



## Toolkit to Support the Administration of Flu Vaccination to Primary School Children in the School Setting

### Seasonal Influenza Vaccination Programme 2023-2024

Document developed by:	National Immunisation Office
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#### 1 Introduction

The Department of Health have asked the HSE to provide the nasal flu vaccine to all children aged 2-12 years for the 2023-2024 seasonal influenza programme. Children aged 13-17 years at risk of influenza related complications can also receive the free HSE flu vaccine as per DOH policy. The aim of the influenza programme for children is to protect children from influenza related morbidity and mortality, particularly those aged under four years in whom influenza infection can be more severe. In addition, young children may shed and transmit influenza for longer than adults and are therefore important drivers of influenza infection in the community.<sup>1</sup> Therefore, reducing infection among children provides direct protection to vaccinated children and decreases transmission of flu within the wider community, providing indirect protection to those at higher risk of severe disease.<sup>2</sup>

#### 1.1 The Seasonal Influenza Programme 2023-2024

The goal for the seasonal influenza campaign for the 2023-2024 season is to increase the overall uptake of flu vaccinations with a focussed target for key groups including children aged 2-12 years. The 2023-2024 HSE seasonal vaccination programme will offer two vaccines:<sup>1</sup>

- An injectable Quadrivalent Influenza Vaccine (QIV) called Influvac Tetra (manufactured by Mylan) which is given intramuscularly (IM) and is recommended (unless contraindicated) for:
  - Children aged 6-23 months old and adults aged 18-64 years who are at risk of influenza related complications
  - Pregnant women
  - Healthcare workers (HCWs)
  - Carers
  - All those aged over 65 years
- A Live Attenuated Influenza Vaccine (LAIV) called Fluenz Tetra (manufactured by AstraZeneca) which is administered intranasally and is recommended (unless contraindicated) for:
  - All children and young people aged 2-12 years and
  - Children aged 13-17 years who are at risk of influenza related complications

A full list of eligible groups for the influenza vaccines is available at <u>www.hse.ie/flu</u> and in the NIAC guidelines Chapter 11 available at:<sup>1</sup>

#### https://rcpi.access.preservica.com/uncategorized/IO\_cd88ef19-73ea-4630-8e0c-b269c3034fa9/

Vaccination of all children in Ireland aged 2-17 years with LAIV was first added to the national influenza vaccine campaign in the 2020-2021 flu season. At the start of the 2020-21 season LAIV was offered to those aged 2-12 years. Later in the 2020-2021 flu season, this was extended to those aged 13-17 years. All children aged 2-17 were offered the flu vaccine in 2021-22 and 2022-23 seasons.

Younger children were prioritised for vaccination as they are more susceptible to the complications

of flu and more likely to be drivers of infection in the community.<sup>2</sup>

The LAIV was administered in the community by General Practitioners (GPs) and community Pharmacists during the 2020-2021 season.

The target uptake for eligible children is 50% with an ambition of 75%.

Table 1 Uptake of flu vaccine in children

Age group	No. vaccinated (2022/23)*	% Uptake (2022/23)*	No. vaccinated (2021/22)	% Uptake (2021/22)	No. vaccinated (2020/21)	Uptake 2020/21
2-12 years	166,458	15.4	140,376	18.8	217604	29.0
13-17 years			38,986	11.6	8074	2.5

\*provisional data as of May 2023

#### 1.2 The Schools Immunisation Programme

In Ireland, the Schools Immunisation Programme (under the governance of Primary Care-Community Operations) is a well-established programme which is part of a national strategy to protect children from infectious diseases through vaccination.<sup>3</sup> There is strong international evidence that administration of vaccines in school settings increases vaccination uptake and a school setting is an appropriate and safe setting to enable the vaccination of large numbers of students.<sup>4-6</sup> The Schools Immunisation Programme currently protects against the following diseases with the named vaccines:

#### **Junior Infants**

- Measles, mumps, rubella with MMR vaccine.
- Tetanus, diphtheria, pertussis, polio with DTaP/IPV vaccine (4 in 1 vaccine).

#### First year of second level school

- Tetanus, diphtheria, pertussis with Tdap vaccine.
- Human papillomavirus (HPV) with HPV9 vaccine.
- Meningococcal A, C, W, and Y infection with MenACWY vaccine.

For 2023/24 flu season the HSE LAIV Mobile Vaccination Teams (under the governance of COVID-19 Operations) will be administering nasal flu vaccine onsite in schools to senior Infants children in main-stream primary schools and all eligible children in primary-age special schools across Ireland between October and December 2023. All other eligible cohorts of children are expected to receive their flu vaccination in primary care.

#### 1.3 Flu Vaccination in School Settings

In the UK, intranasal live attenuated influenza vaccine (LAIV) has been offered to children aged 2-4 years old by GP's and to older children in primary school since 2013. It was extended to secondary school children in 2020-21. The extension of the influenza immunisation programme to children in a school setting was informed by a number of successful pilot projects that demonstrated that school-based delivery of flu vaccines to children improves uptake and that school-based vaccination is likely to achieve higher coverage than delivery via primary care.<sup>2,7</sup>

In the UK, delivery of the influenza vaccine in a primary school setting was introduced on a phased basis over a number of years for school class groups.<sup>8</sup> In the UK the uptake of the children's flu vaccination in primary school children is 56% when administered in schools (2022/23).

In Ireland, for the 2021-2022 season, flu vaccine was available free of charge to all children, delivered in the community administered by GPs and Pharmacists. In that season small scale pilots in 3 primary schools in Ireland (during 2021/22) were undertaken. Uptake of LAIV in a school setting was 63.9%. Uptake in the community among the study population was 12.4%. Therefore this pilot programme increased uptake within the participating schools populations from 12.4% to 76.3%.

