Patient Group Direction template

Administration of live attenuated intranasal influenza vaccine (LAIV)

Please note trivalent inactivated influenza vaccine, quadrivalent inactivated influenza vaccine or adjuvanted trivalent inactivated vaccine is not covered by this PGD – separate PGDs are available.

This specimen Patient Group Direction (PGD) template has been produced by Health Protection Scotland to assist NHS boards

NHS boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGD.

Change History

The following changes from the PGD used in 2017/18 have been made (20 July 2018):

- Inclusion of the 2018/19 influenza programme eligible cohorts
- Minor rewording in the cautions section to advise that quadrivalent inactivated vaccine should be considered when LAIV is unsuitable
- Minor rewording in the actions if excluded section to advise that quadrivalent inactivated vaccine should be considered when LAIV is unsuitable
- Include recording expiry date in record section

PGD Live attenuated intranasal influenza vaccine (LAIV)

Authorisation

This specimen Patient Group Direction (PGD) template has been produced by Health Protection Scotland to assist NHS Boards. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer live attenuated intranasal influenza vaccine (LAIV)) under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SPC) for all vaccines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS (*insert details*) by

Doctor		Signature	
Pharmacist		Signature	
Nurse		Signature	

Approved on behalf of NHS (*insert details*) by

Medical Director		Signature	
Director of Pharmacy/Senior Pharmacist		Signature	
Clinical Governance Lead		Signature	

Date Approved

Effective from	01/09/2018	Review Date	31/08/2019

Clinical Situation

Indication	Active immunisation against disease caused by influenza virus in line with Scottish Government seasonal influenza immunisation programme 2018-19.
Inclusion Criteria	Valid consent has been given to receive the vaccine. Individuals identified in Scottish Government's seasonal influenza vaccination programme 2018-19 in the following groups; All individuals aged from 2 years to under 18 years in the clinical risk groups laid out in Annex B of CMO seasonal influenza immunisation programme letter All children aged 2 to 5 years of age on 1st September 2018 (born on or before 1st September 2016) not yet at school. All individuals of primary school age. Young carers, defined as, a child or young person under the age of 18 carrying out significant caring tasks and assuming a level of responsibility for another person, which would normally be taken by an adult.
Exclusion Criteria	Aged under 2 years. Aged 18 years and over. Confirmed anaphylactic reaction to a previous dose of influenza vaccine. Confirmed anaphylactic reaction to any component of the vaccine including gelatin and gentamicin. Practitioners must check the marketing authorisation holder's summary of product characteristics (SPC) for details of vaccine components. Confirmed anaphylactic reaction to eggs/egg product or chicken proteins such as ovalbumin. Severe asthma or active wheezing: • Currently taking oral steroids or have been prescribed oral steroids in the last 14 days. • Currently taking a high dose inhaled steroid – Budesonide greater than 800mcg/day or equivalent • Evidence of active wheezing in the previous 72 hours • Evidence of increased use of bronchodilators in the previous 72 hours Known to be clinically severely immunodeficient due to conditions or immunosuppressive therapy such as acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy; cellular immune deficiencies; and high dose corticosteroids until at least three months after treatment has

	stopped. This would include children who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/ kg/day for at least one week, or 1mg/kg/day for one month. Patients currently treated for a malignant disease with immunosuppressive chemotherapy or radiotherapy, or those who have terminated such treatment within at least the last 6 months. Patients who have received a solid organ transplant and are currently on immunosuppressive treatment. Patients who have received a bone marrow transplant, until at least 12 months after finishing all immunosuppressive treatment, or longer where the patient has developed graft-versus-host-disease. Patients receiving other types of immunosuppressive drugs (e.g. azathioprine, cyclosporine, methotrexate, cyclophosphamide, leflinomide and the newer cytokine inhibitors) alone or in combination with lower doses of steroids, until at least 6 months after terminating such treatment. Known to be a close contact of a very severely immunocompromised person (e.g. bone marrow transplant recipient). Known to be taking salicylate therapy (other than for topical treatment of localised conditions). Known to be pregnant. Known to be breastfeeding. Not at same time or within 48 hours of cessation of influenza antiviral agents. Acute febrile illness – consider postponing immunisation until patient has fully recovered.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. There is a theoretical potential for transmission of live attenuated influenza virus in LAIV to very severely immunocompromised contacts (e.g. bone marrow transplant patients requiring isolation) for one to two weeks following vaccination. Where close contact with immunocompromised patients (e.g. household members) is likely or unavoidable, an appropriate quadrivalent inactivated influenza vaccine should be considered. Not all brands of quadrivalent inactivated vaccine are recommended for use in children. There are no data on the effectiveness of LAIV when given to children with a heavily blocked or runny nose (rhinitis) attributable to infection or allergy. As heavy nasal congestion might impede

	delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until resolution of the nasal congestion or an appropriate quadrivalent inactivated influenza vaccine should be considered.
Action if Excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given. The risk to the individual of not being immunised must be taken into account. Temporary exclusion: In case of postponement due to acute febrile illness, arrange a future date for immunisation. Temporary exclusion: In case of postponement due to acute wheezing/increased use of bronchodilators if their condition has not improved after a further 72 hours then to avoid delaying protection in this high risk group, these children should be offered an appropriate quadrivalent inactivated influenza vaccine and a future date for immunisation should be arranged. In case of exclusion of taking high dose inhaled steroid – Budesonide greater than 800mcg/day or equivalent due to limited safety data in these children advice from the child's specialist should be sought on the vaccine and circumstances under which it could be given. In case of exclusion as result of immunosuppression, pregnancy or salicylate therapy (other than for topical treatment of localised conditions), consider use of an appropriate quadrivalent inactivated influenza vaccine. Document in clinical records.
Action if Patient Declines`	Advise about the protective effects of the vaccine, the risks of infection and complications. Document advice given and decision reached. In GP practice setting, inform or refer to GP.

Description of Treatment

Name of Medicine	Live attenuated intranasal influenza vaccine (LAIV)
Form/Strength	Nasal spray, suspension in a prefilled nasal applicator.
Route of administration	Nasal administration only. LAIV must not be injected. The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.
Dosage	0.2ml (administered as 0.1ml per nostril) LAIV is administered as a divided dose in both nostrils

Frequency	Children NOT in clinical risk groups only require one dose of LAIV Children in clinical risk groups aged two to under 9 years who have not received influenza vaccine before should receive two doses of LAIV with the second dose at least 4 weeks after the first.
Duration of treatment	See Frequency section.
Maximum or minimum treatment period	See Frequency section.
Quantity to supply/administer	See Frequency section.
▼ additional monitoring	Yes, all LAIV vaccines are being monitored intensively by MHRA
Legal Category	POM – prescription only medicine.
Is the use outwith the SPC	Yes The SPC states that in children who have not previously been immunised against influenza, a second dose should be given after an interval of at least four weeks. This is superseded by the Green Book recommendation to give a single dose of LAIV to children not in a clinical at risk group.
Storage requirements	Vaccine should be stored at a temperature of +2° to +8°C. If the vaccine has been frozen, it should be discarded. LAIV may be left out of the refrigerator once for a maximum period of 12 hours at a temperature not above 25°C as indicated in the SPC. If the vaccine has not been used after this 12 hour period, it should be disposed of. NHS board guidance on storage and handling of vaccines should be observed.
Additional information	The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff. Administration of either dose does not need to be repeated if the patient sneezes or blows their nose following administration. LAIV can be given at the same time as other vaccines including live vaccines. No specific intervals need to be observed between LAIV and other live vaccines.

