UK Health Security Agency

NHS England

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# National protocol for inactivated influenza vaccine

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| Reference no: | Inactivated influenza vaccine protocol |
| Version no: | v04.00 |
| Valid from: | 1 September 2022 |
| Expiry date: | 1 April 2023 |

This protocol is for the administration of inactivated influenza vaccine to individuals in accordance with the national influenza immunisation programme.

This protocol is for the administration of inactivated influenza vaccine by appropriately trained persons in accordance with regulation 247A of the Human Medicines Regulations 2012 (HMR 2012), inserted by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020.

**UK Health Security Agency (UKHSA) has developed this protocol for authorisation by or on behalf of the Secretary of State for Health and Social Care, to facilitate the delivery of the national influenza immunisation programme commissioned by NHS England (NHSE).**

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see Characteristics of staff). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The provider/contractor is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol under Characteristics of staff must be adhered to.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

Persons must be authorised by name to work under this protocol. They must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing. This can be done by completing Section 4 of this protocol or maintaining an equivalent electronic record.

A clinical supervisor[1], who must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol, must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. Any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol must be recorded for the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains overall responsibility. Staff working to the protocol must understand who the clinical supervisor for their practice at any time is and can only proceed with their authority. The clinical supervisor may withdraw this authority for all members of staff or

[1] This role is different to the Band 6 'COVID-19 Vaccination Programme - RHCP Clinical Supervisor (Vaccinations)' (see Accountability and delegation under the national protocols for COVID-19 vaccines: visual diagram at Coronavirus » Summary of the legal mechanisms for administering the COVID-19 vaccine(s) (england.nhs.uk)).

individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Operation under this protocol is the responsibility of service providers/contractors. Provider organisations/contractors using this protocol should retain copies, along with the details of those authorised to work under it, for 25 years after the protocol expires.

Persons must check that they are using the current version of this protocol and current versions of any documents this protocol refers to. Amendments may become necessary prior to the published expiry date. Current versions of national protocols for the national influenza immunisation programme, authorised by the Department of Health and Social Care Ministers in accordance with regulation 247A of the HMR 2012, can be found at Annual flu programme.

Any concerns regarding the content of this protocol should be addressed to: immunisation@ukhsa.gov.uk

## Change history

| Version | Change details | Date |
|---|---|---|
| V01.00 (unapproved) | New national protocol for inactivated influenza vaccine | 7 December 2020 |
| V02.00 | National protocol for inactivated influenza vaccine V01.00 amended to:<br>• include inactivated influenza vaccines for the 2021 to 2022 season<br>• include eligible cohorts for the 2021 to 2022 season<br>• reflect the staff and supervision requirements of the national protocols for COVID-19 vaccination | 15 August 2021 |
| V03.00 | National protocol for inactivated influenza vaccine V02.00 amended to:<br>• include primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums<br>• update additional information and drug interactions sections<br>• update for change of organisation from PHE to UKHSA | 12 October 2021 |
| V04.00 | National protocol for inactivated influenza vaccine V03.00 amended to:<br>• include only eligible cohorts for the 2022 to 2023 season<br>• include the inactivated influenza vaccines for the 2022 to 2023 season<br>• remove the exclusion of 'individuals who are less than 2 years of age and have had a severe anaphylactic reaction to egg which has previously required intensive care' and update cautions and off-label section to advise egg-free cell-based influenza vaccine is offered off-label to these individuals in accordance with JCVI advice and the annual flu letter<br>• include minor rewording, layout and formatting changes for clarity and consistency with other national protocols | 24 June 2022 |

## 1. Ministerial authorisation

This protocol is not legally valid, in accordance with regulation 247A of the HMR 2012, inserted by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, until it is approved by or on behalf of the Secretary of State for Health and Social Care.

On 22 August 2022 Department of Health and Social Care Ministers approved this protocol in accordance with regulation 247A of HMR 2012.

Any provider/contractor administering inactivated influenza vaccine under this protocol must work strictly within the terms of this protocol and contractual arrangements with the commissioner, for the delivery of the national influenza immunisation programme.

