Inactivated Influenza Vaccine National Protocol

Reference No.:	Inactivated Influenza Vaccine
Protocol Version no:	V05.0
Valid from:	1 September 2024
Review date:	30 August 2025
Expiry date:	31 August 2025

1. About the National Protocol

This protocol is for the supply and administration of Inactivated Influenza Vaccine to individuals in accordance with the national influenza vaccination programme.

This protocol is for the supply and administration of Inactivated Influenza Vaccine by appropriately trained persons in accordance with regulation 247A of the Human Medicines Regulations 2012 .

The Scottish Government has developed this protocol which has been approved bythe Scottish Ministers to facilitate the delivery of the national influenza vaccination programme by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as "theprovider". Please note that in the context of this protocol, "the provider" means:

(a) a Health Board,
(b) a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
(c) an organisation delivering services on behalf of a Health Board.

This protocol may be followed wholly from patient assessment through to post- vaccination by a single person. Alternatively, obtaining consent and patient assessment may be undertaken by a registered healthcare professional with theprocess of administration undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision.

Where multiple person models are used the provider must ensure that all elements of the protocol are complied with in the provision of the vaccination to each patient.

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this protocol. As a minimum, competence requirements stipulated in the protocol under 'Characteristicsof staff' must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the protocol at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the protocol.

The clinical supervisor must be a registered healthcare professional trained andcompetent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

The clinical supervisor must be identifiable to service users. Whenever the protocol is used, the name of the clinical supervisor taking responsibility and all of the peopleworking under

different activity stages of the protocol must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the protocol must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the protocol as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working underthe protocol in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this protocol. Individuals working in accordance with this protocol must ensure they meet the staffcharacteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this protocol or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this protocol. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that the provider adheres to this protocol. The final authorised copy of this protocol should be kept, by Health Boards for 8 years after the protocol expires. Providers adopting authorised versions of this protocol should also retain copies, along with the detailsof those authorised to work under it, for 8 years after the protocol expires.

It is Health Boards' responsibility to ensure they and any organisations they make arrangements with to deliver services on their behalf operate the specified vaccination services in accordance with the protocol. Any provider administering Inactivated Influenza Vaccine under protocol must work strictly within the terms of this protocol.

The national influenza vaccination programme may also be provided under patient group direction, under written instruction for supply and administration in the course of an occupational health scheme, or on a patient specific basis, by or on the directions of an appropriate prescriber. Supply and administration in these instances are not related to this protocol.

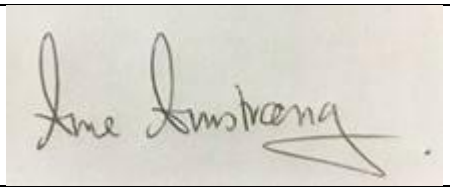
Providers must check that they are using the current version of this protocol. Amendments may become necessary prior to the published expiry date. Current versions of protocols authorised by the Scottish Ministers in accordance with regulation 247A of the Human Medicines Regulation 2012 can be requested by emailing ImmunisationPolicy@gov.scot. Any concerns regarding the content of this protocol should also be sent to this email address.

2. Approval and Clinical Authorisation

This protocol is not legally valid, in accordance with regulation 247A of the the Human Medicines Regulations 2012 until approved by the Scottish Ministers.

On 27 August 2024 the Scottish Ministers, approved this protocol in accordance with regulation 247A of the Human Medicines Regulation 2012. Approval of clinical information in Annex A is via the Scottish Government Chief Medical Officer, Chief Pharmaceutical Officer and Chief Nursing Officer for the delivery of the national influenza vaccination programme, with defined limitations to authorisation that may be updated from time to time as may be required.

Authorised for use by the following organisations and/or services
All Health Boards in Scotland, and organisations Health Boards makearrangements with to deliver services on their behalf.
Limitations to authorisation
This authorisation applies to the supply and administration of the vaccine(s) onlyunder the conditions set out in the authorisation for supply or license set out by the Medicines and Healthcare products Regulatory Agency.

