Pre-Hospital Emergency Care Council

Clinical Practice Guidelines

Version 2 – 29/03/2021

Updated 12/04/2021

Pre-Hospital Emergency Care Council

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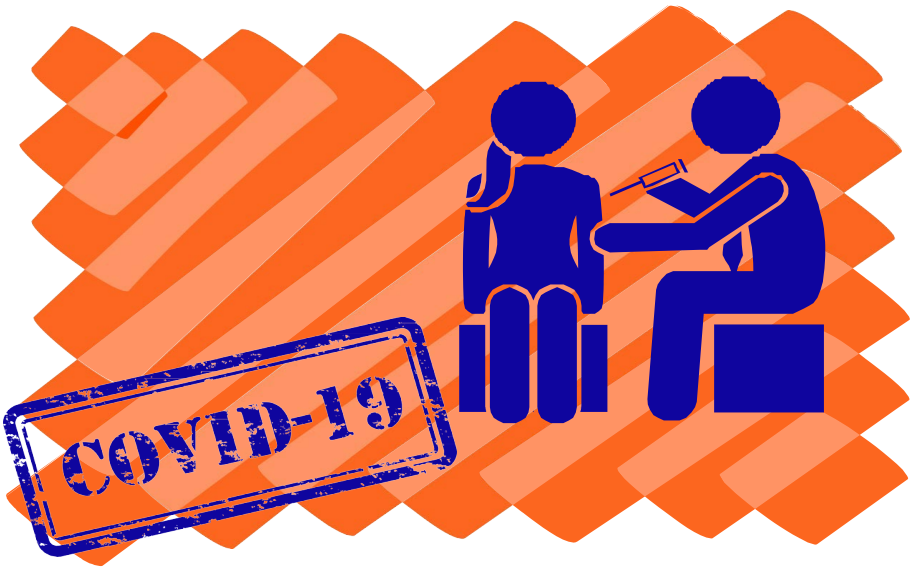


Version 2 – 12/04/2021

Introduction

As part of the national response to the COVID-19 pandemic, PHECC and the Medical Advisory Committee have acted to enable Practitioner administration of licensed COVID-19 vaccines in support of the National Vaccination Programme.

The administration of COVID-19 vaccines by PHECC Registered Practitioners is now permitted according to the specially created vaccination edition of the Clinical Practice Guidelines.

These CPGs permit PHECC Registered Practitioners who operate for Licensed CPG Providers to participate in the National Vaccination Programme.

This edition will be maintained separately to the general Clinical Practice Guidelines publication to enable the swift addition of further medications as they are approved for use.

As with all CPGs, PHECC Registered Practitioners are subject to the PHECC triple lock of licensing, credentialing, and privileging and the PHECC care principles.

All PHECC Registered Practitioners who participate in the vaccination process must complete training, as specified by the HSE, prior to conducting any vaccinations.

Dr David Menzies, Chair Medical Advisory Committee

SECTION 1 - Care Principles

Care principles are goals of care that apply to all patients. Scene safety, standard precautions, patient assessment, primary and secondary surveys and the recording of interventions and medications on the Patient Care Report (PCR) or the Ambulatory Care Report (ACR), are consistent principles throughout the guidelines and reflect the practice of practitioners. Care principles are the foundations for risk management and the avoidance of error.

PHECC Care Principles

1. Ensure the safety of yourself, other emergency service personnel, your patients, and the public.
   1.1 Ensure correct PPE is utilised in all situations and is compliant with latest guidance on standard, contact, droplet and airborne PPE. Place facemasks on patients when required. Handwashing and hand hygiene should be performed before and after all patient interactions. Utilise PPE checklists for correct donning and doffing procedures.

2. A person has capacity in respect to clinical decisions affecting themselves unless the contrary is shown (Assisted Decision-Making (Capacity) Act 2015).

3. Seek consent prior to initiating interventions and/or administering medications.

4. Identify and manage life-threatening conditions.

5. Ensure adequate ventilation and oxygenation.

6. Optimise tissue perfusion.

7. Make a working diagnosis, after considering differential diagnoses.

8. Provide appropriate pain relief within the scope of practice. Pain management:
   8.1 should not delay the diagnosis of conditions or injuries,
   8.2 should be implemented for all relevant patients,
   8.3 should commence within ten minutes on scene,
   8.4 goal is to reduce pain to a tolerable level,
   8.5 to take cognisance of immediate and short-term pain management requirements by administering appropriate combinations of analgesia.

