

National COVID-19 Vaccination Programme - General Practice

Operational Guidance for Vaccination in General Practice

VERSION 5

Dated: 04/04/24

Version	Date	Prepared by	Version Updates
V2.0	28/02/23	Head of Vaccinations Primary Care Contractors	<ul style="list-style-type: none">• Updated with bivalent vaccine types• Operational information updated throughout• Detailed clinical information replaced with links to latest guidance
V3.0	04/05/23		<ul style="list-style-type: none">• Update on Adapted (Bivalent) vaccine recommended use• Update on the use of PPE Equipment• Update on anaphylaxis• Update to useful contacts
V4.0	25/09/23		<ul style="list-style-type: none">• How to join the COVID-19 Vaccination Programme• Where mRNA vaccines are contraindicated• Update on distribution of printed materials &• Waste management• Periodic products/batch removal from GP Practice Management Systems (PMS)• Update on EU Digital COVID-19 Certificates
V5.0	04/04/24		<ul style="list-style-type: none">• Reviewed and updated document to reflect current practice and guidance. Document sections naming & numbering revised.• Section 1 clinical references removed• Section 2 renamed Clinical Governance and Guidance, NIAC link, NIO links updated• Section 3 added section on Vaccination Primary Care Contractors and Webpage details

			<ul style="list-style-type: none"> • Section 7.1 added section on accessing COVID-19 information resources and link to VPCC FAQ's to replace Update on Printed Material Distribution • Section 8 updated to include section on Vaccine Interval, Pregnancy & Breastfeeding, Immunocompromised and included link to VPCC Guidance Note 6 • Section 9 updated to Ordering Vaccine Stock and Consumables, included link to VPCC Guidance Note 1. Removed Cold Chain Preservation & Monitoring of Fridges & Receipt of Vaccines and Management of Multiple Vaccines • Section 9.1 updated to include Vaccine Equipment for General Practice • Added Section 9.2 Return of Expired Vaccine Stock • Removal of Anaphylaxis Updates July 2022 and February 2023 • Section 10 Management of Vaccines in General Practice includes link to HSE Guidelines • Section 12 addresses Data Quality replacing Importance of Data Returns • Section 15 workflow considerations referenced and moved to Appendix 5, Contingency List and Emergency Cover deleted. • Section 16 Delivery of Vaccine to Housebound people: link to VPCC information for General Practice inserted, removal of Vaccination of People in Hospitals. • Section 18 Observation Post Vaccination replaces previous Recovery Section
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Table of Contents

1. Overview and Introduction	5
2. Clinical Governance and Guidance	5
2.1 Clinical Governance	5
2.2 Clinical Supporting Information	5
3. Vaccination Primary Care Contractors (VPCC)	5
4. Indemnity	5
5. Training	6
6. How to join the Vaccination Programme for COVID-19	6
7. Communications	6
7.1 Access to COVID-19 Information Materials	6
8. Vaccine Updates	6
8.1 Vaccine Type	6
8.2 Vaccine Interval	7
8.3 Eligibility	7
8.4 Pregnancy and Breastfeeding	7
8.5 Immunocompromised	7
8.6 Where mRNA Vaccines are Contraindicated	7
9. Ordering Vaccine Stock and Consumables	7
9.1 Vaccine Stock	7
9.2 Return of Expired Vaccine Stock	7
9.3 Vaccine Consumables for General Practice	8
10. Management of Vaccines in General Practice	8
10.1 Removal of Waste from General Practice	8
11. Record Keeping	9
12. Data Quality	9
13. Periodic Product/Batch Removal	9
14. Preparing for a Vaccination Service	9
15. Clinic Requirements	10
15.1 Practice Premises Requirements	10
15.2 Practice Staff Requirements	10
15.3 Participation in Vaccination Programme for COVID-19	10
16. Delivery of COVID-19 Vaccines (and Flu Vaccine) to Housebound People	10
17. Observation Post Vaccination	10
18. Adverse Reaction Reporting	11
18.1 Reporting of Incidents During a Vaccination Session	11