The administration of the vaccines must also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics (SPC) and/or in accordance with official national recommendations.

Note: The national influenza immunisation programme may also be provided under a patient group direction or on a patient specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient specific direction (PSD)). Supply and administration in these instances should be in accordance with arrangements with the commissioner for the delivery of the national influenza immunisation programme and are not related to this protocol.

For occupational health provision, influenza immunisation may be provided under an occupational health written instruction or on the directions of an appropriate independent prescriber, such as under a PSD.

## 2. Characteristics of staff

| Classes of persons permitted to administer medicinal products under this protocol |
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This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see Table 2). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that there is a clinical supervisor present at all times and that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

This protocol is separated into operational stages of activity as outlined in Table 1.

The clinical supervisor[1] must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see page 1, for the overall provision of clinical care provided under the legal authority of the protocol.

**Table 1: Operational stages of activity under this protocol**

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| Stage 1 | a. Assessment of the individual presenting for vaccination<br>b. Provide information and obtain informed consent[2]<br>c. Provide advice to the individual | Specified Registered Healthcare Professionals Only (see Table 2) |
| Stage 2 | Vaccine Preparation | Registered or non-registered persons |
| Stage 3 | Vaccine Administration | Registered or non-registered persons |
| Stage 4 | Record Keeping | Registered or non-registered persons |

Persons must only work under this protocol where they are competent to do so.

Non-professionally qualified persons operating under this protocol must be adequately supervised by experienced registered healthcare professionals.

Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must also abide by their professional code of conduct.

To undertake the assigned stage(s) of activity under this protocol, persons working to this protocol must meet the criteria specified in Table 2 (see below).

[2] For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the Mental Capacity Act 2005

**Table 2: Protocol stages and required characteristics of persons working under it**

| Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol: | Stage 1 | Stage 2 | Stage 3 | Stage 4 |
|---|---|---|---|---|
| must be authorised by name as an approved person under the current terms of this protocol before working to it, see Section 4 | Y | Y | Y | Y |
| must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent[2] and must be an appropriately qualified prescriber or one of the following registered professionals who can operate under a PGD or as an occupational health vaccinator in accordance with HMR 2012:<br>• nurses, nursing associates and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>• chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)<br>• dental hygienists and dental therapists registered with the General Dental Council<br>• optometrists registered with the General Optical Council | Y | N | N | N |
| must be familiar with the vaccine product and alert to any changes in the manufacturers SPC and familiar with the national recommendations for the use of the vaccine | Y | Y | Y | N |
| must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book | Y | Y | Y | N |
| must be familiar with, and alert to changes in relevant local Standard Operating Procedures (SOPs) and commissioning arrangements for the national influenza immunisation programme | Y | Y | Y | Y |
| must have undertaken training appropriate to this protocol and relevant to their role, as required by relevant local policy and SOPs. For further information see Flu immunisation training recommendations | Y | Y | Y | N |
| must have undertaken training to meet the minimum standards in relation to vaccinating those under 18, if relevant, as required by national or local policy. | Y | N | Y | N |
| must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine | N | Y | Y | N |
| must be competent in intramuscular injection technique if they are administering the vaccine | N | N | Y | N |
| must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions | Y | N | Y | N |
| must have access to the protocol and relevant influenza immunuisation programme online resources such as the Green Book, particularly Chapter 19, and the Inactivated influenza vaccine: Information for healthcare practitioners document | Y | Y | Y | N |
| must understand the importance of making sure vaccine information is recorded on the relevant data system, meeting the relevant competencies of the flu vaccinator competency assessment tool | Y | Y | Y | Y |
| must have been signed off as competent using the flu vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months), or have used the tool for self-assessment if an experienced vaccinator (vaccinating within past 12 months) | Y | Y | Y | Y |
| should fulfil any additional requirements defined by local or national policy | Y | Y | Y | Y |

