Limitations to authorisation
None

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director	**Dr. Ian Gibson**		**19/01/2023**

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Screening and Immunisation Lead	**Dr. Pam Hall**		**18.01.2023**
Pharmacist	**Dr Paul Duell**		**18.01.2023**
Screening and Immunisation Coordinator	**Rachel Turner**		**10.01.2023**

For East Anglia email: England.eaimms@nhs.net
For Essex email: England.essexatimms@nhs.net
For Bedfordshire, Hertfordshire, Luton and Milton Keynes email: England.immsqa@nhs.net
For the Health Protection Team email: eastofenglandhpt@phe.gov.uk

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	Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists 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) The practitioners above must also fulfil the Additional requirements detailed below. 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 health 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 and/or 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	Vaccination 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 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 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
Criteria for exclusion[2] Continued over page	Individuals for whom no valid consent has been received. Individuals who: • are less than 9 months • have a clear history of chickenpox • have previously had varicella vaccine • have active chickenpox infection • have active untreated tuberculosis • are immunosuppressed (for full details see 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 • 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) within the last three 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. • 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) 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. 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. 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 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.

Action to be taken if the patient is excluded	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. Pregnancy should be avoided for one month following the last dose of varicella vaccine (see 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. In individuals who have received immunoglobulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies (see off-label and Chapter 34). 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. **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 Royal College of Paediatrics and Child Health, the British HIV Association (BHIVA) Immunisation guidelines for HIV-infected adults (BHIVA, 2006) and the Children's HIV Association of UK and Ireland (CHIVA) immunisation guidelines. Individuals who have a history of anaphylactic allergy to latex should not be administered varicella vaccine unless the benefit of vaccination outweighs the risk of an allergic reaction. Refer to an appropriate clinician for assessment of risk: benefit and a PSD will be required. 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. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged.
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Action to be taken if the patient is excluded (continued)	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 patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Advise the individual/parent/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[1] Oka strain (live, attenuated) not less than $10^{3.3}$ PFU[2]
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, 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. Varivax® vaccine is not interchangeable with another varicella vaccine as per the SPC. 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 Chapter 34 and Chapter 11. Varivax® SPC 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 Chapter 34. 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 the Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. 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.
Route and method of administration Continued over page	Varicella vaccine is given as a 0.5ml dose by intramuscular injection or subcutaneous injection.

Route and method of administration (continued)	IM 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 Chapter 4). In infants it is recommended that all doses of vaccine(s) be given in the anterolateral aspect of the left 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). Where two or more injections need to be administered at the same time, they should be given at separate sites, preferably in a different limb. If more than one injection is to be given in the same limb, they should be administered at least 2.5cm apart. The site at which each injection is given should be noted in the individual's records. The vaccine must not be injected intravenously or intradermally and must not be mixed with other vaccines in the same syringe. **Varivax®** The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration (see the SPC). Single dose 0.5 ml per administration. The vaccine is to be injected intramuscularly (IM). The vaccine should be administered subcutaneously (SC) in individuals with a bleeding disorder. 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. Avoid contact with disinfectants. The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation in physical appearance. The vaccine must not be used if any particulate matter is noted or if the appearance is not a clear colourless to pale yellow liquid after reconstitution. Do not freeze the reconstituted vaccine. Once reconstituted withdraw the entire content of the vial into a syringe, change the needle, and inject the vaccine by the subcutaneous or intramuscular route. The vaccine should be administered immediately after reconstitution, to minimise loss of potency. Discard if reconstituted vaccine is not used within 30 minutes. See SPC for full instructions. **Varilrix®** The vaccine must be reconstituted in accordance with the manufacturer's instructions prior to administration (see the SPC). Single dose 0.5 ml per administration. Administer intramuscularly (IM) in the deltoid region or in the anterolateral area of the thigh. Varilrix® should be administered subcutaneously (SC) in individuals with bleeding disorders.
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Route and method of administration (continued)	Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine. Before reconstitution, the powder is slightly cream to yellowish or pinkish coloured cake and the solvent is a clear colourless liquid. The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine. 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. In the event of other variation being observed, do not administer the vaccine. Once reconstituted, withdraw the entire contents of the vial. A new needle should be used to administer the vaccine. 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. See SPC for full instructions. The vaccines' SPCs provide further guidance on administration and is available from the electronic Medicines Compendium website.
Dose and frequency of administration Continued over page	Single 0.5ml dose per administration. **Pre-exposure: Non immune household contacts of immunocompromised patients** 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** 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

