UK Health Security Agency

NHS England

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National protocol for inactivated influenza vaccine

Reference no:	Inactivated influenza vaccine protocol
Version no:	v6.00
Valid from:	1 September 2024
Expiry date:	1 April 2025

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.

The 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 or contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The provider or 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 or 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, 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 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 or contractors. Provider organisations or 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.

Individual users 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
v1.00 (unapproved)	New national protocol for inactivated influenza vaccine	7 December 2020
v2.00	National protocol for inactivated influenza vaccine v1.00 amended to: • include inactivated influenza vaccines for the 2021 to 2022 season • include eligible cohorts for the 2021 to 2022 season • reflect the staff and supervision requirements of the national protocols for COVID-19 vaccination	15 August 2021
v3.00	National protocol for inactivated influenza vaccine v2.00 amended to: • include primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums • update additional information and drug interactions sections • update for change of organisation from PHE to UKHSA	12 October 2021
v4.00	National protocol for inactivated influenza vaccine v3.00 amended to: • include only eligible cohorts for the 2022 to 2023 season • include the inactivated influenza vaccines for the 2022 to 2023 season • 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 • include minor rewording, layout and formatting changes for clarity and consistency with other national protocols	24 June 2022
v5.00	National protocol for inactivated influenza vaccine amended to: • include eligible cohorts for the 2023 to 2024 season • include the recommended influenza vaccines for the 2023 to 2024 season • include updated advice on co-administration of aQIV with Shingrix® (shingles) vaccine	17 July 2023
v6.00	National protocol for inactivated influenza vaccine amended to: • update eligibility criteria for the 2024 to 2025 season • advise earlier immunisation of pregnant women and children from 1 September; remaining cohorts to commence October (precise date TBC by NHS England) • reflect reduction in QIVc licensed age from 2 years to 6 months of age • incorporate amendments to the flu letter from 12 June 2024, including choice of vaccines recommended by age; separation of the 18 to 64 year cohort into 18 to 59 years and 60 to 64 years to reflect QIV-HD licensing • include pharmacy technicians as an additional professional group, as outlined in the relevant amendments to HMR 2024 • include minor rewording, layout and formatting changes for consistency with other UKHSA PGDs and National Protocols	20 June 2024

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 28 June 2024, Department of Health and Social Care Ministers approved this protocol in accordance with regulation 247A of HMR 2012.

Any provider or contractor administering inactivated influenza vaccines 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.

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 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.

1. Characteristics of staff

Classes of persons permitted to administer medicinal products under this protocol

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 or contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider or 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 or 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 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

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent[1] 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).

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[1] 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: • nurses, nursing associates and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)	Y	N	N	N

	• 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) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council				
	must be familiar with the vaccine product and alert to any changes in the manufacturer's 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 immunisation programme online resources such as the Green Book, particularly Chapter 19, and 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

[1] For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the Mental Capacity Act 2005 (for further information on consent, see Chapter 2 of the Green Book).

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.
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. Immunisation is indicated 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 and publications from the UKHSA and NHSE.
Criteria for inclusion (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.** For the 2024 to 2025 influenza season, influenza vaccine should be offered under the NHS influenza immunisation programme to the following groups: **From 1 September 2024**: • all pregnant women (including those women who become pregnant during the influenza season) • children eligible for the Routine Childhood Seasonal Influenza Vaccination Programme and for who live attenuated influenza vaccine (LAIV) is contraindicated or is otherwise unsuitable, for instance due to the route or non-acceptance of porcine gelatine content. See the LAIV PGD for more information. For the 2024/2025 influenza season, eligible children include: • children aged 2 or 3 years of age, on or before 31 August 2024[2] • all primary school-aged children (from Reception to Year 6)[3,4] • all secondary school-aged children (from Years 7 to 11)[3,4] • those in clinical risk groups (as outlined below) aged from 6 months to less than 18 years **The precise date from which all other eligible individuals may be vaccinated will be communicated by NHSE; at the time of writing, this has been planned from October.** **Upon announcement of this date, this Protocol may be used for vaccination of the following cohorts**: • individuals aged 65 years or over (including those turning 65 years by 31 March 2025) • individuals aged from 18 years to less than 65 years of age in a clinical risk group category listed in Chapter 19 **Clinical risk groups** ○ 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 chronic bronchitis ○ chronic heart disease and vascular disease ○ chronic kidney disease at stage 3, 4 or 5

[2] Children born between 1 September 2020 and 31 August 2022 are considered eligible.
[3] School children outside the usual age range for their class (for example those accelerated or held back a year) may be offered and given the vaccine alongside their peers.
[4] Includes children who are home-schooled or otherwise not in mainstream education.

