

**Advice to PCN, LVS, VS Centres, Community Pharmacy and GPs
For individuals with a previous allergic reaction having
Pfizer-BioNTech, AstraZeneca or Moderna COVID-19
vaccines.**

AstraZeneca COVID-19 vaccine excipients**:	Pfizer-BioNTech COVID-19 Vaccine excipients:	Moderna COVID-19 vaccine excipients* :	Novavax COVID-19 Vaccine excipients:
<ul style="list-style-type: none"> L-Histidine 	<ul style="list-style-type: none"> ALC-0315 = (4-hydroxybutyl) azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) 	<ul style="list-style-type: none"> Lipid SM-102 	<ul style="list-style-type: none"> Disodium hydrogen phosphate heptahydrate
<ul style="list-style-type: none"> L-Histidine hydrochloride monohydrate 	<ul style="list-style-type: none"> ALC-0159 = 2-[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide 	<ul style="list-style-type: none"> Cholesterol 	<ul style="list-style-type: none"> Sodium dihydrogen phosphate monohydrate
<ul style="list-style-type: none"> Magnesium chloride hexahydrate 	<ul style="list-style-type: none"> 1,2-Distearoyl-sn-glycero-3-phosphocholine 	<ul style="list-style-type: none"> 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) 	<ul style="list-style-type: none"> Sodium chloride
<ul style="list-style-type: none"> Polysorbate 80 	<ul style="list-style-type: none"> Cholesterol 	<ul style="list-style-type: none"> 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG) 	<ul style="list-style-type: none"> Polysorbate 80
<ul style="list-style-type: none"> Ethanol 	<ul style="list-style-type: none"> Potassium chloride 	<ul style="list-style-type: none"> Trometamol 	<ul style="list-style-type: none"> Sodium hydroxide
<ul style="list-style-type: none"> Sucrose 	<ul style="list-style-type: none"> Potassium dihydrogen phosphate 	<ul style="list-style-type: none"> Trometamol hydrochloride 	<ul style="list-style-type: none"> Hydrochloric acid
<ul style="list-style-type: none"> Sodium chloride 	<ul style="list-style-type: none"> Sodium chloride 	<ul style="list-style-type: none"> Acetic acid 	<ul style="list-style-type: none"> Water for injections
<ul style="list-style-type: none"> Disodium edetate dihydrate 	<ul style="list-style-type: none"> Disodium hydrogen phosphate dihydrate 	<ul style="list-style-type: none"> Sodium acetate trihydrate 	<ul style="list-style-type: none"> Adjuvant (Matrix-M) - contains Cholesterol, Phosphatidylcholine (including all-rac-α-Tocopherol), Potassium dihydrogen phosphate, Potassium chloride, Disodium hydrogen phosphate dihydrate, Sodium chloride, Water for injection
<ul style="list-style-type: none"> Water for injections 	<ul style="list-style-type: none"> Sucrose 	<ul style="list-style-type: none"> Sucrose 	
	<ul style="list-style-type: none"> Water for injections 	<ul style="list-style-type: none"> Water for injections 	

* Ref: <https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna>. The vaccine contains polyethylene glycol (PEG)/macrogol as part of PEG2000-DMG.

** No longer available for routine use in UK

According to the Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech, Moderna and Novavax vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers recommended suspension of this requirement for the two mRNA vaccines (Pfizer BioNTech and Moderna) in both children and adults. The suspension of the observation period in individuals without a history of allergy has since been agreed by the Commission on Human Medicines and also applies to the Moderna bivalent vaccine.

Facilities for management of anaphylaxis should be available at all vaccination sites (see [Green Book Chapter 8: Vaccine safety and adverse events following immunisation](#)). Advice has also been issued by the Resuscitation Council.¹

Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended.

1. Proceed with the vaccination as planned for:

- Previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified). Check that the identified substance is not a component of the vaccine.