Dose and frequency of administration (Continued)	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).
Duration of treatment	See dose section above
Quantity to be supplied and administered	Varilrix® Single dose of 0.5ml per administration Varivax® Single dose of 0.5ml per administration
Supplies	Vaccine can be procured directly from the manufacturers: • Varilrix® – manufactured by GlaxoSmithKline (Tel: 0800 221 441) • Varivax® – manufactured by MSD (Tel: 0800 085 5511) Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Green Book Chapter 3).
Storage	**Varilrix®** • Store and transport refrigerated (2°C to 8°C). • Store in the original package in order to protect from light. • Do not freeze. • Shelf life of unopened vaccine is 2 years. • 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®** • Store and transport refrigerated (2°C to 8°C). • Store in the original package in order to protect from light. • Do not freeze the reconstituted vaccine. • Shelf life of unopened vaccine is 2 years. • Administer the vaccine immediately after reconstitution, to minimise loss of potency. The 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. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
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 authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).

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. Varilix® is preferred but Varivax® can be given if rapid protection is required and it is the only product (see Off-label section). 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. 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. If these vaccines are administered on the same day, the vaccines should be given at a separate sites, preferably in a different limb. 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. For further information see electronic Medicines Compendium website.
Identification and management of adverse reactions	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. A detailed list of adverse reactions is available in the vaccine's SPC, which is available from the electronic Medicines Compendium website

Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and individuals/ parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search 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 clinician should be informed.
Written information to be given to patient or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. The following leaflet is available for parent/carer/individual • Scarlet fever: symptoms, diagnosis and treatment For further verbal advice refer to Patient advice and follow up treatment.
Patient advice and follow up treatment	Pregnancy should be avoided for one month following the last dose of varicella vaccine (see Chapter 34). Women who intend to become pregnant should be advised to delay. 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. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction or if they are concerned that their child is unwell at any time. When applicable, advise the individual/parent/carer when the subsequent vaccine dose is due. When administration is postponed advise the individual/parent/carer when to return for vaccination.
Special considerations and additional information Continued over page	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). Other injectable vaccines or other medicinal products must be given as separate injections and at different body sites. 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)

Special considerations and additional information (continued)	• 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. 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. In individuals who have received immunoglobulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies. For further information see electronic Medicines Compendium website.
Records Continued over page	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or a password-controlled immuniser's record 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.

Records (continued)	The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/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 Vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 6, Chapter 11 and Chapter 34 (last updated 26 June 2019) www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Varilrix® Summary of Product Characteristics 12 March 2009 Varilrix 10 3.3 PFU/0.5ml, powder and solvent for solution for injection - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • Varivax® Summary of Product Characteristics 9 November 2022 VARIVAX - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • Guidelines for the public health management of scarlet fever outbreaks in schools, nurseries and other childcare settings www.gov.uk/government/publications/scarlet-fever-managing-outbreaks-in-schools-and-nurseries • Guidance Scarlet fever: symptoms, diagnosis and treatment Updated 29 March 2019 Scarlet fever: symptoms, diagnosis and treatment • NICE CKS Scarlet fever | Health topics A to Z | CKS | NICE **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

Varicella PGD v1.00 Valid from: 5 January 2023 Expiry: 5 January 2025

Before signing this patient group direction (PGD), check that the document has had the necessary authorisations in section two. 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.