



Supporting Information for the Administration of the Nasal Flu Vaccination to Children and Young People in HSE Walk-in Clinics

Seasonal Influenza Vaccination Programme 2023-2024

December 2023 Version 2

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1 Introduction

The Department of Health in line with the National Immunisation Advisory Committee (NIAC) have expanded the influenza (flu) vaccination for all children aged 2-17 years for the 2023-2024 seasonal influenza programme. 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. 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. ²

This document aims to support vaccinators in HSE vaccination bases running HSE walk-in nasal flu vaccine clinics across Ireland as they undertake vaccination of children and young people aged 2-17 years in the 2023-24 seasonal influenza programme. The document should be used in conjunction with NIAC guidelines on influenza (Chapter 11).

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 focused target for key groups including children and young people aged 2-17 years.

The 2023/2024 HSE seasonal vaccination programme will offer:

- Quadrivalent live attenuated influenza vaccine (LAIV), nasal application for those aged 2-17 years.
 Brand available:
 - ✓ Fluenz Tetra nasal spray suspension Influenza vaccine (live attenuated, nasal) manufactured by AstraZeneca AB
- Inactivated quadrivalent influenza vaccine (QIV) available for all other eligible populations including those aged 2-17 with contraindications to LAIV (QIV is licensed for those 6 months of age and older).

 Brand available:
 - ✓ Influvac Tetra marketed by Mylan

The groups recommended the free HSE flu vaccine include: 1

- 1. Quadrivalent Influenza Vaccine (QIV) which is given by intramuscular (IM) injection and recommended for:
 - Children aged 6-23 months old and adults aged 18-64 years who are at risk of influenza related complications
 - Children and young people aged 2-17 years for whom LAIV is contraindicated
 - Pregnant women

- Healthcare workers (HCWs)
- Carers
- All those aged over 65 years
- 2. Live Attenuated Influenza Vaccine (LAIV) which is administered intranasally and is recommended for:
 - Those aged 2-17 years (unless contraindicated)

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

https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

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. For the 2020-21 season, LAIV was initially offered to those aged 2-12 years, and a similar approach was being taken for the 2023-24 flu season. 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 ². Later in the 2020-21 and 2023-24 flu season, the programme was extended to those aged 13-17 years. For the 2021-22 and 2022-23 flu seasons, LAIV was offered to all children and young people aged 2-17 from the beginning of the season.

Based on HPSC data, the uptake in 2022-23 for children aged 2-17 years was 15.4%. The target uptake for those aged 2-17 years for the 2023- 2024 flu season is 50% with an ambition of 75%.

2 LAIV Administration in Children

2.1 Vaccine, Dose and Route of Administration

The vaccine recommended by NIAC for children aged 2-17 years 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 children aged 2-17 years, 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. Children aged 2-17 years, who are not in a high-risk group, should receive a single dose of LAIV as effectiveness studies have shown that a second dose of LAIV is of little added benefit to healthy children ¹.

Those children aged 2-8 years in a clinically at-risk group, who are at higher risk of complications from influenza, should receive two doses of LAIV, at least four weeks apart, where they are receiving

any influenza vaccine for the first time or where they have an unknown vaccination history. This is summarised in Table 1 and information on which groups of children are considered high risk is provided in Section 2.2, overleaf.

However, due to the time frame of this programme in HSE walk-in clinics only one dose will be administered for all children.

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

Table 1 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
group	receiving influenza vaccine for the first time
	or if the vaccination history is unknown

Please note:

- If the child sneezes or their 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
 - LAIV is contraindicated in children with severe immunocompromise due to disease or 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 LAIV four weeks apart unless it is contraindicated (Section 2.4). However due to the time frame of this programme a second dose will not be possible within HSE walk-in clinics and parents should be directed to primary care for their second dose.

2.3 Precautions to LAIV Administration

- 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
- Seek specialist advice for those who require regular oral steroids or who have previously required ICU care for asthma.

2.4 Contraindications to LAIV Administration

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 2.3 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
- Concomitant use of aspirin/salicylates
- Children who live with a severely immunosuppressed person
 - o e.g. living in isolation 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
- Those post cochlear implant until the risk of a CSF leak has resolved
 - Consult with the relevant specialist
- Those with a cranial CSF leak
- Those with severe neutropaenia
 - Absolute neutrophil count <0.5 x 10⁹/L, to avoid an acute vaccine related febrile episode. This does not apply to those with primary autoimmune neutropaenia, 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. If they present to a HSE walk-in clinic where LAIV is being offered, their parents should be advised to bring the child to their GP or pharmacy to receive the QIV.