## STAGE 1: Assessment of the individual presenting for vaccination

| ACTIVITY STAGE 1a: | **Assess the individual presenting for vaccination against the inclusion and exclusion criteria below. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.** |
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| **Clinical condition or situation to which this Protocol applies** | Inactivated influenza vaccine is indicated for the active immunisation of individuals for the prevention of influenza infection, in accordance with the national immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: the 'Green Book', annual flu letter(s) and subsequent correspondence/publications from UKHSA and/or NHSEI. |
| **Criteria for inclusion**<br><br>Continued over page | **This protocol includes vaccination of individuals across the national influenza immunisation programme. Users of this protocol should note that where they are commissioned to immunise certain groups this protocol does not constitute permission to offer influenza immunisation beyond the groups they are commissioned to immunise.**<br><br>For the 2022 to 2023 influenza season, influenza vaccine should be offered under the NHS influenza immunisation programme to the following groups:<br>• individuals aged 65 years or over (including those becoming age 65 years by 31 March 2023)<br>• healthy individuals aged 50 to 64 years (including those becoming age 50 years by 31 March 2023) eligible from 15 October 2022<br>• individuals aged from 6 months to less than 65 years of age in a clinical risk group category listed in Chapter 19 of the Green Book such as those with:<br>  ○ chronic (long-term) respiratory disease, such as asthma (that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission), chronic obstructive pulmonary disease (COPD) or bronchitis<br>  ○ chronic heart disease and vascular disease, such as heart failure<br>  ○ chronic kidney disease at stage 3, 4 or 5<br>  ○ chronic liver disease<br>  ○ chronic neurological disease, such as Parkinson's disease or motor neurone disease<br>  ○ learning disability<br>  ○ diabetes and adrenal insufficiency<br>  ○ asplenia or dysfunction of the spleen<br>  ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)<br>  ○ morbidly obese adults (aged from 16 years) with a BMI of 40 and above<br>• all pregnant women (including those women who become pregnant during the influenza season)<br>• household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable<br>• people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, university halls of residence or boarding schools<br>• those who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill<br>• frontline staff without employer led occupational health schemes, employed:<br>  ○ by a registered residential care or nursing home or registered |

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| **Criteria for inclusion** (continued) | domiciliary care provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza<br>○ by a voluntary managed hospice provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza<br>○ through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals<br>• children eligible for the Routine Childhood Seasonal Influenza Vaccination Programme (aged 2 years to 10 years on 31 August 2022) for whom live attenuated influenza vaccine (LAIV) is contraindicated (or is otherwise unsuitable, for instance due to the route of administration or non-acceptance of porcine gelatine content)<br><br>Additionally, in 2022 to 2023, subject to sufficient influenza vaccine supplies being available nationally, the following additional cohorts will be offered influenza vaccination:<br>• secondary school-aged children focusing on Years 7, 8 and 9 and any remaining vaccine will be offered to years 10 and 11, subject to vaccine availability (see Special considerations / Additional information) |
| **Criteria for exclusion**[3] | Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book). The vaccine product patient information leaflet should be available to inform consent.<br><br>Individuals who:<br>• are less than 6 months of age<br>• are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is not contraindicated (or not otherwise unsuitable, for instance due to the route of administration or non-acceptance of porcine gelatine content) and is available. Note: LAIV should be given to those aged 2 to under 18 years of age in preference to inactivated influenza vaccine where possible, see LAIV PGD<br>• have had a confirmed anaphylactic reaction to a previous dose of the vaccine<br>• have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[4] (other than ovalbumin – see Cautions)<br>• have received a complete dose of the recommended influenza vaccine for the current season, unless they are individuals aged 6 months to less than 9 years in a clinical risk group category listed in Chapter 19 of the 'Green Book' who should, in the first season they are vaccinated against influenza, receive a second dose of an appropriate influenza vaccine at least 4 weeks after the first dose<br>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) |
| **Cautions including any relevant action to be taken**<br><br>Continued over page | Individuals with a bleeding disorder may develop a haematoma at the injection site. 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 |

[3] Exclusion under this protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

[4] Residues from the manufacturing process may include beta-propiolactone, cetyltrimethylammonium bromide (CTAB), formaldehyde, gentamicin, hydrocortisone, kanamycin, neomycin, octoxinol-9, octylphenol ethoxylate, polysorbate 80, sodium deoxycholate. Check the vaccine products SPC for details.

