National COVID-19 and Influenza Vaccination Programme Operational Guidance for General Practice

Version 1

Dated: 11/09/2024

Version	Date	Prepared by	Version Updates
V1.0	11/09/24	Vaccinations Primary Care Contractors	

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1. Overview and Introduction

The Seasonal Vaccination Programme is developed based on the recommendations issued by the National Immunisation Advisory Committee (NIAC), available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland.

The aim of the Vaccination Programme is to ensure equitable access to safe and effective vaccines with the goals of limiting severe disease and death from COVID-19 and Influenza, protecting healthcare capacity and enabling social and economic activity. The COVID-19 and HSE Influenza vaccine is free to all eligible persons of the State.

The National Immunisation Advisory Committee (NIAC) provides evidence-based advice to the Chief Medical Officer and the Department of Health on vaccines, immunisation and related health matters to inform health policies in Ireland, which includes COVID-19 and Influenza vaccination.

General Practice continues to play a key role in the delivery of the vaccination programmes in accordance with the agreed national vaccination schedule.

This operational guidance provides best practice for the implementation of the programme, including logistical arrangements and processes established for the management of the vaccine programmes to patients in General Practice.

The programmes are integrated to maximise available resources, to promote uptake and to provide those eligible with the opportunity to receive both COVID-19 and Influenza vaccinations together.

2. Clinical Governance and Guidance

2.1 Clinical Governance
The clinical governance for ensuring the patient is eligible for vaccination in line with HSE Guidance on eligibility and interval periods, administering the vaccine and managing the person post-vaccine, rests with the GP.

2.2 Clinical Supporting Information
Guidelines and information are available for the COVID-19 and Influenza vaccines. These resources include information such as how to administer the vaccine, the possible side effects, the required post vaccination observation times, the management of anaphylaxis and FAQs. GPs should keep up to date with the latest HSE Clinical Guidance from the National Immunisation Office at NIO Clinical Guidance.

GPs and Practice Nurses should direct all clinical queries to the NIO via immunisation@hse.ie

3. Vaccination Primary Care Contractors (VPCC)

The COVID-19 and Influenza Vaccination Programme is supported by the HSE Vaccinations Primary Care Contractors team, who co-ordinate the service and provide relationship management support to GPs and Community Pharmacists. For further details, please see VPCC Webpage.

There are a number of resources to support vaccinators in the provision of COVID-19 and Influenza vaccines, including FAQs and guidance notes.

4. Indemnity

Claims management in relation to claims and litigation initiated in connection with COVID-19 vaccination has been delegated to the State Claims Agency by means of Government Order. Registered medical practitioners (including GPs), nurses and other health professionals in receipt of relevant training with regard to administration of the vaccine, who are administering vaccines on the direction of, or on behalf of, the HSE will be indemnified with regard to any adverse product liability-related events arising from their administration of the COVID-19 vaccine.

GPs and Nurses will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.

5. Training

Vaccines may be given by doctors and nurses. Nurses may administer vaccines under doctor or registered nurse practitioner prescription or under a medicine protocol within their scope of practice.

- In line with indemnity cover, the GP must be satisfied that all staff, employed or engaged, have the requisite knowledge and skills to deliver the vaccination service safely. The GP must be satisfied that all staff are registered and have completed the required training on HSeLanD, and all are familiar with the provision of vaccination services and are trained according to their level of involvement in the process.
- Extensive information, Immunisation Bulletins and training on COVID-19 and Influenza vaccines has been prepared by the NIO and other clinical experts. This information is reviewed regularly; please ensure to have up to date and accurate information when vaccinating.

Influenza vaccination resources are available on the immunisation website.

6. How to Join the Vaccination Programme

For information on joining the Vaccination programme, please see Information for General Practices.

7. Communications

HSE.ie has comprehensive information available on HSE COVID-19 and Influenza vaccinations.

7.1 Access to COVID-19 and Influenza information materials
See Guidance Note 1 – Guidance on COVID-19 and Influenza Vaccine Consumables and Information Resources

Additional resources are available at COVID-19 Vaccine Materials and at Flu Vaccine Information.

8. Vaccine Updates

8.1 Vaccination and Eligibility

The vaccine programme is informed by NIAC guidance. Clinical guidance and supporting information including eligibility for COVID-19 and Influenza is available from National Immunisation Office (NIO) at www.immunisation.ie.

A number of vaccine resources are available at:
COVID-19 vaccines quick reference table see Clinical Information on COVID-19 Vaccines.
Influenza vaccines quick reference table see Quick Reference Guide to Influenza Vaccines.
Risk Management Considerations when Multiple Vaccines are in use, see **Appendix 1**.
Frequently Asked Questions for Healthcare Professionals about immunisation see Frequently Asked Questions about immunisation.