Clinical authorisation			
Role	**Name**	**Sign**	**Date**
CMO	Gregor Smith		27 August 2024
Interim CNO	Anne Armstrong		27 August 2024
CPO	Alison Strath		27 August 2024

3. Change history

Version number	Change details	Date
V01.00	New protocol for Inactivated Influenza Vaccine	24 August 2021
V02.00	Updated protocol to add Military General Duties Vaccinators	14 October 2021
V02.10	Clinical annex updated	24 November 2021
V03.00	Protocol and clinical annex updated for 2022/23 season	05 August 2022
V03.10	Clinical annex updated	22 September 2022
V04.00	Protocol and clinical annex updated for 2023/24 season Added Scottish Ambulance Service Ambulance Technicians to the list of professions permitted to administer under the protocol with appropriate supervision.	23 August 2023
V04.10	Clinical annex updated to include avian flu information for poultry workers.	19 December 2023
V05.00	Protocol and clinical annex updated for 2024/25 season	27 August 2024

4. Characteristics of staff

The provider is responsible for the designation and authorisation of persons withinthe classes set out below permitted to administer medicinal products under this protocol. In doing so the provider must establish that those persons:

a) demonstrate appropriate knowledge and skills to work under the NationalProtocol for the supply/administration of Inactivated Influenza Vaccine.
b) have met the requirements of the relevant NES Vaccination Proficiency document as appropriate at https://learn.nes.nhs.scot/14743/immunisation/seasonal-flu

Classes of persons permitted to administer medicinal products under this protocol		
This protocol may be adhered to wholly from assessment through to post-vaccination by asingle appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this protocol. Activity stages of the vaccination pathway under this protocol:		
Stage 1	a) Assessment of the individual presentingfor vaccination b) Provide information and obtain informedconsent	Registered Healthcare Professionals Only

	c) Provide advice to the individual	
Stage 2	Vaccine Preparation	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
Stage 4	Record keeping	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff

Providers are responsible for assessing the competency of, designating and recording the names of all those persons permitted to supply and administer under this protocol.

The following specified registered healthcare professionals are permitted to administer under the protocol subject to the requirements set out below:

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- Pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- Pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC).
- 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 currently registered with the General Dental Council.
- Optometrists currently registered with the General Optical Council.
- Doctors currently registered with General Medical Council.
- Dentists currently registered with General Dental Council.

The following professionals (who are in the main non-registered) are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Healthcare support workers
- provisionally registered pharmacists, pre-registration pharmacists and other pharmacy support practitioners
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists,orthotists/prosthetists, paramedics, pharmacy technicians,

physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Healthcare Scientists
- Dental nurses
- Physician's assistants
- Scottish Ambulance Service Ambulance Technicians

The following non-registered Armed Forces staff are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 &3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic
- Healthcare Assistant (HCA)
- Military General Duties Vaccinators

Requirements

All those working under this protocol must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person models are used, the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider 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 must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this protocol before working to it, and listed on the practitioner authorisation sheet in Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the influenza vaccination programme in that locality. Protocols do not remove inherent obligations or accountability.

All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this protocol must adhere.

1. Training

- They must have undertaken training appropriate to this protocol and relevant to

their role, as required by local policy and health board standard operating procedures and in line with the training recommendations for influenza vaccinators.
- They must have met the requirements set out in the relevant NES Vaccination Proficiency document.

2. Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications / exclusions or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
- All persons must either be an appropriate prescriber or one of above noted registered professionals. Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant NES Vaccination Proficiency document. They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.
- Experienced vaccinators should use the relevant NES Vaccination Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer inactivated influenza vaccine. They must have completed local IPC training and comply with the vaccination guidance.

In addition and where indicated as relevant to the role:

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SPC) and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of Influenza: the green book, chapter 19 - GOV.UK (www.gov.uk)
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the national for the national influenza vaccination programme
- They 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.
- They must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions.
- They must have access to the provider's protocols and relevant influenza vaccination programme online resources.
- They must be competent in intramuscular injection technique if they are administering the vaccine, this should include a practical element.
- For those preparing the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management

app.
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

3. Supervision

- A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential.
- Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the influenza immunisation programme.
- Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
- The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

5. Clinical condition or situation to which this Protocol applies

Inactivated Influenza Vaccine is indicated for active immunisation against diseasecaused by influenza virus in accordance with Scottish Government influenza immunisation programme and recommendations given in Chapter 19 of the Immunisation Against Infectious Disease: the 'Green Book' Influenza: the green book, chapter 19 - GOV.UK (www.gov.uk) and Scottish Government CMO letters relating to influenza vaccination.

ANNEX A: Clinical Information

This Annex provides information about the clinical situation or condition and treatmentin relation to the National Protocol.