Warnings including possible adverse reactions and management of these	Nasal congestion/runny nose, reduced appetite, weakness and headache are common adverse reactions following administration of LAIV It is uncommon, but some children may experience a nosebleed following administration of LAIV. For full details/information on possible side effects, refer to the marketing authorisation holder's SPC. 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	All LAIV vaccines are subject to intensive monitoring by Medicines and Healthcare products Regulatory Agency (MHRA). Any adverse events that may be attributable to LAIV should be reported using the yellow card system on http://yellowcard.mhra.gov.uk/ Any serious adverse reaction to the vaccine should be documented in an individual's record. GP should also be informed.
Advice to Patient/carer including written information	Supply marketing authorisation holder's patient information leaflet (PIL) provided with vaccine. Advise individual to seek medical advice in case of severe adverse reaction. 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.
Monitoring	Following immunisation patients remain under observation in line with NHS board policy.
Follow-up	If appropriate remind parents/guardian that a further dose will be required to complete the course.
Additional Facilities	Immediate access to Epinephrine (adrenaline) 1 in 1000 injection Access to telephone.

Characteristics of staff authorised under the PGD

Professional qualifications	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions
Specialist competencies or qualifications	Approved by the organisation as competent: • to undertake immunisation and discuss issues related to immunisation, • to assess the person's capacity to understand the nature and purpose of the immunisation in order to give or refuse consent, • to work with this patient group direction, • in the recognition and management of anaphylaxis,
Continuing education and training	The practitioner must be familiar with the SPC for all vaccines administered in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of immunisation and in the recognition and management of anaphylaxis.

Audit Trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each vaccine administered and may be required to share information with appropriate parties in line with confidentiality protocols.The information relating to immunisation of each individual must include as a minimum: • Patient's name and date of birth, • Dose, • Name of vaccine, brand, batch number and expiry date of vaccine • Date given and by whom. All records must be clear and legible and, ideally, in an easily retrievable format. Depending on the clinical setting where immunisation is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • GP practice computer, • Individuals GP records, • Child Health Systems/Scottish Immunisation Record, • Consent forms, • Handheld records such as Red Book.
Additional references	Practitioners operating the PGD must be familiar with: Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book Immunisation against Infectious Disease [Green Book] chapter 19 https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 Current edition of British National Formulary (BNF) and BNF for children Marketing authorisation holder's Summary of Product Characteristics All relevant Scottish Government advice including the relevant CMO letter(s) NMC (2015) Code of Professional Conduct. NMC (2010) Standards for Medicines Management

PGD for administration of Live attenuated intranasal influenza vaccine (LAIV– Authorisation

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the manufacturer's summary of product characteristics for all vaccines administered in accordance with this PGD.