VPCC have developed a range of resources to support General Practice in the delivery of the programmes see Information and Resources for Vaccination Programme, including vaccination programme guidance notes and FAQ's.

GPs are required to familiarise themselves with the updated clinical guidance including appropriate vaccine selection in pregnancy and breastfeeding, and for immunocompromised individuals. For further information on inputting immunocompromised status in GP PMS, see Guidance Note 10.
See Guidance Note 3 Guidance on Repeat Primary Course COVID-19 Vaccination.
Alternative pathways are in place for patients where mRNA vaccines are contraindicated refer to Guidance Note 6.

9. Ordering Vaccine Stock and Consumables

See National Immunisations Office for comprehensive information on Vaccine Ordering and Storage.

9.1 Vaccine Stock

The vaccine supply chain is managed by the NIO and the HSE National Cold Chain Service (NCCS).
Practices order online through www.ordervaccines.ie.

9.2 Return of Expired Vaccine Stock

Any expired stock should be returned to NCCS using the normal process, see Vaccine Return Form.

9.3 Vaccine Consumables for COVID-19 in General Practice

A national distribution service (JMC Logistics) will deliver Personal Protective Equipment (PPE) and clinical and non-clinical consumables.   For further information, please refer to Guidance Note 1.

In addition, there is a PPE demand system, where requests can be made through the HSE PPE Portal.

• Hand Gel Small (100ml) • Hand Gel Medium (500ml) • Nitrile Standard (Small) • Nitrile Standard (Medium) • Nitrile Standard (Large) • Nitrile Standard (X-Large) • Goggles • Face Shields • Isolation Gowns • Disposable Aprons • FFP2 Any Brand	• Type II Surgical Mask – Ear loop • Type IIR Surgical Mask – Ear loop • Type IIR Surgical Mask With Clear Window • Type II Surgical Mask - Tie-back • Type IIR Surgical Mask - Tie-back • Rapid Antigen Diagnostics Tests – 5 Pack • COVID-19 Specimen Testing Kit - 5 Pack

10. Management of Vaccines in General Practice

See HSE Guidelines for Maintenance of Cold-Chain in Vaccine Fridges and Management of Vaccine Stock

10.1 Removal of Waste from General Practice
Waste vaccines and empty vials must be disposed of into sharps bins according to normal local waste management procedures.

11. Record Keeping

There are a number of record keeping requirements that apply to the supply and administration of a COVID-19 and Influenza vaccination. The following particulars should be recorded contemporaneously in respect of each administration:

a) the date of administration;
b) the name, address, contact number(s), email address(es), ethnicity, pregnancy status, date of birth and sex of the person to whom the product was administered, to the extent that the person can provide such particulars;
c) Consent (see further information in Section 17 on consent);
d) the patient's Personal Public Services Number (PPSN);
e) the name and batch number of the product (not serial number);
f) expiry date / use before date (and/or time) of the product;
g) the vaccinator's name, their business address, email and telephone number of the person who supplied and administered the product and the number of his or her certificate of registration issued by his or her professional regulatory body (this is known as the PNV i.e. NMBI or MCRN);
h) the name, MCRN, address and telephone number of the general medical practitioner (where provided) of the person to whom the product was administered to the extent that the person can give such particulars.

For those practices without a recognised GP Practice Management System (PMS), the HSE has developed HSE GPVax an IT portal solution which will allow these records to be transferred to the national COVAX IT system.
A patient vaccination record card with batch level detail must be provided to the patient.

12. Data Quality

Sometimes the data messages coming from the source systems may not communicate correctly or the data entered may not be fully complete. In order to clarify and address the data issue, the NIO will work with HSELive to seek clarification. This will mean that vaccinators may receive a phone call from HSELive to clarify data items. HSELive is part of the HSE and the team work closely with the NIO and contracting office to seek clarification to resolve DQ issues. There is dedicated line for GP's to ring HSELive, in relation to DQ issues which is: 01 2408786.

Please ensure to capture all details accurately on the system including expiry date and dose sequence as appropriate at time of vaccination.

13. Periodic Product/Batch Removal

Vaccines and any batches which are no longer available for use, will be periodically communicated to GPs prior to removal from the GP PMS.

It is important that all vaccinations relating to products being removed are input into systems prior to the relevant dates, to ensure that patient records are up to date and payment issued. There will be no facility for retrospective entry once the vaccines are removed from the GP PMS.

