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

Patient Group Direction For The Administration Of Varicella Vaccine (Live Attenuated) By Nurses Working Within NHS Grampian, Orkney, Shetland, Tayside And Western Isles

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/Varicella/ MGPG1095	**Review Date:** May 2022 **Expiry Date:** May 2023	**Date Approved:** May 2020

NHS Grampian, 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:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD Supersedes NHSG/PGD/varicellaHCW/ MGPG916 Version 7, NHST Patient Group Direction for the Administration of Varicella Vaccination to Susceptible Health Care Workers by Occupational Health

Date of change	**Summary of Changes**	**Section heading**
September 2019	New NoS PGD developed for use across all NoS Boards.	
February 2020	Addition of contacts of immunocompromised individuals added as an indication for vaccination.	Throughout
February 2020	Change of title to remove reference to OHS and healthcare workers.	Throughout
May 2020	NHSH removed from PGD at their request.	Throughout

NoS Identifier: NoS/PGD/Varicella/MGPG1095
Keyword(s): PGD Patient Group Direction varicella vaccine, Occupational Health Varilrix® VARIVAX®

Policy Statement: It is the responsibility of the individual nurse and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

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.

Document:	Drafted:	September 2019
	Completed:	February 2020
	Approved:	May 2020 (published – July 2020)
	Amended:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Simon Hilton **Health Board:** NHSG **Title:** Consultant in Public Health Medicine **Contact email:** simon.hilton@nhs.net **Signature** .....
Senior representative of the professional group who will provide care under the direction.	**Name:** Fiona Browning **Health Board:** NHSG **Title:** Health Protection Nurse Specialist **Contact email:** Fiona.browning@nhs.net **Signature** .....
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** f.adamson@nhs.net **Signature** .....
Pharmacist	**Name:** Mary McFarlane **Health Board:** NHSS **Title :** Principal Pharmacist **Contact email:** mary.mcfarlane@nhs.net **Signature** .....

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		June 2020

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Amanda Croft		June 2020

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist NHSG
Mary McFarlane	**Pharmacist:** Principal Pharmacist NHSS
Dr Simon Hilton	**Medical Practitioner:** Consultant in Public Health Medicine NHSG
Fiona Browning	**Senior Representative:** Health Protection Specialist Nurse NHSG
Claire Bonnar	Nurse Manager Occupational Health NHSG
Fiona Browning	Health Protection Nurse Specialist NHSG
Jane Forbes	Vaccine Programme Manager NHST

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise nurses to administer varicella vaccine to non-immune adults and children to protect against varicella zoster (VZ) virus, to prevent cross infection/transmission of VZ virus. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC) and the Green Book Chapter 34.
Inclusion criteria	• Individuals aged one year and older who have not had chickenpox before and are in close contact with an immunocompromised individual. • All Health Care Workers (HCW) aged 16 years and over who work in primary care or in hospitals and have direct patient contact, and fulfil one of the following criteria: **Pre-exposure management** • Those who **do not** have a definite history of either chickenpox or herpes zoster and are subsequently shown to have no VZ antibody by serological testing. (All those with an unknown or doubtful history of previous VZ infection need to have a serological test to confirm their non-immunity). • Those who cannot provide written evidence of having had two previous doses of varicella containing vaccines. **Post-exposure management** • 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. **N.B.** 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. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals: • Aged less than one year old • With current acute systemic or febrile illness • Who have had an anaphylactic reaction to previous dose of the vaccine or to any of its excipients • Who **do have** a definite history of chicken-pox or herpes zoster (apart from those raised oversees- see inclusion criteria) • Have documented VZ antibodies following serological testing or written evidence of having had two doses of varicella containing vaccine • Who are, or maybe pregnant. Before vaccination, pregnancy or the possibility of pregnancy **must** be checked in female recipients and advice must be given to take adequate precautions to prevent pregnancy occurring between the 2 doses and for one month following the last dose of varicella vaccine • Who have severe humoral or cellular (primary or acquired) immunodeficiency • Who have blood dyscrasias, leukaemia, lymphomas of any type, or other malignant neoplasms affecting the hemic and lymphatic systems • Who are receiving immunosuppressive therapy (including high doses of corticosteroids). Refer to an medical practitioner • Who have a family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient is demonstrated • Who have active untreated tuberculosis (VARIVAX® vaccine only)

