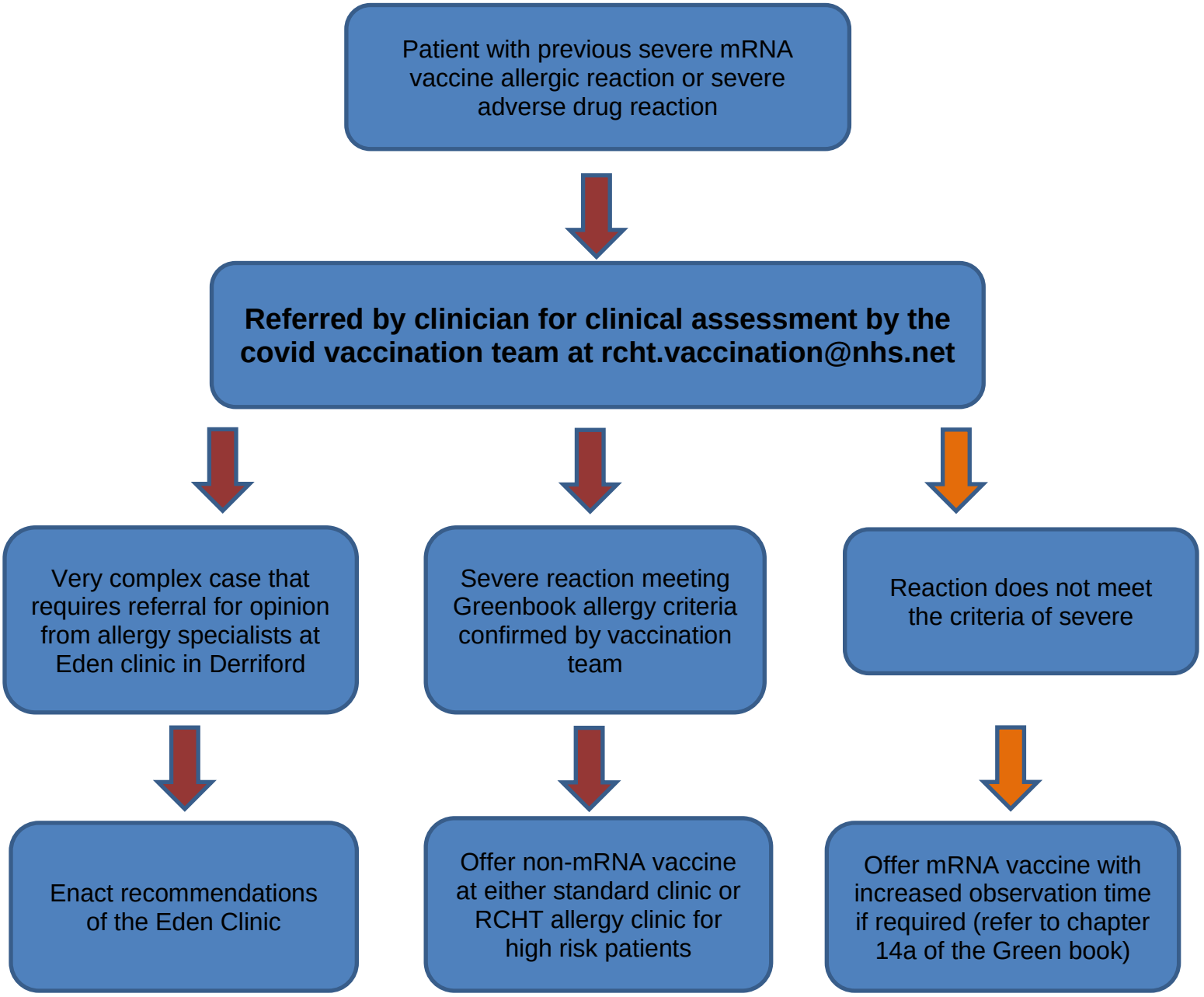
Royal Cornwall Hospitals
NHS Trust

Covid-19 Vaccination for Complex Allergy Patients and Severe Adverse Reactions Clinical Guideline

V3.0

August 2023

Summary


Patient with previous severe mRNA vaccine allergic reaction or severe adverse drug reaction
Referred by clinician for clinical assessment by the covid vaccination team at rcht.vaccination@nhs.net
Very complex case that requires referral for opinion from allergy specialists at Eden clinic in Derriford
Severe reaction meeting Greenbook allergy criteria confirmed by vaccination team
Reaction does not meet the criteria of severe
Enact recommendations of the Eden Clinic
Offer non-mRNA vaccine at either standard clinic or RCHT allergy clinic for high risk patients
Offer mRNA vaccine with increased observation time if required (refer to chapter 14a of the Green book)

1. Aim/Purpose of this Guideline

1.1. This guideline is aimed at ensuring people that have potential allergy considerations or other special considerations receive appropriate advice and vaccination in a safe environment.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. A very small number of people are known to have severe allergic reactions to mRNA vaccines or its components, such as Polyethylene Glycol PEG. The numbers impacted is not precisely known but is believed to be ~5000 people nationally, not all of whom will need ongoing boosters. These individuals will be offered a non-mRNA vaccine in line with JCVI guidance.

2.2. There will also be patients that have experienced serious adverse reactions to the mRNA vaccines, mainly myocarditis and pericarditis, who may have been advised not to receive a further dose. Whilst previous myocarditis or pericarditis is not a contraindication to a further dose of mRNA vaccine, there may be situations where the non-mRNA vaccine should be offered as an alternative rather than the patient not receiving any vaccine. These numbers should be small.

2.3. non-mRNA vaccine will not be offered to meet individual preference or to other non-allergic individuals as a means to reduce vaccine wastage.

2.4. The allergy section of the Covid Vaccination Greenbook Chapter 14a should be used as the main reference source when deciding how to manage these patients.