19. Consent	11
20. ICT	11
20.1 Vaccination History Lookup Portal	12
20.2 Individual Health Identifier.....	12
21. Technical Support and Other Contact Details	13
22. Fees, Contractual Arrangements & Reimbursement	15
22.1 Fees	15
22.2 Reimbursement.....	15
Appendix 1 - Risk Management Considerations when Multiple Vaccines are in Use	16
Appendix 2 - HSE Guidelines for Maintenance of Cold-Chain in Vaccine Fridges and Management of Vaccine Stock	18
Appendix 3 - Sample Checklist for COVID-19 Vaccination Clinics.....	19
Appendix 4 - Workflow Considerations	21
Appendix 5 - Useful Links & Resources	22

1. Overview and Introduction

COVID-19 is a highly infectious disease that can cause serious illness, hospitalisation and even death. COVID-19 vaccination gives the best protection against serious COVID-19 illness and reduces the risk of hospitalisation from illness. 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, protecting healthcare capacity and enabling social and economic activity¹. The COVID-19 vaccine is free to all eligible persons of the State. It is not available privately. While the vaccine is not mandatory, it is recommended and vaccination depends on a person's age and if they are at higher risk from COVID-19.

GPs continue to play a key role in the delivery of the Vaccination Programme in accordance with the agreed national vaccination schedule. In particular, GPs and Practice Nurses are instrumental in delivering the COVID-19 Vaccination Programme in line with current guidelines.

This document sets out guidance in relation to the approach, logistical arrangements and processes established for the management of the vaccine programme to patients in General Practice.

2. Clinical Governance and Guidance

2.1 Clinical Governance

The clinical governance for ensuring the patient is eligible for the vaccine in line with [NIAC 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 vaccines and 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 Vaccine Programme is supported by the HSE Vaccinations Primary Care Contractors (VPCC) team, who coordinate the service and provide Relationship Management Support to GPs and Community Pharmacists. For further details, please see [VPCC Webpage](#)

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

¹ COVID-19 Vaccine Allocation Strategy (2021) at [12], Department of Health & National Immunisation Advisory Committee

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 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 and training on the various COVID-19 vaccines has been prepared by the NIO and other clinical experts. This information is updated regularly, and it is recommended you check this information often to ensure you have up to date and accurate information when vaccinating. This includes [Immunisation Bulletins](#).

NIO developed Standard Operational Procedures (SOPs)

[SOPs for COVID-19 Vaccines](#), contains specific information on the safe handling and administration of each vaccine.

6. How to join the Vaccination Programme for COVID-19

For information on joining the Vaccination programme, please see the [VPCC Vaccination Programme](#).

7. Communications

HSE.ie has comprehensive information available on COVID-19 vaccinations available [HSE COVID-19](#).

7.1 Access to COVID-19 Information Materials

COVID-19 booklets and record cards are available to order on the [Health Promotion Website](#). For further information on COVID-19 resources see [VPCC FAQs](#). Patient information leaflets and resources are available at [COVID-19 Vaccine Materials](#).

8. Vaccine Updates

8.1 Vaccine Type

The adapted vaccine is expected to increase the breadth of immunity against current dominant and emerging variants. For guidance on vaccine selection for primary doses or booster doses please refer to [NIO Clinical Guidance](#). This operational guide focuses on the guidance for the adapted **mRNA vaccines** and their administration within General Practice.

For a quick reference table on the different types of COVID-19 vaccines currently available, please see: [COVID-19 Vaccine Information for Health Professionals](#)
Please see **Appendix 1** for Risk Management Considerations when Multiple Vaccines are in Use.

Frequently Asked Questions for Vaccinators on the administration of COVID-19 Vaccines can be accessed at [NIO FAQs for Vaccinators](#)

8.2 Vaccine Interval

GPs should be aware of changes in the recommended intervals for vaccines used in primary and booster courses for some cohorts, as well as updated guidance on the recommended COVID-19 vaccine intervals in pregnancy.

