Patient Group Direction 1444 version 9.0
Administration of Inactivated Quadrivalent Influenza Vaccine (Split Virion) to Healthcare Workers by Registered Nurses and Registered Midwives employed by Torbay and South Devon NHS Foundation Trust

Date of Introduction:  September 2018
Review Date:  August 2019

<table>
<thead>
<tr>
<th>Developed By</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Physician</td>
<td>Medical Director</td>
<td></td>
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<tr>
<td>Pharmacist</td>
<td>Antimicrobial Pharmacist</td>
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<tr>
<td>Lead Professional</td>
<td>Associate Director of Nursing for Community Services Delivery Unit</td>
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Note: The Lead Professional is responsible for ensuring the co-ordination, composition, consultation, revision and distribution of the PGD to practitioners who will be using the PGD as well as ensuring that the PGD is no longer used if becomes out of date and once it has expired.

The Clinical Effectiveness Department will write to the Lead Professional approximately 4 months before the review date as a reminder that a review is required.

Ratified on behalf of:  TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST

Medicines Management Committee Chair

Signed:
Name:  Clinical Director – Pharmacy and Prescribing
Date:

Lead Officer

Signed:
Name:  Medical Director
Date:
### Objective

Prophylaxis of Influenza for staff that potentially come into contact with patients as part of the Corporate Seasonal Immunisation Programme.

### 1. Clinical Condition

#### Definition of condition/situation

- Prophylaxis of influenza to frontline staff as part of the seasonal immunisation programme, in line with a Trust’s responsibility to ensure, as far as is reasonably practicable, that health workers are free of, and are protected from exposure to infections that can be caught at work, and that all staff are suitably educated in the prevention and control of infections. This includes ensuring that occupational health policies and procedures in relation to the prevention and management of communicable diseases in healthcare workers, including immunisation, are in place.
- Decisions on offering immunisation should be made on the basis of a local risk assessment as described in the current version of ‘Immunisation against infectious disease’.
- Employers should make vaccines available free of charge if a risk assessment indicates they are needed.
- Staff directly involved in delivering care will be encouraged to be immunised, and processes will be in place to facilitate this.
- Other supporting staff, who do not have face-to-face patient contact, involved in the delivery of health care can be offered immunisation.

#### Facilities required

- Access to the current version of the electronic Green Book Immunisations against Infectious Diseases Chapter 19 Influenza – Updated August 2015 (this is updated regularly on GOV.UK).
- Access to the Data sheet PIL for the product being used.
- Facilities for treating anaphylaxis must be available, with the ability to call for emergency medical assistance.
- Be able to maintain the cold chain.

#### Criteria for inclusion

- Staff directly involved in delivering care (see above).
- Students and trainees in these disciplines who are working with patients should also be included.
- All pregnant women.
- Other staff in supporting roles who may come into face to face contact with patients.

This is not an exhaustive list, and decisions to provide immunisation should be based on local assessment of likely risk and exposure to flu.

#### Criteria for exclusion

- Individuals with either confirmed anaphylaxis to egg or with egg allergy and severe uncontrolled asthma, should not be given a vaccination under this PGD.
- Current febrile illness or acute infection.
- Hypersensitivity to the active substances of the product, to any of the excipients and to residues e.g. eggs (ovalbumin, chicken proteins).
- The vaccine may also contain residues (see contra-indications below).
- Confirmed anaphylactic reaction to a previous dose of, or any component of, the vaccine.
2. Characteristics of Staff

### Qualifications required

- Registered Nurses and Registered Midwives

### Additional requirements

- Working knowledge of relevant Organisation Policies, including Medicines Policy and associated Standard Operating Procedures, Anaphylaxis Policy, Consent Policy and Injectable Medicines Policy and associated risk assessments where appropriate.
- Working knowledge of relevant Organisation protocols.
- Evidence of continuing professional development, (and any training and competence relevant to this PGD).
- Registered Nurses / Registered Midwives who are authorised to work under the PGD and have completed approved theoretical and practical training regarding:
  - Immunisation and vaccination
  - Basic life support
  - The recognition and treatment of anaphylaxis
- Registered Nurses / Registered Midwives working to this PGD are also required to regularly review the relevant online sections of:

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**Action if excluded**

- For those with current febrile illness or acute infection, postpone until recovered.
- For those with hypersensitivities, refer to medical practitioner [GP] for prescription of alternative vaccine product without the causative ingredients.