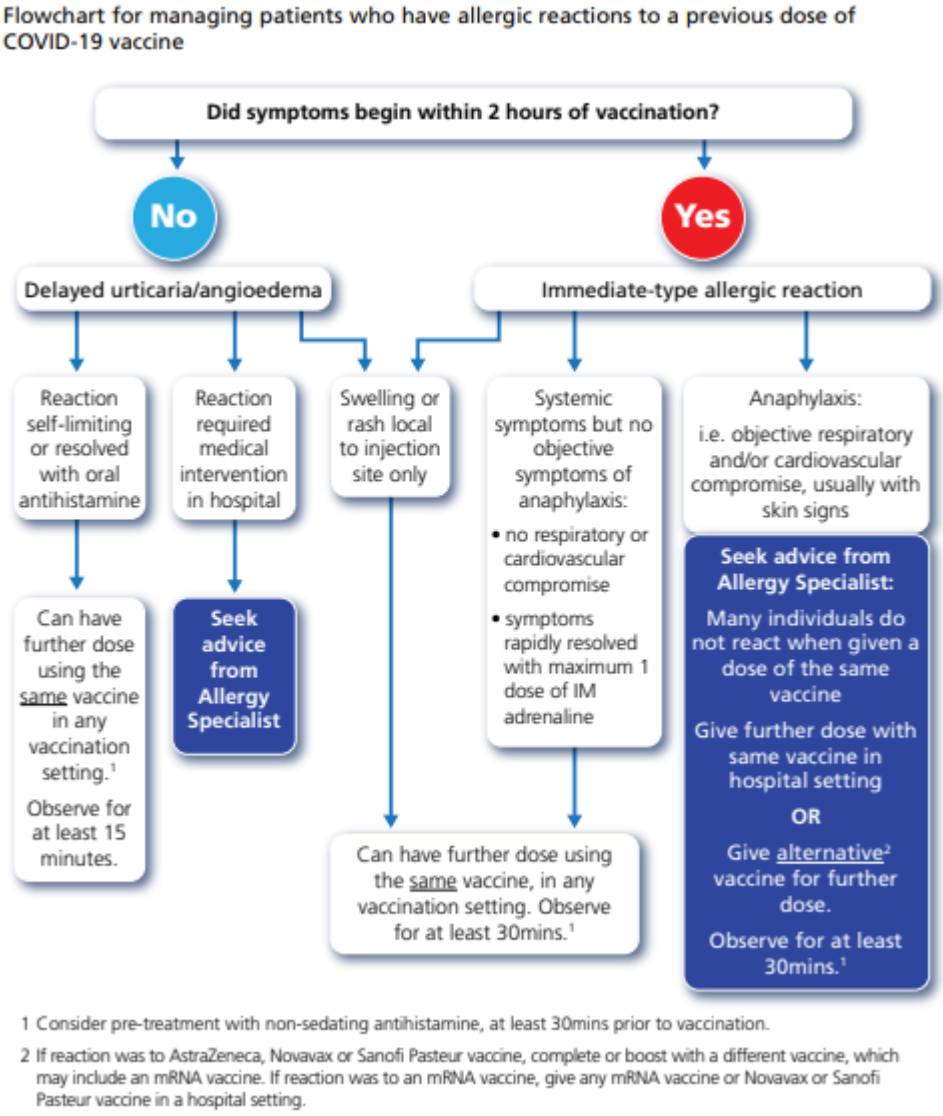
Table 5: Management of patients with a history of allergy

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis	• prior anaphylaxis reaction to COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine (for known PEG allergy see text above)
ACTIONS	• proceed with vaccination in any setting • some individuals may be reassured by being observed for 15 minutes (may not be required if previously tolerated the same vaccine) • some patients (e.g. those with mastocytosis) may benefit from pretreatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a person has previously tolerated a dose of the same vaccine, it is safe to administer in any setting. Otherwise - consider giving vaccine and observe for 30 minutes	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to a non-mRNA vaccine give alternative vaccine in any setting • consider observation for 30 minutes

From the NHS site linked below:

Policies / clinical-medicines-commissioning / covid-19-interim / vaccination-programme / 652-allergy-management

2.5. Table 5 is from the Greenbook chapter 14a- use the most up-to-date version on-line



Flowchart is from the Greenbook chapter 14a-and the most up-to-date version is online linked below:

Gov.uk/government/publications/covid-19-the-green-book-chapter-14a

2.6. Patients who have suffered severe allergic reactions or adverse reactions should be referred by a healthcare professional to the covid vaccination team at RCHT via rcht.vaccination@nhs.net.

2.7. This referral should only take place after consulting the basic guidance set out in the covid-19 chapter of the Greenbook (chapter 14a) and taking a thorough history of the reaction. In many cases, previous reactions do not meet the criteria and the patient is fine to receive mRNA vaccines.

2.8. The RCHT covid vaccination team will contact the patient to triage and discuss the available options (see section 2.16). If the patient cannot receive an mRNA vaccine then they will be offered a non-mRNA alternative. For high-risk allergy patients they will be booked into a covid vaccine allergy clinic at RCHT, for patients that have tolerated other vaccines with no issues, they will likely be

booked into a standard vaccination clinic where a non-mRNA vaccine is available.

2.9. If a patient is not contraindicated to an mRNA vaccine but there is concern regards severe reaction, the patient may attend the covid vaccine allergy clinic for their mRNA vaccine, where there is increased supervision post-vaccination and quick access to advanced life support if required.

2.10. The covid vaccine allergy clinics will be undertaken in the outpatient department of RCHT. These clinics must only take place where there is access to full resuscitation (Advanced Life Support) with appropriately equipped and trained staff available if required.

2.11. Very complex allergy queries will be referred to an allergy specialist following the decision tree in the 'Greenbook' chapter 14a. The 'Eden' allergy service at Derriford can be accessed using the referral form as per the Peninsula Clinical Reference Guideline (see appendix 3and4) and sent to the email address: plh-tr.eden@nhs.net.

2.12. The recommendation letter from the Eden Allergy Clinic at Derriford will be sent to the patient, the referrer and to the patient's GP practice. Where an individual is a member of RCHT or CFT staff, a copy of this recommendation letter should be forwarded to the occupational health department for their records.