8.3 Eligibility

The vaccine programme is informed by [NIAC guidance](#) with regards to the provision of primary course and the ongoing roll out of booster doses. Clinical guidance and supporting information on current eligibility for primary course or booster doses can be found [here](#).

GPs are required to familiarise themselves with the updated clinical guidance to aid with correct vaccine selection.

8.4 Pregnancy and Breastfeeding

Pregnant women can also receive the vaccine in GPs and this includes the adapted booster vaccines. The updated information on interval selection for COVID-19 mRNA vaccines for women who are pregnant or breastfeeding and their healthcare professionals can be found in the [clinical guidance](#) and the HSE webpage [pregnancy, breastfeeding and fertility: COVID-19 vaccination](#).

8.5 Immunocompromised

It is important that the correct vaccination course type is selected for the correct patient. Please do not enter regular booster doses (vaccines given based on age eligibility criteria) as immunocompromised (additional doses).

8.6 Where mRNA Vaccines are Contraindicated

Alternative pathways are in place for patients where mRNA vaccines are contraindicated – please refer to [VPCC 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 General Practice

A national distribution service (JMC Logistics) will deliver Personal Protective Equipment (PPE) and critical clinical and non-clinical consumables. For further information, please refer [to VPCC Guidance Note 1](#) on COVID-19 Vaccine Consumables.

COVID-19 clinical packs can be ordered from [NCCS](#) as required with COVID-19 vaccines. Tick the “YES” box on the Cold Chain vaccine order platform to receive packs in line with your order volume.

- If sufficient packs are available in your site tick the “NO” box and none will be delivered.

A standard clinical consumables pack (for each 10 vaccines) includes:

- Disposable syringes
- Needles
- Pre-injection alcohol swabs

JMC can also send, on request:

- Sharps bins
- Medical tape
- Cotton wool
- Detergent/disinfectant wipes
- Kidney dishes
- Additional syringes/needles
- Alcohol swabs

In addition, there is a PPE demand system, where requests can be made through the [HSE PPE Portal](#).

<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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
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10. Management of Vaccines in General Practice

See **Appendix 2** – 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 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 19 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 name, 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;
- h) the name, professional number value (PNV) i.e. NMBI or MCRN, address and telephone number of the general medical practitioner (if any) 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

Data Quality errors or inconsistencies that are identified within COVAX are followed up by the HSE Data Quality Team on 01 240 8786 (GP direct line only). This may require the team to contact the GP to clarify information in order to amend the record.

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 vaccines and to determine the number of vaccinations that they can administer safely. Please see **Appendix 3** for a Sample Checklist for Preparing for COVID-19 Vaccination Clinics.

15. Clinic Requirements

For workflow considerations when setting up a COVID-19 clinic please see **Appendix 4**

15.1 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 the COVID-19 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.

15.2 Practice Staff Requirements

The Practice must be able to provide, at a minimum, the following personnel:

- One administration staff member for registration.
- One administration staff member for observation area.
- Where clinics are being run by a single handed GP, there must be another suitably qualified person in attendance i.e. another GP or Nurse.

15.3 Participation in Vaccination Programme for COVID-19

Where a GP does not have a current contractual relationship with the HSE, participation in the Vaccination Programme will be on the same terms as for those with a contractual relationship. Such GPs will be required to formally register their intention to participate in the COVID-19 Vaccination Programme with the HSE's National Contracts Office similar to the arrangement that was put in place for the 2020/21 Influenza Vaccination Campaign. On receipt of the Doctor's completed and signed registration (including Garda Clearance, where applicable) the National Contract's Office will notify NIO for NCCS registration purposes and PCRS for reimbursement set up purposes.

16. Delivery of COVID-19 Vaccines (and Flu Vaccine) 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](#).

17. Observation Post Vaccination

Scheduling of people should allow for a safe space to observe the person for 15 minutes after the vaccine. NIAC in a letter to the CMO on October 6, 2022, noted that "*Vaccine recipients should be observed for at least 15 minutes after vaccination. If this is not practicable, vaccine recipients should wait in the vicinity for 15 minutes*". NIAC recommends the following post vaccination observation periods:

- Those with no history of anaphylaxis: 15 minutes

- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated.