This document is intended to support the vaccination teams administrating LAIV to children in a primary school setting. It aligns with the:

- Supporting Information for Staff School Immunisation Programme 2023-2024 academic year document,
- The NIAC guidelines in relation to LAIV administration for children and
- An operational guidance document. <sup>1,3</sup>

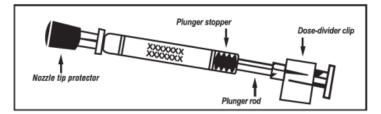
#### 2 LAIV Administration in Children

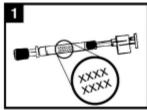
#### 2.1 Vaccine, Dose and Route of Administration

The vaccine recommended for all children aged 2-12 years and children aged 13-17 years who are at risk of influenza related complications (see Section 2.2) is a Live Attenuated Influenza Vaccine (LAIV), it is called Fluenz Tetra and is manufactured by Astra Zeneca. This vaccine may be given to all eligible children, unless contraindicated. Vaccinators should be aware that LAIV viruses cannot cause influenza as they are cold adapted and cannot replicate efficiently at body temperature.

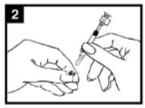
The dose of this vaccine is 0.2ml. LAIV must only be given intranasally, one spray (0.1ml) should be given in each nostril. Refer to the Fluenz Tetra administration diagram (Figure 1) for step-by-step administration instructions.

Figure 1 Fluenz Tetra Administration





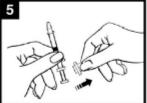
Check expiry date Product must not be used after date on applicator label.



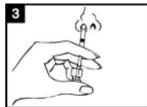
Prepare the applicator Remove rubber tip protector. Do not remove dose-divider clip at the other end of the applicator.



Depress the plunger With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.



Remove dose-divider clip For administration in the other nostril, pinch and remove the dose-divider clip from plunger.



Position the applicator With the patient in an upright position, place the tip just inside the nostril to ensure Fluenz Tetra is delivered into the nose.



Spray in other nostril Place the tip just inside the other nostril and with a single motion, depress plunger as rapidly as possible to deliver remaining vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements for medical waste.

All eligible children who are not in a high-risk group, should receive a single dose of LAIV. Parents will be advised not to consent for their child to receive the flu vaccine in school if their child has already received a flu vaccine since September 2023.

Children aged 2-8 years in a clinically at-risk group, who are at higher risk of complications from influenza, who are receiving **any** influenza vaccine for the first time or who have an unknown vaccination history should receive two doses of LAIV, at least four weeks apart. This is summarised in Table 2.

Please see Appendix A for list of training material available to support administration of the LAIV.

#### Table 2 Dose of LAIV

Age Group	Dose
Children aged 2-17 years	One dose
Children aged 2-8 years in a clinically at-risk	Two doses 4 weeks apart if they are receiving
group	influenza vaccine for the first time or if the
	vaccination history is unknown

Please note:

- If the child sneezes or nose drips, the vaccine does not need to be repeated. LAIV is
  immediately absorbed after administration and there is a surplus of attenuated virus
  particles in the vaccine required for immunity.
- If LAIV is only tolerated / given in one nostril, the vaccine does not need to be repeated. A
   0.1ml dose given into one nostril contains enough attenuated viral particles to induce an immune response.
- If all of the vaccine doses are given in the same nostril, the vaccine does not need to be repeated.

#### 2.2 Children in Clinically At-Risk Groups

The following children are considered to be in clinically at-risk groups:

- Those with chronic illness, e.g., chronic heart disease, chronic liver disease, chronic neurological disease, chronic renal failure, chronic respiratory disease (including cystic fibrosis, moderate or severe asthma, and bronchopulmonary dysplasia), diabetes mellitus, or haemoglobinopathies
- Those with immunosuppression due to disease or treatment, including asplenia or hyposplenism, and all cancer patients. Note LAIV is contraindicated in children with severe immunocompromise due to disease of treatment (Section 2.4)
- Those with any condition that can compromise respiratory function (e.g., spinal cord injury, seizure disorder, or other neuromuscular disorder) especially those attending special schools/ day centres
- Children with Down syndrome
- Children with moderate to severe neurodevelopmental disorders such as cerebral palsy and intellectual disability
- Residents of long stay facilities where rapid spread is likely to follow introduction of infection
- Morbid obesity

Children aged 2-8 years who fall into any of the above categories and who have never had any influenza vaccine before should be offered two doses of the LAIV four weeks apart unless it is contraindicated (Section 2.4). For the purposes of this programme, children in high-risk groups who have never had any influenza vaccine before will be identified by the immunisation teams from the information provided on the consent form completed by parents (which includes a pre-vaccination screening questionnaire). Children in this category will be offered a dose of the LAIV in school and, following vaccination, their parents will be sent a letter by the CHO/School immunisation team advising them to attend their GP or pharmacy for the second dose of LAIV four weeks after the first dose.

#### 2.3 Precautions to LAIV

- In the event of acute severe febrile illness, vaccination should be deferred until recovery
- LAIV can be given to children with confirmed egg anaphylaxis or egg allergy in a primary care or school setting. LAIV has an ovalbumin content ≤0.024 micrograms per dose. However, children who have required ICU/Critical care admission for a previous severe anaphylaxis to egg should be given LAIV in hospital

#### 2.4 Contraindications to LAIV

The following are contraindications to receiving the LAIV:

- Anaphylaxis following a previous dose of influenza vaccine or any of its constituents except ovalbumin (See precautions in Section 2.4 above)
- Asthma
  - If a child has had an acute exacerbation of symptoms, increased wheezing and/or additional bronchodilator treatment in the last 72 hours vaccination is contraindicated
  - If a child has severe asthma, is on regular oral steroids or has had previous
     ICU/Critical care for asthma, specialist advice should be sought
- Concomitant use of aspirin/salicylates
- Children who live with a severely immunosuppressed person
  - o e.g., post haematopoietic stem cell transplant
- Use of influenza antiviral medications within the previous 48 hours
- Pregnancy
- Significant immunosuppression due to disease or treatment
  - e.g., acute/chronic leukaemia, lymphoma, HIV positive not on highly active antiretroviral therapy, cellular immune deficiency, high-dose steroids
     >0.5mg/kg/day in children <40kgs or other immunosuppressing drugs</li>
- Those post cochlear implant until the risk of a CSF leak has resolved

- o Consult with the relevant specialist
- Those with a cranial CSF leak
- Those with severe neutropoenia
  - Absolute neutrophil count <0.5 x 10<sup>9</sup>/L, to avoid an acute vaccine related febrile episode. This does not apply to those with primary autoimmune neutropoenia who can receive influenza vaccine unless contraindicated.
- Those on combination checkpoint inhibitors
  - e.g., ipilumumab plus nivolumab because of a potential association with immune related adverse reactions
  - Patients on combination checkpoint inhibitors should not receive any influenza vaccines

Children for whom the LAIV is contraindicated should be offered the QIV provided it is also not contraindicated. For the purposes of this programme, children who fall into this category should be advised to attend their GP or pharmacy to receive the injectable QIV.