Note to Authorising Managers

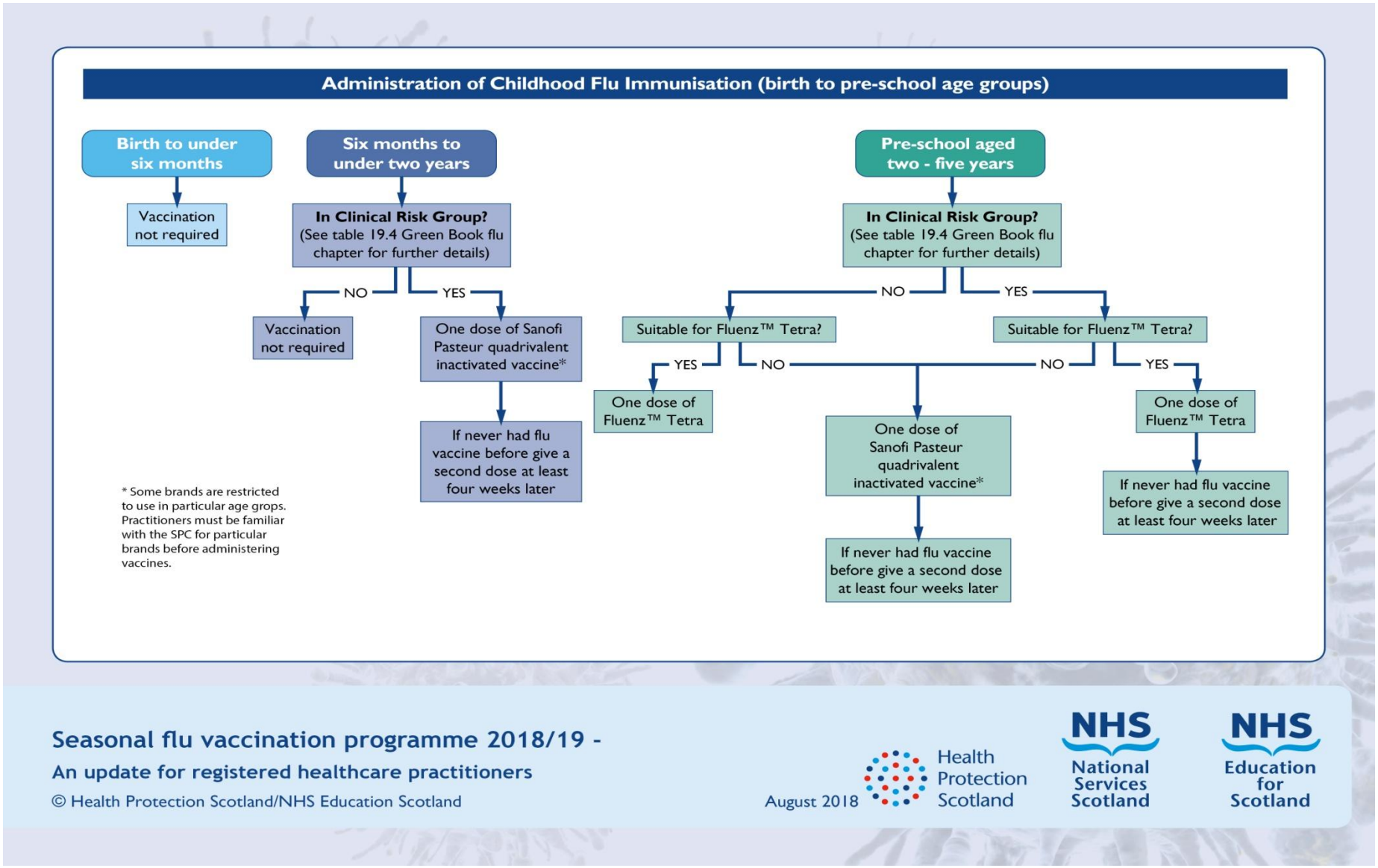
Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I agree to administer live attenuated intranasal influenza vaccine (LAIV) vaccine only in accordance with this PGD.

Name of Professional	Signature	Date

I agree that the professionals listed above are authorised to supply/administer medicines in accordance with this PGD to patients cared for in this service area.

Lead Clinician for the service area (Doctor)		
Name:	Signature:	Date:


