

**CONTROLLED DOCUMENT**

**PATIENT GROUP DIRECTION FOR THE ADMINISTRATION  
OF INACTIVATED INFLUENZA VACCINE TO DIALYSIS  
PATIENTS WHO ARE AGED 18 YEARS AND OVER**

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| <b>CATEGORY:</b>   | Procedural document   |
| <b>CLASSIFICATION:</b>   | Clinical/Governance   |
| <b>PURPOSE</b>   | Administration of seasonal influenza vaccine to dialysis patients without prescription under a PGD  |
| <b>Controlled Document Number:</b>   | 003/0816  |
| <b>Version Number:</b>   | 1   |
| <b>Controlled Document Sponsor:</b>  | Chief Pharmacist  |
| <b>Controlled Document Lead:</b>   | Renal consultant  |
| <b>Approved By:</b>  | Medicines Management Advisory Group   |
| <b>On:</b>   | 1 <sup>st</sup> Sept 2016   |
| <b>Review Date:</b>  | 1 <sup>st</sup> Sept 2017   |
| <b>Distribution:</b> <ul style="list-style-type: none"> <li><b>Essential Reading for:</b></li> </ul> | Registered nurses administering seasonal influenza vaccine against a PGD including: <ul style="list-style-type: none"> <li>UHBFT Band 6, 7 or 8 nurses employed by Renal Services</li> <li>All senior registered nurses in dialysis partnership organisations administering the flu vaccine.</li> <li>All renal medical consultants providing dialysis care</li> <li>Senior nurses and ward managers within Renal Services</li> <li>Pharmacy Staff</li> </ul> |
| <b>Information for:</b>  |   |

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| <b>Division/unit/area to which the PGD applies</b>  | Division B Group 2.<br>Renal Services and partnership satellite dialysis units  |
| <b>Description of the medication to which the PGD applies</b>                                 | <p>Trivalent Seasonal Inactivated Influenza Vaccine (Split Virion) BP. Sanofi-Pasteur MSD brand.</p> <p><b>Vaccine composition for 2016/17</b></p> <ul style="list-style-type: none"> <li>• an A/California/7/2009 (H1N1)pdm09-like virus</li> <li>• an A/Hong Kong/4801/2014 (H3N2)-like virus</li> <li>• a B/Brisbane/60/2008-like virus</li> </ul>   |
| <b>Group of registered professional staff who are authorised to administer under this PGD</b> | <ol style="list-style-type: none"> <li>1) Registered Nurses employed by Renal services UHBFT, who have undertaken appropriate training, been assessed and deemed competent to administer inactivated influenza vaccine against this PGD.</li> <li>2) Registered Nurses who work within partnership dialysis organisations providing haemodialysis for UHBFT patients who have undertaken appropriate training, been assessed and deemed competent to administer inactivated influenza vaccine against this PGD.</li> </ol>  |
| <b>Training and method of assessment of competence</b>  | <ul style="list-style-type: none"> <li>• In house training given following guidelines for training in immunisation issued by Public Health England in association with the Royal College of Nursing;<br/><a href="https://www.gov.uk/government/publications/immunisation-training-core-curriculum">https://www.gov.uk/government/publications/immunisation-training-core-curriculum</a><br/><a href="https://www.gov.uk/government/publications/immunisation-training-of-healthcare-support-workers-national-minimum-standards-and-core-curriculum">https://www.gov.uk/government/publications/immunisation-training-of-healthcare-support-workers-national-minimum-standards-and-core-curriculum</a></li> <li>• Evidence of up-to-date training in Basic Life Support and treatment of anaphylaxis.</li> <li>• Registered nurses will be required to familiarise themselves with the content of this PGD with particular attention to exclusion criteria;</li> <li>• Registered nurses will be required to familiarise themselves with documentation and evaluation questionnaire which accompanies the vaccination programme;</li> <li>• Each registered nurse is responsible for their own practice. Anyone who feels it is necessary must arrange to attend Occupational Health to familiarise themselves with the procedure involved.</li> </ul> <p>The education session will be delivered either face-to-face by a senior Renal nurse, Renal Professional</p> |