There is an algorithm which outlines the procedure for the LAIV in children aged 2-17 years included as Appendix B.

#### https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/laivalgorithm.pdf

LAIV is not contraindicated for use in those with asymptomatic HIV infection, those who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g., for adrenal insufficiency.

#### 2.5 Adverse Reactions

Local Side Effects:

• Nasal congestion is very common (≥ 1/10)

General Side Effects:

- Malaise is very common (≥ 1/10)
- Decreased appetite, headache, myalgia and fever are common ( $\geq 1/100$  to < 1/10)
- Fever is no more frequent than that following other recommended childhood vaccines, is generally mild and resolves in a few days

Very Rare Side Effects (< 1/10,000)

• Immediate allergic reactions

Very rare cases of Guillain-Barré syndrome (GBS) have been observed in post marketing surveillance following the flu vaccine. However, the risk of GBS following influenza infection is significantly greater than that following influenza vaccination.

Read the Summary of Product Characteristics (SmPC) contains further information on adverse events associated with Fluenz Tetra. Available here: <u>https://www.ema.europa.eu/en/documents/product-information/fluenz-tetra-epar-product-information\_en.pdf</u>

#### 2.6 Co-administration in Primary School Age Children

- LAIV can be given at the same time or at any time before or after any other live (e.g., MMR or varicella) or non-live vaccine. It should ideally be provided to eligible children between October and December 2023.
- Parents should not be routinely invited to attend school vaccinations. There is no requirement to have a parent present at the time of vaccination.
- If there is a valid consent form from parents, all children should be vaccinated regardless of whether a parent is present or not. Children should be treated in the same manner regardless of whether a parent is present or not.
- If a parent refuses consent this must be recorded on the consent form and on COVAX. This will form part of a future record for the child when they become of age of consenting in their own right, and wish to have oversight of their personal vaccination status.

# 3 Supporting teams for the Administration of LAIV in the Primary School Setting

#### 3.1 Preparation for Administration of LAIV in the School Setting

The roles and responsibilities of staff involved in the Schools Immunisation Programme are outlined in the

- Supporting Information for Staff School Immunisation Programme 2023-2024 academic year document which should be adapted to the LAIV administration in the school setting.<sup>3</sup>
   <a href="https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff.pdf">https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff.pdf</a>
- Operational Guidance document <u>https://healthirl.sharefile.eu/home/shared/fo0d129e-</u>
   <u>a2b6-4942-b61a-41d7791f1d0f</u>

As part of preparation for the vaccination session, vaccine information packs should be sent to the school for onward distribution to all parents. Parents/legal guardian/students should receive this pack through the schools in advance of the planned vaccination session.

This pack should contain:

- An information leaflet for parents in English and Irish (Appendix C)
- A consent form in English and Irish including a pre-vaccination screening questionnaire (Appendix D). Parents should be advised that if their child has already received an influenza

vaccine since September this year they should not consent for their child to receive a vaccine in school

- A letter for parents in English and Irish (Appendix E)
- An envelope to return the completed consent form

Prior to the vaccination date it should be ensured that:

- All consent forms are reviewed and children with contraindications to LAIV and children in high-risk groups who require two doses of LAIV are identified (Section 3.5.2)
- All queries should be dealt with by the relevant provider of the vaccination service so no child attends for vaccination with an outstanding query
- A system should be available locally to deal with immunisation queries or concerns from parents/legal guardians/students and schools. The contact details for vaccination bases will be uploaded onto immunisation.ie for parents to access. Please ensure these details are correct and the communication channels are routinely monitored
- The target cohort (denominator) should be identified
- The composition of immunisation teams should be agreed locally in advance and will depend on the number of students in the school. At least two trained vaccinators are required at each vaccination clinic

LAIV may be administered by

- Registered and trained doctors,
- Registered and trained pharmacists in line with PSI guidance:
   <u>https://www.thepsi.ie/gns/education/Training\_for\_Pharmacists\_Vaccinations.aspx</u>
- Registered and trained nurses and midwives under a valid prescription or medicines protocols and
- HSE COVID-19 vaccinators working in- line with the Statutory Instrument working under medicines protocols to administer vaccines under the appropriate governance.

Prior to vaccination, all clinical staff should be familiar with the following documents

- Medicines protocols relevant to them and training materials for LAIV will be available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/">https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/</a>
- Immunisation Guidelines for Ireland available at <u>https://bit.ly/NIACGuide</u>
- Summary of Product Characteristics (SmPCs) for LAIV available at www.hpra.ie
- Undertaken the HSELand Module developed on LAIV by the NIO available at <u>www.hseland.ie</u>
- "Anaphylactic Reactions: Treatment in the Community" protocol, in the Immunisation Guidelines for Ireland available at <u>https://www.rcpi.ie/Healthcare-</u> Leadership/NIAC/Immunisation-Guidelines-for-Ireland

- HSE Communicating Clearly with Patients and Service Users guidelines
   <u>http://bit.ly/CommClear</u>
- Each vaccinator must also be familiar with
  - Techniques for resuscitation of a patient with anaphylaxis and have completed a Basic Life Support training course within two years
  - Medicine protocols for LAIV and epinephrine/adrenaline, without individual prescription

#### 3.2 Resources and Equipment

The following resources and equipment are required for administration of the LAIV

- The nasal flu vaccine- LAIV (This comes as a suspension in pre-filled nasal applicator. Ready to use. No reconstitution or dilution needed)
- Fridge/Cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/trays
- Sharps bins, and bins for the disposal of healthcare risk and non-risk waste
- Alcohol hand sanitiser
- Surgical facemasks
- Access to telephone
- Resuscitation equipment and drugs in accordance with Anaphylaxis: Immediate Management in the Community (National Immunisation Advisory Committee, 2023) available at <u>https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</u>
- Safe storage areas for medicines and equipment
- LAIV medicine protocol
- Access to ICT equipment to record vaccinations

#### 3.3 Vaccine Ordering, Storage and Handling

Vaccines for the programme should be ordered through the National Cold Chain Service using the usual online ordering system using the following website <u>www.ordervaccines.ie</u>. The vaccine expiry date should be checked prior to administration. It is important to be particularly aware of the short shelf-life of the LAIV compared to other vaccines when arranging and planning LAIV clinics.