2.13. Where high risk allergy patients are being administered vaccine the following should be in place;

2.13.1. An anaphylaxis kit must be available in the room and staff trained on how to use it.

2.13.2. Two BLS trained support staff must be available in the clinic (this can include the general Outpatient staff).

2.13.3. The resus (ALS) team is notified that the clinic is happening and is on stand-by.

2.14. The allergy clinic will use the appropriate electronic point of care system to record vaccination events in real time.

2.15. Check recommendations regarding co-administration with flu vaccine. In complex allergy patients it may be preferable not to co-administer to ensure any subsequent reaction can be attributed to the correct vaccine.

2.16. RCHT Clinic requirements are:

2.16.1. Access to prescriber with vaccine experience and able to prescribe the most appropriate vaccine.

2.16.2. On site healthcare staff able to assess and counsel patients.

2.16.3. 30-minute wait for most patients after administration (or in line with the current Greenbook/NHSE advice).

2.16.4. Capability to provide Advanced Life support level resuscitation.

2.16.5. Use of the electronic point of care system.

2.17. Vetting of Patients and Referral Information to the Prescriber

2.17.1. All referrals should be thoroughly vetted by the vaccination team. No patient should be booked into the allergy clinic without approval by the covid vaccination matron or appropriately trained deputy. If an individual's circumstances do not fall in line with the Greenbook flowchart, then refer the case to the clinic prescriber before booking the patient.

2.17.2. Appendix 6 should be completed for each clinic and sent to the prescriber, to support advanced prescribing ahead of the clinic.

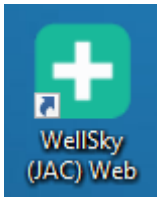
2.18. Prescribing the non- mRNA Vaccine

2.18.1. Confirm the license for the Non mRNA vaccine. Sometimes the vaccine may only be licensed for booster doses (for example) rather than a primary course, but are recommended by the JCVI. Patients should be informed of this 'off-label' use.

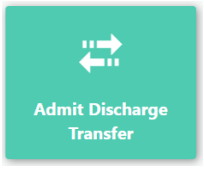
2.18.2. Ensure you are prescribing and follow-up doses if required e.g. 2nd primary.

2.18.3. In some situations, there may be no Patient Group Directive or National Protocol in place and therefore a 'patient specific direction' is the required legal mechanism for supply/administration.

2.18.4. The vaccine will be prescribed on the WellSky ePMA system as an inpatient.

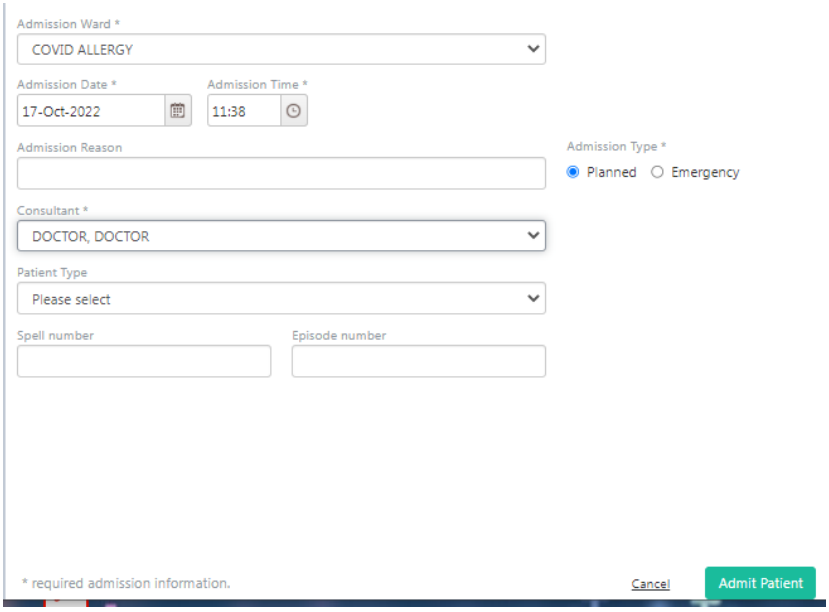


2.18.5. The Prescriber will first need to admit the patient onto the ePMA system using the 'Admit Discharge Transfer' function.

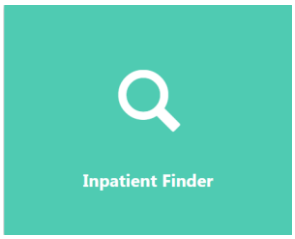


2.18.6. Enter the patient name/ NHS number etc into the 'patient finder' screen and select the patient. If the patient is not listed then contact a member of the ePMA team (x2078) or a ward clerk who are able to add patients to core.

2.18.7. On the Admission screen select ‘Covid Allergy’ for the ward and ‘DOCTOR DOCTOR’ for consultant. You do not need to populate or change anything else on the screen (leave the admission time and date as it is, even if the patient is coming in until the following day). Then click on the ‘Admit Patient’.