9. Identify and manage other conditions.

10. Place the patient in the appropriate posture according to the presenting condition.

11. Ensure maintenance of normal body temperature (unless a CPG indicates otherwise).

12. Provide reassurance at all times.

13. Monitor and record patient's vital observations.

14. Maintain responsibility for patient care until handover to an appropriate practitioner.

15. Arrange transport to an appropriate medical facility if clinically required, and in an appropriate time frame.

16. Complete a patient care record following an interaction with a patient.

17. Identify the clinical lead on scene; this shall be the most qualified practitioner on scene. In the absence of a more qualified practitioner, the practitioner providing care during transport shall be designated clinical lead as soon as practical.

18. Ambulances, medical rooms and equipment should be decontaminated as appropriate following an interaction with a patient.

CLINICAL PRACTICE GUIDELINES FOR ADMINISTRATION OF:

I) **COMIRNATY**

II) **JANSSEN**

III) **MODERNA**

IV) **VAXZEVRIA (formerly AstraZeneca)**

4/5/6.11.2
Version 3, 01/2021

Covid-19 Vaccine – Comirnaty

EMT P AP

Consideration for Administering Vaccination - 16 years of age and older

Follow current National Immunisation Office guidance on inclusion / exclusion criteria

Review summary of product characteristics of medication

All vaccinators must have completed the HSE approved COVID-19 vaccination training

Ensure correct preparation of medication

Refer to SmPC for handling instructions thawing, dilution, preparation and administration of individual dose

Comirnaty is administered intramuscularly after dilution as a course of 2 doses (0.3mL each) at least 21 days apart

Obtain Patient information / complete register

Discuss vaccination and confirm patient consent

A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Comirnaty

Comirnaty 30mcg (0.3mL- post dilution) IM

Vaccination to be administered in a suitable and appropriate place

-having regard to public convenience
- to protect the health and safety of the public
- to safely administer the product

Administer Medication in accordance with dosage and conditions of administration

Monitor for 15 minutes - Be prepared for allergic reaction and/or syncope. If history of Anaphylaxis from any cause monitor for 30 minutes

Allergic Reaction

Yes → Go to allergic reaction CPG

No

Ensure reporting and record keeping data complete

Release patient with advice to contact their doctor if any side effects experienced

Ensure arrangements in place for 2nd dose

When administering the second dose ensure that it is the same brand as the first

Record Keeping

- Make an entry in a register kept for the purpose
- Date of administration
- Name, address, date of birth and sex of the person
- Patient's personal public service number*
- Name, dosage, marketing authorisation number, batch number and expiry date of the product
- Name of the person administering the product and PHECC PIN
- Name, address and contact particulars of the general medical practitioner*
- *Unless that person fails to provide such particulars

Reporting Requirements

Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

*Unless that person fails to provide such particulars

Reference: SmPC as approved by the EMA - December 2020

Updated 12/04/2021

4/5/6.11.3
Version 3, 02/2021

COVID-19 Vaccine Moderna Dispersion for Injection
COVID-19 mRNA Vaccine

EMT P AP

Consideration for Administering Vaccination - 18 years of age and older

Follow current National Immunisation Office guidance on inclusion / exclusion criteria

All vaccinators must have completed the HSE approved COVID-19 vaccination training

Review summary of product characteristics of medication

This is a multi-dose vial which is ready for use once thawed.
No further dilution is required

Ensure correct preparation of medication

This vaccine is administered as a course of 2 doses (0.5mL each) at least **28** days apart

Obtain Patient information / complete register

Refer to SmPC for handling instructions thawing, preparation and administration of individual dose

Discuss vaccination and confirm patient consent

A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Moderna

COVID-19 Vaccine Moderna
100mcg (0.5mL) - IM

Vaccination to be administered in a suitable and appropriate place

-having regard to public convenience
- to protect the health and safety of the public
- to safely administer the product

Administer Medication in accordance with dosage and conditions of administration

Monitor for 15 minutes - Be prepared for allergic reaction and/or syncope. If history of Anaphylaxis from any cause monitor for 30 minutes

Allergic Reaction

Yes → Go to allergic reaction CPG

No

Ensure reporting and record keeping data complete

Release patient with advice to contact their doctor if any side effects experienced

Ensure arrangements in place for 2nd dose

When administering the second dose ensure that it is the same brand as the first

Record Keeping

- Make an entry in a register kept for the purpose
- Date of administration
- Name, address, date of birth and sex of the person
- Patient's personal public service number*
- Name, dosage, marketing authorisation number, batch number and expiry date of the product
- Name of the person administering the product and PHECC PIN
- Name, address and contact particulars of the general medical practitioner*
- *Unless that person fails to provide such particulars

