Patient Group Direction For The Administration Of Varicella Vaccine To Non-Immune Adult Healthcare Workers By Nurses Working Within NHS Grampian Occupational Health

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<tr>
<th>Co-ordinators:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
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<tr>
<td>Deputy Director of Pharmacy and Medicines Management, Pharmacy and Medicines Directorate</td>
<td>See relevant page in the PGD</td>
<td>Medicine Guidelines and Policies Group</td>
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This PGD covers vaccination in adult Healthcare Workers only.

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the Employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 6
Title: Patient Group Direction For The Administration Of Varicella Vaccine To Non-Immune Adult Healthcare Workers By Nurses Working Within NHS Grampian Occupational Health

Identifier: NHSG/PGD/varicellaHCW/MGPG762

Replaces: NHSG/PGD/varicellaHCW/MGPG582, Version 5

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Author: Deputy Director of Pharmacy and Medicines Management
Subject: Patient Group Direction
Key word(s): PGD patient group direction nurse varicella vaccine chickenpox herpes zoster occupational health

Policy application: NHS Grampian

Purpose: This Patient Group Direction (PGD) authorises appropriately qualified and trained nurses in occupational health to administer varicella vaccine to individuals without the requirement for a patient specific prescription written by a medical practitioner.

Responsibilities for implementation:
- Organisational: Chief Executive and Management Teams
- Corporate: Senior Managers
- Departmental: Heads of Service/Clinical Leads
- Area: Line Managers
- Hospital/Interface services: Deputy General Managers and Clinical Leads
- Operational Management Unit: Unit Operational Managers

Policy statement: It is the responsibility of individual nurses in occupational health 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 patient, 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.

Review: This policy will be reviewed at least every two years or sooner if current treatment recommendations change.
This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

Responsible for review of this document: Pharmacy and Medicines Directorate
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<td>Section 2.3</td>
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Patient Group Direction For The Administration Of Varicella Vaccine To Non-Immune Adult Healthcare Workers By Nurses Working Within NHS Grampian Occupational Health

Part A

1. Introduction

This patient group direction (PGD) will authorise nurses in Occupational Health to administer varicella vaccine to non-immune adult (aged over 16 years) healthcare workers.

This PGD should be used in conjunction with the recommendations in the current British National Formulary, The Green Book and individual Summary of Product Characteristics.

2. Clinical Decision Making

2.1. Patients who may be considered for the administration of varicella vaccine

Non-pregnant, non-immune adult healthcare workers who work in primary care or in hospitals who have direct patient contact. Those having direct patient contact include ambulance drivers, cleaners on wards, catering staff, and receptionists as well as medical, nursing, dental and other professional staff whether employed directly or through a sub-contract. Those with a definite history of chickenpox or herpes zoster can be considered protected. Those with a negative or uncertain history of chickenpox or herpes zoster should be serologically tested and vaccine offered only to those without varicella zoster antibody. A history of chickenpox is a less reliable predictor of immunity in individuals born and raised overseas and routine testing should be considered.

2.2. Patients who may receive the administration of varicella vaccine

All patients in 2.1 above who do not want specifically to consult with a doctor and are happy for the administration to be given by the nurse.

2.3. Contraindications

Varicella vaccine should never be administered intravascularly or intradermally.

Patients may be administered varicella vaccine under this PGD unless:

(i) They are 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.

(ii) They have known anaphylactic hypersensitivity to any of the excipients which include neomycin and gelatin.

(iii) They have a history of severe (i.e. anaphylactic) allergy to latex. Vaccination should be deferred until it can be ascertained that the vaccine to be used is latex-free.

For latex allergies other than anaphylactic allergies (e.g. contact allergy to latex) vaccination may proceed as normal.

(iv) They have severe humoral or cellular (primary or acquired) immunodeficiency.

(v) They have blood dyscrasias, leukaemia, lymphomas of any type, or other malignant neoplasms affecting the hemic and lymphatic systems.

(vi) They are receiving immunosuppressive therapy (including high doses of corticosteroids). See Green Book for further information or refer to an Occupational Health doctor.