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|   | Development Nurse, Public Health England nurse or an Occupational Health nurse, or delivered within an on line platform. Competence will be assessed by answering of written questions at the end of the presentation. The assessment of competence will be recorded on the competence sheet at the back of this PGD and retained within the registered nurse's workplace. A copy will be kept in the registered nurse's personal file.   |
| <b>Clinical situation to which this direction applies</b> | Renal haemodialysis patients.   |
| <b>Exclusion criteria</b>                                 | <ul style="list-style-type: none"> <li>• Patients with previous confirmed anaphylactic reaction to egg or egg allergy with uncontrolled asthma (BTS SIGN step 4 or above)</li> <li>• Hypersensitivity to ovalbumin, chicken protein, neomycin, formaldehyde and octoxinol 9, to the active substances or vaccine excipients including sodium chloride, potassium chloride, disodium phosphate dehydrate, potassium dihydrogen phosphate, water for injections (see current Summary of Product Characteristics (SPC)).</li> <li>• Hypersensitivity to bromobutyl, chlorobutyl or chlorobromobutyl elastomers. These allergies will be assessed by asking if any previous allergy to an influenza or other vaccine as per guidance from Public Health England.</li> <li>• Febrile illness or acute infection.</li> <li>• Patients who have had a previous severe reaction to any influenza vaccine.</li> <li>• Patients with bleeding disorders including, e.g. thrombocytopenia, defined as platelet count &lt;50 or any other coagulation disorder. <u>The following clinical circumstances are not defined as coagulation disorders:</u> those on aspirin, clopidogrel, therapeutic warfarin or standard dialysis anticoagulation (as per Public Health England PGD for IM administration of inactivated influenza vaccine, and Clinical Haematology).</li> <li>• Patients who refuse.</li> <li>• Patients who have already received vaccination from GP.</li> </ul> |

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| <b>Action to be taken when a patient is excluded from treatment according to the PGD</b>   | <ul style="list-style-type: none"> <li>• Advice on flu symptom management.</li> <li>• Document refusal if needed.</li> <li>• Patients excluded due to hypersensitivity to eggs or ingredients of the vaccine may be referred to unit consultant and then primary care as an alternative vaccine may have different ingredients.</li> <li>• Advise when treatment may be administered if appropriate.</li> </ul>  |
| <b>Treatment to be administered under the protocol</b>                                     | Trivalent Seasonal Inactivated Influenza Vaccine (Split Virion) BP 2016/2017. Sanofi-Pasteur MSD brand.  |
| <b>Security, storage and labelling of medicines</b>  | <p>Prescription only medicine (POM)</p> <p>Store in locked fridge (+2-8°C). Monitor daily. Do not freeze.</p> <p>Protect from light.</p> <p>Should fridge temperatures deviate from range of +2-8°C, contact Medicines Information to advise whether the product can still be used.</p>  |
| <b>Route of administration and method</b>  | <p>Intra-muscular in last hour or immediately after dialysis session. Press for 5 mins after vaccination.</p> <p>Where the client has a bleeding disorder as previously defined, via deep subcutaneous injection (at 45° angle)</p> <p>Shake before use.</p> <p>N.B. Vaccine must be at room temperature before administration.</p>  |
| <b>Dose to be administered</b>   | 0.5ml  |
| <b>Frequency of administration</b>   | Annual single dose   |
| <b>Maximum dosage &amp; minimum/maximum period over which the drug may be administered</b> | One dose every year in accordance with Department of Health recommendations.   |
| <b>Warnings &amp; potential adverse reactions</b>  | <ul style="list-style-type: none"> <li>• Access to facilities for CPR and treatment of anaphylaxis including epinephrine 1 in 1000 injection must be available at all times.</li> <li>• Individuals with a bleeding disorder may need to be given the vaccine by deep subcutaneous injection at a 45° angle to reduce the risk of bleeding. If unsure, refer to satellite liaison team.</li> </ul> <p>The following advice to patients must be given with issue of the manufacturer's information leaflet:</p> |

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|  | <ul style="list-style-type: none"> <li>• Localised reactions: redness, swelling, pain, ecchymosis, induration;</li> <li>• Systemic reactions: fever, malaise, shivering, fatigue, headache, sweating, myalgia. Rarely: neuralgia, paraesthesia, convulsions, transient thrombocytopenia.</li> <li>• Allergic reactions: urticaria, pruritus, erythematous rash, dyspnoea in rare cases leading to shock.</li> </ul> <p>As outlined in the Trust Incident Procedure (Controlled Document No 685), any incidents, near misses or adverse events must be reported immediately to the senior professional on duty and a Trust Incident Report Form (IRF) must be completed as soon as possible using the online incident reporting system (Datix).</p> <p>If the patient who has been administered seasonal influenza vaccine as detailed in this PGD suffers an adverse drug reaction, then it is the responsibility of the registered nurse identified within the “Professional Group” to ensure the patients safety and seek advice from the consultant or registrar on duty.</p> <p>Report serious adverse reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA) on a Yellow Card. Yellow cards and guidance on their use are available at the back of the BNF, or online via the link in eBNF, or at <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></p> |
| <b>Follow up - circumstances under which further advice should be sought and arrangements for referral</b> | <ul style="list-style-type: none"> <li>• Patients with febrile illness or infection will be advised to return for vaccination if appropriate.</li> <li>• Anyone experiencing serious adverse effects should seek appropriate medical advice and/or Trust resuscitation procedures should be followed if necessary. The unit consultant or delegated deputy must be informed of any serious adverse reactions and any treatment required should be given at the earliest opportunity.</li> </ul>  |
| <b>Written or verbal advice to be given to patients or carers before, during or after treatment</b>        | <ul style="list-style-type: none"> <li>• Consent must be obtained and documented by completion of the flu consent form (Appendix 1).</li> <li>• Patients must be advised about: <ol style="list-style-type: none"> <li>1. Management of local reactions;</li> <li>2. Management of pyrexia.</li> </ol> </li> </ul>   |