Administration of Childhood Flu Immunisation (birth to pre-school age groups)
Birth to under six months
Vaccination not required
Six months to under two years
In Clinical Risk Group? (See table 19.4 Green Book flu chapter for further details)
NO
YES
Vaccination not required
One dose of Sanofi Pasteur quadrivalent inactivated vaccine*
If never had flu vaccine before give a second dose at least four weeks later
* Some brands are restricted to use in particular age grops. Practitioners must be familiar with the SPC for particular brands before administering vaccines.
Pre-school aged two - five years
In Clinical Risk Group? (See table 19.4 Green Book flu chapter for further details)
NO
YES
Suitable for Fluenz™ Tetra?
YES
NO
One dose of Fluenz™ Tetra
Suitable for Fluenz™ Tetra?
NO
YES
One dose of Sanofi Pasteur quadrivalent inactivated vaccine*
If never had flu vaccine before give a second dose at least four weeks later
One dose of Fluenz™ Tetra
If never had flu vaccine before give a second dose at least four weeks later
Seasonal flu vaccination programme 2018/19 -
An update for registered healthcare practitioners
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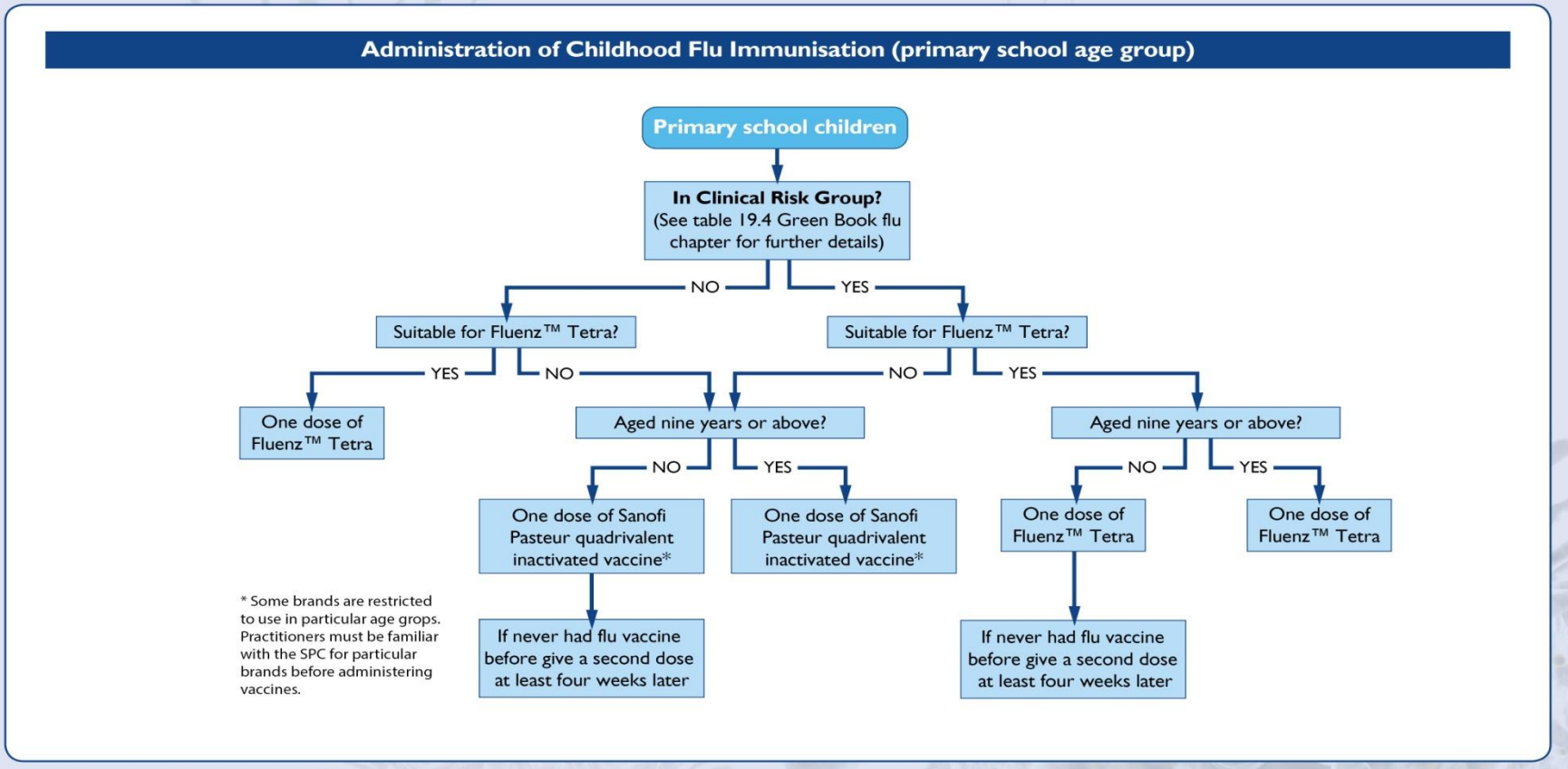