Annex Version History

Version	Date	Summary of changes
1.0	24 August 2021	Version 1.0 new Annex A
2.1	24 November 2021	The following changes have been made: Various sections updated to include Recombinant quadrivalent influenza vaccine ▼ (QIVr) (Sanofi Pasteur)
3.0	05 August 2022	New Annex A for 2022/23 season. The following changes from the clinical annex used in 2021-22 have been made: • Removal of Recombinant quadrivalent influenza vaccine ▼ (QIVr) (Sanofi Pasteur) throughout • Indication section updated for dates for 2022-23 season • Inclusion criteria section updated to include cohorts eligible in 2022-23 season • Name of medicine section updated to reflect vaccines procured for 2022-23 programme • Use outwith SPC section updated for dates for 2022-23 season • Advice to patient section updated to remove advice about COVID-19
3.1	22 September 2022	• Exclusions section updated adding an exclusion for those who have received Nuvaxovid (Novavax) COVID-19 vaccine in the previous 7 days. • Name of medicine section (eligible group and current recommended vaccines) updated to include vaccine recommendation for those aged six months to less than two years and known to be allergic to eggs). • Route of administration section updated to align with wording in Green Book chapter 19 • Frequency section updated to align with wording in Green Book chapter 19 • Is use outwith SmPC section updated to include vaccine recommendation for those aged six months to less than two years and known to be allergic to eggs). • Additional information section updated to include

		information about co-administration with shingles vaccines.
4.0	1 August 2023	• Dates for 2023-24 season updated throughout the document. • Removal of Quadrivalent influenza vaccine (Sanofi Pasteur) (egg grown QIV) (QIVe) from the document • Frequency section updated to advise only children in clinical risk group aged six months to less than nine years in clinical risk group who have not received influenza vaccine before should receive a second dose of vaccine at least four weeks later. • Use outwith the SmPC section updated to include use of Cell-based quadrivalent influenza vaccine ▼(QIVc) (Seqirus vaccines) is licensed from age six months. • Additional information section updated to align with Green Book advice on co-administration with Shingrix vaccine.
4.1	19 December 2023	The following changes from version 4.0 have been made: • Section 1.2 inclusion criteria: updated to include poultry workers • Section 2.1 name of product: updated to include poultry workers • Appendix 1 updated following information from manufacturer that QIVc needle shield does not contain latex
5.0	27 August 2024	The following changes to the 2023/24 season PGD have been made: • minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs • dates changed for 2024/25 season. • Inclusion criteria section updated to generic inclusion criteria. • Name of medicine/form/strength section updated to simplified information on eligible group and current recommended influenza vaccine for national programme. • Green book advice on co-administration with respiratory syncytial virus (RSV) vaccine added.

1. Clinical condition or situation to which this Protocol applies

Category	Description
Inclusion criteria	Valid consent has been given to receive the vaccine. Vaccine should be offered to individuals invited, or eligible in accordance with the recommendations in Green Book **Chapter 19**, and/or in line with **Scottish Government seasonal influenza vaccination programme** and subsequent correspondence/publications from Scottish Government. National policy must be followed in relation to the groups eligible for vaccination at a particular point in time. Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the **Scottish Haematology Society Revaccination Schedule.**
Exclusion criteria	Individuals who: Are aged under 6 months. Have had a confirmed anaphylactic reaction to a previous dose of influenza vaccine. Have had a confirmed anaphylactic reaction to any component of influenza vaccine. Different brands may contain traces of neomycin, ,kanamycin, , formaldehyde and other excipients – practitioners must check the marketing authorisation holder's SmPC for the particular brand. Have a history of confirmed anaphylactic reaction to eggs/egg productor chicken proteins such as ovalbumin where vaccine was produced using eggs. Have a history of severe (i.e. anaphylactic) reaction to latex where vaccine is not latex free. Are suffering from an acute febrile illness (the presence of a minor infection is not a contraindication for immunisation).

Cautions/ needfor further advice/ circumstances when further advice should be sought froma doctor	The Green Book advises that there are very few individuals whocannot receive inactivated influenza vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation coordinator or health protection team. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. **Syncope** 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. **Co-administration with other vaccines** Inactivated influenza vaccine can be given at the same time as other vaccines including COVID-19 vaccines. In older adults (aged 75-79 years) it is recommended that RSV vaccine is not routinely scheduled to be given at the same appointment or on the same day as an influenza or COVID-19 vaccine. No specific interval is required between administering the vaccines. If it is thought that the individual is unlikely to return for a second appointment or immediate protection is necessary, RSV vaccine can be administered at the same time as influenza and/or COVID-19 vaccination. 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 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. The site at which each vaccine was given should be noted in the individual's records.

Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual not being immunized must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the clinician in charge. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.
Action if patient declines	Advise the individual about the protective effects of the vaccine, the risks of infection and potential complications of disease. Advise how future immunisation may be accessed if they subsequentlydecide to receive the vaccine. Document advice given and decision reached. Inform or refer to the clinician in charge.