14. Preparing for a Vaccination Service

In preparation for the ongoing rollout of the vaccines, GPs should conduct periodic risk assessments and capacity assessments to determine if their site is appropriate (premises and staffing levels) for the preparation and administration of the COVID-19 and Influenza vaccines and to determine the number of vaccinations that they can administer safely. Please see **Appendix 2 on Workflow Considerations**

14.1 Practice Premises Requirements

All GMS and GP Visit Card services will already be meeting the premises standards as set out in those contracts but in addition to same, in order to provide vaccines in a safe and efficient manner, GP practices will require the following separate areas:

- Registration/reception area for patients.
- Refrigeration area.
- Vaccination area for patients.
- Observation area for patients - This need not be within the practice building but may be on the practice grounds.

The Practice must be able to provide sufficient staff to meet their requirements.

15. Delivery of Vaccines to Housebound People

Housebound individuals may be referred for COVID-19 Vaccination and / or Flu vaccination once they meet the housebound criteria. The referral pathway for housebound patients can be accessed here VPCC information for General Practice.

16. Adverse Reaction Reporting

The Health Products Regulatory Authority (HPRA) is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the European Medicines Agency (EMA). This enables the EMA to continue to safeguard public health safety.

16.1 Reporting of Incidents During a Vaccination Session

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 incident must also be recorded in the GP incident records and a full investigation should be undertaken to identify the root cause of the incident. The vaccine recipient and/or significant others should be informed of the incident. The NIO will be able to advice on required follow up contact using immunisation@hse.ie Please do not use patient identifiers in this communication.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA. The HPRA must be informed using the Adverse Reaction Report (Yellow) Card System.

17. Consent

For specific information on consent, please see:
- Consent for Vaccination for COVID-19: Guiding Principles.
- Healthcare Professional information for Flu including consent.

GPs must be aware of how consent is obtained for a young person.

The GP/Practice Nurse should record if a patient does not consent and the reason for non-consent, (where such reason is given) as applicable, on the patient's record and on the GP PMS.

18. ICT

The GP PMS for COVID-19 and Influenza vaccination are designed to be used in 'real time', with data being entered as work is completed and patients are vaccinated. In order to prevent duplicate vaccinations please record client vaccinations contemporaneously following vaccination. It also supports appropriate SMS messaging to individuals who are eligible for vaccination.

18.1 Vaccination History Lookup Portal

A 'Vaccination History Search' facility is available to health professionals, such as GPs via the HSE's 'Health Provider Portal'. This allows a GP to look up the patient's national vaccination record, and check eligibility in advance of vaccination, it has details of vaccinations that they have received. This

service is also available to non-clinical staff, subject to having a valid Healthmail account and approval from A2I-HIDS.

Accessing the portal:
• Login at https://www.services.hse.ie preferably at the same computer where Healthmail is routinely accessed.
• Login using Healthmail address and password.
• Once logged in, a verification code will be sent to the alternative email account associated with the Healthmail account. Please check this account for the code and enter at verification stage.

Browser
• Google Chrome, Firefox and MS Edge (latest version) are the recommended browsers.
• Internet Explorer is not recommended. Chrome is preferred.

18.2 Individual Health Identifier

An Individual Health Identifier (IHI) is a number that identifies each person who has used or may use a health or social care service in Ireland. Each individual will be assigned their own personal number which is unique to them. The main benefit of having an IHI is to uniquely identify each service user and therefore, improve patient safety by reducing errors that might happen, such as ensuring patients receive the correct medication, vaccinations, and treatment. The IHI is established first and foremost as a patient safety mechanism. See VPCC Guidance Note 2.

19. Technical Support and Other Contact Details

See General Practice - Contact Details

For further useful contacts and links, see **Appendix 3**

20. Fees, Contractual Arrangements and Reimbursement

20.1 Fees

Any update regarding fees will be communicated with campaign information on HSE Circulars.   See GP Circulars .

20.2 Reimbursement

The Primary Care Reimbursement Service (PCRS) will receive, process and integrate electronic COVID-19 and Influenza vaccination payment claims to ensure that GPs are paid promptly for services provided with minimal administration overhead, and return electronic acknowledgements. Payments will be based on the electronic claims submitted by GPs from their PMS. Payment claims will be validated, loaded, reimbursed and included on the GP's monthly statement.

Each patient will be asked to bring their Personal Public Services Number (PPSN) (if they have one) when attending for vaccination, so that a valid PPSN can be submitted with each electronic claim to facilitate automated payment by the PCRS. A valid PPSN is required for the administration of HSE Influenza vaccines.

Please note that the monthly file of Medical Card and GP Visit Card patients provided by the PCRS to GPs includes the PPSN for each patient. The GP PMS will be updated to auto-populate the PPSN when the patient presents.

COVID-19 claims for the small number of people who do not have a PPSN can be processed through an exceptional reimbursement process through PCRS, every effort should be made to capture the PPSN. Any queries regarding the exceptional reimbursement process can be directed to pcrs.doctorsqueries@hse.ie.