**Action if patient refuses medication**

- None as vaccination is on a voluntary advised basis only in frontline care.
### 3. Description of Treatment

<table>
<thead>
<tr>
<th>Name of Medicine Supplied</th>
<th>Influenza vaccine for use in 2018-2019 influenza season. The vaccine is not a &quot;black triangle&quot; drug</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>*<em>Influenza virus (inactivated, split) of the following strains</em>:</td>
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<tr>
<td></td>
<td>- A/Michigan/45/2015 (H1N1)pdm09 - like strain - 15 micrograms HA**;</td>
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<tr>
<td></td>
<td>- A/Singapore/INFIMH-16-0019/2016 (H3N2) – like strain - 15 micrograms HA**</td>
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<tr>
<td></td>
<td>- B/Colorado/06/2017 - like strain - 15 micrograms HA**</td>
</tr>
<tr>
<td></td>
<td>- B/Phuket/3073/2013 - like strain - 15 micrograms HA**</td>
</tr>
<tr>
<td>Per 0.5 ml dose</td>
<td>* propagated in fertilised hens' eggs from healthy chicken flocks</td>
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<tr>
<td></td>
<td>** haemagglutinin</td>
</tr>
<tr>
<td></td>
<td>- This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2018/2019 season.</td>
</tr>
<tr>
<td></td>
<td>- Quadrivalent Influenza Vaccine (Split Virion, Inactivated) may contain traces of eggs, such as ovalbumin, and of neomycin, formaldehyde and octoxinol- 9, which are used during the manufacturing process.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Medicine Administered</th>
<th>As above</th>
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</thead>
<tbody>
<tr>
<td>Legal Class</td>
<td>POM (Prescription Only Medicine)</td>
</tr>
<tr>
<td>Storage</td>
<td>－Store in a refrigerator (2°C - 8°C).</td>
</tr>
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<td></td>
<td>－Do not freeze.</td>
</tr>
<tr>
<td></td>
<td>－Keep syringe in original outer container in order to protect from light.</td>
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<tr>
<td>Dose to be used</td>
<td>0.5ml</td>
</tr>
<tr>
<td>(including criteria for use of differing doses)</td>
<td></td>
</tr>
<tr>
<td>Method or route of administration</td>
<td>－Immunisation should be carried out by intramuscular or deep subcutaneous injection.</td>
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<td></td>
<td>－Precautions to be taken before handling or administering the medicinal product:</td>
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<td></td>
<td>－The vaccine should be allowed to reach room temperature before use.</td>
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<td></td>
<td>－Shake before use (the vaccine after shaking gently is a slightly whitish and opalescent liquid).</td>
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<td></td>
<td>－Inspect visually prior to administration. The vaccine should not be used if foreign particles are present in the suspension.</td>
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</table>

<table>
<thead>
<tr>
<th>Total dose and number of times drug to be given. Details of supply (if supply made)</th>
<th>Boxes of 10 vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.5ml in pre-filled syringes with attached needle equipped with a plunger stopper.</td>
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<tr>
<td></td>
<td>To be given <strong>ONCE only</strong>.</td>
</tr>
</tbody>
</table>
Contra-indications
- Individuals with either confirmed anaphylaxis to egg or with egg allergy and severe uncontrolled asthma, should not be given a vaccination under this PGD.
- Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9.
- Immunisation shall be postponed in patients with febrile illness or acute infection.

Cautions
- If employee is taking any other medications consult BNF Appendix 1 for any potential interactions.
- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
- Quadrivalent Influenza Vaccine (Split Virion, Inactivated) should under no circumstances be administered intravascularly.
- As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.
- Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.
- Interference with serological testing. See interactions.

Interactions
- Quadrivalent Influenza Vaccine (Split Virion, Inactivated) may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.
- The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.
- Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false positive reactions could be due to the IgM response by the vaccine.

Pregnancy
- Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

Breastfeeding
- Inactivated influenza vaccine (Split Virion) BP may be used during breastfeeding.

Fertility
- No fertility data are available.
### Potential side-effects and adverse reactions

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
- Headache
- Sweating
- Myalgia
- Arthralgia
- Fever
- Malaise
- Shivering
- Fatigue,
- Local reactions i.e. redness, swelling, pain, ecchymosis, induration.
- Transient thrombocytopenia, lymphadenopathy.
- Allergic reactions, in rare cases leading to shock, angioedema.
- Neuralgia, paresthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré syndrome.
- Vasculitis associated in very rare cases with transient renal involvement.
- Generalized skin reactions including pruritus, urticaria or non-specific rash.
- The vaccine has no or negligible influence on the ability to drive or use machines.

### Management of potential side-effects and adverse reactions

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.
- The patient should follow the guidance in the PIL.
- Side effects will usually disappear within one to three days without treatment. If they persist, the patient should consult their doctor.
- If any side effects become serious, or if the patient notices any side effects not described in the leaflet, they should contact their doctor.

