**Written instruction for registered nurses to administer inactivated seasonal influenza vaccine as part of an occupational health scheme, which may include peer to peer immunisation (2020/21).**

**Blue highlighted sections must be locally completed and the final written instruction signed by a doctor and approved through local governance processes prior to implementation *(remove yellow highlighted text from final approved document)***

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| **Organisation name:** | Text to be added by organisation  |
| **Date of issue:** | Text to be added by organisation  |
| **Date of review (not to exceed one year from date of issue):** | Text to be added by organisation  |
| **Reference number:** | Text to be added by organisation  |
| **Version number:**  | Text to be added by organisation  |
| **Details of local ratifying committee/governance approval or similar as appropriate:** | Text to be added by organisation or section removed as locally appropriate  |

**Name and signature of the registered doctor authorising registered nurses, who declare themselves (in Section 3) to have met the training and competency requirements defined in this written instruction, to operate under this written instruction on behalf of the named organisation.**

*Note in the absence of an Occupational Health Service (OHS) physician this can be signed by an organisation’s medical director or partner GP etc.* *The Doctor signing this written instruction on behalf of the organisation they are employed by must be working within their own competency when signing.*

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| **Name** | **GMC Registration Number** | **Job Title** | **Signature** | **Date** |
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1. **Training requirements**

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| **Qualifications and professional registration** | Nurses currently registered with the Nursing and Midwifery Council (NMC). |
| **Training and competency**  | The registered nurse must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continuing Professional Development (CPD).The registered nurse should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information. The registered nurse must have undertaken training appropriate to deliver influenza immunisation under this written instruction as required by local policy. This should be informed by the  [National Minimum Standards and Core Curriculum for Immunisation](https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners) and tailored to the skills and competencies required for the safe and effective delivery of influenza immunisation services, including peer to peer immunisation.The registered nurse must be competent in the handling and storage of vaccines, and management of the cold chain. Insert details of and additional local training and competency requirements |
| **Competency assessment** | Insert details of local competency assessment. Registered nurses operating under this written instruction are personally responsible for ensuring they remain up to date with the use of the vaccine/s included. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the Written Instruction and further training provided as required. |

1. **Details of inactivated influenza vaccine to be administered:**

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| **Clinical condition or situation to which this written instruction applies** | Inactivated influenza vaccine is indicated for the immunisation of staff for the prevention of influenza.*Note: Staff refers to staff of the authorising organisation or staff members of another organisation the authorising organisation is commissioned to provide this vaccination service to.* |
| **Criteria for inclusion** | Inactivated influenza vaccine should be offered to the following staff:* Locally adapt to include staff group/s to be included in seasonal influenza vaccination scheme (e.g. all patient facing staff/all staff etc) including peer to peer. Consider if offering vaccination to contracted/commissioned staff including site workers, hospitality staff, volunteers and students.
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| **Criteria for exclusion** | Individuals who:* Have not provided valid consent (for further information on consent see DH [Reference guide to consent for examination or treatment](https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition))
* Are under 16 years of age
* Have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[[1]](#footnote-2) (other than ovalbumin – see [Cautions](#Cautions)).
* Have received a dose of influenza vaccine for the current season
* Are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
* Any additional locally agreed exclusion criteria
 |
| **Cautions including any relevant action to be taken** | Individuals with a bleeding disorder may develop a haematoma at the injection site (see [Route of administration](#Route)). Individuals with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using an egg-free vaccine, for instance Flucelvax® Tetra▼. Individuals with less severe egg allergy can be immunised in any setting using an egg-free vaccine or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms in a 0.5 ml dose). For details of the influenza vaccines available for the 2020/21 season and their ovalbumin content see [The national flu immunisation programme 2020/21](https://www.gov.uk/government/collections/annual-flu-programme%22%20%5Cl%20%222020-to-2021-flu-season)Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. |
| **Action to be taken if the client is excluded** | Where appropriate, such individuals should be referred to the Occupational Health Consultant (adapt to reflect local policy).In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed.Document the reason for exclusion and any action taken in the individual’s Occupational Health records (adapt to reflect local policy). |
| **Action to be taken if the client declines treatment** | Advise the individual about the protective effects of the vaccine, the risks of infection to themselves, their families and the organisation’s service users and potential complications if not immunised.Advise how future immunisation may be accessed if they subsequently decide to receive the inactivated influenza vaccine. Document, in accordance with local policy, advice given and the decision reached.Any additional locally agreed action to be taken  |
| **Arrangements for referral for medical advice** | Insert details of local arrangements for referral to Occupational Health Consultant or GP. |
| **Description of treatment** |
| **Name, strength & formulation of drug** | Inactivated influenza vaccine suspension in a pre-filled syringe, including:* Cell grown quadrivalent vaccine (QIVc), Flucelvax® Tetra▼
* Standard egg cultured quadrivalent inactivated vaccine (QIVe)
* Adjuvanted trivalent inactivated vaccine (aTIV)
* High-dose trivalent vaccine (TIV-HD), see [below](#TIVHD)