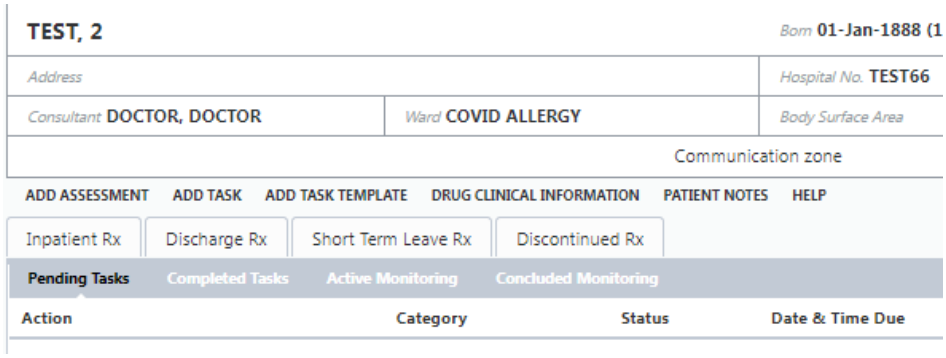


2.18.8. Return to the home screen and select ‘Inpatient Finder’.



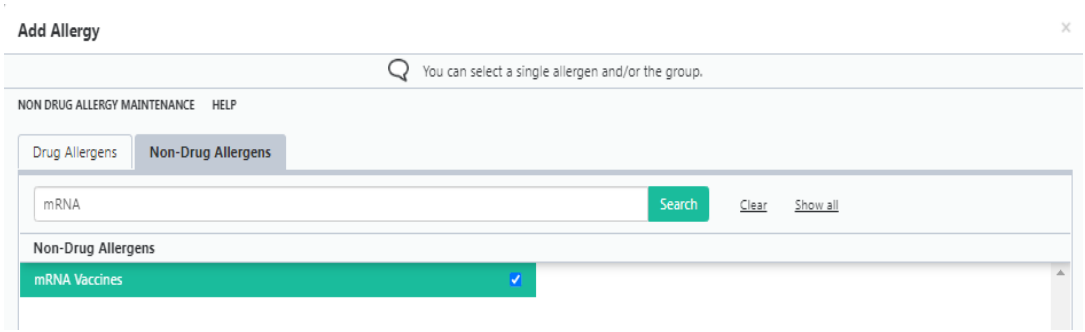
2.18.9. Search for the patient, or search via the ward name and select the patient.

2.18.10. Select ‘Inpatient Rx’ and then ‘Add Drug’.



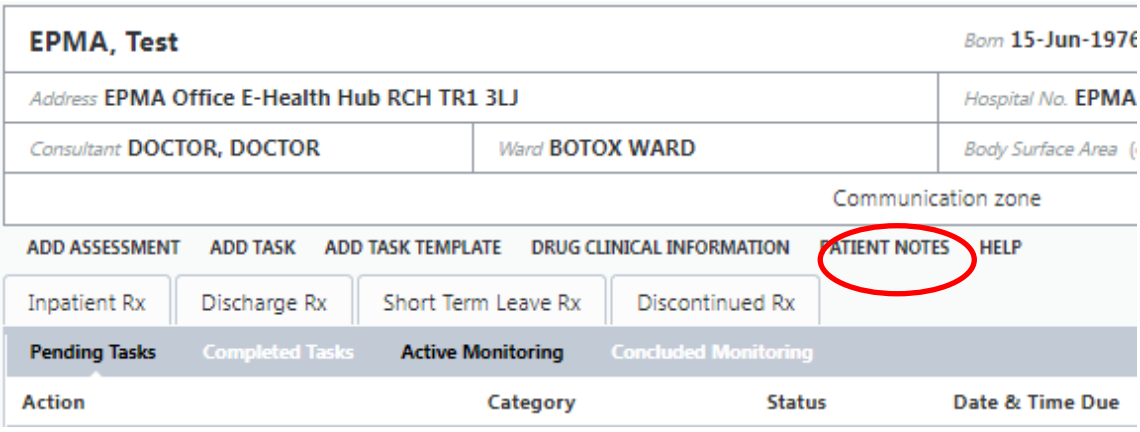
2.18.11. The patient may need their allergy status entering if this hasn’t been done previously or does not reflect the mRNA vaccine allergy. Click on the ‘Allergy Status’ box.

2.18.12. Covid vaccines do not show well on ePMA systems yet as they are populated directly from a databank (FDB) which uses the drugs generic names- tozinameran, riltozinameran for Pfizer and bivalent and elasomeran for Spikevax. For this reason, we have entered ‘mRNA Vaccines’ under the **non-drug allergen** tab. This means the allergy will show in a way that people understand but it will not be linked to the decision support regards warnings if you try and prescribe it.