The GP/Practice Nurse must be aware of signs and symptoms of adverse reactions and manage any that arise. For more information regarding anaphylaxis, please refer to [Immunisation Guidelines](#).

GPs should be aware of the risk of fainting particularly in hot weather and in younger patient cohorts. Advice to minimise the risk can be found [here](#).

18. 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 EMA. Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in benefit risk balance can be promptly detected and acted upon. This enables the EMA to continue to safeguard public health safety.

18.1 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 your 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 advise 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.

19. Consent

For specific information on consent, please see [Consent for Vaccination for COVID-19: Guiding Principles](#).

Written consent forms are available [here](#).

A module on HSeLand has been developed to provide advice and guidance on the process for gaining consent from parents and legal guardians of 12-15 year olds to support the programme. We strongly recommend that any GP offering vaccine to this age group views this module on www.hseland.ie (search for COVID-19 Vaccine Training Programmes and complete the programme).

GPs must be aware of how [consent](#) is obtained for a young person aged 12-15 years.

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 on the GP's own PMS.

20. ICT

The GP PMS/GPVax enable the GP to:

- Register people for the COVID-19 Vaccination Programme.

- Record their details as outlined in Section 13 of this guidance - Record Keeping including PPSN and contact details².
- Record their eligibility and consent.
- Set up the COVID-19 vaccines and related schedules.
- Record stocks of vaccines as they are delivered.
- Record the batch number and 'use by' date³ of each vaccine administered.
- Automatically communicate electronic vaccination details to COVAX (via Healthlink).
- Automatically communicate electronic payment claims to PCRS (via Healthlink).

The GP PMS for COVID-19 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.

20.1 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 COVID-19 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 you normally access Healthmail.
- Login using Healthmail address & password.
- Once logged in, a verification code will be sent to the alternative email account associated with your 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.

20.2 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](#).

² If the service user doesn't have a mobile phone and/or email address, please include the contact details for their carer, next of kin, or enter "087 1234567" and/or "none@hse.ie" in the short term.

³ A 'Use By' date for each vaccine is assigned when the item is removed from the freezer.

21. Technical Support and Other Contact Details

Support teams available within business hours unless otherwise stated.

Query	Service	Telephone	Email	Commentary
Vaccine ordering & delivery issues	National Cold Chain Service (NCCS)	01 463 7770	vaccines@udd.ie	Any queries relating to quantity/allocation should be raised through the email address
Queries relating to order / delivery of vaccine consumables	Consumables Support	081 800 8811	vaccine.support@jmc.ie	Must be emailed from a non Healthmail account
Clinical queries and queries relating to cold chain maintenance or breakdown	National Immunisation Office (NIO)		immunisation@hse.ie	
Data quality errors support	HSE Data Quality Team	01 240 8786		
Payment queries / claims regarding any vaccines	HSE Primary Care Reimbursement Service (PCRS)	01 864 7100	Pcrs.doctorsqueries@hse.ie	Reimbursement of vaccinations only
General queries / information & relationship management	Relationship Management	081 800 8811	gpvaccines@vision.com	
Healthmail issues	Healthmail Support	061 203 779	ictsupport@three.ie	Any queries relating to your Healthmail account including the secondary email address attached to your account
GP liaison team	HSE GP Liaison	1800 807 113		Monday to Friday 9am to 5pm
Antigen kit ordering portal	HSE Portal		https://hseppe.powerappsp.ortals.com/signin	

For contract queries	National Contracts Office	044 939 5519	natcontractsoffice@hse.ie	
Vaccines outside cold chain parameters	National Immunisation Office (NIO)		pharmacynio@hse.ie	If vaccines are exposed to temperatures outside parameters, please contact a National Immunisation Office pharmacist immediately
Contact HSE	HSELive	1800 700 700	You cannot contact HSE Live by email. See HSELive	Monday to Friday, 8am to 8pm, Saturday, 9am to 5pm