Reporting Requirements

Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

*Unless that person fails to provide such particulars

Reference: SmPC as approved by the EMA – January 2021

Updated 12/04/2021

4/5/6.11.5
Version 1, 03/2021

COVID-19 Vaccine Janssen

EMT P AP

Consideration for Administering Vaccination - 18 years of age and older

Follow current National Immunisation Office guidance on inclusion / exclusion criteria

Review summary of product characteristics of medication

Ensure correct preparation of medication

Obtain Patient information / complete register

Discuss vaccination and confirm patient consent

COVID-19 Vaccine Janssen
0.5mL - IM

Administer Medication in accordance with dosage and conditions of administration

Monitor for 15 minutes - Be prepared for allergic reaction and/or syncope. If history of Anaphylaxis from any cause monitor for 30 minutes

Allergic Reaction

Yes → Go to allergic reaction CPG

No

Ensure reporting and record keeping data complete

Release patient with advice to contact their doctor if any side effects experienced

All vaccinators must have completed the HSE approved COVID-19 vaccination training

Single dose vaccine.

Unopened/Unpierced vial
- stable at -25° to -15°C for 2 years. Once thawed, the vaccine should not be re-frozen.

Opened vial (after first puncture of the vial)
- preferable to use immediately
-can be stored between 2°C - 8°C for a maximum of 6 hours or remain at room temperature (maximally 25°C) up to 3 hours after first puncture of the vial.

Discard after time period has passed

Vaccination to be administered in a suitable and appropriate place

-having regard to public convenience
- to protect the health and safety of the public
- to safely administer the product

Refer to SmPC for handling instructions, preparation and administration of individual dose

Record Keeping

- Make an entry in a register kept for the purpose
- Date of administration
- Name, address, date of birth and sex of the person
- Patient's personal public service number*
- Name, dosage, marketing authorisation number, batch number and expiry date of the product
- Name of the person administering the product and PHECC PIN
- Name, address and contact particulars of the general medical practitioner*
- *Unless that person fails to provide such particulars

Reporting Requirements
Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

*Unless that person fails to provide such particulars

Reference: SmPC as approved by the EMA – March 2021

Updated 12/04/2021

4/5/6.11.4
Version V2, 04/2021

COVID-19 Vaccine Vaxzevria suspension for Injection
(formerly COVID-19 vaccine Astra Zeneca)
COVID-19 Vaccine (ChAdOx1-S [recombinant])

EMT P AP

Consideration for Administering Vaccination - 18 years of age and older

Follow current National Immunisation Office guidance on inclusion / exclusion criteria

All vaccinators must have completed the HSE approved COVID-19 vaccination training

Review summary of product characteristics of medication

A multi-dose vial which is ready for use. No further dilution required.

Unopened/Unpierced vial
- stable at 2°- 8°C for 6 months

Opened vial
- (1) administration for no more than 48 hours at 2°- 8°C
- (2) Vaccine may be kept and administered at <30°C for a single period for up to 6 hours.
Discard after time period has passed.

Ensure correct preparation of medication

This vaccine is administered as a course of 2 doses (0.5 mL each).
2nd dose **between 4 and 12 weeks (28 – 84 days)**

Obtain Patient information / complete register

Discuss vaccination and confirm patient consent

Refer to SmPC for handling instructions, preparation and administration of individual dose

COVID-19 Vaccine AstraZeneca
0.5 mL - IM

Vaccination to be administered in a suitable and appropriate place

-having regard to public convenience
- to protect the health and safety of the public
- to safely administer the product,

Administer Medication in accordance with dosage and conditions of administration

A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Vaxzevria

Monitor for 15 minutes - Be prepared for allergic reaction and/or syncope. If history of Anaphylaxis from any cause monitor for 30 minutes

Allergic Reaction

Yes → Go to allergic reaction CPG

No

Ensure reporting and record keeping data complete

Record Keeping
- Make an entry in a register kept for the purpose
- Date of administration
- Name, address, date of birth and sex of the person
- Patient's personal public service number*
- Name, dosage, marketing authorisation number, batch number and expiry date of the product
- Name of the person administering the product and PHECC PIN
- Name, address and contact particulars of the general medical practitioner*

- *Unless that person fails to provide such particulars.