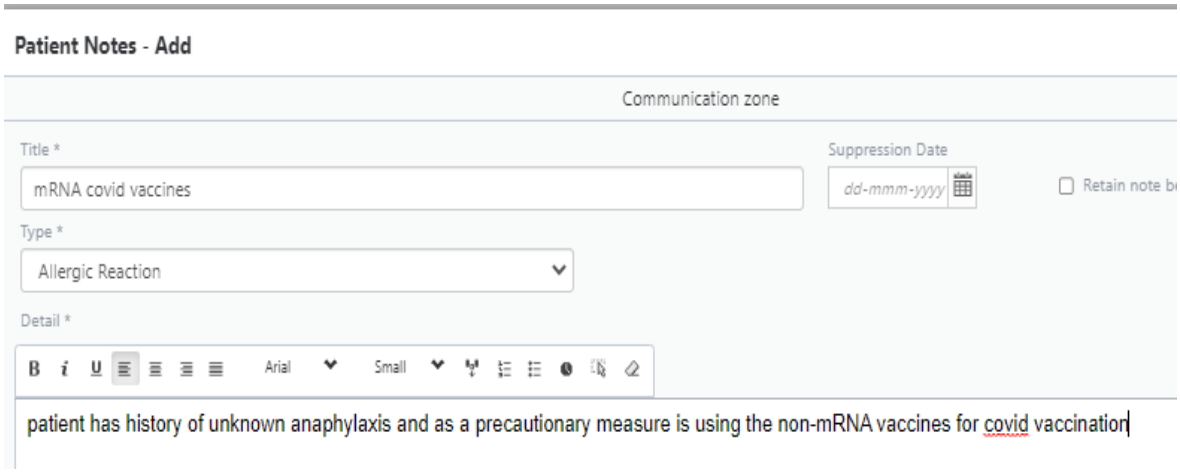


2.18.13. The ePMA system will require details of the type of reaction. In most cases select ‘other- see patient note’.

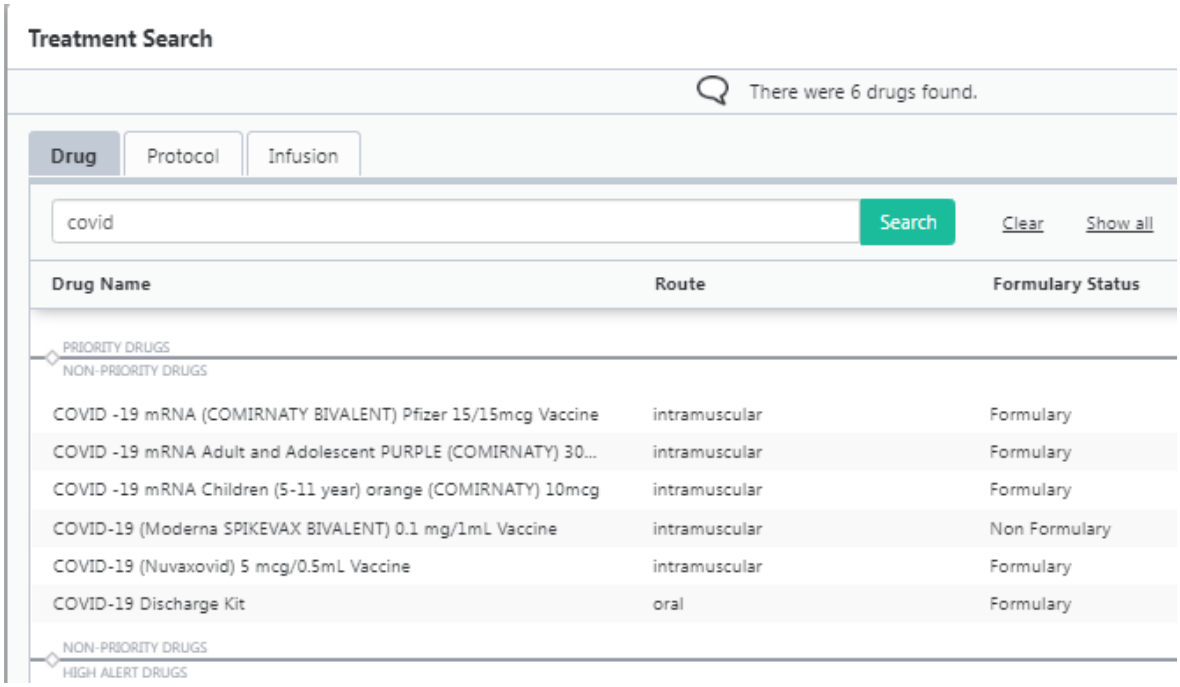
2.18.14. Click on the ‘patient notes’ tab.



2.18.15. Then click on ‘add note’, enter the note title e.g., mRNA covid vaccines and select the type as ‘allergic reaction’. Then enter the details regarding the allergy or other reason for caution with mRNA vaccines.



2.18.16. Once the allergy is entered, return to the 'add drug' screen and enter '**COVID'** in the drug search box and this will bring up all the covid vaccines.

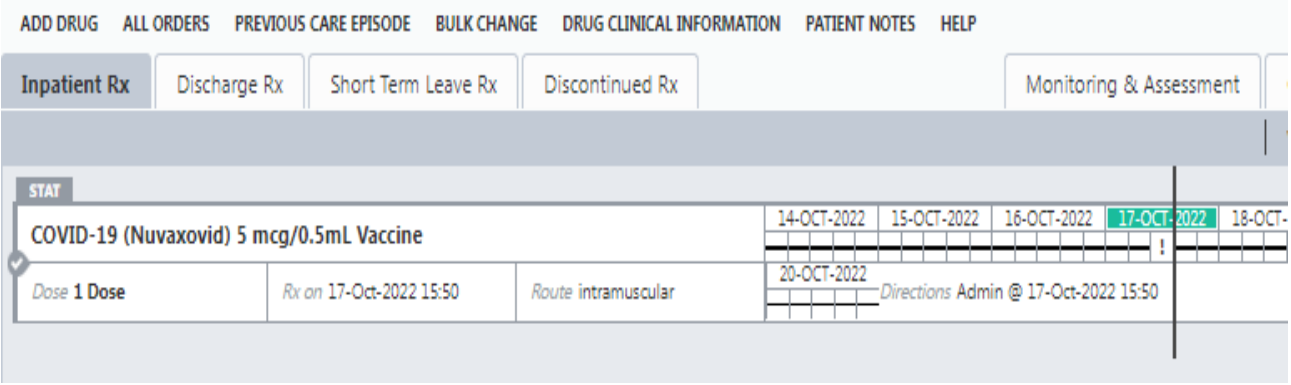


2.18.17. Click on the relevant drug name to select it.

2.18.18. The dosing details have automatically been set up in the ePMA system, so just press 'NEXT'. No VTE risk assessment is required.

2.18.19. Select 'Confirm'. The vaccine will now show up on the electronic drug chart, ready to administer.

2.18.20. If the individual is receiving another covid vaccine e.g., Pfizer Comirnaty, under close supervision in the allergy clinic, then select that vaccine instead.



2.19. Dispensing of the Vaccine and Shelf-Life Information

2.19.21. Please refer to the pharmacy SOP for the dispensing and transportation process.

2.19.22. The vaccinating nurse will need to attend pharmacy on the way to clinic to pick up the vaccine, which will be provided in a cool box with an accompanying preparation and administration worksheet and 23G syringes.

2.19.23. A cytotoxic spillage kit, a sharps bin and an anaphylaxis kit can be provided on request.

2.19.24. Refer to the specific product characteristics for details regards shelf-life, storage out of the fridge etc.

2.20. Administration of the Vaccine

2.20.1. Go through the consenting process and clinical screening questions on electronic point of care system before vaccinating. Confirm they are willing to proceed before administering the vaccine.