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

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 to the Vaccination

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 (≥ 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: https://www.ema.europa.eu/en/documents/product-information_en.pdf

2.6 Co-administration of LAIV

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 vaccines.

However, as a precaution for children 6 months to 4 years other vaccines (including the flu vaccine) should be separated from COVID-19 vaccines in this age group by 14 days.

3 Practical considerations for the administration of LAIV in School or Community settings.

3.1 Planning

Following identification of a location and time, key practical aspects to consider when planning a vaccination clinic might include:

- Vaccine supply
- Vaccine storage
- Vaccinators
- o Prescriber (if needed) or medicines protocols
- o Materials for circulation to parents of children attending the clinic
- Administrative approach to recording vaccinations
- o Procedures and equipment for managing adverse reactions to the vaccine

3.2 Preparation

As part of preparation for the vaccination session, vaccine information packs should be developed for onward distribution to all parents when they arrive with the child at the clinic. Parents/legal guardian/young people should receive the following information:

- 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) or they can complete the medical eligibility with the vaccinator on COVAX prior to vaccine administration.

Prior to vaccination it should be ensured that:

- Check the child is aged between the age of 2-17 years before receiving LAIV
- If paper consent forms are used they should be reviewed, completed by the appropriate person and children with contraindications to LAIV identified (Section 2.2)
- Vaccinators are working within their scope of practice remember a vaccine is a prescription only product.

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

- Immunisation Guidelines for Ireland available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- Summary of Product Characteristics (SmPCs) for LAIV available at www.hpra.ie
- " Anaphylaxis: Immediate Management in the Community " protocol, in the Immunisation Guidelines for Ireland available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
- HSE Communicating Clearly with Patients and Service Users guidelines http://bit.ly/CommClear
- 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 the previous two years

3.3 Resources and Equipment

Each local context will have access to different amounts of staff resource to facilitate vaccinations in a community setting but it is important that the following aspects are considered when forming a vaccination team:

- There should be a sufficient number of appropriately trained vaccinators to meet the predicted or expected demand in the clinic, particularly in 'walk-in' clinics where care needs to be taken to avoid the congregation of a large number of people in confined indoor spaces.
- Having administrative staff on site may allow an increased efficiency in checking-in attendees and logging/recording vaccinations delivered.
- Support staff may be helpful, to assist with the transport of equipment and the practical set up
 of the space. They may be useful to assist in 'crowd management' activities.

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

 LAIV (This comes as a suspension in pre-filled nasal applicator. Ready to use. No reconstitution or dilution needed)

- 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: Treatment in the Community (National Immunisation Advisory Committee, 2019) available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland)
- Safe storage areas for medicines and equipment
- Medicine protocols if being used by nurse vaccinators or a prescription

3.4 Vaccine Ordering and Storage

Flu vaccines can be ordered by vaccination sites at the HSE National Cold Chain Service (NCCS) using the online ordering system <u>ordervaccines.ie</u> where your calendar is available, indicating order dates and delivery dates. There is limited availability of LAIV - please only order what you require.

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 pharmaceutical fridge tomaintain 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.

Please note ideally only vaccines that need to be used should be removed from the fridge temperature controlled environment. Once the vaccine is removed from the fridge it should be administered to a patient soon after.

3.5 Pre-Vaccination Procedures

3.5.1 Consent

Informed consent must be obtained prior to vaccination.

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

o "(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 http://bit.ly/MC8thEd

In order to support the provision of appropriate information to children and their parents/legal guardians, an information leaflet is available in Appendix C, (https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/information/information-material.html).

A suggested consent form for LAIV administration in children and young people has been developed and can be found in Appendix D or the medical eligibility questions available on COVAX can be used to assess suitability prior to vaccination.

3.5.2 Assessment of the Child or Young Person for Vaccination

Before assessing the suitability of a child or young person for vaccination:

- Confirm their 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?"
- Confirm that informed consent has been given by a parent/legal guardian (for children under 16 years of age). Children under the age of 16 should be accompanied by their parents or legal guardians to provide consent at the time of vaccination.
- Address any clinical issues raised on the consent form or on the medical eligibility question on COVAX
 - This process should identify children for whom the LAIV is contraindicated
- Vaccines should only be given to children and young people who are well on the day, and for whom no contraindication is identified as per the Immunisation Guidelines of Ireland (https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland):
 - The child or young person's temperature should not be checked routinely in the school or community clinic at the time as this is not conclusive and is therefore unhelpful in the decision-making process
 - Any child or young person 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 advised to re-attend their GP or Pharmacist for vaccination at an appropriate time.