Seasonal flu vaccination programme 2018/19 -

An update for registered healthcare practitioners

August 2018

Health Protection Scotland

NHS National Services Scotland

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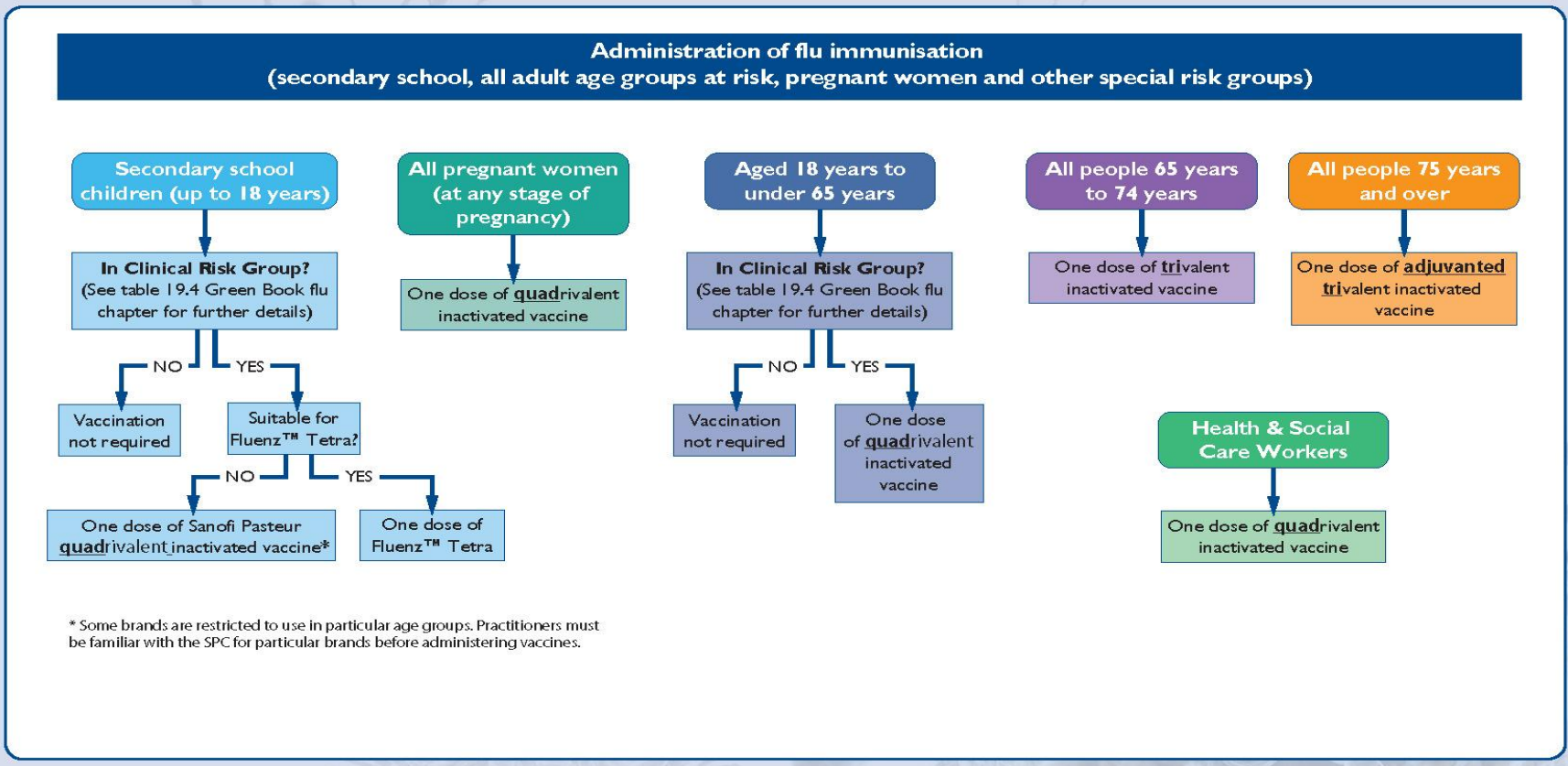

National Specimen PGD for administration LAIV vaccine Aug 2018, review date 31/08/19