2.20.2. Use the worksheet provided by pharmacy with the vaccine to guide the preparation process.

2.20.3. Inject the vaccine by intramuscular injection only, preferably into the deltoid muscle of the upper arm.

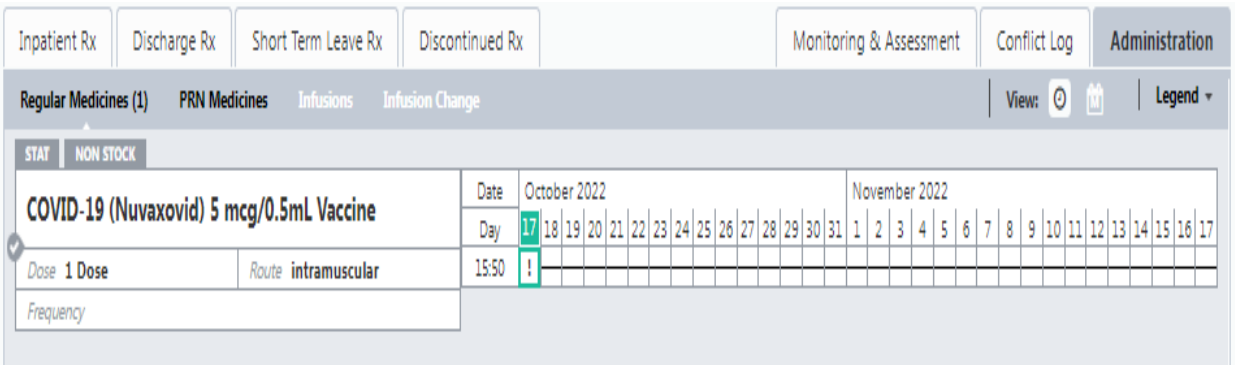
2.20.4. Discard the vial and syringe into a yellow sharps bin with a purple lid (hazardous medicinal waste).

2.21. ePMA Process for Vaccine Administration

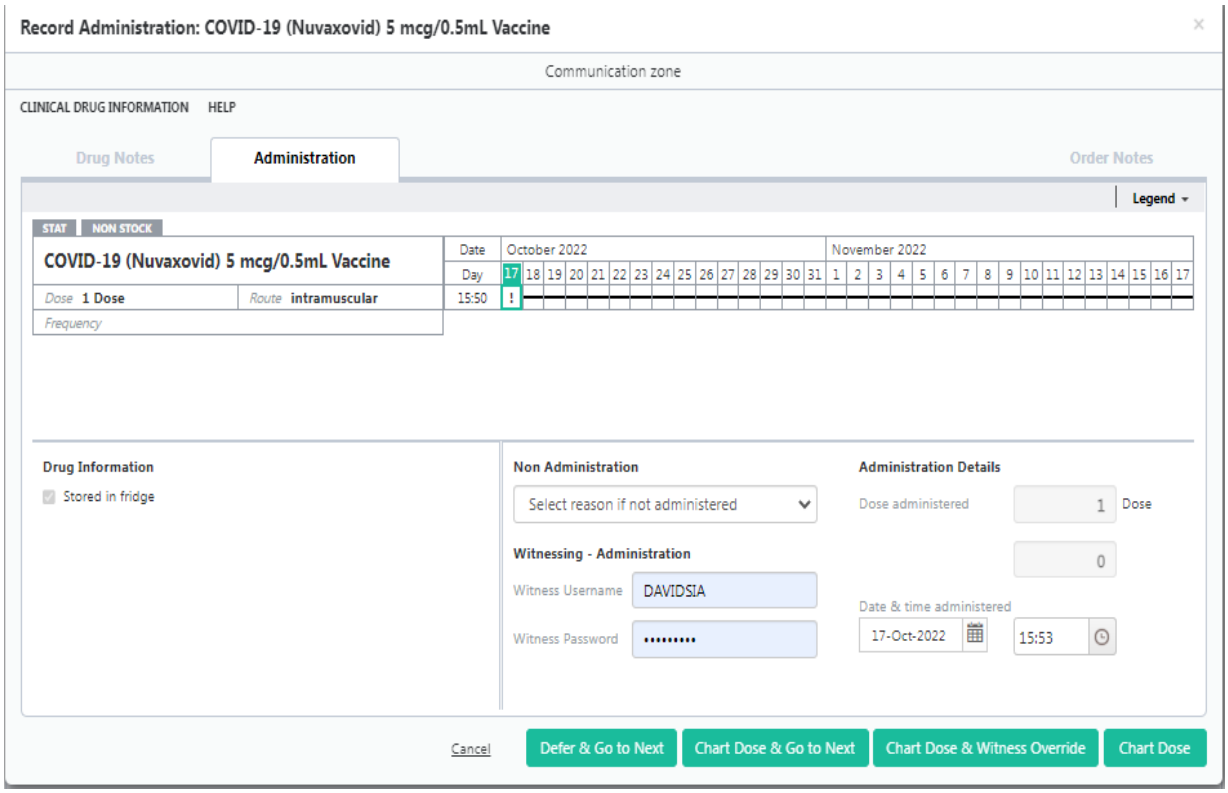
2.21.1. Log on to the ePMA system and select ‘Inpatient Finder’ tile (as described earlier).

2.21.2. Search for the patient by hospital/NHS number or search the ward name ‘Covid Allergy’.

2.21.3. Click on the patient’s name and on ‘Inpatient Rx’. This will take you through to the drug chart, where the vaccine will have been prescribed. Click on the ‘administration’ tab on the right of the screen.



2.21.4. Click on ‘Continue to Chart’ and then click on the drug name/ schedule- this will take you through to the administration page.



2.21.5. Follow the preparation and administration process set out in the earlier section to administer the drug.

2.21.6. Click on ‘Chart Dose and Witness Override’ to administer the dose on ePMA.

2.22. Electronic point of care process for recording administration

2.22.1. It is vital the vaccination event is recorded in real time on the electronic point of care system (e.g. NIVS and Pinnacle).

2.22.2. Enter the patient details and follow the system prompts through the consenting and administering process.

2.22.3. Complete and save the record.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Number of patients treated through this outpatient clinic. Number of allergic reactions. Patient harm.
Lead	Iain Davidson- Chief Pharmacist and clinical lead for the covid vaccination programme.
Tool	Datix reports. Outpatient clinic template.
Frequency	Monthly review.
Reporting arrangements	To the covid project board and MPC.
Acting on recommendations and Lead(s)	The clinical lead for the covid vaccination programme will lead on actions through the MPC, Clinical effectiveness grp and the Clinical Support care grp governance committee.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 2 weeks. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Covid-19 Vaccination for Complex Allergy Patients and Severe Adverse Reactions Clinical Guideline V3.0
This document replaces (exact title of previous version):	Covid-19 Vaccination for Complex Allergy Patients and Severe Adverse Reactions Clinical Guideline V2.1
Date Issued/Approved:	July 2023
Date Valid From:	August 2023
Date Valid To:	August 2026
Directorate / Department responsible (author/owner):	Iain Davidson, Chief Pharmacist and Clinical Lead / SRO for Covid-19 vaccination centres and hospital hub
Contact details:	01872 252593
Brief summary of contents:	Arrangements for covid vaccination in patients with severe allergy and adverse reactions.
Suggested Keywords:	Covid, c-19, vaccination, allergy. pregnancy
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Occupational Health. Peninsula Allergy pathway taskforce. Medicine Practice Committee. Clinical Support Governance Committee. Covid vaccination Project Board.
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	Chapter 14a of the Greenbook- Vaccination- Covid 19.