2. Description of treatment

Category	Description
Name of medicine	**Name of medicine** Inactivated influenza vaccine suspension for injection in a pre-filled syringe, including: • adjuvanted quadrivalent influenza vaccine▼ (aQIV) (Seqirus vaccines). • cell-based quadrivalent influenza vaccine▼ (QIVc) (Seqirus vaccines). **Eligible Group and current recommended influenza vaccine for national programme:** **Aged 65 years and over (including those 64 year olds who are 65 years old by 31 March 2025)** Offer Adjuvanted quadrivalent influenza vaccine▼ (aQIV) **Eligible individuals aged from six months to under 65 years**

	Offer Cell-based quadrivalent influenza vaccine▼ (QIVc) (Seqirus vaccines). **Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment** Please refer to age-based recommendation for vaccine choice as set out above.
Form / strength	Suspension for injection.
Route of administration	Administer by intramuscular injection. The preferred site for children older than 12 months or adults is deltoid area of upper arm. The preferred site for infants is anterolateral thigh. Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) (Seqirus vaccines) and cell-based quadrivalent influenza vaccine▼ (QIVc) (Seqirusvaccines) must only be administered via the intramuscular route. 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 theupper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressureapplied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonablesafety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. A fine needle (23 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/parent/carer should be informed about the risk of haematoma from the injection. The vaccine should be visually inspected for particulate matter and discolouration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being

	observed, do not administer the vaccine.
Dosage	0.5ml
Frequency	Single dose. Children aged six months to less than nine years who are clinical risk groups and have not received influenza vaccine before should receive a second dose of vaccine at least four weeks after the first dose. Children aged six months to less than nine years who are not in clinical risk groups should be offered a single dose, even if they have not previously received influenza vaccine. **Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment** In accordance with the schedule recommended by the Scottish Haematology Society **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment** R
Duration of treatment	See above
Maximum or minimum treatment period	See above
Quantity to supply/administer	See above
▼ black triangle medicines	Yes, the following vaccines are ▼ Cell-based quadrivalent influenza vaccine ▼ (QIVc) (Seqirus vaccines), Adjuvanted quadrivalent influenza vaccine▼ (aQIV) (Seqirus vaccines) This information was accurate at the time of writing. Seeproduct SmPCs at www.medicines.org.uk for indication ofcurrent black triangle status.
Legal category	Prescription Only Medicine (POM)

Is the use outwith the SPC?	Yes Adjuvanted quadrivalent influenza vaccine ▼ (aQIV) is licensed for administration to individuals aged 65 years and over. It may be administered under this protocol to those people who are 64 years old at the point of immunisation butare 65 years by 31 March 2025.. Revaccination of individuals following haematopoietic stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule.** Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. Vaccine should be stored according to the conditions detailedbelow. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS board guidance on storage and handling of vaccines or vaccine incident guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this protocol is allowed.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C.Store in the original packaging to protect from light. Do not freeze. NHS Board guidance on storage and handling of vaccinesshould be observed. 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.
Additional information	Minor illnesses without fever or systemic upset are not validreasons to postpone immunisation. If an individual is acutelyunwell, immunisation may be postponed until they have fullyrecovered.

3. Adverse reactions

Category	Description
Warnings including possible adverse reactions and	Pain, swelling or redness at the injection site, low grade fever, malaise, shivering, fatigue, headache, aching muscles and joint pain are among the commonly reported symptoms after vaccination. A small painless nodule (induration) may also appear at the injection site. These symptoms usually disappear within one to two days without treatment.
Management of these	For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. In the event of a severe adverse reaction individual should be advised to seek medical advice.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on http://yellowcard.mhra.gov.uk/ Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.
Advice to patient or carer including written information	Written information to be given to individual • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with thevaccine. • Immunisation promotional material may be provided as appropriate Individual advice / follow up treatment • Inform the individual/carer of possible side effects andtheir management. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Cardreporting scheme on:

	http://yellowcard.mhra.gov.uk • Give general advice relating to good hygiene practice to prevent the spread of germs – always have tissues to hand, use a clean tissue to cover your mouth and nose when you cough and/or sneeze, bin any tissue after one use, wash your hands with soap and hot water or a sanitiser gel often. • When applicable, advise individual/parent/carer when the subsequent dose is due.
Observation following vaccination	Following immunisation patients remain under observation inline with NHS board policy. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.
Follow up	As above
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccinesare given. Immediate treatment should include early treatmentwith intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Audit Trail/Records

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP withwhom the individual is registered • name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration

	• dose, form and route of administration of vaccine • batch number • where possible expiry date • anatomical site of vaccination • advice given, including advice given if excluded ordeclines immunisation • details of any adverse drug reactions and actions taken • administered under national protocol • Records should be kept line with local procedures. Local policy should be followed to encourage informationsharing with the individual's General Practice. All records should be clear, legible and contemporaneous and in an easily retrievable format.