### Advice and information to patient/carer including follow-up

Appropriate information and advice about the influenza vaccine must be provided for each person offered the vaccine, and the nurse or midwife should ensure that the individual fully understands which immunisation is to be administered; the diseases against which it will protect; the risks of not proceeding; the side-effects that may occur and how these should be dealt with; and any follow-up action required.

Individuals coming for immunisation should be given a reasonable opportunity to discuss any concerns before being immunised.

Ensure that the patient information leaflet for the specific product administered is available and is offered to the patient. Specific information that should be given includes:

- advice on the prevention and management of fever and local reaction and other adverse effects
- description of the common adverse effects post-vaccination
- that protection against the strains of virus in the vaccine are likely to be obtained in 2-3 weeks
- that immunity persists for 6-12 months
- that revaccination each year is advised.
Specify method of recording supply /administration including audit trail

Document allergies and other adverse drug reactions clearly in staff members medical record in Occupational Health and advise them to inform their GP and other relevant practitioners/patient/carer for further reporting and action if required.

Report any adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card reporting system (www.mhra.gov.uk).

The following will be recorded in the staff members Occupational Health medical records:

- The name of the vaccine
- Batch number and expiry date
- The route of administration and site of administration where appropriate
- The date of supply/administration and verbal consent given
- The name of the person supplying/administering the medication
- Provide current PIL if requested for the specific product administered, patient record card and explain the patient can also directly report any suspected adverse reactions directly to the MHRA.
- Document any reaction or side effects in staff members Occupational Health medical records, together with action taken.
- Vaccine uptake for healthcare workers will be collected through the ImmForm website, with trusts entering data directly onto the site. The HPA will coordinate the national collection and publication of data.
- Endorse ‘PGD’

4. Other Information

Follow up treatment:
Not usually applicable, but see ‘Management of Potential Side Effects and Adverse Reactions’ above.

Arrangements for medicine supply:
- Obtained from the Pharmacy Department at Torbay Hospital.
- Stored in a refrigerator (2°C – 8°C).

Arrangements for medical referral:
Any health professional administering a vaccination must be able to identify and contact an appropriate member of medical staff as necessary, e.g. in the case of an egg allergy.

Lines of accountability:
- Individual Nurses / Midwives are accountable for their own practice and in accordance with their relevant professional code of conduct and must work within their individual Scope of Practice.
- Nurses are accountable to their Nurse Manager.
- Midwives are accountable to their Midwifery Manager.
5. Appendices

References used in the development of this PGD:
- NICE guidance
- MIMMS
- Green Book
- Stockley for Drug Interactions
- Current SPC (Updated 8th August 2018) https://www.medicines.org.uk/emc/product/666
- Department of Health Information
- Trust Protocols and Documents
- Local Formularies
- Immunisation Audit Spreadsheet + Immunisation Audit Aims
- Public Health - England
- Updated from Green Book Chapter 19 v10-0 August 2015

Audit details
Updated from Green Book Chapter 19 v10-0 August 2015


Training
- **Medical treatment:** Approved Immunisation programme. Topics include:
  - Aims of Immunisation and how vaccines work
  - Legal Aspects
  - The management of vaccines
  - Correct administration of vaccines
  - Record Keeping and Reporting
  - Recognising and managing Anaphylaxis
- **Competency assessment:** Sign off from E learning, OH Specialist Nurse Confirmation/ check competency/practice. Appraisal.
- **Frequency of training / review process:** Yearly
Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from the start of September 2018 and expires end of August 2019

Version History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Brief Summary of Change</th>
<th>Owner’s Name</th>
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<tbody>
<tr>
<td>V 6.0</td>
<td>July 2016</td>
<td>Annual review of Influenza PGD following announcement of new influenza strain for 2016/17.</td>
<td>Torbay and South Devon NHS Foundation Trust</td>
</tr>
<tr>
<td>v 7.0</td>
<td>October 2016</td>
<td>PGD updated to include midwives in the professional group authorised to administer the influenza vaccine.</td>
<td>Torbay and South Devon NHS Foundation Trust</td>
</tr>
<tr>
<td>V 8.0</td>
<td>September 2017</td>
<td>Annual Review of PGD</td>
<td>Torbay and South Devon NHS Foundation Trust</td>
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<tr>
<td>V 9.0</td>
<td>September 2018</td>
<td>Annual Review of PGD</td>
<td>Torbay and South Devon NHS Foundation Trust</td>
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For more information on the status of this document, contact:

Medicines Governance Team Administrator
Pharmacy Department
Torbay Hospital
tsdft.medicinesgovernance@nhs.net 01803 655338 (ext 55338)

Date of Issue        September 2018
Reference              PGD 1444 v 9.0 Influenza Vaccine
Path                  V:Medicines Governance/PGDs/Occupational Health/PGD 1444 v 9.0 Administration of Inactivated Flu Vaccine Sept18 – Aug19
Objective: Prophylaxis of Influenza for staff that potentially come into contact with patients as part of the Occupational Health Seasonal Immunisation Programme.