Information Category	Detailed Information
Related Documents:	None required
Training Need Identified?	Yes
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
12/3/21	V1.0	Initial issue.	Iain Davidson Chief Pharmacist.
12/10/22	V2.0	Comprehensive update to reflect the removal of AstraZeneca vaccine from the programme and the introduction of Nuvaxovid vaccine for allergy patients. Incorporated some of the learning from the first allergy clinic: Need for more detailed referral information to the prescriber (section 2.16 and appendix 6). Further information on how to enter the allergy details on ePMA.	Iain Davidson Chief Pharmacist.
22/02/22	V2.1	Appendix 3. Information included to show where the form can be located to be completed and updated watermark.	Iain Davidson Chief Pharmacist.
27/2/23	V3	Updated to reflect there are more than one non mRNA vaccines available for allergy patients and that administration does not always need to be in a specific allergy clinic if they have been fine with other vaccines before.	Iain Davidson Chief Pharmacist.

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Covid-19 Vaccination for Complex Allergy Patients and Severe Adverse Reactions Clinical Guideline V3.0
Directorate and service area:	Pharmacy, Clinical support
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Iain Davidson, Chief Pharmacist
Contact details:	01872 252593

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Arrangements for covid vaccination in patients with complex allergy or severe adverse reactions to the mRNA vaccines.
2. Policy Objectives	Safe and equitable covid vaccination.
3. Policy Intended Outcomes	Covid vaccination.
4. How will you measure each outcome?	Numbers of people vaccinated.
5. Who is intended to benefit from the policy?	Those citizens that need special consideration due to risk factors before vaccination.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Occupational Health. Peninsula Allergy pathway taskforce. Medicine Practice Committee. Clinical Support Governance Committee. Covid vaccination Project Board.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	

Protected Characteristic	(Yes or No)	Rationale
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Iain Davidson, Chief Pharmacist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Allergy Referral Form

Regional Covid Vaccine Allergy Referral Form – Please contact the COVID team in the Incident Control Centre on rcht.incident@nhs.net for a copy of the form.

Please use this referral form:

- following a suspected allergy to any Covid vaccine.

or

- if the patient has a suspected allergy to another substance (vaccine, PEG, vaccine excipient) that raises concern about future Covid vaccination.

It is expected that the healthcare professional who has identified a potential risk to a patient receiving a Covid vaccination should take responsibility for completing this form.

Please complete the form as fully as possible. Failure to do so risks the referral being returned.

Section A: Patient Details			
Name:		Date of Birth:	
Address:		GP Surgery:	
Postcode:			

Section B: COVID Vaccination Status										
Has the patient received a COVID Vaccine?	YES		N			Date:				
If yes, which one?						Batch No (If known):				
Which category is the patient in? (Circle one)										
1 Care Home Resident	2 Aged over 80	2 Health and Social care worker	3 Aged over 75	4 Aged over 70	4 Clinically Extremely Vulnerable	5 Aged over 65	6 Underlying health conditions	7 Aged over 60	8 Aged over 55	9 Aged over 50
Other (please explain):										

Section C: Suspected Allergen				
Was the suspected allergic reaction after the COVID Vaccine?	YES		NO	
If No, please provide as much detail as possible regarding the drug, vaccine or vaccine excipient that prompted the suspected allergic reaction.				

Year/date of reaction (approx.):					
How long after the suspected allergen did the reaction occur?					
Has the patient tolerated any vaccines since the suspected reaction? (If yes, which one(s)?					
Has the patient previously tolerated an injectable influenza vaccine?	YES		NO		

Section D: Suspected Reaction

How quickly did the reaction start after exposure to the suspected allergen?	

Please categorise the reaction (Please tick all that apply):

a.	Anaphylaxis/cardiac/respiratory compromise	
b.	Rash or swelling distant from the site of injection	
c.	Large local swelling, heat and tenderness at site of injection only	
d.	Patient hospitalised or required adrenaline	

Please give additional details:

Section E: Other required Information

Please provide a list of current medications:		
Please list any known drug allergies:		
Does the patient have any of the following medical conditions (please tick):		Chronic lung disease (e.g., COPD/Asthma) – if yes please provide baseline Peak Flow or FEV1:
		Heart disease
		Other relevant condition (please list)

Appendix 4. Covid vaccine allergy CRG guideline

COVID VACCINE ALLERGY

Key Messages

This referral pathway is for patients with a history of allergic disease that raises concerns about receiving COVID vaccination.

All referrals will be reviewed by the allergy department and advice and guidance will be provided as soon as possible to avoid unnecessary delays in receiving vaccination.

A very small number of individuals have experienced anaphylaxis when vaccinated with the mRNA vaccines.

Refer to Chapter 14a of the Greenbook for the most up to date information.

Red Flags

Patients that experience red flag symptoms should receive emergency management and be admitted to hospital via ambulance (even if symptoms have settled):

Amended criteria for the diagnosis of anaphylaxis, proposed by the WAO Anaphylaxis Committee, 2019.

Anaphylaxis is highly likely when any one of the following 2 criteria are fulfilled:
Acute onset of an illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (e.g., generalized hives, pruritus or flushing, swollen lips-tongue-uvula) **AND AT LEAST ONE OF THE FOLLOWING:** Respiratory compromise (e.g., dyspnoea, wheeze-bronchospasm, stridor, reduced PEF, hypoxemia). Reduced BP or associated symptoms of end-organ dysfunction (e.g., hypotonia [collapse], syncope, incontinence). Severe gastrointestinal symptoms (e.g., severe crampy abdominal pain, repetitive vomiting), especially after exposure to non-food allergens. Acute onset of hypotension* or bronchospasm or laryngeal involvement[a] after exposure to a known or highly probable allergen[b] for that patient (minutes to several hours[c]), even in the absence of typical skin involvement.