LAIV should be stored in a fridge/cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°. Vaccines which have been exposed to temperatures outside the permitted range should not be disposed of. These vaccines should

be quarantined and maintained between +2° to +8° until advised by the National Immunisation Office.

The SmPC for Fluenz Tetra recommends to keep the nasal applicator in the outer carton in order to protect from light.

Any vaccine that has been removed from its packaging and is not used in a timely
manner within the session should not be returned to the cool box but should be
discarded safely into a sharps bin. The sharps bin should be securely sealed when three
quarters full or filled to the manufacturer's fill line.

SmPC for Adrenaline BP 1:1,000 advises that it should not be stored above 25°C and it should be kept in the outer carton

#### 3.4 Maintenance of the Cold Chain

The National Immunisation Office have published guidance on maintenance of the cold chain including cold boxes. See <a href="http://bit.ly/VaccOrder">http://bit.ly/VaccOrder</a>

- See Appendix J for additional information about maintaining the cold chain
- Record the current temperature of the probe in the cool box:
  - o when vaccines are packed
  - o upon arrival at the immunisation clinic
  - throughout the immunisation clinic
  - when returning vaccines to the fridge
- Ensure that the cool box is placed in,
  - An appropriately ventilated room,
  - Away from any heat source,
  - Away from direct sunlight.
- Ensure that the cool box remains closed as much as possible.
- Ensure that where vaccines are not used on a particular day and are in their original
  packaging and have been maintained under cold chain conditions, these vaccines may be
  returned to the vaccine fridge. They should be clearly marked so that they are used first at
  the next vaccinating session. The temperature of the vaccine being returned to the vaccine
  fridge should be recorded as well as the time of return to the fridge.
- If these marked vaccines are taken to a second vaccination session and are not used, providing the cold chain has been maintained, these vaccines can be returned to the vaccine fridge again, for administration at the next session. The vaccines should be marked differently to differentiate them from vaccines which were returned after the previous vaccination session and from marks used during a cold chain breach. Vaccines which have

remained in temperature at all times and have not been used after 1 or 2 transportations to school have not experienced a cold chain breach. However, it is important not to take more vaccines than will be required to a vaccination session so the return of vaccines without being used more than twice should be exceptional.

- If a temperature deviation has occurred, please contact the National Immunisation Office immediately.
  - Contacts include:

Achal Gupta: mobile 087 4064810 Leah Gaughan: mobile 087 1881667 Cliona Kiersey: mobile 087 9915452 Email pharmacynio@hse.ie

The National Immunisation Office will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines later or whether they should be discarded.

Do not use or dispose of any vaccine which has been exposed to temperatures outside the permitted range. Quarantine and maintain these vaccines between +2°C and +8°C until advised by the National Immunisation Office.

#### 3.5 Pre-Vaccination Procedures

#### 3.5.1 Consent

Informed consent must be obtained prior to vaccination. This is done through distribution of consent forms via the schools and return of the forms to the schools immunisation team through an envelope included in the immunisation information pack.

The Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition, 2019 (Medical Council) states in section 11.1 that:

- "(You must) give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.
- Consent is not valid if the patient has not been given enough information to make a decision" See <u>http://bit.ly/MC8thEd</u>
- If consent is not given this should be respected, no further appointments for the flu vaccine in the 2023-2024 season will be offered. However, parents/legal guardians can subsequently choose to avail of LAIV through their GP or community pharmacy for as long as supplies are available.
- Informed consent must be obtained prior to vaccination.

- Under normal circumstances, the parent(s) of a child can give consent for vaccination on their child's behalf. For students aged under 16, consent must be obtained from a parent/legal guardian. Students aged 16 years and older can consent on their own behalf.
- Under current Irish law, the following guardianship rules apply:
  - Where a child's mother and father are married both are the legal guardians.
  - Following a separation or divorce, both parents remain the child's legal guardian even if the child is not living with them and they have not been awarded custody of the child.
  - Where a child has been jointly adopted, the adoptive parents are the child's legal guardians.
  - Where a same sex couple are married, the child's biological parent is a legal guardian. The partner/spouse may apply to become a legal guardian.
- Where the child's parents are not married:
  - the child's mother is an automatic legal guardian
  - the child's father is an automatic legal guardian if:
    - since 18 January 2016, he has lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth.
    - the mother and father of the child may make a statutory declaration to the effect that they agree to the appointment of the father as legal guardian.
    - the father may apply to court to be appointed legal guardian.
- Any adult may apply to court for legal guardianship:
  - if he or she is married to or in a civil partnership with, or has been cohabiting for at least 3 years, with the child's parent and has shared parental responsibility for the child's
  - day-to-day care for at least 2 years.
  - if he or she has provided for the child's day-to-day care for a continuous period of more than 12 months and the child has no parent or guardian who is able or willing to act as guardian.
- A guardian may nominate another person to act as temporary guardian in the event of the guardian's incapacity. This is subject to court approval.
- A guardian may appoint a person to act as the child's guardian in the event of the guardian's death.
- For Children/young people in voluntary care the usual legal rules of parental consent apply.
- For Children/young people under a care order:

- Young person over 16 years admitted to the care of Tusla, (i.e. an order of the court), the normal rules apply.
- For a child/young person under 16 years admitted to the care of Tusla under a care order, the normal rules do not apply (best practice to involve the parents in the decision - making process where possible) when:
- Under an interim or emergency care order, an application may be made to the District Court in regard to consent to treatment/intervention, including that a social care professional involved with the child's care is permitted to give consent to treatment/intervention.
- Under a full care order (permanent or temporary), Tusla is authorised by the court to consent to any necessary medical or psychiatric treatment, assessment or examination. Different procedures apply to admission and treatment under the Mental Health Act 2001.
- There is no maximum duration for consent. Consent remains valid for an indefinite period unless
  - o It is withdrawn
  - $\circ$   $\;$  There has been a change in the client's capacity to give consent
  - There has been a change to the proposed vaccine schedule to which the client has not given consent
  - If a parent/legal guardian contacts the local health office to withdraw consent they should speak to the staff member, ideally a clinical staff member looking after the vaccine programme. The information provided should be recorded by the recipient on the consent form by drawing a double line through the vaccine administration details section with the words 'refused dose' with the date and time and name and PIN/staff number of the person taking the information down.
- HSE consent policy is here: <u>http://bit.ly/ConsentQID</u>
- Read "Who can give consent for vaccination of a young person aged under 16 years?" From <u>https://bit.ly/ConsentU16</u>
- Watch this video from Dr. Siobhan Ni Bhriain, HSE National Lead Integrated Care covering Consent for vaccination. <u>https://youtu.be/8uKqmkFe8hs</u>

#### 3.5.2 Assessment of the Student for Vaccination

Before assessing the suitability of a student for vaccination:

• Confirm student's identity

- Confirm name, address, date of birth and parent or legal guardian's name by asking: "What is your full name? When is your Birthday? Where do you live? Who signed the consent form? What is their name?"
- For younger children it may be necessary to confirm identity with the child's teacher or an appropriate liaison person (as agreed with the School Principal) from the school
- Confirm that informed consent has been given by a parent/legal guardian
- Address any clinical issues raised on the consent form
  - This process should identify children for whom the LAIV is contraindicated and children who are in high-risk groups and require two doses of the LAIV 4 weeks apart (Template letters for parents in these circumstances are included in Appendix F)
- Vaccines should only be given to students who are well on the day, and for whom no contraindication is identified as per the Immunisation Guidelines of Ireland available at <u>https://bit.ly/NIACGuide</u>
  - The student's temperature should not be checked routinely in the school at the time as this is not conclusive and is therefore unhelpful in the decision-making process
  - Any student feeling unwell on the day or considered by the clinical lead in charge of the vaccination clinic to require deferral of the vaccine should be advise to attend their GP or Pharmacist for vaccination. In this case a letter can be sent home with the child, suggested wording in Appendix F)

#### 3.5.3 Vaccination Record Forms

Once the parent/legal guardian completes their part of the consent form, and the HSE staff introduce clinical content to the form, it should be considered as a clinical record and treated accordingly and stored in accordance with General Data Protection Regulations (GDPR) and HSE records retention policy. The immunisation record will be captured on the COVAX system. All clinical notes on events around vaccination should be stored as part of the vaccination record on the vaccination form and on COVAX. It is important to ensure that all written information recorded is in black ink, in block capitals and is clear and legible.

For the purposes of the programme in 2023-2024 an evaluation is being planned and plans for this will be disseminated prior to the start of the programme.

Further detail on the operational aspects of the schools immunisation programmes are available in the Supporting Information for Staff School Immunisation Programme 2023-2024 academic year document.<sup>3</sup> <u>https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff.pdf</u>

#### 3.5.4 Clinical Staff Roles

- If the parent/legal guardian requests further clinical advice about the vaccine they can be referred to a clinical member of the vaccination team
- If a parent consents but the student refuses vaccination on the day of the session, the student should not be vaccinated. This must be recorded on the consent form
- If vaccines are refused, the date of refusal and PIN of the person writing the refusal should be added to the form. Please record a reason if stated.
- Where parents/legal guardians have refused consent for vaccination, the reason for refusal should be reviewed by a clinical member of the vaccination team. If there is a clear refusal, parents/legal guardians should not be contacted.
- Where a consent form is returned and a parent/legal guardian has left the consent blank or only filled in the Yes/No sections, a clinical member of the team should phone the parent/legal guardian to seek clarification about their consent. The date and time of the phone call should be recorded on the consent form and the clinician's PIN, consent or refusal witnessed by two members of staff.

#### 3.6 Post-Vaccination Advice

This post-vaccination information leaflet also called the tear sheet

https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/postvaccchildflu.pdf (Appendix H) should be given to children/their teachers to be sent home with the child following vaccination. If appropriate, depending on the age of the child, vaccinators may reiterate some of the information that is contained in the information leaflet.

This information leaflet advises parents that:

- Their child received Fluenz Tetra nasal flu vaccine.
- Most children have no problem after this vaccine.
- Some children may get:
  - a runny or blocked nose
  - headache or muscle aches
  - a fever (temperature) after the vaccine.
  - These are usually mild and only last a day or two.
- If their child has a fever (temperature) or a headache they can give them paracetamol or ibuprofen.
- Their child should not be given aspirin or medicines called salicylates, unless they have been prescribed by a doctor.
  - This is especially important in the 4 weeks after getting the vaccine.

- Child should avoid influenza antiviral medication for 2 weeks after getting the vaccine.
- Serious side effects such as a severe allergic reaction are very rare.
- If their child is very unwell after the vaccine, they should talk to their GP (doctor) or Pharmacist as it may be for some other reason

There may be a number of circumstances where additional correspondence with parents is necessary. A number of suggested letter templates are included as Appendix F for these scenarios, for example:

- In relation to a child in a high-risk group who requires two doses of the LAIV vaccine (Section 3.8.1)
- In relation to a child who is eligible for the LAIV but could not receive it on the day e.g., due to a child feeling unwell or refusing vaccination
- In relation to a child for whom the LAIV is contraindicated (Section 2.4), advice should be given to parents that their child should get the QIV (unless also contraindicated). For this programme, children in this category can be referred to their GP or Pharmacist to receive the QIV.

#### 3.7 Post-Vaccination Procedures

Following administration of the vaccine the child should be advised to remain in the vaccination clinic for at least 15 minutes to allow monitoring for any immediate reaction including possible anaphylactic reaction. The vaccination should be recorded on a vaccination record form and given to the child/teacher to be taken home.

#### 3.7.1 Adverse Reactions

In the unlikely event of adverse reaction occurring following administration of the vaccine, parents/legal guardians/students should inform the school immunisation team of any adverse reactions to the vaccine by contacting the HSE area office.

