ROYAL COLLEGE OF PHYSICIANS OF IRELAND

21 December 2020

NIAC Recommendations for COVID-19 vaccination rollout in Ireland

NIAC has developed recommendations for initiation of the rollout specific to COVID-19 vaccines. These are based on the recommendations for safe administration of any vaccine and are subject to change as more information becomes available.

Background

Given the ongoing pandemic and current escalation in case numbers, there is an urgent need to roll out an effective vaccination programme. A new generation of vaccines, mRNA vaccines, have been proven to have efficacy against COVID-19 disease. The first of these, Pfizer/BioNTech COVID-19 162B, will be available in December.

mRNA vaccines are reactogenic, can cause pain at the injection site, local site reactions and systemic symptoms such as fever, myalgia and headache. Importantly, no significant safety concerns were identified by the regulatory agencies on their evaluation of the data. While there remain some unknowns, including long term immunogenicity of the vaccines and whether there may be some very uncommon unanticipated reactions due to the vaccine, the known and potential benefits of the vaccine outweigh any potential risk.

Since the vaccination programmes have been introduced in the UK and US, there have been a small number of reports of immediate serious adverse allergic reactions that prompted NIAC to issue precautionary recommendations. Since then, vaccine rollout has continued in those countries. In the US, as of 19 December, 272,001 doses of vaccine have been administered with 6 case reports of anaphylaxis, meeting the Brighton Collaboration criteria, notified. In Northern Ireland, 15,000 people in care homes have been vaccinated with one reported immediate reaction in a resident. It remains to be determined whether the incidence of anaphylaxis is greater that one might anticipate.

It is critical that in the vaccine rollout all appropriate precautions are taken to ensure the settings for vaccination are optimal to:

a) allow correct management of any adverse events in vaccine recipients
b) support the vaccinators
c) manage logistical challenges
d) maintain confidence in the programme to maximise vaccine uptake

Today, December 21st 2020, the EMA recommended granting a conditional marketing authorisation for the Pfizer/BioNTech COVID-19 vaccine. The recommendations below are in concordance with EMA documentation.

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NIAC recommendations

Recommendation 1. Optimal settings in which to commence rollout of the vaccine

1a. Initiation in late December 2020

NIAC recommends, on a precautionary basis, that the initial COVID-19 vaccine rollout in late December 2020 should take place in facilities where there is immediate access to a medical team that can help to support the identification and management of any acute severe reaction.

This follows from concerns raised by reports of anaphylaxis, an awareness of new logistical challenges (cold chain considerations, use of multidose vials, scheduling of vaccinations and observation times) and vaccinating at a time when general resources may be constrained.

This recommendation will allow experience to be gained and additional emerging information regarding vaccine safety to be assessed. It will also allow for confidence that the recommended procedures are in place to manage any immediate adverse events.

Vaccinators should have appropriate training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support. They should also be familiar with the anaphylaxis section of the Immunisation Guidelines for Ireland.

Emergency telephone numbers should be available as well as a fully charged phone or landline.

1b. Continued rollout from January 2021

Provided there are no unanticipated issues, a full rollout in all planned sites can take place from January 2021. In anticipating this, we are taking into account the additional information that will be provided by the international roll-out over that time, and benefit from the local experience, balanced with the urgency of vaccinating all who are most at risk from the disease, especially given current escalation in case numbers.

Vaccinators should have appropriate training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support. They should also be familiar with the anaphylaxis section of the Immunisation Guidelines for Ireland. A second person should be available to assist and to call for help if needed.

Emergency medical technicians are not required on site.

Emergency telephone numbers should be available as well as a fully charged phone or landline.

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Recommendation 2. Observation time following vaccination

a) Those with no history of anaphylaxis from any cause: 15 minutes
b) Those with a history of anaphylaxis (serious systemic allergic reaction requiring medical intervention) from any cause: 30 minutes
c) Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Recommendation 3. Required equipment

The recommended anaphylaxis kit for each vaccinator includes the following:

- Copy of "Anaphylaxis: Treatment in the Community" from Immunisation Guidelines Ireland, anaphylaxis 2016
- Epinephrine
    - 3 x 1ml ampoules epinephrine (1:1000, 1mg/ml) and syringes (3 x 1ml) and needles (3 x 25mm, 3x 37-40mm)

    or

    - 3 x epinephrine auto-injectors with 500 mcg/25mm needle
- Pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of epinephrine.

Note: The availability of protocols, equipment and drugs necessary for management of anaphylaxis should be checked before each vaccination session. Anaphylaxis kits should be kept closed to ensure the drugs are not exposed to light and stored at room temperature.

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Appendix

International recommendations regarding best practice:

The following are selected extracts from relevant texts. Links to full text documentation is provided.