3.5.3 Vaccination Record Forms

Vaccination data including medical eligibility should be recorded onto COVAX during the vaccination session. However, if paper consent forms are used; once the parent/legal guardian completes their part of the consent form, and once vaccination 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).

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 E) should be given to children/parents/legal guardians. Vaccinators should reiterate some of the information that is contained in the information leaflet.

This information leaflet advises parents/legal guardians that:

- Their child received Fluenz Tetra nasal flu vaccine.
- Most children have no problem after this vaccine.
- Some children may get:
 - o a runny or blocked nose
 - o headache or muscle aches
 - o a fever (temperature) after the vaccine.
 - o 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.
- 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.

3.7 Post-Vaccination Procedures

Following administration of the vaccine the child or young person should be advised to remain in the vaccination clinic for 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/parents/legal guardians 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 should inform the GP or pharmacist who organised the vaccination clinic.

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 F). 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 http://bit.ly/HPRAar
- 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 http://bit.ly/HPRAIssue
- 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.

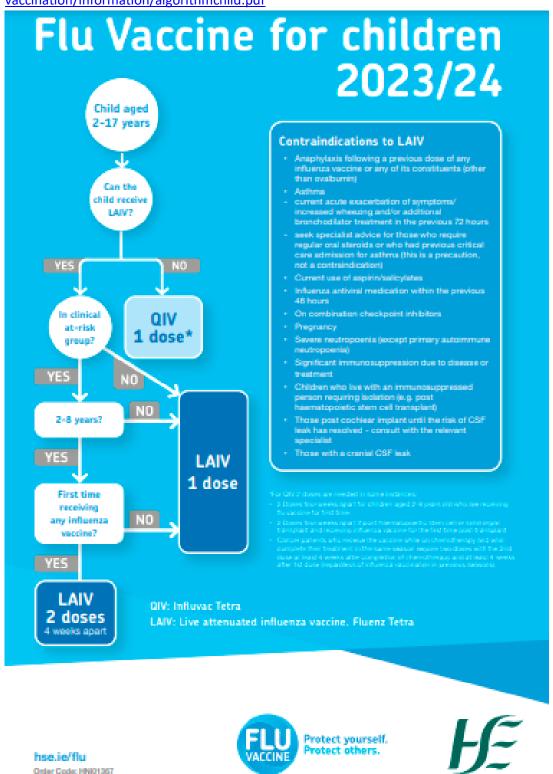
Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

Appendix A: Training Available for Community administration of LAIV

- 2 HSELanD training modules on LAIV developed by NIO. These programmes can be found by following these steps:
 - o Register or Log into hseland.ie
 - Select Course Catalogues along the top ribbon
 - o Select Clinical skills on the page that opens
 - o 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.
- FAQs to support vaccinators available here:
 www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/flufaq/
- A video to demonstrate how to give a nasal flu vaccine produced by the NIO available here: https://youtu.be/89N1Yf9svRk
- A webinar for HSE vaccinations teams offering the children's flu vaccine in schools might also be helpful: https://youtu.be/8E_28WCanhQ
- Information for healthcare professionals on the flu vaccine including immunisation guidelines: www.immunisation.ie
- Clinical enquires please email: immunisation@hse.ie
- There are also limited training nasal applicators that could be made available if vaccinators wish to practice administration of nasal flu vaccine.

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/information/algorithmchild.pdf



Appendix C: Pre-Vaccination Information Leaflet for Parents

Patient information leaflet is in different translations, is available here:

 $\underline{\text{https://www.hse.ie/eng/health/immunisation/pubinfo/flu-}}$

vaccination/information/flu2022childleaflet.pdf



Appendix D: Consent Form and Pre-Screening Questionnaire for LAIV in Schools:

https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/englaivconsentformall.pdf

https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/irishlaivconsentformall.pdf

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Appendix E: 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-

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Vaccination Date:						
Vaccine Given: Fluenz Tetra (Live Attenuated	Influe	enza	a V	acc	oin	e)
Batch No: Expiry Date:						

Today your 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 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





vaccination/postvaccchildflu.pdf

Appendix F: Adverse Clinical Record Form

Adverse event clinical record is available if you wish to use it: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/aeci.pdf

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- 1. National Immunisation Advisory Committee. NIAC Guidelines Chapter 11 Influenza. Dublin: NIAC; 2022.
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