	• Who have received Mumps, Measles and Rubella (MMR) combined live vaccine in the preceding 30 days. **N.B.** MMR combined vaccine can however be given at a different site at the same time as VZ vaccine • Where there is no valid consent.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. The Green Book states that as the vaccine virus is not transferred in breast milk, breastfeeding women can be vaccinated if indicated. This advice is out with the Summary of Product Characteristics (SmPCs) for VARIVAX® and Varilrix® which state that vaccination should be avoided and is not generally recommended. Discuss with an Occupational Health medical practitioner before vaccination is given under this PGD. Varilrix® (Oka viral strain) vaccine has been shown to be sensitive to aciclovir. Individuals currently taking aciclovir should be discussed with an Occupational Health medical practitioner and deemed suitable before vaccination is given under this PGD. In individuals who have received immunoglobulins or a blood transfusion, vaccination should be delayed for at least three months for Varilrix® and five months for VARIVAX® because of the likelihood of vaccine failure due to passively acquired antibody to the VZ virus. Individuals currently taking salicylates, e.g. aspirin should avoid their use for 6 weeks after vaccination with VARIVAX®. Caution should be used in individuals with generalised septic skin conditions as the rash produced may be more severe. If eczema exists, a site free from skin lesions must be chosen.
Action if excluded from treatment	The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged.

	If the reason for exclusion is 'temporary', e.g. pregnancy or MMR within previous 30 days then reschedule vaccination for when the exclusion period ends. Document the reason for exclusion under the PGD and any action taken in the individuals appropriate clinical records. **HCW's** If there is a permanent reason for exclusion, advise the HCW about the potential risk if exposed to VZ virus and the possible requirement for varicella-zoster immunoglobulin (VZIG) if a significant exposure occurs. With consent advise the manager that the HCW is susceptible to VZ Infection.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material, e.g. the Patient Information Leaflet (PIL) available to print here and here. Document advice given and decision reached. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records. **HCW's** If vaccination is declined this should be documented in a HCW's Occupational Health file. The HCW should be invited to come back to Occupational Health if they subsequently decide that they wish to proceed with vaccination. Where HCW's are non-immune and work with, or may, be employed in areas where immunosuppressed patients are cared for, further advice on continued employment in that area must be obtained from an Occupational Health medical practitioner.

Description of vaccine available under the PGD

Name form and strength of vaccine	Varicella vaccine (live attenuated) VARIVAX® (Oka/Merck strain) and Varilrix® (Oka strain). VARIVAX® is presented as a vial containing white to off-white powder for reconstitution and a pre-filled syringe containing solvent for suspension for injection. When reconstituted provides a 0.5mL dose of vaccine.

	Varilrix® is available as a vial containing clear peach to pinkish powder or cake and solvent for reconstitution. When reconstituted provides a 0.5mL dose of vaccine.
Legal status	VARIVAX® and Varilrix® are Prescription-only Medicines (PoM). **N.B.** The administration of either varicella vaccine to woman who are breastfeeding is outside the terms of the marketing authorisation and constitutes an off-label use of the vaccines. However, the use of the vaccine in this instance is in-line with recommendations in the Green Book Chapter 34. The HCW should be informed prior to the administration that the use is off-label. **N.B**. VARIVAX ®is only licensed for use from the age of 12 months. Varilrix® is licenced for use from the age of 9 months.
Dosage/Maximum total dose	Dosage 0.5mL. Maximum total dosage is 1mL given in two 0.5mL doses. Doses should be given at an interval as per the manufacturer's instructions.
Frequency of dose/Duration of treatment	**Varilrix®** Doses should be given 6 weeks apart and must not be given less than 4 weeks apart. **VARIVAX®** Interval between doses should be 4 - 8 weeks. If the interval between doses exceeds 8 weeks, the second dose should be given as soon as possible. **N.B.** Some individuals may not be protected until after the second dose has been administered.
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section above.
Route/Method of administration	VARIVAX® - Administration should be given by **Intramuscular (IM) Injection** or **Subcutaneous injection** preferably into the deltoid region. Varilrix® - Administration should be given by **Subcutaneous injection** preferably into the deltoid region or in the anterolateral area of the thigh. These vaccines **should not be given** by the intravenous or intradermal routes under any circumstances.