The individual practitioners named below are authorised to operate within the above PGD, being employees of Torbay and South Devon NHS Foundation Trust

<table>
<thead>
<tr>
<th>CLINICAL AREA</th>
<th>LOCATION / DEPARTMENT</th>
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The following list must be kept with a copy of the PGD in each clinical area using that PGD. Each practitioner will receive and sign for an individual copy of the PGD. Only fully competent, qualified and trained professionals may operate within PGDs.

I agree to administer/supply the above preparation in accordance with this Patient Group Direction and I have received an up to date copy of the ratified PGD:

<table>
<thead>
<tr>
<th>NAME (please print)</th>
<th>PROFESSIONAL TITLE</th>
<th>SIGNATURE</th>
<th>AUTHORISING MANAGER (please print)</th>
<th>MANAGER’S SIGNATURE</th>
<th>DATE</th>
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Protocols & Guidelines – Document Control

This is a controlled document. It should not be altered in any way without the express permission of the author or their representative. On receipt of a new version, please destroy all previous versions.

Ref: 1444  
Title: Influenza Vaccine (Inactivated Quadrivalent Influenza Vaccine (Split Virion) to Healthcare Workers by Registered Nurses and Registered Midwives

Date of Issue: 1 October 2018  
Next Review Date: 31 August 2019

Version: 9

Author: Physican and Medical Director  
Antimicrobial Pharmacist  
Associate Director of Nursing for Community Services Delivery Unit

Index: Patient Group Direction

Classification: Patient Group Direction

Applicability: As indicated in PGD

Equality Impact: The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief.

Evidence based: Yes

References: See page 8

Produced following audit: See page 8

Audited: See page 8

Approval Route: See ratification  
Date Approved: 26 September 2018

Approved By: Chair, Trust Medicines Management Committee  
Medical Director

Links or overlaps with other policies: All TSDFT Trust strategies, policies and procedure documents.

PUBLICATION HISTORY:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Date</th>
<th>Status</th>
<th>Authorised</th>
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<tbody>
<tr>
<td>1</td>
<td>3 November 2011</td>
<td>New</td>
<td>Trust Medicines Management Committee Lead Officer for the Trust</td>
</tr>
<tr>
<td>2</td>
<td>23 November 2012</td>
<td>Revised</td>
<td>Chair, Trust Medicines Management Committee Medical Director and Lead Officer for the Trust</td>
</tr>
<tr>
<td>3</td>
<td>18 October 2013</td>
<td>Revised</td>
<td>Chair, Trust Medicines Management Committee Medical Director and Lead Officer for the Trust</td>
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<td>4</td>
<td>3 October 2014</td>
<td>Revised</td>
<td>Chair, Trust Medicines Management Committee Interim Medical Director and Lead Officer for the Trust</td>
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<tr>
<td>5</td>
<td>18 September 2015</td>
<td>Revised</td>
<td>Chair, Trust Medicines Management Committee Medical Director and Lead Officer for the Trust</td>
</tr>
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<td>6</td>
<td>26 August 2016</td>
<td>Revised</td>
<td>Medicines Management Committee Chair Medical Director</td>
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<tr>
<td></td>
<td>Date</td>
<td>Event</td>
<td>Responsible Party</td>
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<td>----------------------------------------------------------------</td>
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<tr>
<td>7</td>
<td>8 November 2016</td>
<td>Amendment</td>
<td>Medicines Management Committee Chair Medical Director</td>
</tr>
<tr>
<td>7</td>
<td>10 August 2017</td>
<td>Withdrawn</td>
<td>Deputy Director of Nursing – Professional Practice</td>
</tr>
<tr>
<td>8</td>
<td>21 September 2017</td>
<td>Reinstated and Revised</td>
<td>Medical Director Chair, Trust Medicines Management Committee</td>
</tr>
<tr>
<td>9</td>
<td>1 October 2018</td>
<td>Revised</td>
<td>Medical Director Chair, Trust Medicines Management Committee</td>
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</table>
Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet).

For more information:
- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net.
- See TSDFT's Data Protection & Access Policy.
- Visit our Data Protection site on the public internet.