The vaccinator should report relevant suspected adverse reactions to the HPRA. Details of adverse events may be recorded on the adverse event clinical record (Appendix I). When reporting suspected adverse reactions to the HPRA, details of the brand name and batch number of the vaccine should be included in the report. An adverse reaction report form can be accessed by:

 Following the links to the online reporting options accessible from the HPRA website at <u>http://bit.ly/HPRAar</u>

- Using a downloadable report form also accessible from HPRA website, which may be completed manually and submitted to the HPRA via "freepost" available from the HPRA website <u>http://bit.ly/HPRAIssue</u>
- By using the traditional "yellow card" report which can be requested in bulk from the HPRA. The "yellow card" also utilises the free post system.
- By telephoning the HPRA Pharmacovigilance Section 01-6764971.

#### 3.7.2 Incident Reporting

In the event of an incident occurring during a vaccination session, an incident report must be completed by the professional primarily involved in the incident and forwarded to the relevant manager and/or to local or regional Risk Manager as per local policy. The vaccine recipient and/or significant others should be informed of the incident.

In the case of medication errors that directly involve the vaccine recipient, i.e., wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions. The recipient should be reviewed by the relevant medical practitioner/clinical lead/ lead vaccinator and the vital signs should be recorded. The incident must be reported to the relevant line manager/person in charge as soon as possible and the vaccine recipient and/or significant others should be informed of the incident. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. The National Incident Report Form (NIRF 01 – V11) (2020) is available at: <a href="https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person-interactive.pdf">https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person-interactive.pdf</a> Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

The HSE open disclosure policy should be adhered to and the parents/legal guardian should be notified of the error as soon as possible.

#### 3.8 Special Considerations for the LAIV programme in schools 2023/24

#### 3.8.1 Management of Children in High-Risk Groups

Children age 2-8 years who are in an at-risk group (practically this will be those aged 4-8 years in a primary school setting) and who have never had **any** flu vaccine before should get two doses of the LAIV four weeks apart. It is expected that this will be a small number of children as the LAIV has been available since 2020 and the QIV prior to that for medically at-risk children. For the purposes of the programme the vaccination teams in conjunction with the schools immunisation teams should identify children with underlying conditions, via information on the consent form completed by parents (which includes a pre-vaccination screening questionnaire). Children in this category should

be offered one dose of LAIV administered by the school vaccination team and the child should be given a letter advising the parent to attend their GP or Pharmacist four weeks later to receive their second dose (Suggested wording of letter to parent included as Appendix F).

#### 3.8.2 Delayed Vaccination

In the context of the LAIV programme it will not be possible to offer a mop-up clinic as is the case with other schools immunisations. Children who have consented but have missed their vaccination should be directed to their GP or pharmacy to receive their vaccine.

#### 3.8.3 Impact of COVID-19

There have been a number of challenges to the Schools Immunisation Programme due to the COVID-19 pandemic. Some schools remain unable to accommodate school immunisation teams. Where schools are unable to accommodate school immunisation team vaccination can take place in locally established clinics or mobile vaccination clinics if available. Given international evidence of the advantages of a school-based programme, the schools immunisation programme should continue to be delivered in schools where possible. See Appendix G.

#### 3.8.4 Evaluation

For the purposes of the LAIV programme in 2022-2023 an evaluation is currently being planned and details will be disseminated before the programme commences.

#### 3.9 Additional Information

Details of training available to support the flu pilot programmes is available in Appendix A. A template for a letter from Vaccination Based to local school Principals explaining the LAIV programme is included as Appendix J.

Information on immunisation during COVID-19 including infection prevention and control advice is included as Appendix G.

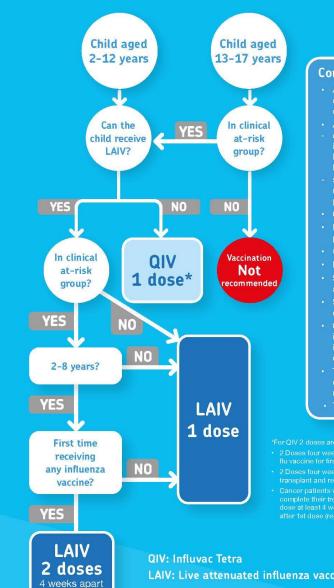
#### **Appendix A: Training Available to Support Vaccination Teams**

- 2 HSELanD training modules on LAIV developed by NIO. These programmes can be found by following these steps:
  - Register or Log into HSEland
  - o Select Course Catalogues along the top ribbon
  - $\circ$  ~ Select Clinical skills on the page that opens
  - $\circ$   $\;$  Select National Immunisation Office from the programme options
  - Select Influenza vaccination and begin the programmes by enrolling.
- Website <u>www.hse.ie/flu</u> has been updated to provide information for those who are recommended the influenza vaccine through the HSE programme.
- LAIV Medicines Protocols available here:
   www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/
- FAQs to support vaccinators available here:
   www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/flufag/
- A video to demonstrate how to give a nasal flu vaccine produced by the NIO available here: <u>https://youtu.be/89N1Yf9svRk</u>
- There are also limited training nasal applicators that could be made available if vaccinators wish to practice administration of nasal flu vaccine.
- Operational Guidance document located on SHAREFILE: <u>https://healthirl.sharefile.eu/home/shared/fo0d129e-a2b6-4942-b61a-41d7791f1d0f</u>

#### **Appendix B: LAIV in Children Algorithm**

Algorithm outlining the procedure for the LAIV in children aged 2-17 years available at: https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/laivalgorithm.pdf

# Flu Vaccine for children 2023/24



#### Contraindications to LAIV

- increased wheezing and/or additional bronchodilator treatment in the previous 72

- Children who live with an immunosuppressed person requiring
- Those post cochlear implant until the risk of CSF leak has resolved consult with the

- Complete their treatment in the same season require two doesn's with the 2nd complete their treatment in the same season require two doesn's with the 2nd dose at least 4 weeks after completion of chemotherapy and at least 4 weeks after 1st dose (regardless of influenza vaccination in previous seasons).