Release patient with advice to contact their doctor if any side effects experienced

Ensure arrangements in place for 2nd dose

When administering the second dose ensure that it is the same brand as the first

Reporting Requirements
Within 7 days of the administration, forward, by electronic means or otherwise, a copy of the particulars, entered in "the register" to the Health Service Executive

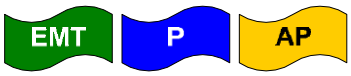
*Unless that person fails to provide such particulars.

Reference: SmPC as approved by the EMA – April 2021

Updated 12/04/2021

APPENDIX:

I) MEDICATION FORMULARY

Clinical level: 

Medication	Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	A multi-dose vial which must be diluted before use. One vial (0.45 mL) contains 6 doses of 0.3 mL after dilution - If it is not possible to withdraw 0.3mL for a 6th dose, the vial should be discarded. There should be no pooling of vaccine solution from different vials. Concentrate for dispersion for injection (sterile concentrate). Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles
Administration	**IM administration** Frozen vials should be transferred to an environment of 2ºC to 8ºC to thaw, where they remain stable for 5 days. Allow the thawed vial to come to room temperature. Gently invert vial 10 times prior to dilution. **Do not shake** The thawed vaccine must be diluted in its original vial with 1.8 mL Sodium Chloride 0.9%. Gently invert the diluted dispersion 10 times. **Do not shake.** Once diluted, the vaccine is stable for 6 hours at 2ºC to 30ºC.
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	***Adult:*** Administered intramuscularly after dilution as a course of 2 doses (0.3 mL each). It is recommended to administer the second dose not less than 21 days after the first dose. The preferred site is the deltoid muscle of the upper arm. ***Paediatric:*** Not Indicated
Side effects	Headache, Nausea, Arthralgia, Myalgia, Injection site pain, Fatigue, Pyrexia
Additional information	The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present Discard any unused vaccine within 6 hours after dilution Do not inject the vaccine intravascularly, subcutaneously or intradermally. Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes is recommended following vaccination. If history of Anaphylaxis from any cause monitor for 30 minutes. **All vaccinators must have completed the HSE approved COVID-19 vaccination training**

Clinical level: EMT P AP

Medication	COVID-19 Vaccine Janssen suspension for Injection COVID-19 Vaccine (Ad26.COV2-S [recombinant])
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	Suspension for injection – colourless to slightly yellow, clear to very opalescent suspension. Each multi-dose vial contains 5 doses of 0.5 mL per 2.5 mL vial, which is ready for use. No further dilution is required. An additional overfill may be included in each vial. Do not pool excess from multiple vials. Each dose (0.5 mL) contains: Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein* (Ad26.COV2-S), not less than 8.92 log10 infectious units (Inf.U).
Administration	**IM administration** Each multidose vial is ready for administration, no further dilution required. Unopened/Unpierced vial storage: -25°C to -15°C at expiry as indicated by manufacturer **or** 2°- 8°C for 3 months (Record new expiry on outer packaging) Opened vial – Use immediately after first opening. Record date and time of opening vial or time vial should be discarded. - Chemical and physical in-use stability has been demonstrated for 6 hours at 2°- 8°C. Discard after this time period. - Product may be kept and administered at maximum 25°C for a single period for up to 3 hours. Discard after this time period. - Prior to administration of a dose of vaccine, gently swirl the vial in an upright position for 10 seconds. **Do not shake.**
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	***Adult:*** Covid-19 Vaccine Janssen is administered as a single-dose of 0.5 mL by intramuscular injection only. The preferred site is the deltoid muscle of the upper arm. ***Paediatric:*** Not Indicated
Side effects	Headache, Nausea, Cough, Arthralgia, Myalgia, Injection site erythema or swelling, Fatigue, Pyrexia, Chills, Tremor, Sneezing, Oropharyngeal pain, Rash, Hyperhidrosis, Muscular weakness, Pain in extremity, Back pain, Asthenia, Malaise.
Additional information	Discard the vaccine vial if particulates or discolouration are present prior to administration. Do not inject the vaccine intravascularly, intravenously, subcutaneously or intradermally. Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes. If history of Anaphylaxis from any cause, monitor for 30 minutes. **All vaccinators must have completed the HSE approved COVID-19 vaccination training**