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| **Cautions including any relevant action to be taken** (continued) | haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. 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 (23 gauge or 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. If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.<br>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 QIVc or QIVr. 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 for 0.5 ml dose). For details of the influenza vaccines available for the 2022 to 2023 season and their ovalbumin content see All influenza vaccines marketed in the UK for the 2022 to 2023 season.<br>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 individual is excluded** | The risk to the individual of not being immunised must be taken into account. The indications for flu vaccination are not exhaustive, and the healthcare practitioner should consider the risk of flu exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from flu itself. Where appropriate, such individuals should be referred, or a PSD obtained for immunisation.<br>In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.<br>Document the reason for exclusion and any action taken.<br>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.<br>Inform or refer to the GP or a prescriber as appropriate. |
| **Action to be taken if the individual or carer declines treatment** | Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests.<br>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.<br>Document advice given and the decision reached. |
| **Referral procedure** | As per local policy. |

## STAGE 1b: Description of treatment

<table>
<tr><th>ACTIVITY STAGE 1b:</th><th>Consider any relevant cautions, interactions or adverse drug reactions.<br>Provide advice to the individual and obtain informed consent[2].<br>Record individual's consent[2] and ensure vaccinator, if another person, is informed of the vaccine product to be administered.</th></tr>
<tr><td>Name, strength & formulation of drug</td><td>Inactivated influenza vaccine suspension in a pre-filled syringe, including:<ul><li>adjuvanted quadrivalent influenza vaccine (aQIV)</li><li>cell-based quadrivalent influenza vaccine (QIVc)</li><li>egg-grown quadrivalent influenza vaccine (QIVe)</li><li>recombinant quadrivalent influenza vaccine (QIVr), Supemtek▼</li></ul>Note: This protocol does not include high-dose quadrivalent influenza vaccine (QIV-HD) or trivalent influenza vaccines as these vaccines are not eligible for re-imbursement under the NHS influenza vaccination programme for the 2022 to 2023 season, see All influenza vaccines marketed in the UK for the 2022 to 2023 season.<br><br>Some influenza vaccines are restricted for use in particular age groups. The SPC for individual products should always be referred to.<br><br>Summary table of which influenza vaccines to offer (by age)<br><table><tr><th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals (see Criteria for inclusion)</th></tr><tr><td>6 months to under 2 years</td><td>Offer QIVe<br>For egg-allergic children under 2 years it is advised that QIVc may be offered off-label (see Cautions).</td></tr><tr><td>2 years to under 18 years</td><td>If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc[5]</td></tr><tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVr<br>Or, if QIVc or QIVr are not available, offer QIVe.</td></tr><tr><td>65 years[6] and over[7]</td><td>Offer aQIV or QIVr<br>Or, if aQIV or QIVr is not available, offer QIVc<br>For those aged 64 who turn 65 years of age before 31 March 2023, aQIV may be offered off-label.</td></tr></table></td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM)</td></tr>
<tr><td>Black triangle▼</td><td>QIVc, QIVr and aQIV products are black triangle.<br>The QIVe vaccine from Viatris (formerly Mylan), Influvac® sub-unit Tetra, is black triangle.<br>This information was accurate at the time of writing. See product SPCs for indication of current black triangle status.</td></tr>
<tr><td>Off-label use<br><br>Continued over page</td><td>Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</td></tr>
</table>

[5] QIVe is suitable to offer to these children but as a second option. QIVe has not been procured by UKHSA for this age group.
[6] Including those turning age 65 years by 31 March 2023
[7] JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.