LAIV: Live attenuated influenza vaccine. Fluenz Tetra







### **Appendix C: Pre-Vaccination Information Leaflet for Parents**

Patient information leaflet is in different translations, is available here: <u>https://www.hse.ie/eng/health/immunisation/pubinfo/flu-</u> vaccination/information/information-material.html





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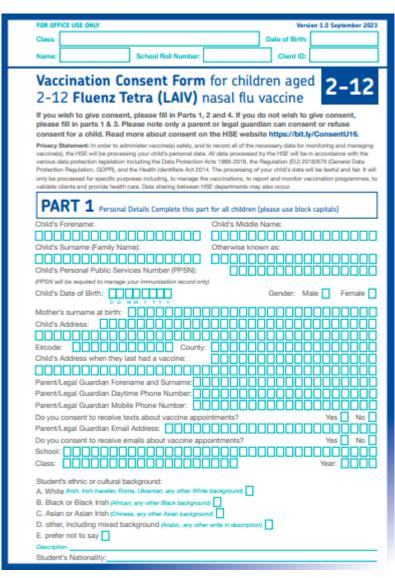




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#### Appendix D: Consent Form for LAIV in Schools:

https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/laivconsentform.pdf https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/irishlaivconsentform.p df



#### **Appendix E: Example Letter for Parents in School Packs**



Oifig Náisiúnta Imdhíonta HSE National Immunisation Office www.hse.ie/flu

September 2023

#### Re: Nasal Flu Vaccine for pupils in Senior Infants

Dear Parent or Guardian,

In this pack you will find information about the nasal flu vaccine. Please read the information, complete the consent form and return it in the envelope provided.

The flu vaccine is recommended for all children aged 2-12 years. This year children in Senior Infants are being offered the flu vaccine in school by HSE vaccination teams. The vaccine that your child is being offered is called Fluenz Tetra. It is a safe and effective vaccine that is given as a nasal spray.

#### What you will find with this letter

- Information leaflets about the vaccine and the disease they prevent. Please read this
  information carefully and you can also use them to discuss these vaccinations with your
  child.
- Consent form for vaccination.
  - Please complete consent form.
  - Return this form in the envelope provided before the vaccinations begin.
  - This form must be completed in BLOCK CAPITALS in pen and signed by the parent or guardian.

What you could do to help on the day of vaccination

On the day of vaccination, please make sure your child:

- Eats breakfast
- Brings their immunisation record card/immunisation passport to school, if they have one.

Please contact the HSE vaccination team before your child is vaccinated if there are any changes in your child's health.

Visit <u>www.hse.ie/flu</u> for more information about this vaccine and for contact details for the HSE vaccination team.

Kind Regards

Dr Lucy Jessop Consultant in Public Health Medicine – National Immunisation Lead National Immunisation Office MRCN 424447

#### **Appendix F: Suggested Template Letters**

### Template letter 1: Child in high-risk group (aged 2-8 years and has not received the flu vaccine in previous seasons) who requires second dose of LAIV in four weeks

Dear Parent/Legal Guardian,

Your child received their nasal spray flu vaccine today given by the schools immunisation team. Along with this letter, you will also receive a post-vaccination information leaflet sent home from school with your child.

Based on the information you provided to the immunisation team in the pre-vaccination consent form, your child is in a group **at high-risk of complications from influenza infection and therefore requires a second dose of the vaccine for maximum protection**.

This second dose of the nasal spray flu vaccine should be given in **four weeks time.** This will be available free of charge from your child's GP or Pharmacist. Please make an appointment with your GP or Pharmacist for your child to receive this vaccine and bring this letter and the post-vaccination information leaflet with the details of your child's vaccination with you.

Yours sincerely,

Template letter 2: Child who is eligible for LAIV but did not receive on the day as, for example, the child felt unwell or refused vaccination

Dear Parent/Legal Guardian,

Unfortunately, due to an issue identified on the day by the schools immunisation team, **your child did not receive the nasal spray flu vaccine in school today.** 

Your child can still receive the nasal spray flu vaccine at an alternative time from your GP or Pharmacist and your child should still be vaccinated against the flu to protect them against infection with flu which can sometimes cause complications in children. Vaccinating your child benefits them and also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions.

The flu vaccine is available free of charge from your GP or pharmacy to all children aged 2-12 years and children at risk of flu related complications aged 13-17. Please make an appointment with your GP or Pharmacist for your child to receive this vaccine.

Yours sincerely,

## Template letter 3: Child identified as having a contraindication to the LAIV advising them to get QIV

Dear Parent/Legal Guardian,

Many thanks for completing the consent form for your child to receive the nasal spray flu vaccine. Based on the information provided to the schools immunisation team in this form, your child **should not receive the nasal spray flu vaccine** due to their pre-existing medical condition or current medical treatment.

Your child should still be vaccinated against the flu to protect them against infection with flu which can sometimes cause complications in children. Vaccinating your child benefits them and also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions. **Therefore, your child should receive the injected flu vaccine**.

Please make an appointment with your GP or Pharmacist for your child to get the injected flu vaccine and bring this letter with you.

Yours sincerely,

#### Appendix G: Immunisations during COVID-19

The World Health Organization state that immunisation services are an essential health service and should be maintained. The Departments of Health and Education are supportive of continuing immunisation services in schools during academic year 2023/2024.

The school should be reassured that all staff will be following HSE/HPSC infection prevention & control guidelines and will take every precaution to ensure the safety of pupils and staff when on the premises.

Children should not be attending school if they have COVID-19. Usual checks should be made to ensure that the child is feeling well on the day of immunisation.

#### Infection Prevention and Control Advice

All current COVID-19 infection prevention and control (IPC) guidance should be followed

#### **IPC Standard precautions**

Adherence to Standard Precautions with all individuals at all times is paramount to maintain the safety of the students and staff at the vaccine clinic which include:

- Hand hygiene
- Perform hand hygiene with alcohol hand gel before vaccine preparation
- Perform hand hygiene immediately before and after each physical contact with the student.
- Hand gel dispensers: Alcohol hand gel sanitisers can be provided at the entrance and exit of the vaccine session, if the school does not have these already, to promote the hand hygiene for all staff and students.
- Promotion of respiratory hygiene and cough etiquette: Use tissue or sleeves to cover nose and mouth while coughing /sneezing and followed by hand hygiene.

Please refer to HPSC guidelines for up to date information on infection prevention and control: <a href="https://www.hpsc.ie/a-">https://www.hpsc.ie/a-</a>

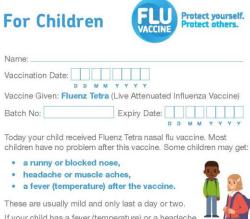
z/respiratory/coronavirus/novelcoronavirus/guidance/guidanceforhealthcareworkers/

No additional specific personal protective equipment is required for the administration of nasal flu vaccine.