5. References

Name	Description
Additional references	Practitioners must be familiar with: • **Immunisation against Infectious Disease [Green Book]** • **Immunisation against Infectious Disease [Green Book] chapter 19** • Current edition of British National Formulary (BNF) and BNF for children • Marketing authorisation holder's Summary of Product Characteristics • **Educational resources for registered professionals produced by National Education for Scotland** • All relevant Scottish Government advice including therelevant CMO letter(s) • **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019** • **Professional Guidance on the Safe and Secure Handling of Medicines** • **Scottish Haematology Society advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**

ANNEX A: Seasonal Influenza Vaccine Protocol 2024-25 - UK Licensed Influenza Vaccines

Manufacturer / supplier	Name ofproduct	Vaccine type	Age indication	Ovalbumin content per 0.5ml dose	Latex Formaldehyde Other	Amino-glycosides
Astra Zeneca UK Ltd	Fluenz® LAIV	Trivalent live attenuated influenza vaccine – nasal spray suspension	From 24 months to less than 18 years ofage	≤0.024 µg (0.2mldose)	Latex free[1] Contains gelatin (porcine) Formaldehydefree	Gentamicin[3]
Seqirus	FlucelvaxTetra ®▼ QIVc	Cell grown quadrivalent influenza vaccine – surface antigen inactivated prepared in cell cultures	From 2years	Not applicable – egg free	Latex free Formaldehydefree	Not applicable
	Fluad Tetra ®▼aQIV	Adjuvanted quadrivalent influenza vaccine – surface antigen, inactivated – adjuvanted with MF59C.1	From 65years	≤1 µg	Latex free[2] Risk of formaldehyde residue	Kanamycin[3] Neomyci$_n$3

Notes

None of the influenza vaccines for the 2024/25 season contain thiomersal as an added preservative.

No latex is present in the product but manufacturer is unable to confirm if latex hascome into contact with the product during the manufacturing process.

None of the components of the staked needle prefilled syringe presentation that arein direct contact with the vaccine (syringe barrel, plunger and rubber stopper) are made with natural rubber latex. The needle shield contains natural rubber latex.

Chapter 6 of the Green Book states it is theoretically possible that latex protein from these tip caps, plungers or vial stoppers may cause allergic reactions when the vaccines are administered to latex-sensitive individuals. There is little evidence that such a risk exists and any such risk would be extremely small. The Green Book chapter states as a precaution, if an individual has a history of severe (i.e. anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of anallergic reaction to the vaccine. Where possible, an alternative latex-free vaccine thatcovers the same disease should be administered.

Cross sensitivity to aminoglycosides is common, assume potential reaction for all, ifallergic response to one has been demonstrated.

Ovalbumin, latex and aminoglycoside content for vaccines are correct as at **29 July 2024** however, these may be subject to change in manufacturing practice at any time.

ANNEX B: Practitioner authorisation sheet

Inactivated Influenza Vaccine Protocol
Valid from:
Expiry:

Before signing this Protocol, check that the document has had the necessary authorisations. Without these, this Protocol is not lawfully valid.

Practitioner
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.

It is the responsibility of each practitioner to practise only within the bounds of theirown competence and any appropriate professional code of conduct.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Person authorising on behalf of the Provider

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this Protocol. I give authorisation on behalf of **insert name of organisation**for the above named health care professionals who have signed the Protocolto work under it.			
Name	Designation	Signature	Date

Note to person authorising on behalf of Provider

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of thosepractitioners authorised to work under this Protocol.

ANNEX C: Clinical Supervision sheet

Inactivated Influenza Vaccine Protocol
Valid from:
Expiry:

This sheet must record the name of the clinical supervisor taking responsibility andall of the people working under different activity stages of the protocol.

Activity stages of the vaccination pathway under this protocol:

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation	Registered Healthcare Professionals, non-registered professionalsor non-registered Armed Forces staff
Stage 3	Vaccine Administration	Registered Healthcare Professionals, non-registered professionalsor non-registered Armed Forces staff
Stage 4	Record Keeping	Registered Healthcare Professionals, non-registered professionalsor non-registered Armed Forces staff

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this Protocol, check that the document has had the necessary authorisations. Without these, this Protocol is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date

Note to Clinical Supervisor

Score through unused rows in the list of practitioners to prevent practitioner additionspost managerial authorisation.

This authorisation sheet should be retained to serve as a record of clinicalsupervision arrangements for those working under this Protocol.