Clinical level: EMT P AP

Medication	COVID-19 Vaccine Moderna Dispersion for Injection COVID-19 mRNA Vaccine
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	Dispersion for injection – white to off-white dispersion A multi-dose vial which is ready for use once thawed. No further dilution is required One 5 mL vial contains 10 doses of 100 mcg/0.5 mL mRNA each. An additional overfill is included to ensure 10 doses can be delivered.
Administration	**IM administration** Frozen storage: -25° to -15°C until expiry date (store in original carton to protect from light) Thaw each vial before use: • 2 hr 30min in refrigerator at 2°- 8°C ***OR*** • 1 hr at room temperature 15°- 25°C Once thawed, maximum expiry of ***unpunctured*** vials: • 30 days refrigerator 2°- 8°C • 12 hrs cool storage up to room temperature 8°- 25°C **Swirl vial gently after thawing and before each withdrawal.** (Do not shake or dilute) **The withdrawn dose in the syringe should be administered immediately.** After **first dose** has been withdrawn: • Vial may be held between 2°- 25°C (refrigerator or room temperature) • Record date and time on vial • **Discard punctured vial after 6 hours of first dose**.
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	***Adult:*** Administered intramuscularly as a course of 2 doses (100 mcg/0.5 mL mRNA each). It is recommended to administer the second dose not less than 28 days after the first dose. The preferred site is the deltoid muscle of the upper arm. ***Paediatric:*** Not Indicated
Side effects	Headache, Nausea, Arthralgia, Myalgia, Injection site pain, Fatigue, Pyrexia, Chills, Fever
Additional information	The dispersion for injection vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present Discard any unused vaccine after 6 hours after withdrawal of first dose/ vial puncture. Do not inject the vaccine intravascularly, subcutaneously or intradermally. Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes. If history of Anaphylaxis from any cause monitor for 30 minutes. A second dose should not be administered to those who experience anaphylaxis from first dose. **All vaccinators must have completed the HSE approved COVID-19 vaccination training**

Clinical level: EMT P AP

Medication	**Vaxzevria suspension for injection (formerly COVID-19 vaccine Astra Zeneca)** **COVID-19 Vaccine (ChAdOx1-S [recombinant])**
Classification	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Presentation	Suspension for injection – colourless to slightly brown, clear to slightly opaque. One dose (0.5 ml) contains: Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S) * , not less than 2.5 × 108 infectious units (Inf.U) A multi-dose vial which is ready for use. No further dilution is required Multidose vials which contain 8 doses of 0.5ml per vial. (8 doses in 4ml vial) Multidose vials which contain 10 doses of 0.5ml per vial (10 doses in 5ml vial) An additional overfill is included in each vial. Do not pool excess from multiple vials.
Administration	**IM administration** Each multidose vial is ready for administration, no further dilution required. Unopened/Unpierced – stable at 2°- 8°C for 6 months Opened vial – Use immediately after first opening. Record date and time of opening vial. Chemical and physical in-use stability has been demonstrated from the time of vial opening (first puncture) to administration for no more than 48 hours at 2°- 8°C. Product may be kept and administered at <30°C for a single period for up to 6 hours. Discard after this time period.
Indications	Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients.
Usual Dosages	***Adult:*** Administered intramuscularly as a course of **2 separate doses of 0.5ml** each containing *Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S) *, not less than 2.5 × 108 infectious units (Inf.U).* It is recommended to administer the second dose between 4 and 12 weeks (28 – 84 days) after the first dose. The preferred site is the deltoid muscle of the upper arm. ***Paediatric:*** Not Indicated
Side effects	Very common / common: Headache, Nausea, Arthralgia, Myalgia, Injection site pain, Fatigue, Pyrexia, Chills, Fever Very rare: Thrombosis in combination with thrombocytopenia
Additional information	The dispersion for injection vaccine should present as an colourless to slightly brown, clear to slightly opaque. Discard the diluted vaccine if particulates or discolouration are present Discard any unused vaccine after 6 hours at <30° (48 hours if 2°- 8°C) after withdrawal of first dose/ vial puncture. Do not inject the vaccine intravascularly, subcutaneously or intradermally. Hypersensitivity and anaphylaxis: Close observation for at least 15 minutes. If history of Anaphylaxis from any cause monitor for 30 minutes. A second dose should not be administered to those who experience anaphylaxis from first dose. **All vaccinators must have completed the HSE approved COVID-19 vaccination training**

Bibliography

European **Medicines Agency (2020). Comirnaty (Pfizer/BioNTech):** https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf. Accessed online 01/02/2020

European Medicines Agency (2020). Covid 19 Janssen vaccine:

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf Accessed online 15/03/2021

European **Medicines Agency (2020). Covid 19 Moderna vaccine:** https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf . Accessed online 01/02/2020

European **Medicines Agency (2020). Covid 19 Astra Zeneca vaccine:** https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf. Accessed online 01/02/2020

HSE Immunisation guidelines. Chapter 5a Covid 19. https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf. Accessed online 03/02/2020

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