	Varilrix® must be reconstituted by adding the entire contents of the supplied ampoule of water for injections diluent to the vial containing the powder. After the addition of the diluent to the powder, the mixture should be well shaken until the powder is completely dissolved in the diluent. VARIVAX® must be reconstituted using only water for injections provided in the prefilled syringe. Inject the entire content of the pre-filled syringe into the vial containing the powder. Gently agitate to mix thoroughly. Both vaccines must be visually inspected for foreign particles or variation of physical aspect before use and should be used immediately after reconstitution. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to VARIVAX® or Varilrix®. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individuals records. Although there is no available data on interchangeability, it is likely that a course can be completed effectively with a different varicella vaccine.
Quantity to be administered	0.5mL per administration (1mL given in two 0.5mL doses).
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed.
Follow-up (if applicable)	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.

	If attending for the first dose of the varicella vaccine an appointment must be made to attend for the second dose of the vaccine. Where proof of vaccination is required, a certificate, stamped vaccination booklet or equivalent must be supplied.
Advice (Verbal)	Advise the individual what to expect and what to do for minor and major reactions, e.g. injection site reactions, fever, etc. If serious adverse or persistent effects occur, they should be advised to contact their GP/Accident and Emergency department/NHS24. When administration is postponed advise when to return for vaccination. If appropriate, advise when subsequent dose(s) are due. Females **must** be advised against pregnancy between the first and second doses **and** for one month following the second dose of varicella vaccine. Individuals currently taking salicylates, e.g. aspirin should be advised to avoid their use for 6 weeks after vaccination with VARIVAX®. Up to 10% of adults develop a vaccine-associated rash, either localised at site of injection or generalised, within one month of immunisation. Rashes may be papular or vesicular. Should a close contact develop a widespread vaccine related rash they should avoid contact with any immunocompromised family or friends. 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. **N.B.** HCW's should seek advice from Occupational Health should they develop a rash post vaccination. If a localised or widespread vaccine related rash does occur (papular or vesicular) then the HCW **must** avoid contact with: • Varicella susceptible pregnant women • Newborns of mothers without documented and positive history of VZ virus or lab evidence of prior infection

	• Individuals at high risk of severe varicella, including those with immunodeficiency states, including post-transplant patients or those receiving immunosuppressive therapy, including high dose steroids. HCW's who develop a generalised rash after vaccination **must** avoid contact with patients until lesions have crusted. Those who develop a localised rash must cover the lesions with a bandage or clothing and can continue to work unless they are likely to come into contact with the groups described above. Once the rash has crusted over any temporary restriction can be lifted.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	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. The most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site. Additionally, it is common for a rash to develop post vaccination. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNF**: https://about.medicinescomplete.com/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

	Report any severe reactions or reactions to any ▼vaccines using the MHRA using the Yellow Card System https://yellowcard.mhra.gov.uk/.
Facilities and supplies required	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 the individuals right to confidentiality and safety • Resuscitation equipment • 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 the this PGD in print or electronically.

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	Registered Nurses as recognised by the Nursing and Midwifery Council (NMC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individuals capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the handling and storage of vaccines, and management of the “cold chain” • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by each individual Health Board • Have undertaken immunisation training where available • Have attended basic life support training which is required to be updated annually • Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis

	• Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board.

Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Nurses working in NHS Grampian, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the vaccine(s) specified in this PGD by their Professional Line Manager or Occupational Health Consultant. 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.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the vaccine specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of vaccine administration • Individuals name and CHI • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained

	• The name, brand, dose, form, batch number, expiry date, route/site of the vaccination administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Consent forms • Occupational health systems • Individual service specific systems.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk VARIVAX®– Date of revision of text 19/11/18, accessed 01/10/19. Varilrix® - Date of revision of text 18/02/20, accessed 19/05/20. British National Formulary https://about.medicinescomplete.com/ accessed 01/10/19. Department of Health (2006): Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book Department of Health (2006): Immunisation against Infectious Disease [Green Book] Chapter 34 Varicella. https://www.gov.uk/government/publications/varicella-the-green-book-chapter-34 American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

	MacMahon E, Brown LJ, Bexley S et al. (2004) *Identification of potential candidates for varicella vaccination by history: questionnaire and seroprevalence study*. BMJ 329 (7465): 551–2.

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

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 (Live Attenuated) By Nurses Working Within NHS Grampian, Orkney, Shetland, Tayside And Western Isles

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 _____

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

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 (Live Attenuated) By Nurses Working Within NHS Grampian, Orkney, Shetland, Tayside And Western Isles
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**