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| **Off-label use** (continued) | The aQIV is licensed for administration to individuals aged 65 years and over. It may be administered under this protocol to those aged 64 years and turning 65 years of age by 31 March 2023 in accordance with the recommendations for the national influenza immunisation programme for the 2022 to 2023 season (see Appendix C of the annual flu letter dated 22 April 2022).<br><br>QIVc is licensed for those aged from 2 years. QIVc, which is egg-free, can be administered under this Protocol to egg allergic children aged 6 months to less than 2 years as advised by JCVI (see Appendix D of the annual flu letter dated 22 April 2022).<br><br>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this protocol.<br><br>Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this protocol, unless permitted off-label administration is detailed above. Refer to products' SPCs, available from the electronic medicines compendium website, and All influenza vaccines marketed in the UK for the 2022 to 2023 season for more information. |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.<br><br>Because of the absence of data on co-administration of Shingrix® vaccine with adjuvanted influenza vaccine, it should not be routine to offer appointments to give this vaccine at the same time as the adjuvanted influenza vaccine. Based on current information, scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals attend requiring both vaccines, however, and require rapid protection or are considered likely to be lost to follow up, co-administration may still be considered.<br><br>Inactivated influenza vaccine may be given at the same time as other vaccines (See Route / method of administration). Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects.<br><br>As all of the current COVID-19 vaccines are considered inactivated (including the non-replicating adenovirus vaccine), where individuals in an eligible cohort present having recently received COVID-19 vaccination, influenza vaccination should still be given.<br>A detailed list of drug interactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website. |
| **Identification and management of adverse reactions**<br><br>Continued over page | 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 1 to 2 days without treatment.<br><br>Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur. |

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| **Identification and management of adverse reactions** (continued) | A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines.<br><br>The frequency of injection site pain and systemic reactions may be higher in individuals vaccinated concomitantly with inactivated influenza vaccine and pneumococcal polysaccharide vaccine (PPV23) compared to vaccination with influenza vaccine alone and similar to that observed with PPV23 vaccination alone. Influenza vaccine and PPV23 may be administered at the same visit or at any interval from each other.<br><br>A detailed list of adverse reactions is available in the SPC for each vaccine, which are available from the electronic medicines compendium website. |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.<br><br>QIVe vaccine from Viatris (formerly Mylan), QIVc, QIVr and aQIV are black triangle. Therefore, any suspected adverse reactions should be reported via the Yellow Card Scheme.<br><br>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed as appropriate. |
| **Written information to be given to individual or carer** | Offer the individual the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. |
| **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.<br><br>Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Therefore, consideration should be given to the influenza vaccination of their household contacts.<br><br>Inform the individual/parent/carer of possible side effects and their management.<br><br>The individual/parent/carer should be advised when to seek medical advice in the event of an adverse reaction.<br><br>When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due. |
| **Special considerations / additional information**<br><br>Continued over page | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.<br><br>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.<br><br>For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent see Chapter 2 of 'The Green Book').<br><br>Individuals with learning disabilities may require reasonable adjustments to support vaccination (see Flu vaccinations for people with learning disabilities). A PSD may be required. |

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| **Special considerations / additional information** (continued) | The licensed ages for the 2022 to 2023 season influenza vaccines are:<br>• QIVe licensed from 6 months of age<br>• QIVc licensed from 2 years of age (see off-label section)<br>• QIVr licensed from 18 years of age<br>• aQIV licensed from 65 years of age (see off-label section)<br><br>For 50 to 64 year olds, the advice of JCVI is the most vulnerable cohorts should be prioritised over the otherwise healthy 50 to 64 year olds and given the most effective vaccines available first, QIVr or QIVc where possible, while QIVe should be reserved for otherwise healthy 50 to 64 year olds. However, QIVe is suitable to offer as a second option for vulnerable cohorts.<br><br>School aged children will be offered the flu vaccination through the school age immunisation service via school or community settings. Primary school aged children will be prioritised earlier in the season with secondary school aged children in years 7, 8 and 9 being invited later. Should vaccine supplies allow further secondary school years may be included upon the instruction of the Commissioner. The date from which individuals in these additional cohorts may be vaccinated will be communicated directly with the Provider by their Commissioner. |