(vii) They have a family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential vaccine recipient is demonstrated.

(viii) They have active untreated tuberculosis.

2.4. Precautions

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

(ii) An Occupational Health doctor should be consulted if they have had significant local or general allergic reaction to a previous administration of varicella vaccine.

(iii) As with all vaccines, injections of IM adrenaline 1:1000 must be available to treat an anaphylactic reaction should this occur (refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals).

(iv) 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 outwith the Summary of Product Characteristics (SPCs) for Varivax® and Varilrix® which state that vaccination should be avoided and is not generally recommended. Discuss with an Occupational Health doctor.

(v) Following varicella vaccine administration, no immunoglobulin should be given for 1 month thereafter unless its use outweighs the benefits of vaccination.
(vi) In subjects who have received immunoglobulins or blood or plasma transfusions, vaccination should be delayed for up to 5 months dependent on the vaccine used. Check with vaccine SPC.

(vii) Caution should be used in persons 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.

(viii) Administration of the vaccine to subjects who are in the incubation period of the infection cannot be expected to protect against clinically manifest varicella or to modify the course of the disease.

(ix) If possible, both vaccinations should be with the same vaccine brand as there are no data on interchangeability although it is likely that a course can be completed effectively with a different vaccine. Check with Medicines Information.

2.5. Action to be taken when a patient is excluded from treatment under this PGD

If a patient is excluded from treatment under this PGD, medical advice should be sought – refer to a doctor.

2.6. Action to be taken when a patient does not wish the treatment to be received under this PGD

3. Description Of Treatment Available Under This Direction

3.1. Varicella vaccine

Varicella vaccine (live attenuated) is available from Sanofi Pasteur MSD Limited as Varivax® (Oka/Merck strain) and from GlaxoSmithKline UK as Varilrix® (Oka strain). Vaccines do not contain thiomersal.

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. Do not allow to freeze, protect from light. The entire contents of the pre-filled syringe should be injected into the vial containing the powder then gently agitated to mix thoroughly. When reconstituted, each dose (0.5mL) of vaccine is a clear, colourless to pale yellow liquid.

Varilrix® is available as a vial containing cream to yellowish or pinkish powder or cake and solvent for reconstitution. To reconstitute, the diluent is added to the vial containing the powder/cake and shaken well until dissolved. When reconstituted, each dose (0.5mL) of the vaccine may vary from peach to pink in colour.

For both vaccines:

(i) Inspect the diluent and the reconstituted vaccine visually for any foreign particulate matter and/or variation of physical appearance prior to administration. In the event of either being observed, the diluent or reconstituted vaccine should be discarded.

(ii) Store vaccines between +2°C and +8°C.
(iii) Use immediately after reconstitution.

Varicella vaccine is a Prescription-only Medicine (PoM).

3.2. Dose, route and frequency

Non-immune healthcare workers should receive 2 doses of 0.5mL of varicella vaccine. The outer aspect of the upper arm (deltoid region) is the preferred site of injection.

Varilrix®

(i) **Subcutaneous injection only.**
(ii) Doses should be given 4 - 8 weeks apart but **must not** be given less than 4 weeks apart.

Varivax®

(i) **Subcutaneous or intramuscular injection.**
(ii) Interval between doses 4 - 8 weeks.

If the interval between doses of either vaccine exceeds 8 weeks, the second dose should be given as soon as possible. Some individuals may not be protected until after the second dose has been administered.

3.3. Concurrent medication

Varicella vaccine must not be mixed with any other vaccine or medicinal product in the same syringe.

Administration of another live vaccine at the same time must be given as a separate injection, preferably into another limb. If given into the same limb, they should be given at least 2.5cm apart. If administration is not concomitant, a four week interval between the two live virus vaccines should be observed.

3.4. Adverse effects

The following adverse effects have been reported following vaccination in adolescents and adults:

Very common: Injection site reactions, pain, redness and swelling, fever.

Common: Injection site rash, pruritis and varicella-like rash.