Appendix 1 - Risk Management Considerations when Multiple Vaccines are in Use

The introduction of Vaccines for COVID-19 coincided with the Seasonal Flu Vaccination Programme. Internationally, there have been multiple reports of administration mix-ups between COVID-19 vaccines and flu vaccines[1].

Note that vaccine requirements for recipients may vary:
- Some may require COVID-19 vaccine only.
- Some may require flu vaccine only.
- Some may require both COVID-19 vaccine and flu vaccine.

There are also different doses, different age cohorts, different intervals and there are also different types of flu vaccines in use, increasing the complexity of the process.

Effective planning for safe and robust workflow practices is required. No one single step will eliminate the risk and an active approach to risk reduction is required at all steps in the process from scheduling, to arrival/ registration at the pharmacy, to vaccination and record keeping.

Key steps to Reduce Risk
- Ensure consistent use of **approved terminology (NCCS/SmPC)** for the **names of each vaccine.**
- Schedule vaccine-specific days or sessions where possible.
- Training to ensure awareness of the risks of multiple vaccines being in use is required for all staff involved in any of the steps in the process, even if not working as a vaccinator.
- Avoid the use of the term 'booster' without specifying which vaccine.
- A second independent check on the vaccine(s) to be administered
- And/or ask the vaccine recipient to read the syringe label / vial aloud to confirm the correct vaccine.

COVID-19 Vaccines
Confirm vaccine type with recipient at check-in, consent and immediately prior to administration; and please check before each vaccination:

- Is this a primary course, an additional dose or a booster dose?
- What age is the person?
- What is the recommended vaccine for this age-group?
- What is the recommended dose?
- What is the recommended interval since the last dose?
- Has the person had COVID-19 infection? What is the recommended interval since confirmed COVID-19 infection?

COVID-19 Vaccines and Flu Vaccines
If co-administering COVID-19 and flu vaccines at the same appointment, ensure that:
- Only the required vaccine(s) for the individual recipient are taken into the vaccination area
- Vaccines should be administered in different arms.

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[1] https://www.ismp.org/alerts/mix-ups-between-influenza-flu-vaccine-and-covid-19-vaccines

Appendix 2 – Workflow Considerations

It is envisaged that Practices will:

- Identify priority patients and ensure that they require vaccination (*e.g. use the HSE's Vaccination History Lookup Portal to check the clients' national vaccination record, to see what vaccinations have already been administered and what shots are due)* .
- Facilitate co-administration of vaccines in clinical eligible groups, where possible.
- Contact patients with indicative appointment times.
- Be informed of the vaccine availability and delivery schedule by NCCS.
- Contact patients to confirm appointment times and run through eligibility criteria, including any recent history of COVID-19 infection.
- Receive vaccines from the NCCS as per agreed delivery schedule.
- Check, verify and accept stock delivery.
- Store correctly in fridge.
- Select the correct vaccine on GP practice system (with batch number and expiry date).
- Pre-clinic setup (*e.g. stock control, patient/clinic list*).
- Patient arrival/reception.
- Patient registration (*e.g. verify ID*and update PPSN, mobile phone number and email address)*.
- Verify patient consent and eligibility.
- Vaccinate patient.
- Record and save details on the patient record.
- Submit electronic vaccination details to COVAX (via Healthlink). The electronic payment claim details are submitted automatically to the Primary Care Reimbursement Service (PCRS) (via Healthlink).
- Post-clinic wrap up (*e.g. number of patients vaccinated, stock used/returned to fridge/cannot be used*).
- Patient observation period as required, in line with NIAC Guidelines.
- Treat and record any immediate adverse reactions as per HPRA procedures.
- Provide patient with completed record card.
- Process any electronic vaccination/payment rejections (*e.g. practice staff to correct the details and re-submit, with only the corrected message(s) being sent*).

*Where not known by the GP, patients are required to bring photographic ID and this must be validated.

Appendix 3 - Useful Links and Resources

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

Clinical Guidelines for COVID-19 vaccines
COVID-19 Vaccine Information for Health Professionals - HSE.ie

Anaphylaxis management
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool box
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf

Reporting adverse reactions to the Health Products Regulatory Authority (HPRA). Details of the brand name and batch number of the vaccine must be included.
Online reporting at www.hpra.ie
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
https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction

Summary of Product Characteristics (SmPC) for the COVID-19 vaccine used in the HSE COVID-19 Vaccination Programme available at https://www.ema.europa.eu/en

In the event of a sharps injury the local procedure must be followed. This will require immediate first aid and follow-up. For further information on the Emergency Management of Injuries (EMI) and Post-Exposure Prophylaxis (PEP) please see https://www.hpsc.ie/a-z/emi/