## STAGE 2: Vaccine Preparation

| ACTIVITY STAGE 2: | Vaccine preparation |
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| **Vaccine presentation** | Single (0.5ml) dose pre-filled syringe |
| **Supplies** | Centrally procured vaccine is available via ImmForm for children.<br>Supplies for administration to adults should be ordered from the influenza vaccine manufacturers/wholesalers as in previous years.<br>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3). |
| **Storage** | Store at +2°C to +8°C. Do not freeze.<br>Store in original packaging in order to protect from light.<br>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 Vaccine Incident Guidance. |
| **Vaccine preparation** | Vaccine supplied in single (0.5ml) dose pre-filled syringe.<br>Shake vaccine before administration.<br>Inspect visually prior to administration for foreign particulate matter and/or discoloration and ensure appearance is consistent with the description in the product's SPC. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). |

## STAGE 3: Vaccine administration

<table>
<tr><td>ACTIVITY STAGE 3:</td><td>Before administering the vaccine, ensure:<br>1. The individual has been assessed in accordance with stage one of this protocol.<br>2. The vaccine to be administered has been identified, by the registered practitioner consenting the individual<br>3. Consent for vaccination has been provided and documented[2].<br>Administer the inactivated influenza vaccine recommended by the assessing practitioner, in accordance with the summary table below, and provide any post-vaccination advice.</td></tr>
<tr><td>Vaccine to be administered</td><td>Inactivated influenza vaccine 0.5ml dose.<br>Summary table of which influenza vaccines to offer (by age)
<table>
<tr><th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals (see Criteria for inclusion)</th></tr>
<tr><td>6 months to under 2 years</td><td>Offer QIVe<br>For egg-allergic children under 2 years it is advised that QIVc may be offered off-label (see Cautions).</td></tr>
<tr><td>2 years to under 18 years</td><td>If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc[8]</td></tr>
<tr><td>18 years to under 65 years</td><td>Offer QIVc or QIVr<br>Or, if QIVc or QIVr are not available, offer QIVe</td></tr>
<tr><td>65 years[9] and over[10]</td><td>Offer aQIV or QIVr<br>Or, if aQIV or QIVr are not available, offer QIVc<br>For those aged 64 years who turn 65 years of age before 31 March 2023, aQIV may be offered off-label</td></tr>
</table></td></tr>
<tr><td>Dose and frequency of administration</td><td>Single 0.5ml dose to be administered for the current annual flu season.<br>Children in a clinical risk group aged 6 months to less than 9 years old who have not previously received any doses of influenza vaccine should be offered a second dose of vaccine at least 4 weeks later. The influenza vaccines are interchangeable, although the individual’s age, recommended vaccine and vaccine licence should be considered (see Off-label use section).<br>JCVI has advised that when a choice of either a 0.25ml or 0.5ml dose is indicated in the SPC, the 0.5ml dose of inactivated influenza vaccine should be given to individuals from age 6 months because there is evidence that this dose is effective in young children.</td></tr>
<tr><td>Duration of treatment</td><td>Single 0.5ml dose for the current annual flu season (1 September 2022 to 31 March 2023).<br>Children aged 6 months to less than 9 years old in a clinical risk group who have not received influenza vaccine previously should be offered a second dose of the vaccine at least 4 weeks later.</td></tr>
</table>

[8] QIVe is suitable to offer to these children but as a second option. QIVe has not been procured by UKHSA for this age group.
[9] Including those turning age 65 years by 31 March 2023
[10] JCVI recommended use of QIV-HD in this age group but this is not currently available in the UK market.

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| **Quantity to be supplied / administered** | Single dose of 0.5ml per administration. |
| **Route / method of administration** | Administer by intramuscular injection, preferably into deltoid region of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under 1 year old.<br><br>Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, a fine needle (23 gauge or 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/carer should be informed about the risk of haematoma from the injection.<br><br>When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all of the vaccinations.<br><br>The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. If aQIV needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs. The site at which each vaccine was given should be noted in the individual's records.<br><br>Shake vaccine before administration.<br><br>Inspect visually prior to administration and ensure appearance is consistent with the description in the products SPC.<br><br>The SPCs provide further guidance on administration and are available from the electronic medicines compendium website. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). |
| **Post-vaccination advice** | Ensure the individual has been provided appropriate written information such as the:<br>• Market authorisation holder's patient information leaflet (PIL) |