#### **Appendix H: Post-Vaccination Information Leaflet for Parents**

Post-vaccination information leaflet for parents/tear sheet available at:

https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/postvaccchildflu.pdf



If your child has a fever (temperature) or a headache you can give them paracetamol or ibuprofen.

Do not give your child aspirin or medicines called salicylates, unless they have been prescribed by a doctor. This is especially important in the 4 weeks after getting the vaccine. Serious side effects such as a severe allergic reaction are very rare.

Talk to your GP (doctor) or pharmacist if your child is very unwell after the vaccine, as it may be for some other reason.

Please visit www.hse.ie/flu for more information.

hse.ie/flu Public Health Advice





#### **Appendix I: Adverse Clinical Record Form**

Adverse event clinical record available from

https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/aeci.pdf

#### **Appendix J: Maintenance of Cool Box Temperature**

- Vaccines should be stored in the vaccine fridges at the main health centres in accordance with the NIO Vaccine Fridge Standard Operating Procedure (SOP). See <a href="https://bit.ly/CCSOP1">https://bit.ly/CCSOP1</a>
- Solid walled or vaccine specific soft walled insulated cool boxes and ice packs/gel packs from a recognised medical supply company must be used and should be used in conjunction with a validated thermometer or data logger device with an external display. Domestic cool boxes should not be used.
- Cool box temperature should be maintained between +2°C and +8°C at all times.
- For all packing materials and equipment, ensure that the specifications of each item are adhered in accordance with the manufacturer guidelines. Each site should have SOPs on how to pack a cool box with the ice/gel packs and vaccines. The risk of freezing of vaccines in cool boxes increases if ice/gel packs are not correctly conditioned or separated by insulating material.
- The number of packs used should be as per cool box manufacturer's instruction and local SOP.
- The ice packs should be positioned appropriately above, below and around the vaccines as space in the cool box allows.
- Thermometer probe (or data logger) should be placed in the middle of vaccines and should not touch ice packs/gel packs. To prevent probe from moving during transport, it can be placed in an empty vaccine box, placed in the middle of the vaccines.
- The lid of the cool box should be tightly shut and kept closed as much as possible (reducing lid opening helps to keep internal temperatures stable.
- It may be necessary to add/remove ice packs as the temperature dictates.
- Only the number of vaccines estimated for administration on any particular day should be brought to the school.
- The vaccines must be transported in their original packaging, and placed in the cool box as per the manufacturer's instructions.
- The time of packing and returning the vaccines should be recorded.
- The cool box should be placed in,
- An appropriately ventilated room
- Away from any heat source
- Away from direct sunlight
- Record the temperature of the probe in the cool box:
  - $\circ$   $\,$  when vaccines are packed
  - o upon arrival at the immunisation clinic
  - o throughout the immunisation clinic
  - when returning vaccines to the fridge.
- Vaccines, in their original packaging that have been maintained under cold chain conditions, and are returned to the health centre fridge following school vaccination session should be marked and used first on their next excursion to a school.

- If these marked vaccines are taken to a second vaccination session and are not used providing the cold chain has been maintained these vaccines can be returned to the vaccine fridge again, for administration at the next session.
- A data logger should be used in the cool boxes where external temperature display records only current temperature. This will provide an accurate account of temperatures reached and the duration of any temperature breach. The information on the data logger can be downloaded at the end of a vaccination day to confirm that any returned vaccines have remained within temperature. A data logger does not replace the need to check cool box temperatures each time when removing vaccines prior to administration.
- The cool box thermometer / data logger should calibrated annually.
- Procedures following breakdown in the "Cold Chain"
- If temperatures outside the permitted range are recorded, first check the position of the temperature probe. The temperature probe should be in a vaccine box in the middle of the vaccines if it is not correctly positioned reset the probe and ensure it is positioned correctly away from ice packs or at the lid of cool box then close the box firmly and recheck the temperature in 15 minutes.
- If the temperature is still outside the permitted range please contact the National Immunisation Office immediately.

Contacts include:

Achal Gupta: mobile 087 4064810 Leah Gaughan: mobile 087 1881667 Cliona Kiersey: mobile 087 9915452 or Email pharmacynio@hse.ie

The NIO will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines or whether they should be discarded. Do not use or dispose of any vaccine which has been exposed to temperatures outside the permitted range. Quarantine and maintain these vaccines between +2°C and +8°C until advised by the National Immunisation Office.

#### **Appendix K: Emergency drugs and Equipment**

Emergency Anaphylaxis Kit –as per updated section February 2023 in Immunisation Guidelines : <u>https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland</u>

NB Updated advice from NIAC: the use of autoinjectors is no longer recommended. Adrenaline (epinephrine) auto-injectors are not recommended as first line treatment by health professionals for the immediate management of anaphylaxis or suspected anaphylaxis following vaccination unless they are the only source of adrenaline available, as they may not allow IM delivery of an age appropriate dose

The availability of protocols, equipment and drugs necessary for the management of anaphylaxis should be checked before each vaccination session

- Copy of "Anaphylaxis: Immediate Management in the Community" from Immunisation Guidelines for Ireland
- 3 x 1ml ampoules of Adrenaline (1:1,000, 1mg/ml)
- 3 x 1 ml syringes
- Needles 3 x 25mm, 3 x 38 40mm
- 1 pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of Adrenaline

The kits should be kept closed to ensure the drugs are not exposed to light and stored at room temperature. The kits require regular verification to replace drugs before their expiry date.

There should also be a back-up emergency anaphylaxis kit so that a vaccination session can continue in the event that a student has been treated for anaphylaxis using up the anaphylaxis kit.

**Emergency equipment** 

- Access to a telephone to call an ambulance.
- Copy of "Anaphylaxis: Immediate Management in the Community" from Immunisation Guidelines for Ireland.
- Adverse event clinical record (Appendix I) and pen to record time of administration of adrenaline and clinical condition of patient.
- Headed notepaper to write referral letter for hospital.
- Sphygmomanometer x 1 with adult and paediatric cuff.
- Stethoscope x 1.

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