GP Vendors & GPVax - Support Contact Details

Technical Support			
Support Team	Telephone	Email	Operating Hours
Socrates	071 919 3600	support@clanwilliamhealth.com	Monday to Friday 8am to 5:30pm
Helix Practice Manager	01 463 3098	gpsupport@clanwilliamhealth.com	Monday to Friday 8am to 5:30pm
HEALTH one	01 463 3098	gpsupport@clanwilliamhealth.com	Monday to Friday 8am to 5:30pm
CompleteGP	01 524 0830	support@completegp.ie	Monday to Friday 9am to 5pm
GPVax - A2I HIDS support team Note: Contact from your Practice Healthmail account for any technical queries, usability or system issues.	01 778 4998	Healthmail contact: a2ihids.support@healthmail.ie Email contact: a2ihids.support@hse.ie	Monday to Friday 9am to 5pm

For other useful contacts and links see **Appendix 5**

22. Fees, Contractual Arrangements & Reimbursement

22.1 Fees

Following a process of consultation involving the Department of Health, the HSE and the Irish Medical Organisation, the Minister for Health, with the consent of the Minister for Public Expenditure, pursuant to Section 42 of the Public Service (Pay and Pensions) Act, 2017 has determined a schedule of fees rates to be paid to GPs for the delivery of the COVID-19 Vaccination Programme. Any update re fees will be communicated with campaign information.

22.2 Reimbursement

The Primary Care Reimbursement Service (PCRS) will receive, process and integrate electronic COVID-19 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 which are 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.

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.

Claims for the people who do not bring their PPSN to the GP will be reimbursed when the GP submits the PPSN for that person. While 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 Adapted mRNA 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 vaccines⁴.

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.

In the context of COVID-19 vaccines, 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 practice, 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 for a person who is immunocompromised or a booster dose?
- What is the age of 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?
-

⁴ <https://www.ismp.org/alerts/mix-ups-between-influenza-flu-vaccine-and-covid-19-vaccines>

Ensure the **correct patient information** is available for the vaccine in use for the Primary Vaccination Programme and/or the Booster Programme as appropriate.

COVID-19 Vaccines and Flu Vaccines

If provision is being made to administer both 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.

Appendix 2 - HSE Guidelines for Maintenance of Cold-Chain in Vaccine Fridges and Management of Vaccine Stock

Definitions and the guidance around “expiry date”, “use before” and “discard time” for COVID-19 vaccines are detailed within the [Clinical Guidance](#).

[HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock](#)



Appendix VIII: Report following breakdown in Cold Chain

(Please fill this form separately for each fridge and email to the immunisation@hse.ie)

Name of Site		Phone	
Account no.	300.....	Email	
Contact person		Mobile	

Date and time “Cold Chain” breach occurred (noticed)			
Date (DD/MM/YYYY):		Time (use 24 h clock):	
FRIDGE temperature at time of breach in “Cold Chain” identification			
Fridge ID	Current (°C)	Minimum (°C)	Maximum (°C)
Description of incident:			

Last recorded temperature of fridge and reset

Fridge ID	Date last record (DD/MM/YYYY):	Time last record (use 24 h clock):	Date last reset (DD/MM/YYYY):	Time last reset (use 24 h clock):

Current Fridge temperature at present (if vaccines moved to another fridge -indicate by recording in the Fridge ID*)

Fridge ID*	Date (DD/MM/YYYY):	Time (use 24 h clock):	Current (°C)	Minimum (°C)	Maximum(°C)

DATA LOGGER details

Fridge ID	Time when reading exceeded +8°C or dropped below +2°C (use 24 h clock):	Time when reading became normal i.e. between +2°C and 8°C (use 24 h clock):	Duration (when fridge outside of +2 and + 8 °C) - (use 24 h clock): ____ hour ____ min

ROOM TEMPERATURE (where fridge is located)

Minimum room temperature during the excursion period (°C)	Maximum room temperature during the excursion period (°C)

- Note:**
1. Please do not use or dispose of any vaccines unless advised by the NIO.
 2. Quarantine all vaccines within cold chain conditions and notify relevant staff.
 3. Temperature excursions are cumulative and if some of the vaccines were exposed to previous breaches please specify and give details.
 4. HSE sites only - please fill the National Incident Report Form (NIRF-04 Complaint/Dangerous occurrence).