Criteria for inclusion (continued)	○ chronic liver disease ○ chronic neurological disease, such as Parkinson's disease or motor neurone disease ○ learning disability ○ diabetes and adrenal insufficiency ○ asplenia or dysfunction of the spleen ○ a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as for cancer) ○ morbidly obese adults (aged from 16 years) with a BMI of 40kg/m^2 and above • household contacts of immunocompromised individuals. This specifically includes individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable • 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 • carers: those who are in receipt of a carer's allowance, or who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill • frontline staff without employer-led occupational health schemes, employed: ○ by a registered residential care or nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable individuals who are at increased risk from exposure to influenza ○ 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 ○ through Direct Payments (personal budgets) or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to individuals ○ to deliver social care services and are in direct contact with those who are clinically vulnerable to flu, who receive care and support services from the social care provider
Criteria for exclusion[5] (continued over page)	Individuals who have not given valid consent (or for whom a 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. Several sources are available to inform consent (see written information to be given to individual, parent or carer section). Individuals who: • are less than 6 months of age • are aged 2 years to under 18 years for whom live attenuated influenza vaccine (LAIV) is suitable or not contraindicated (for instance due to the route of administration or non-acceptance of porcine gelatine content). 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 • have had a confirmed anaphylactic reaction to a previous dose of the vaccine • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)

[5] 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.

Criteria for exclusion (continued)	• have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[6] (other than ovalbumin – see cautions) • 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 (or other eligible) 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 **Note: This Protocol covers NHS commissioned services. It may not be used for the provision of inactivated influenza vaccine via occupational health schemes or peer-to-peer influenza immunisation. A written instruction should be used instead, for which the NHS Specialist Pharmacy Service produces a template.**
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Individuals with a bleeding disorder may develop a haematoma at the injection site (see route and method of administration). Adults with a severe anaphylaxis to egg which has previously required intensive care can be immunised in any setting using a suitable egg-free vaccine, for instance QIVc. Individuals with a less severe egg allergy can be immunised in any setting using a suitable egg-free vaccine, or an inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml (equivalent to 0.06 micrograms per 0.5 ml dose). For details of the influenza vaccines available for the current season and their ovalbumin content, follow this link. 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. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Document the reason for exclusion and any action taken in the individual's clinical records. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. Inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the individual or carer declines treatment (continued over page)	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. Further information on consent may be found in Chapter 2 of the Green Book.

[6] 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's SPC for details

Action to be taken if the individual or carer declines treatment (continued)	Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached. Inform or refer to the individual's GP or a prescriber as appropriate.
Referral procedure	As per local policy.