1. UK: Medicines and Healthcare products Regulatory Agency (MHRA), 9 Dec. 2020

Confirmation of guidance to vaccination centres on managing allergic reactions following COVID-19 vaccination with the Pfizer/BioNTech vaccine

Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose of the Pfizer/BioNTech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer/BioNTech vaccination.

Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment.

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer/BioNTech vaccine is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

The individuals concerned received prompt treatment and are recovering well.

Like all medicines and vaccines, this vaccine can cause side effects. Most of these are mild and short-term, and not everyone gets them.

2. US: CDC "Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 vaccine

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Anaphylactic reactions in persons who received Pfizer-BioNTech COVID-19 vaccine outside of clinical trials have been reported. While these reports are further investigated, CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines (as these vaccines contain ingredients in common). These persons may still receive mRNA COVID-19 vaccination, but they

should be counselled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

A history of mild allergic reaction to a vaccine or injectable therapy, such as localized urticaria alone without signs or symptoms of anaphylaxis, is not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. In addition, allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, or environmental allergies; allergies to oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. The vial stoppers of these mRNA vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy'.

CDC: Risk assessment for mRNA COVID-19 vaccination

When assessing a person's history of allergic reaction to a vaccine or injectable therapy, it can sometimes be challenging to determine whether the reaction was truly severe. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination:

- *Type of reaction and symptoms (e.g., whether symptoms were generalized and consistent with anaphylaxis)*
- *For a reaction to a medication, whether the medication was administered by injection or another route*
- *Whether the reaction required use of epinephrine (EpiPen®, etc.) or resulted in advanced medical care, (e.g., emergency room visit, hospitalization)*
- *How long ago the reaction occurred and whether the same vaccine or medication was subsequently administered without symptoms*
- *Whether the patient has been evaluated by an allergist-immunologist and the diagnosis has been confirmed*

Persons who are determined to have had a severe allergic reaction (e.g., anaphylaxis) to an mRNA COVID-19 vaccine should not receive a second dose. For those determined to have had a severe allergic reaction to another vaccine or injectable medication, considerations for the administration of an mRNA COVID-19 vaccine might include:

- *Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)*
- *Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)*
- *The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of anaphylaxis to other vaccines or injectable therapies*
- *Ability of the patient to be vaccinated in a setting where advanced medical care is immediately available for anaphylaxis*

- *Risk of adverse events after anaphylaxis treatment with epinephrine (older adults with hypertension and atherosclerotic heart disease may be at increased risk for cardiac adverse events following anaphylaxis treatment with epinephrine)*
- *Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago*

*Note: Vaccination is recommended for persons with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, persons with a history of anaphylaxis to another vaccine or injectable therapy and recent COVID-19 may choose to defer vaccination until further informa*tion is known about the risk of anaphylaxis following vaccination.

Management of allergic reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions.

3. CDC: Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine.

Observation period following COVID-19 vaccination

CDC currently recommends that persons who receive a Pfizer-BioNTech COVID-19 vaccine be observed after vaccination for the following time periods:

- *Persons with a history of anaphylaxis (due to any cause): 30 minutes*
- *All other persons: 15 minutes*

Early recognition of anaphylaxis

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and symptoms, including:

- *Respiratory: sensation of throat closing, stridor (high-pitched sound while breathing), shortness of breath, wheeze, cough*
- *Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain*

- *Cardiovascular: dizziness, fainting, tachycardia (abnormally fast heart rate), hypotension (abnormally low blood pressure)*
- *Skin/mucosal: generalized hives, itching, or swelling of lips, face, throat*

Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions. Symptoms are considered generalized if there are generalized hives and/or more than one body system is involved. If a patient develops itching and swelling confined to the injection site, the patient should be observed closely for the development of generalized symptoms (beyond the recommended observation periods noted above, if necessary). If symptoms are generalized, epinephrine should be administered as soon as possible, and emergency medical services should be sought.

Medications and supplies for assessing and managing anaphylaxis

COVID-19 vaccines will likely be administered in a wide variety of clinical settings, including hospitals, long-term care facilities, outpatient medical offices, pharmacies, mass vaccination sites, and curbside or drive-through sites. These settings differ in terms of usual on-hand human and material resources to manage anaphylaxis. The following medications and supplies are important for evaluating and managing of anaphylaxis and are recommended for COVID-19 vaccination sites.

A clinical provider with access to the emergency equipment should be immediately available to assess and manage anaphylaxis.

Medications and supplies for assessing and managing anaphylaxis

Should be available at all sites	***If feasible, include at sites (not required)***
*Epinephrine prefilled syringe or autoinjector**	*Pulse oximeter*
H1 antihistamine (e.g., diphenhydramine)†	*Oxygen and face masks*
Blood pressure cuff	*Bronchodilator (e.g., albuterol)*
Stethoscope	*H2 antihistamine (e.g., famotidine, cimetidine)*
Timing device to assess pulse	*Intravenous fluids*
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

**COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.*
†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.