Uncommon: Injection site ecchymosis, haematoma, induration, numbness and warmth, headache, lymphadenopathy, somnolence, cough, rhinitis, irritability, nausea, vomiting, arthralgia, myalgia.

Rare: Conjunctivitis, abdominal pain, diarrhoea, urticaria, heaviness, hyperpigmentation, stiffness.
Very rare: Dizziness, facial oedema, anaphylaxis.

**Medical advice in cases of anaphylaxis**

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals).

**Overdose**

Accidental administration of an excessive dose is very unlikely because the vaccine is presented in single dose vials. However, overdose has been reported.

The following adverse events were reported:

Varivax\textsuperscript{®}: injection site redness, soreness, inflammation; irritability; gastrointestinal complaints; cough and viral infection. None of the cases had long term sequelae.

Varilrix\textsuperscript{®}: lethargy and convulsions. In other cases, no associated adverse events were reported.

**3.5. Advice to patient**

(i) Advice should be given on what to expect and what to do for major and minor reactions.

(ii) Healthcare workers should be advised that if they develop a rash in the month after vaccination, they should report to their Occupational Health department for assessment as contact with varicella-susceptible pregnant contacts and immunosuppressed contacts must be avoided. If the rash is generalised and consistent with a vaccine-associated rash (papular or vesicular) the healthcare worker should avoid patient contact until all the lesions have crusted. Healthcare workers with localised vaccine rashes that can be covered with a dressing and/or clothing should be allowed to continue working unless in contact with high-risk patients, when an individual risk assessment should be made.

(iii) The vaccine does not completely protect all individuals from naturally acquired varicella and cannot be expected to provide maximal protection until about 6 weeks after the second dose.

(iv) Advice should be given to use paracetamol or ibuprofen tablets symptomatically for relief of mild pyrexia and aches. The directions on the package should be followed.

(v) If more serious adverse or persistent effects occur, the patient should be advised to contact their GP/Accident and Emergency Department/NHS 24.
(vi) The patient information leaflet contained in the medicine(s) should be made accessible to the patient/parent/guardian. Where this is unavailable, or unsuitable, sufficient information should be given to the patient/parent/guardian in a language that they can understand.

3.6. Follow up treatment

Patients should not leave if they are feeling at all unwell without speaking to the nurse first. If necessary a doctor or the patient’s GP should be contacted for advice.
4. Designated Staff Authorised To Administer Under This PGD

The following staff are authorised to administer the drug specified in this PGD without an individual medical prescription providing the patient falls into one of the categories listed in 2.2 of this PGD. Staff must be employed either directly by NHS Grampian, or contracted to provide NHS services, or providing services in partnership with NHS Grampian under the direction of this authorised PGD.

(i) Registered Nurse working in Occupational Health as recognised by the NMC.

In addition the following requirements are necessary. Staff must:

(i) agree to be professionally accountable for their work (Appendix 1).

(ii) be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.

(iii) be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.

(iv) have been trained and assessed as being competent in the administration of the drug. All staff will have access to the current PGD.

(v) have undertaken the NHS e-anaphylaxis training session which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF or the AT Learning® tool.

(vi) be competent in basic life support which is required to be updated annually.

(vii) have immediate access to the appropriate equipment and drugs to treat anaphylaxis and have access to the current PGD for the management and treatment of anaphylaxis should this occur.

(viii) maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

(ix) agree to work within the terms of the NHS Grampian PGD.

Professional Managers/Nurse managers/Lead nurses will be responsible for:

(i) Ensuring that the current PGD is available to staff providing care under this direction.

(ii) Ensuring that the staff have access to all relevant Scottish Government Health Directorate advice, including any relevant CMO letter(s).

(iii) Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.
(iv) Maintaining a current record of all staff authorised to administer the drug specified in this PGD.

5. Documentation

5.1. Authorisation of administration

Nurses in Occupational Health can be authorised to administer varicella vaccine by the Consultant in Occupational Health Medicine, NHS Grampian.

A certificate of competence (Appendix 2) signed by the authorising doctor/manager should be supplied. This should be held in the individual staff records or as agreed locally.