Stage 1b and 1c : Description of treatment and advice to the individual

<table>
<tr><td>Activity stages 1b and 1c:</td><td>Consider any relevant cautions, interactions or adverse drug reactions. Provide advice to the individual and obtain informed consent[1]. Record individual's consent[1] and ensure the vaccinator (if another person) is informed of the vaccine product to be administered.</td></tr>
<tr><td>Name, strength & formulation of drug</td><td>Inactivated influenza vaccine suspension in a pre-filled syringe, including:
adjuvanted quadrivalent influenza vaccine (aQIV)▼
cell-based quadrivalent influenza vaccine (QIVc) ▼
egg-grown quadrivalent influenza vaccine (QIVe)
high-dose quadrivalent influenza vaccine (QIV-HD)▼
Some influenza vaccines are restricted for use in particular age groups. Refer to the vaccine's SPC, recommended vaccines and the off-label use section for further information.
Summary table of which inactivated influenza vaccines to offer (by age)
<table>
<tr><th>Age</th><th>Inactivated influenza vaccine to offer eligible individuals</th><th>Notes</th></tr>
<tr><td>6 months to under 2 years</td><td>Offer QIVc.
If QIVc is not available, offer QIVe.</td><td></td></tr>
<tr><td>2 years to under 18 years</td><td>If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc.
If QIVc is not available, offer QIVe.</td><td>QIVe not available via ImmForm for this cohort.</td></tr>
<tr><td>18 years to 59 years (including in pregnancy)</td><td>Offer QIVc.
If QIVc is not available[7], offer QIVe.</td><td></td></tr>
<tr><td>60 to 64 years</td><td>Offer QIVc or QIV-HD.
If QIVc or QIV-HD are not available[8], offer QIVe.</td><td></td></tr>
<tr><td>65 years and over, including those turning 65 by 31 March 2025</td><td>Offer aQIV or QIV-HD.
If aQIV or QIV-HD are not available[9], offer QIVc.
Note: QIVe is not recommended for those 65 years and over.</td><td>aQIV may be offered off-label for those aged 64 who turn 65 years of age by 31 March 2025</td></tr>
</table></td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM)</td></tr>
<tr><td>Black triangle▼
(continued over page)</td><td>QIVc, QIV-HD and aQIV vaccines are designated as black triangle products. Being newer vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these</td></tr>
</table>

[7] QIVe should be offered only when every attempt to use QIVc has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

[8] QIVe should be offered only when every attempt to use QIVc or QIV-HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

[9] QIVc should be offered only when every attempt to use aQIV or QIV-HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

Black triangle▼ (continued)	products. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme. This information was accurate at the time of writing. See product SPCs for indication of current black triangle status.
Off-label use	Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance. 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 2025, in accordance with the recommendations for the national influenza immunisation programme for the 2024 to 2025 season (see annual flu letter). Vaccines 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 vaccines are assessed in accordance with these guidelines as appropriate for continued use, this would constitute off-label administration under this protocol. Note: Different influenza vaccine products are licensed from different ages and should be administered within their licence when working to this protocol, with the exception of off-label administration of aQIV as detailed above. Refer to product SPCs, and Flu vaccines for the 2024 to 2025 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. Influenza vaccines can be co-administered with other vaccines including COVID-19 and shingles vaccines (see route and method of administration). Initially, a 7 day interval was recommended between Shingrix® (shingles) vaccine and adjuvanted influenza vaccine (aQIV) because the potential reactogenicity from 2 adjuvanted vaccines may reduce the tolerability in those being vaccinated. Interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. Therefore, an appointment for administration of the seasonal influenza vaccine can be an opportunity to also provide shingles vaccine (see Shingrix® PGD). Where aQIV is given with other vaccines, including other adjuvanted vaccines, the adverse effects of both vaccines may be additive and should be considered when informing the recipient. Individuals should also 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. A detailed list of drug interactions is available in the SPC for each vaccine.
Identification and management of adverse reactions (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 one to 2 days without treatment. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur. A higher incidence of mild post-immunisation reactions has been reported with adjuvanted compared to non-adjuvanted influenza vaccines. 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

Identification and management of adverse reactions (continued)	interval from each other. A detailed list of adverse reactions is available in the SPC for each vaccine.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and 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. QIVc, QIV-HD and aQIV are designated as black triangle products. All suspected adverse reactions to these vaccines should be reported via the Yellow Card Scheme, as these particular vaccines are newer to market. 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 marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Offer promotional material as appropriate: • the flu vaccination: who should have it and why (as updated for winter 2024 to 2025) • protect yourself from flu, have the flu vaccine: information for people with a learning disability leaflet For information leaflets in accessible formats and alternative languages, please visit Home-Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Advice and 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. Therefore, consideration should be given to influenza vaccination of their household contacts. Inform the individual, parent or carer of possible side effects and their management. The individual, parent or carer should be advised when to seek medical advice in the event of an adverse reaction and encouraged to report this via the Yellow Card reporting scheme. In case of postponement due to acute illness, advise when the individual can be vaccinated and how future vaccination may be accessed. When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations and additional information (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. 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. 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).