A [list of the influenza vaccines](https://www.england.nhs.uk/wp-content/uploads/2020/05/national-flu-immunisation-programme-2020-2021.pdf) available in the UK was published in the [annual flu letter](https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan) for England and subsequent updates can be found in [Vaccine Update](https://www.gov.uk/government/collections/vaccine-update). Standard egg based inactivated trivalent influenza vaccines (TIVe) are not one of the recommended vaccines for the 2020/21 influenza season. Both QIVc and QIVe are preferable to TIVe for those aged up to 64 years.High-dose trivalent vaccine (TIV-HD) is not recommended as part of the national programme in 2020/21 due to a significantly higher list price than the equally suitable vaccines for those aged over 65 years. However, it is clinically equally appropriate as aTIV or QIVc for individuals from 65 years of age.**Recommended vaccine choice**

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| 16 years to under 65 years | Offer QIVc or QIVe (as an alternative to QIVc).  |
| 65 years and over (including 64 year olds turning 65 years by 31 March 2021) | Offer aTIV, or QIVc is suitable for use in this age group if aTIV is not available. |

Staff from 65 years of age may be immunised with QIVe as part of an occupational health scheme. Where a vaccine recommended for the over 65’s is not provided by the organisation’s occupational health scheme and the individual is unlikely to access another provider for an alternative recommended vaccine the available vaccine should be offered. |
| **Legal category** | Prescription only medicine (POM). |
| **Black triangle▼**  | TIV-HD, QIVc and some QIVe products are black triangle. |
| **Off-label use** | The aTIV is licensed for administration to individuals aged 65 years and over. It may be administered ‘off label’ under this written instruction to 64-year olds turning 65 years of age by 31 March 2021 in accordance with the recommendations for the national influenza immunisation programme for 2020/21.Vaccine should be stored according to the conditions detailed in the [Storage section](#Storage) below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to [PHE Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration.Where a vaccine is recommended off-label, as part of the consent process, consider informing the client that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this written instruction, unless permitted off-label administration is detailed above. Refer to products’ SPCs at [www.medicines.org.uk](http://www.medicines.org.uk) and the [annual flu letter](https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan)) for more information. |
| **Route / method of administration** | Administer by intramuscular injection, preferably into deltoid region of the upper arm.Influenza vaccines licensed for intramuscular or subcutaneous administration may alternatively be administered by the subcutaneous route. Note: Fluarix® Tetra, Flucelvax® Tetra▼ and aTIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this written instruction.Shake vaccine before administration.Inspect visually prior to administration and ensure appearance is consistent with the description in the product’s SPC.The SPCs provide further guidance on administration and are available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) **Individuals on stable anticoagulation therapy**, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy.**Individuals with bleeding disorders** may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual should be informed about the risk of haematoma from the injection.  |
| **Dose and frequency of administration** | Single 0.5ml dose to be administered for the current annual flu season. |
| **Obtaining supplies** | Given that some influenza vaccines are restricted for use in particular age groups, the SPCs for individual products should always be referred to, to ensure that they can be given appropriately to particular age groups.Supplies for administration to adults should be ordered from the influenza vaccine manufacturers/wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book [Chapter 3](https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3)). |
| **Storage** | Store at +2°C to +8°C. Store in original packaging to protect from light. Do not freeze. In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to [PHE Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors) and consult local pharmacy team for further advice.  |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment but it is important to still immunise this group.Inactivated influenza vaccine may be given at the same time as other vaccines (See [Route / method of administration](#Route)).A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Identification & management of adverse reactions** | Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, myalgia and arthralgia are among the commonly reported symptoms after intramuscular vaccination. A small painless nodule (induration) may also form at the injection site. These symptoms usually disappear within one to two days without treatment.Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur (confirmed anaphylaxis to an influenza vaccine is rare). Other allergic conditions, such as rashes, may occur more commonly and are not contraindications to further immunisation.A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Management of and reporting procedure for adverse reactions** | Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk> If vaccine administered is black triangle any suspected adverse reactions should be reported via the Yellow Card Scheme (see [Green Book Chapter 9](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/147870/Green-Book-Chapter-9.pdf)).Any adverse reaction to a vaccine should be documented in the individual’s occupational health record (if given by an OHS or other appropriate employment record if not given by an OHS) and the individual’s GP should be informed. |
| **Written information to be given to client** | Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.  |
| **Client advice / follow up treatment** | Individuals should be advised regarding adverse reactions to vaccination and reassured that the inactivated vaccine cannot cause influenza. However, the vaccine will not provide protection for about 14 days and does not protect against other respiratory viruses that often circulate during the flu season. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. It is important to still immunise this group. The individual should also consider directing their household contacts to their GPs for vaccination. Inform the individual of possible side effects and their management. The individual should be advised to seek medical advice in the event of an adverse reaction.When administration is postponed advise the individual how future vaccination may be accessed.Individuals should be advised that annual vaccination is recommended.Individuals in a clinical risk group recommended seasonal influenza vaccine should be encouraged to inform their GP (and midwife if relevant) once they have received influenza vaccine for the current season so their medical records (and maternity records if relevant) can be updated accordingly. Individuals who decline immunisation from their OHS provider and who are immunised elsewhere should be encouraged to inform their employer of their immunisation status as per local policy. Resources to share with clients are available at: <https://www.gov.uk/government/collections/annual-flu-programme>  |
| **Special considerations / additional information** | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. Inactivated influenza vaccine may be administered to breastfeeding women. Inactivated influenza vaccine should be administered to pregnant women, who are in a clinical risk group for influenza. |
| **Records** | Record in line with local procedure: * that valid informed consent was given
* name of individual, address, date of birth and GP with whom the individual is registered
* name of immuniser
* name and brand of vaccine
* date of administration
* dose, form and route of administration of vaccine
* quantity administered
* batch number and expiry date
* anatomical site of vaccination
* advice given, including advice given if excluded or declines immunisation
* details of any adverse drug reactions and actions taken
* administered under written instruction