2. First dose of Pfizer-BioNTech or Moderna COVID-19 vaccine:

The Green book advises:

- Individuals with a prior history of systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose or any component of the Pfizer-BioNTech or Moderna vaccine, or another mRNA vaccine **should not receive it. Refer patient to allergy clinic.**

- A very small number of individuals have experienced anaphylaxis when vaccinated with the Pfizer BioNTech vaccine. Following close national surveillance, the MHRA are now advising that individuals with a history of anaphylaxis to any vaccine (excluding the COVID-19 vaccine), medicine or food to receive the vaccine. Anyone with a previous history of allergic reactions to the ingredients of the vaccine should not receive it, but those with any other allergies (such as a food allergy) can now have the vaccine.

Further information regarding PEG:

- The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG).
- PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of this vaccine (Sellaturay *et al*, 2020). It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine.
- Patients with undiagnosed PEG allergy often have a history of immediate onset-unexplained

¹ [RCUK publishes anaphylaxis guidance for vaccination settings | Resuscitation Council UK](#)

anaphylaxis or anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis. Such individuals should not be vaccinated with the Pfizer BioNTech or Moderna vaccines, except on the expert advice of an allergy specialist. The AstraZeneca or Novavax vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. The vaccine should be administered in a setting with full resuscitation facilities (e.g. a hospital), and a 30 minute observation period is recommended.

- Published data now show that some individuals with prior allergic reaction to PEG-containing medicines (eg. PEG-asparaginase) can tolerate the Pfizer BioNTech vaccine (although the historical reaction may have been due to a non-PEG component). Expert advice should be obtained and if a decision is made to administer an mRNA vaccine, then this should only be done in hospital under medical supervision
- NB: Based on current evidence JCVI is advising a preference for an alternative COVID-19 vaccine other than the AstraZeneca vaccine, for healthy people under 40 years of age.

3. First dose of AstraZeneca COVID-19 vaccine:

The Green book advises:

- Individuals with a prior history of systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose or any **component** of the AstraZeneca vaccine **should not receive it. Refer patient to allergy clinic.**
- The rate of anaphylaxis reported to date to the AstraZeneca vaccine is in line with the expected rate of anaphylaxis to non-COVID vaccines.
- The AstraZeneca vaccine does not contain PEG but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80.

4. Second, third and booster doses of Pfizer, AstraZeneca, Moderna and Novavax Covid-19 vaccine: see Appendix 1

- Please see the flowchart below (**Appendix 1**) for managing patients who have had allergic reactions to a previous dose of the COVID-19 vaccine.
- Individuals who had a previous systemic anaphylaxis reaction with Astra-Zeneca vaccine may be given an alternate vaccine in any setting, with observation for 30 minutes
- AstraZeneca vaccine is no longer being supplied for routine use in the UK. When mRNA vaccines are not considered clinically suitable, Novavax COVID-19 vaccine may be used for primary vaccination of adults over 18 years, including to complete a course or as a booster, although the latter is currently off-label.
- As per BSACI, many individuals with initial apparent allergic reaction to an mRNA vaccine can tolerate a second dose of the same vaccine. Where there were no objective signs of anaphylaxis and symptoms rapidly resolved (with no more than 1 dose of IM adrenaline), a further dose of the same vaccine can be given in any vaccination setting. If the reaction might have been anaphylaxis, obtain

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expert advice; if a decision is made to administer the same vaccine, then this should be done under medical supervision in the hospital setting. See flowchart (**Appendix 1**) for further information.

5. Contact process for allergy specialist advice:

Advice and guidance for the COVID-19 vaccine:

- L/VS centres to fill in table in Appendix 3 and refer patients back to respective GPs for individual case review.
- The appropriate clinician requesting allergy specialist advice is most likely to be the patient's GP due to the detail of information required.
- See Appendix 3 for referral process to local Hospital Trusts and Adult and Paediatric Allergy Specialist Services in NEL

Reference:

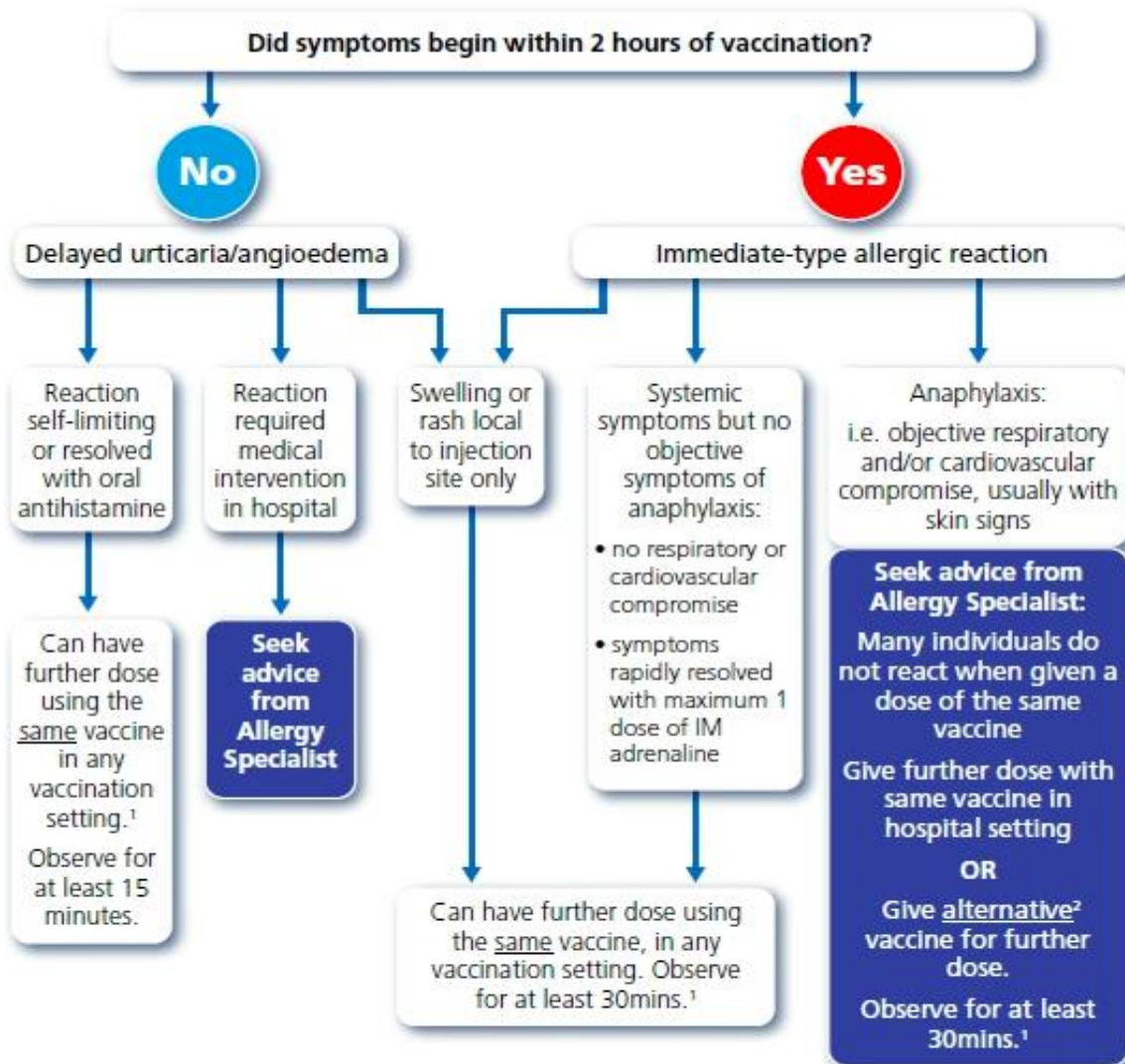
Green Book:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1098808/Greenbook-chapter-14A-17August2022.pdf

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Appendix 1: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine. Taken from The Green book:



1 Consider pre-treatment with non-sedating antihistamine, at least 30mins prior to vaccination.

2 If reaction was to AstraZeneca or Novavax vaccine, complete or boost with an mRNA vaccine. If reaction was to an mRNA vaccine, give any mRNA vaccine or Novavax vaccine in a hospital setting.

Appendix 2: Management of patients with a history of allergy taken from Chapter 14a of the Green book.