PEF, Peak expiratory flow; BP, blood pressure.

*Hypotension defined as a decrease in systolic BP greater than 30% from that person's baseline, OR.

i. Infants and children under 10 years: systolic BP less than (70 mmHg + [2 x age in years]).

ii. Adults: systolic BP less than <90 mmHg.

[a]Laryngeal symptoms include: stridor, vocal changes, odynophagia.

[b]An allergen is a substance (usually a protein) capable of triggering an immune response that can result in an allergic reaction. Most allergens act through an IgE-mediated pathway, but some non-allergen triggers can act independent of IgE (for example, via direct activation of mast cells).

[c]The majority of allergic reactions occur within 1–2 hours of exposure, and usually much quicker. Reactions may be delayed for some food allergens (e.g., alpha-gal) or in the context of immunotherapy, occurring up to 10 hours after ingestion."

Investigations

Patients with suspected anaphylaxis reactions should have:

- Mast Cell Tryptase taken at least 24 hours after acute anaphylaxis, and also ideally during the reaction in line with RCUK and NICE anaphylaxis management guidelines (as soon as possible; and 1-2 hours but no later than 4 hours after onset of symptoms).

Management

The following groups of people can receive any of the available vaccines without prior allergy assessment:

- People with no history of allergy or anaphylaxis.
- People with a history of non-allergic reactions (e.g., vasovagal episodes, non-urticarial skin reactions, non-specific symptoms).
- People with local skin reactions at the site of injection.
- (These individuals can have a second dose of the same vaccine in any setting with observation for 30 minutes; those with delay (>2h) in onset of symptoms can consider premedicating with a non-sedating antihistamine 30 minutes prior to vaccination).
- People with delayed-onset (>2 hours) symptoms following vaccination that didn't require medical attention.
- People with allergic diseases such as hayfever, eczema, or asthma.
- People with spontaneous urticaria and angioedema, without features of anaphylaxis (these individuals can have a second dose of the same vaccine in any setting with observation for 30 minutes).
- People with a history of allergy or anaphylaxis to foods or venom.
- People with a history of allergy or anaphylaxis to a single drug class (e.g., penicillins).
- People with a history of anaphylaxis to any non-COVID vaccine (as long as they are not known to be allergic to any component (excipient) of the vaccine).

Referral

Referral Criteria

- Anaphylaxis following COVID vaccination.
- Anaphylaxis to a COVID vaccine excipient (e.g., PEG, polysorbate 80).
- Anaphylaxis to multiple classes of drugs or vaccinations.
- Anaphylaxis to biologic medications.
- Spontaneous or unexplained anaphylaxis.
- Cutaneous or systemic mastocytosis.
- People with delayed-onset (>2 hours) symptoms following vaccination that did require medical attention.

Referral Instructions
e-Referral Service Selection.
Specialty: Clinical Immunology.

Clinic Type: Outpatient Telephone Clinic.

Service: Peninsula Immunology and Allergy Service.

Referral Forms.
DRSS Referral Form.

Regional COVID Vaccine Allergy Referral form – please ensure the form is completed as fully as possible. Failure to do so may result in the referral being returned and a delay in patient assessment.

All referrals without a Regional COVID Vaccine Allergy Referral form attached will be returned.

Please note these need to be sent by the referring clinician and not directly from the patient.

Supporting Information

GP Information:

Green Book Chapter 14a Gov.UK

Patient Information:

www.allergyuk.org (Allergy and the coronavirus (COVID-19) Vaccine)

MHRA statement on the Oxford/Astra Zeneca vaccine and update on the Pfizer/BioNTech Vaccine.

Pathway Group Publication date: Feb 2021.

Appendix 5. National Covid-19 Vaccination Programme KLOE

Clinical considerations for the Deployment of Nuvaxovid (Novavax) to Complex Patients.

These reflective questions are reviewed by the National Covid-19 Vaccination Programme Operations and Delivery team and evolve based on the continuous learning.

Site Setting: Royal Cornwall NHS Trust *If your answer is no to the following questions, the site will not be suitable for delivering Nuvaxovid (Novavax).*
Does the site have Advanced Life support level resuscitation facilities? Yes
Does the site have Advanced Life Support or equivalent trained staff on site during the clinic opening hours? Yes
Is there a clear escalation plan and ability for a crash team to support in a hospital setting or to get Ambulance support quickly in the event of an emergency? Yes
Does the site have facilities for the patient to have minimum of 30-minute observation period post vaccination? Yes
Does the site have Prescribing Clinicians to assess the individual need and allergy history, to counsel and prescribe correct vaccines for patients? Yes
Can the site safely manage multiple vaccines? Yes
Is the site currently or planning to co-administer? Not for the Novovax patients (as per Greenbook recommendations).
Bookings: If your answer is no to the following question, the site will not be suitable for delivering Nuvaxovid (Novavax).

Does the site already have a process for accepting referrals? Yes
If no, can it create one? Yes/No
Vaccine Recording: If your answer is no to the following question, the site will not be suitable for delivering Nuvaxovid (Novavax).
Does your site currently use NIVS or NIMS App as a Point of Care system? Yes
If no, is the site prepared to be onboarded to those systems? Yes/No

Date completed: **16/9/22**	**Completed by:** **Iain Davidson**
Name of Responsible Clinical Pharmacist: **Iain Davidson**	

Appendix 6. Covid Vaccination Allergy Clinic

Clinic date: _____ **List Co-ordinator: _____**

Patient Name	Hospital Number	DOB	Request received from	Request vetted by	Reason for request	Previous covid vaccines received	Details of the allergy (what drug, what reaction and when)	Recommended Vaccine (Nuvaxovid, Pfizer or no vaccine)	Does this decision meet the Greenbook decision tree recommendations? Y/N