Records should be signed and dated (or password-controlled immuniser’s record on e-records). All records should be clear, legible and contemporaneous.As a wide variety of influenza vaccines are available on the UK market each year, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual’s records. It is important that vaccinations given within Occupational Health settings are recorded according to OH principles and ethics and in a timely manner. Local policy should be followed to encourage information sharing with the individual’s General Practice where the individual would be eligible for immunisation under the national influenza programme to allow appropriate clinical follow up, improve data capture of vaccination status and to avoid duplicate vaccination.A record of all individuals receiving treatment under this written instruction should also be kept for audit purposes in accordance with local policy. |

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| **Key references**  | **Inactivated influenza vaccination*** Immunisation Against Infectious Disease: The Green Book, [Chapter 19](https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19). Published 23 April 2019.

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>* Collection: Annual Flu Programme. Updated 10 June 2020.

<https://www.gov.uk/government/collections/annual-flu-programme>* The national flu immunisation programme 2020 to 2021: supporting letter. Published 14 May 2020.

<https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan>* PHE Inactivated Influenza Vaccine PGD.

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

<https://www.gov.uk/government/publications/influenza-vaccine-ovalbumin-content>* Summary of Product Characteristics

[www.medicines.org.uk](http://www.medicines.org.uk)**General*** Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>
* National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 <https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners>
* NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <https://www.nice.org.uk/guidance/mpg2>
* NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.

<https://www.nice.org.uk/guidance/mpg2/resources> * Reference guide to consent for examination or treatment, Department of Health, published 4 August 2009.

<https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>  |

1. **Practitioner authorisation sheet**

**Details of registered Nurses working for ……………..*Insert name of organisation*………………who have completed the required training and been assessed as competent (as detailed in Section 2 and confirmed by line manager/clinical supervisor signing below) who are authorised and willing to administer inactivated influenza vaccine in accordance with this written instruction as part of the named organisation’s occupational health scheme, which may include peer to peer immunisation:**

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| **Name** | **NMC Registration Number** | **Signature** | **Date** | **Clinical Supervisor/Line manager name** | **Clinical supervisor/line manager signature**  | **Date** |
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1. Residues from the manufacturing process may include barium sulphate, beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, kanamycin, neomycin, octoxinol-9, polymyxin, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details. [↑](#footnote-ref-2)