Special considerations and additional information (continued)	Individuals with learning disabilities may require reasonable adjustments to support vaccination (see Flu vaccinations for people with learning disabilities). **Timing of doses** As outlined in the flu letter, vaccination of pregnant women should begin from 1 September, to ensure that as many newborn babies as possible are protected during the flu season. Children, including those in clinical risk groups should be vaccinated from 1 September, as early as delivery and supply of suitable vaccines allow. Vaccination of remaining cohorts should commence from October (precise date to be confirmed by NHSE). There may be a small number of other adults for whom delaying vaccination is not advised, for example individuals due to commence immunosuppressive treatment before the announced start date for vaccination. Clinicians should use clinical judgement to bring forward vaccination in such exceptions and when vaccine supply becomes available. A PSD should be used.

Stage 2: Vaccine preparation

Activity stage 2:	Vaccine preparation
Vaccine presentation	Single (0.5ml) dose pre-filled syringe
Supplies	Centrally procured vaccine is available via ImmForm for children. Supplies for administration to adults should be ordered from the influenza vaccine manufacturers or their wholesalers as in previous years. 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. Store in original packaging in order to protect from light. 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	Shake vaccine suspensions gently before administration. Visually inspect the vaccine prior to administration for any foreign particulate matter, discoloration or other variation of expected appearance from that described in the vaccine's SPC. Discard the vaccine in accordance with local procedures, should any of these occur. Check product name, batch number and expiry date before administration.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 NHSE guidance in (HTM 07-01): safe and sustainable management of healthcare waste.

Stage 3: Vaccine administration

<table>
<tr><td>Activity stage 3:</td><td>Before administering the vaccine, ensure:
1. The individual has been assessed in accordance with stage one of this protocol.
2. The vaccine to be administered has been identified, by the registered practitioner consenting the individual
3. Consent for vaccination has been provided and documented[1].

Administer the inactivated influenza vaccine recommended by the assessing practitioner, in accordance with the summary table below. Provide any post-vaccination advice.</td></tr>
<tr><td>Vaccine to be administered</td><td>Some influenza vaccines are restricted for use in particular age groups. Refer to the individual vaccine's SPC, recommended vaccines and the off-label use section for further information.
Summary table of which inactivated influenza vaccines to offer (by age)
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<tr><td>6 months to under 2 years</td><td>Offer QIVc.
If QIVc is not available, give QIVe.</td><td></td></tr>
<tr><td>2 years to under 18 years</td><td>If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc.
If QIVc is not available, offer QIVe.</td><td>QIVe not available via Immform for this cohort.</td></tr>
<tr><td>18 years to 59 years (including in pregnancy)</td><td>Offer QIVc.
If QIVc is not available,[10] offer QIVe.</td><td></td></tr>
<tr><td>60 to 64 years</td><td>Offer QIVc or QIV-HD.
If QIVc or QIV-HD are not available[11], offer QIVe.</td><td></td></tr>
<tr><td>65 years and over, including those turning 65 by 31 March 2025</td><td>Offer aQIV or QIV-HD.
If aQIV or QIV-HD are not available[12], offer QIVc.
Note: QIVe is not recommended for those aged 65 years and over.</td><td>aQIV may be offered off-label for those aged 64 who turn 65 years of age by 31 March 2025.</td></tr>
</table></td></tr>
<tr><td>Dose and frequency of administration

(continued over page)</td><td>QIVc, QIVe and aQIV:
Single 0.5ml dose to be administered for the current annual flu season (1 September 2024 to 31 March 2025).
QIV-HD only:
Single 0.7ml dose during the current annual flu season.</td></tr>
</table>

[10] QIVe should be offered only when every attempt to use QIVc has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

[11] QIVe should be offered only when every attempt to use QIVc or QIV-HD has been exhausted- evidence of this may be requested by the commissioner before reimbursement is agreed.

[12] QIVc should be offered only when every attempt to use aQIV or QIV-HD has been exhausted – evidence of this may be requested by the commissioner before reimbursement is agreed.