5.2. Record of administration

An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:

(i) Name and address of patient
(ii) Unit no/CHI No
(iii) Date of birth
(iv) Consultant/General Practitioner details
(v) Risk group, if appropriate
(vi) Physical examination required, if appropriate
(vii) Exclusion criteria, record why drug not administered
(viii) Reason for giving
(ix) Consent to the administration (if not obtained elsewhere)
(x) Drug manufacturer, batch number, expiry date
(xi) Site where drug administered, dose and route of administration
(xii) Signature and name in capital letters of practitioner who administered the drug
(xiii) Date drug given
(xiv) Record of adverse effects (advise patient’s doctor).

These records should be retained:

For children and young people, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

For 17 years and over retain for 6 years after last date of entry.

Or for 3 years after death, or in accordance with local policy, where this is greater than above.

5.3. Consent

Prior to the administration of the drug, consent must be obtained, preferably written, either from the patient, parent, guardian or person with parental responsibility and documented either in the patient’s medical records/notes or on an administration form.
(see section 5.2). Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.

http://intranet.grampian.scot.nhs.uk/ccc_nhsg/15692.html?pMenuID=460

6. Further Points

The manufacturers leaflet inside boxes of drug should be read and advice from them taken into consideration.

The recommendations for storage and handling of vaccines must be followed.

Detailed information on all aspects of immunisation is available in ‘Immunisation against Infectious Disease’ DHSS HMSO 2006.


7. Facilities And Supplies To Be Available At Sites For The Administration Of The Drug Specified In The PGD

The following should be available at sites where the drug is to be administered:

(i) Pharmaceutical refrigerator (or validated cool box for storing vaccine if mobile unit).
(ii) Resuscitation equipment.
(iii) Access to medical support (this may be via telephone).
(iv) Safe storage areas for medicines and equipment.
(v) Approved equipment for the disposal of used materials.
(vi) Clean and tidy work areas.
(vii) Copies of the current PGD for the drug specified in the PGD
(viii) PGD for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

8. Audit

All records of administration of the drug specified in this PGD will be filed with the normal records of medicines administration in each practice/service. A designated person within each HSCP/practice/service will be responsible for auditing completion of drug forms and collation of data.
9. Management And Monitoring Of Patient Group Direction

9.1. Consultative group

Fiona Browning Health Protection Nurse Specialist
Morag Hives Occupational Health Manager
Pamela Molyneaux Consultant Virologist
Wendy Robertson Principal Pharmacist
Katherine Targett Consultant Occupational Physician
Diana Webster Consultant in Public Health Medicine

9.2. Professional advisory group approving PGD

Medicine Guidelines and Policies Group

9.3. Authorising managers

Dr Nick Fluck
Medical Director, NHS Grampian

Mr David Pfleger
Director of Pharmacy and Medicines Management, NHS Grampian

Ms Amanda Croft
Nursing Director, NHS Grampian

10. References

Varivax® - Date of revision of text 11/2013, accessed 14/09/2015
Varilrix® - Date of revision of text 12/2014, accessed 14/09/2015

Document: Drafted: March 2004
Approved: February 2005, August 2007, July 2009, July 2011,
July 2013, October 2015 (published November 2015)

Review date: At least every 2 years or sooner if current treatment recommendations change.
Appendix 1

Health Care Professional Agreement To Administer Medicines Under Patient Group Direction

I: ______________________________ (Insert name)

Working within: ______________________________ e.g. HSCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

Patient Group Direction For The Administration Of Varicella Vaccine To Non-Immune Adult Healthcare Workers By Nurses Working Within NHS Grampian Occupational Health

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: ___________________________________________

Print Name: _______________________________________

Date: ____________________________________________

NMC Registration No: ______________________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: _______________________________________

Working within: ________________________________ e.g. HSCP, Practice

To administer medicines under the following Patient Group Direction

Patient Group Direction For The Administration Of Varicella Vaccine To Non-Immune Adult Healthcare Workers By Nurses Working Within NHS Grampian Occupational Health

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: ________________________________ Authorising Manager/Doctor

Print Name: ________________________________

Date: ________________________________