Appendix 3 - Sample Checklist for COVID-19 Vaccination Clinics

Note: This is a support document for the safe practices for COVID-19 vaccination. Additional requirements may arise based on the type of vaccines, cohort of vaccinators, recipients and location of the clinics.

Before the Vaccine clinic		
		Physical Environment / Layout of the Vaccine clinic
YES	NO	A designated space for registration
YES	NO	Awaiting area for patients to be called for vaccination. This may be the same space as for registration
YES	NO	A designated clean area for vaccine storage and preparation in the clinic
YES	NO	A designated area for vaccine administration
YES	NO	Area for post vaccine observation for 15 minutes (30 minutes if they have a history of allergic reactions) with adequate space and also a private space for medical emergencies (anaphylaxis management)
		Documentation (Check for most up to date version of documents www.immunisation.ie)
YES	NO	Clinical and administrative guidance for Vaccinators
YES	NO	National Immunisation Advisory Committee Immunisation Guidelines for Ireland https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf
YES	NO	Copy of a relevant COVID-19 vaccine medicine protocol (for nurse/midwife vaccinators only)
YES	NO	Anaphylaxis management in the community - Copy of anaphylaxis algorithm https://www.rcpi.ie/healthcare-leadership/niac/immunisation-guidelines-for-ireland
YES	NO	Copy of information on Cold Chain management or access to the same https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/
YES	NO	Vaccination record cards and HSE advice leaflets for after vaccination for the recipients
YES	NO	Current up to date copies of: HSE vaccine information leaflets and European Medicines Agency Patient Information Leaflets (please see https://www.ema.europa.eu/en for most up to date version)
		Infection Prevention & Control Precautions:

YES	NO	Posters in relation to COVID-19/ Cough etiquette/respiratory hygiene/hand hygiene are available from the HSE website http://hsenet.hse.ie/
YES	NO	Hand sanitiser (alcohol gel/foam sanitiser) for staff and patients
YES	NO	PPE for the vaccinator if required as per latest HPSC Guidance
YES	NO	Disposable tissues available for patients and a foot pedal bin for disposal
YES	NO	Disinfectant wipes for worktops and other areas
YES	NO	Sharps waste bin, clinical and non-clinical risk waste bins
Clinical equipment		
YES	NO	Access to pharmaceutical fridge with external display of current temperature and data logger
YES	NO	An anaphylaxis medical kit as per guidelines (https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)
YES	NO	Gloves <input type="checkbox"/> Sharps boxes <input type="checkbox"/> Alcohol gel <input type="checkbox"/> Clinical tray <input type="checkbox"/> Cotton wool <input type="checkbox"/> Tape <input type="checkbox"/> Clinical waste bags <input type="checkbox"/> 70% Alcohol swabs <input type="checkbox"/> Needles <input type="checkbox"/> Syringes
After the vaccination		
YES	NO	Post-vaccination monitoring (recommended for 15 minutes or 30 minutes if patient has a history of allergic reactions): Allocation of staff for post vaccine observation for 15 -30 minutes
YES	NO	Post vaccine documentation: Vaccinations administered recorded in your relevant COVID-19 Vaccination Management System
YES	NO	All patient medical information placed in a secured storage location for data protection

Appendix 4 - 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*).
- Contact patients with indicative appointment times.
- Be informed of the vaccine availability and delivery schedule by NCCS.
- Contact patients to confirm appointment times.
- Receive vaccines.
- 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 is 15 minutes/30 minutes if they have a history of allergic reactions.
- Treat and record any immediate adverse reactions as per HPRA procedures.
- Produce patient record card and give to patient.
- Treat and record any later adverse reactions as per HPRA procedures.
- 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 5 - Useful Links & 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](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)

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/>