Dose and frequency of administration (continued)	Children in a clinical risk group (including household contacts of immunocompromised individuals) 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).
Duration of treatment	As outlined above in dose and frequency of administration.
Quantity to be supplied and administered	**QIVc, QIV and aQIV**: Single dose of 0.5ml per administration. **QIV-HD**: Single dose of 0.7ml per administration.
Route and method of administration	Administer by intramuscular injection, preferably into the deltoid muscle of the upper arm. The anterolateral aspect of the thigh is the preferred site for infants under 1 year old. 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 or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or 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 individual's increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. Influenza vaccines licensed for both intramuscular and subcutaneous administration may alternatively be administered by the subcutaneous route. Note: QIVc and aQIV are not licensed for subcutaneous administration so should only be administered intramuscularly under this protocol. When co-administering with other vaccines, care should be taken to ensure that the appropriate route of injection is used for all of the vaccinations. 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. Shake vaccine suspensions gently before administration. Visually inspect the vaccine prior to administration for any foreign particulate matter, discoloration or other variation of expected appearance from that described in the vaccine's SPC. Discard the vaccine in accordance with local procedures, should any of these occur. The SPCs provide further guidance on administration.

Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 NHSE guidance in (HTM 07-01): Management and disposal of healthcare waste.
Post-vaccination advice	Ensure the individual has been provided with appropriate written information such as the: • Market authorisation holder's patient information leaflet (PIL) • the flu vaccination: who should have it and why (as updated for winter 2024 to 2025) • protect yourself from flu, have the flu vaccine: information for people with a learning disability leaflet For information leaflets in accessible formats and alternative languages, please visit Home – Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.

Stage 4: Recording vaccine adminstration

Activity stage 4:	**Complete a record of vaccination for the individual and in accordance with local policy.** **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.**
Records	The practitioner must ensure the following is recorded: • 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 • 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) • name of clinical supervisor • name of immuniser and, where different from the immuniser, ensure the professional assessing the individual and person completing the vaccine record are identified • 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 the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via national protocol 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 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. For pregnant women, also record immunisation in the hand-held and electronic maternity record if available. A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy.

2. Key references

Key references (continued over page)	**Inactivated influenza vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 19, updated 3 November 2023 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Collection: Annual Flu Programme https://www.gov.uk/government/collections/annual-flu-programme • The national flu immunisation programme 2024 to 2025: supporting letter, published 12 March 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/national-flu-immunisation-programme-2024-to-2025-letter • Statement of amendment to the annual flu letter for 2024 to 2025, published 12 June 2024 https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan-2024-to-2025/statement-of-amendment-to-the-annual-flu-letter-for-2024-to-2025-12-june-2024 • All influenza vaccines marketed in the UK for the 2024 to 2025 season, updated 21 March 2024 https://www.gov.uk/government/publications/influenza-vaccines-marketed-in-the-uk • JCVI advice on influenza vaccines for the 2024/ 2025 season, updated 25 August 2023 https://app.box.com/s/t5ockz9bb6xw6t2mrrzb144njplimfo0/file/1289995245447 • Community Pharmacy Advanced Service Specification: Seasonal Influenza https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service/ • Influenza vaccine written instruction templates for adoption, NHS Specialist Pharmacy Service, published 4 March 2024 https://www.sps.nhs.uk/articles/influenza-vaccine-written-instruction-templates-for-adoption/ • Flu immunisation training recommendations, updated 8 August 2023 https://www.gov.uk/government/publications/flu-immunisation-training-recommendations • Flu Vaccinations: Supporting people with learning disabilities, updated 25 September 2018 https://www.gov.uk/government/publications/flu-vaccinations-for-people-with-learning-disabilities **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • Immunisation Against Infectious Disease: The Green Book. Chapter 2, updated 12 October 2023 https://www.gov.uk/government/publications/consent-the-green-book-chapter-2 • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 February 2018 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners

Key references (continued)	• UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • 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 • UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 https://www.legislation.gov.uk/uksi/2024/729/introduction/made • 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 v6.00
Valid from: 1 September 2024 Expiry: 1 April 2025

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.							
Name	**Designation**	**Activity Stage:**				**Signature**	**Date**
		1	2	3	4		

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.