## STAGE 4: Recording vaccine adminstration

| ACTIVITY STAGE 4: | **Complete a record of vaccination for the individual and in accordance with local policy.**<br><br>**The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.** |
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| **Records** | Record:<br>• that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005<br>• name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP)<br>• name of clinical supervisor<br>• name of immuniser and, where different from the immuniser, ensure the professional assessing the individual and person completing the vaccine record are identified<br>• name and brand of vaccine<br>• date of administration<br>• dose, form and route of administration of vaccine<br>• quantity administered<br>• batch number and expiry date<br>• anatomical site of vaccination<br>• advice given, including advice given if excluded or declines immunisation<br>• details of any adverse drug reactions and actions taken<br>• supplied via national protocol<br><br>All records should be clear, legible and contemporaneous.<br><br>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.<br><br>It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination.<br><br>For pregnant women, also record immunisation in the hand held and electronic maternity record if available.<br><br>A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy. |

## 3. Key references

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| **Key references** | **Inactivated influenza vaccination**<br>• Immunisation Against Infectious Disease: The Green Book, Chapter 19. Updated 29 October 2020 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br>• Collection: Annual Flu Programme 26 July 2022. https://www.gov.uk/government/collections/annual-flu-programme<br>• The national flu immunisation programme 2022 to 2023: supporting letter. Published 22 April 2022 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan<br>• Statement of amendments to annual flu letter – 21 July 2022 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/statement-of-amendments-to-annual-flu-letter-21-july-2022<br>• Enhanced Service Specification, Seasonal influenza and vaccination programme 2022 to 2023 https://www.england.nhs.uk/gp/investment/gp-contract/<br>• Community Pharmacy Seasonal Influenza Vaccine Service https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/<br>• All influenza vaccines marketed in the UK for the 2022 to 2023 season https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk<br>• Live attenuated influenza vaccine (LAIV) PGD https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template<br>• Written instruction for the administration of seasonal 'flu vaccination. NHS Specialist Pharmacy Service. 22 June 2022 https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/<br>• Summary of Product Characteristics www.medicines.org.uk<br>• Flu immunisation training recommendations. Updated 12 August 2022 https://www.gov.uk/government/publications/flu-immunisation-training-recommendations<br>• Flu Vaccinations: Supporting people with learning disabilities. Updated 25 September 2018 https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities<br><br>**General**<br>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/<br>• Immunisation Against Infectious Disease: The Green Book. Chapter 2. Updated 18 June 2021 https://www.gov.uk/government/publications/consent-the-green-book-chapter-2 |

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| **Key references**<br>Continued | • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them<br>• UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation<br>• Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors<br>• Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012, as amended. https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A<br>• UK Statutory Instrument 2022 No. 350, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022. https://www.legislation.gov.uk/uksi/2022/350/made |

## 4. Practitioner/staff authorisation sheet

**Inactivated influenza vaccine protocol v04.00**
**Valid from: 1 September 2022 Expiry: 1 April 2023**

This authorisation sheet should be retained to serve as a record of those persons authorised to work under this protocol.

By signing this protocol you are indicating that you agree to its contents and that you will work within it.

Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must abide by their professional code of conduct.

It is the responsibility of each person operating under this protocol to do so within the bounds of their own competence.

| I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it. | | | | | | | |
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| Name | Designation | Activity Stage: | | | | Signature | Date |
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### Authorising registered healthcare professional

| I confirm that I, as a registered healthcare professional who is familiar with the competence required in all aspects of this protocol, provide authority on behalf of the below named provider organisation, that the persons named above are competent to work under this protocol and may provide vaccination in accordance with this protocol in the course of working for **insert name of organisation / service** | | | |
|---|---|---|---|
| Name | Designation | Signature | Date |
| | | | |

### Note to authorising registered healthcare professional

Score through unused rows in the list of persons to prevent additions post authorisation.

If the clinical supervisor is also the authorising registered healthcare professional, they may make a self-declaration of competency above