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	<ul style="list-style-type: none"> ● 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 	<ul style="list-style-type: none"> ● 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 	<ul style="list-style-type: none"> ● prior anaphylaxis reaction to COVID-19 vaccine ● prior systemic allergic reaction to a component of the vaccine <p>(for known PEG allergy see text above)</p>
ACTIONS	<ul style="list-style-type: none"> ● 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 	<ul style="list-style-type: none"> ● 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. <p>Otherwise</p> <ul style="list-style-type: none"> - consider giving vaccine and observe for 30 minutes 	<ul style="list-style-type: none"> ● refer to allergist or other appropriate specialist ● consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to AstraZeneca or Novavax vaccines give alternative vaccine in any setting ● consider observation for 30 minutes

Appendix 3: Process for referring patients to Barts Health NHS Trust for their COVID-19 vaccine if unsuitable for administration in PCN LVS / VS centres.

- This pathway applies to staff and registered and unregistered people in NEL.
- L/VS clinical lead/Nominated Person to collate list of respective patients from screening team and return patient details to registered GP practice at the end of each clinic, *using the table below*.
- The appropriate clinician requesting allergy specialist advice is most likely to be the patient's GP due to the detail of information required.

Allergy Specialist Service

Trust	Population	Process
Barts Health NHS Trust Covid Vaccination Centre, based at Royal London Hospital (Adults ≥ 16 years old)	NEL Green and Amber Column (as per Appendix 2 above from Green Book)	Complete allergy-vac- form Appendix 4 below and email to: bartshealth.excel.vaccinations@nhs.net
Barts Health NHS Trust (Adults ≥ 16 years old)	NEL Orange Column (as per Appendix 2 above from Green Book)	Referral via eRS 7949265 Adult Allergy (SBH) - Barts Health NHS Trust - R1H
Barts Health NHS Trust (Paediatrics)	NEL Amber and Orange Column (as per Appendix 2 above from Green Book)	If patient in Barts Health NHS Trust catchment area - Refer via eRS If patient out of area – Referral from local paediatric team to allergy service needed

Table for LVS sites to refer back to GPs

Name	NHS Number	DOB	Contact number	GP practice	Reason for referral

DRAFT

					North East London Health & Care Partnership

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DRAFT

Referral Form - Covid19 Vaccination: Anaphylaxis, Complex Allergy/Adverse Reactions/second dose

PATIENT DETAILS

Name	
DOB	
NHS Number	
Mobile Number	
Email Address	
House Number	
Postcode	
Has the patient had Covid-19 Vaccine? If, Yes, please specify : Vaccine brand given Date Given	

REASON FOR REFERRAL - PLEASE INDICATE & COMPLETE ANY THAT APPLY

ANAPHYLAXIS OF UNKNOWN ORIGIN

Please outline history (as fully as possible)	
Year of first incident Any other incidents & date/year of occurrence	
Description of symptoms in time order (if possible)	
Description of treatment, including hospital admission, im/iv/po medication, any investigation or referral	

KNOWN ANAPHYLAXIS TO MULTIPLE DRUGS, NON-COVID VACCINE OR BIOLOGICS

Outline history of known anaphylaxis: Please highlight if anaphylaxis to a <u>non-Covid vaccine or biologic</u> , eg infliximab, adalimumab, tocilizumab, secukinumab, ustekinumab, anakinra	
Is there a contraindication to any other Covid vaccine, eg AstraZeneca and why ?	

<u>Incident :</u>	
Name of known trigger	
Dates of reactions	
Description of symptoms	
COVID-19 VACCINE FIRST DOSE REACTION	
Name of Covid-19 Vaccine Given	
Date of vaccination,	
<u>Description of symptoms of Vaccine Reaction:</u> (How soon after vaccine symptoms started, type of symptoms, duration of symptoms, treatment received, A&E attendance?)	
<u>Reasons FOR MEDICAL SUPERVISION</u>	
Please outline any other reason or consideration supporting request for medical supervision of vaccination, including issues of which they should be aware. Eg level of anxiety/reassurance required, past experience of patient, morbid obesity, undergoing other hospital treatment, etc	
<u>PAST MEDICAL HISTORY</u>	
Relevant Past Medical History	
Current medications and recent acute medications: please attach medication record or list	
Any other allergic reactions to note: e.g.PEG / Polysorbate 80 allergy	
<u>ABOUT THE REFERRER</u>	
Date of Referral	
Name	
Mobile number and email	
Role of Referrer in Vaccination Programme	
Origin of referral (eg Primary Care, Acute Trust, LVS)	
Send Referral to:	bartshealth.excel.vaccinations@nhs.net