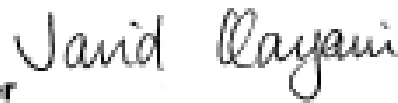
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|  | <ul style="list-style-type: none"> <li>• A manufacturer's patient information leaflet, which is available with the product, must be given to each client.</li> <li>• Advice that they will not require vaccination with GP this season and that the GP will be informed that vaccination has occurred.</li> </ul>  |
| <b>Record keeping</b>  | <ul style="list-style-type: none"> <li>• The name of the medication, dose administered, batch number, expiry date, site of injection and name, signature and designation of the person administering the medication must be recorded on the consent form.</li> <li>• Consent must be recorded by the registered nurse administering against this PGD.</li> <li>• Record evidence of cold chain (e.g. daily monitoring of fridge temperature where vaccine is stored).</li> </ul>   |
| <b>Names of registered professionals who are authorised to administer/supply drug according to PGD</b> | A list of the registered nurses who have undertaken training and assessment in the administration of inactivated influenza vaccine will be held within the registered nurses training records and at their employing organisation.   |
| <b>Professional with responsibility for ensuring review of PGD takes place</b>                         | <p>The Matron for Renal Services will be responsible for ensuring review of the Patient Group Direction. This review will include audit with the support of the Practice Development Team if requested, to address:</p> <ul style="list-style-type: none"> <li>• Adherence to the Patient Group Direction.</li> <li>• Education, training and competence of staff to which this Patient Group Direction applies.</li> </ul> <p>All audits must be logged with the Clinical Audit Registration and Management System (CARMS).</p> |
| <b>Staff responsible for drawing up this PGD</b>   | <p>Dr Clara Day - Renal Consultant<br/>Lucy Binns – Renal Matron<br/>Mayur Mistry – Renal Pharmacist</p>   |

\* Immunisation against infectious diseases (DH 2006 and updated on line), also known as The Green Book. It can be accessed at  
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/525968/Annual\\_flu\\_letter\\_2016\\_2017.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/525968/Annual_flu_letter_2016_2017.pdf)

<https://www.gov.uk/government/publications/intramuscular-inactivated-influenza-vaccine-patient-group-direction-pgd-template>

Patient group direction (PGD) for the administration of inactivated seasonal influenza vaccine to dialysis patients who are aged 18 years and over.  
PGD No: 003/0816 v1

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| <b>Patient group direction approved by:</b>   |   |
| <b>Lead Clinician</b>   | <b>Signature:</b> <br><b>Name:</b> Dr Clara Day<br><b>Designation:</b> Renal Consultant<br><b>Date:</b> 4/10/16   |
| <b>Senior Pharmacists</b>   | <b>Signature:</b> <br><b>Name:</b> Inderjit Singh<br><b>Designation:</b> Chief Pharmacist<br><b>Date:</b> 29/9/16<br><br><b>Signature:</b> <br><b>Name:</b> Emma Suggett<br><b>Designation:</b> Senior Pharmacist<br><b>Date:</b> 30/9/16 |
| <b>Head of professional group (Divisional Associate Director of Nursing or Head of Allied Medical Profession)</b> | <b>Signature:</b> <br><b>Name:</b> Margaret Garbett<br><b>Designation:</b> Associate Director of Nursing, Division B<br><b>Date:</b> 7/10/16   |
| <b>Executive Chief Nurse</b>  | <b>Signature:</b> <br><b>Name:</b> Philip Norman<br><b>Designation:</b> Executive Chief Nurse<br><b>Date:</b> 04/10/16   |
| <b>Executive Medical Director</b>   | <b>Signature:</b> <br><b>Name:</b> David Rosser<br><b>Designation:</b> Executive Medical Director<br><b>Date:</b> 5 <sup>th</sup> October 2016  |
| <b>Date direction comes into force</b>  | 1 <sup>st</sup> October 2016  |
| <b>Date of review</b>   | 1 <sup>st</sup> October 2017  |
| <b>Date direction expires</b>   | 31 <sup>st</sup> October 2017   |

The signed off PGD must be returned to the Patient Safety Pharmacist. The approved document should then be copied, circulated to interested professionals and the Risk and Compliance Unit and recorded on the Risk and Compliance Database. The original must be stored in pharmacy.

UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION  
TRUST  
COMPETENCE SHEET

**Name of PGD:** .....

Name of registered nurse:.....

Name of assessor: .....

I declare that I have expanded my knowledge and skills and undertake to practice with accountability for my decisions and actions. I have read and understood the PGD and agree to use it in accordance with the criteria described.

Signature of registered nurse:.....

Print name: .....

Designation: .....

Date: .....

I declare that I have supervised this registered nurse and have found her/him to be competent as judged by the criteria described in the PGD.

Signature of assessor: .....

Print name: .....

Designation: .....

Date: .....

A copy of this record must be placed in the registered nurse's personal file and a copy retained by the individual. The original must be kept on the ward/department by the Sister/Charge Nurse/Head of Department.



## Appendix 1: Consent

|   |   |       |    |  |
|---|---|-------|----|--|
| <u>Patient details</u>  | Sticker: to include<br>Patient name<br>DOB<br>Address<br>NHS number |       |    |  |
| <u>Patient GP details</u>   |   |       |    |  |
| Do you have a severe allergy to eggs?   | Yes   |       | No |  |
| Have you ever had a severe allergic reaction to either the flu vaccine or another vaccine?  | Yes   |       | No |  |
| <u>Patient consent</u>  |   |       |    |  |
| <ul style="list-style-type: none"> <li>• I agree to be given a flu vaccination by a registered nurse at my dialysis unit.</li> <li>• I confirm I have not already received a flu vaccination for this flu season.</li> <li>• I declare that the information on this form is correct and complete.</li> <li>• I consent to the disclosure of relevant information, where appropriate, from this form to: <ul style="list-style-type: none"> <li>○ my GP practice to help them provide care to me</li> <li>○ NHS England (the national NHS body that manages health services) for the purposes of checking that the service is being provided properly</li> </ul> </li> </ul> |   |       |    |  |
| Signature:  |   | Date: |    |  |

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|--|------------------------------|---|--------------------|--|
| <b><u>To be completed by nursing staff</u></b> |                              |   |                    |  |
| Patient details:                               |                              | Sticker to include:<br>Patient name<br>DOB<br>Address<br>NHS number |                    |  |
| Any relevant allergies:                        |                              |   |                    |  |
| <b><u>Vaccination details:</u></b>             |                              |   |                    |  |
| Name of vaccine/manufacture                    | Sticker if possible          | Date and time of vaccination:                                       |                    |  |
| Batch number                                   |                              | Site of vaccination:  | Left upper arm     |  |
|  |                              |   | Right upper arm    |  |
| Expiry date                                    |                              | Route of administration:  | Intra muscular     |  |
|  |                              |   | Deep sub-cutaneous |  |
| Any immediate adverse effects:                 |                              |   |                    |  |
| Any advice given:                              | Given manufacturer's leaflet | Yes   |                    |  |
|  | Given renal letter           | Yes   |                    |  |
| Other:   |                              |   |                    |  |
| <b><u>Given by:</u></b>                        |                              |   |                    |  |
| Name:  | Signature:                   | NMC number:   |                    |  |
|  |                              |   |                    |  |

## Appendix 2: Evaluation to service

|   |  |                  |  |                    |  |                      |  |
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| Did you have a flu vaccination last winter?   |  |                  |  |                    |  |                      |  |
| If no, why not?   |  |                  |  |                    |  |                      |  |
| If yes, where did you have?   |  |                  |  |                    |  |                      |  |
| Have you had a flu vaccination this year?   |  |                  |  |                    |  |                      |  |
| If yes, where?  |  |                  |  |                    |  |                      |  |
| If no, why not?   |  |                  |  |                    |  |                      |  |
| If you had your vaccination at the dialysis unit how would you rate your satisfaction with the service? |  |                  |  |                    |  |                      |  |
| Very satisfied  |  | Fairly satisfied |  | Not very satisfied |  | Not at all satisfied |  |
| Would you consider having a flu vaccination at your dialysis unit again in the future?                  |  |                  |  | Yes                |  |                      |  |
|   |  |                  |  | No                 |  |                      |  |
|   |  |                  |  | Not sure           |  |                      |  |
| If you had not had your vaccination at the dialysis unit, would you have elsewhere?                     |  |                  |  | Yes                |  |                      |  |
|   |  |                  |  | No                 |  |                      |  |
|   |  |                  |  | Not sure           |  |                      |  |