



COVID-19
PRIMARY CARE
VACCINATION SITE
BRIGHTON RACECOURSE



East & Central Brighton,
Brighton II, Preston Park
Community, The Havens PCNs

COVID-19 Primary Care Vaccination Site Brighton Racecourse

Process for Vaccination for patients who have been participating in COVID Vaccine Trials

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Contents

1. Background	4
2. National Guidance	4
3. Local Process	4
4. National Process	4
5. Current Advice	4
6. Ongoing Safety Monitoring	5
7. Process for Vaccination under a PSD	5
8. Appendix 1 - Individual Patient assessment to assist the creation of Patient Specific Direction (PSD) for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2 [to be adapted]	6
9. Appendix 2 Individual assessment to assist the creation of Patient Specific Direction for the administration of the Covid-19 Vaccine AstraZeneca	9

1. Background

This clarifies the local vaccination policy for patients attending the Brighton Racecourse GP Vaccination Site who have participated in COVID Vaccine Trials. There is a local Vaccine Trial currently being undertaken for a COVID Vaccination made by Janssen. All patients who have received Trial Vaccines will need to have a signed PSD to administer either the Pfizer/BionTech Vaccine or the AstraZeneca Vaccine.

2. National Guidance

From the COVID-19 Greenbook Chapter 14a:

“Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. Eligible persons who are enrolled in vaccine trials should then be provided with written advice on whether and when they can be safely vaccinated in the routine programme”

3. Local Process

- 3.1 When a Trial Participant is identified by the Booking Hub or on-Site they should be advised to contact their trial study team
- 3.2 The Trial Team will then unblind the individual and based on what has been received (Active vaccine or placebo) then will give specific advice to the individual on how to proceed
- 3.3 Patients are then advised to Contact Brighton Racecourse Booking Hub to book further appointment if required

4. National Process

NHS England have confirmed the following should apply and be delivered by NHS vaccinating centres.

- 4.1 For people who have received 2 doses of experimental vaccine (currently Oxford/AZ, Novavax or Janssen) participants - no further immunisation is required.
- 4.2 For people who have received 1 or 2 doses of placebo - a full course of NHS deployed vaccine is required.
- 4.3 For people who have received only 1 dose of currently experimental vaccine (currently possible for the Oxford/AZ trial where some people chose not to receive the booster dose and the Janssen vaccine) - 1 dose only is required (no booster) of whichever NHS deployed vaccine you have available.
- 4.4 Timings for those requiring a second dose will be as for normal NHS Vaccination policy at 12 weeks following one dose of experimental vaccine

5. Current Advice

This advice is based on the current approved vaccines and may change in the coming weeks if the Janssen vaccine is approved on a one dose schedule (but this is not the case at present and is expected in March 2021).

6. Ongoing Safety Monitoring

All Trial Participants will have been encouraged to stay in the trial process for ongoing safety monitoring.

7. Process for Vaccination under a PSD

In order for these individuals to be vaccinated this needs to be done separately under a Patient Specific Direction:

- For Pfizer BioNTech see Appendix 1
- For AstraZeneca see Appendix 2

- This needs to be handwritten and completed initially by a Clinical Prescriber.

- Once completed and the Vaccination has been given then the form needs to be handed back to one of the On-site Learning & Development Team Members.

- If you need clarification on this process, please speak with either the On-Site Clinical or Pharmacy Lead.

8. Appendix 1 - Individual Patient assessment to assist the creation of Patient Specific Direction (PSD) for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2 [to be adapted]

Name		Date of birth	
Surname			
Home Address			
		Postcode	

Assessors Name or ID Number	ID No	
Please ask the person presenting for vaccination these questions and record that they have received appropriate counselling as to the purpose of the vaccine and side effects		
Have you had any vaccination in the last 7 days?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
Are you currently unwell with fever?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
* Have you ever had any serious allergic reaction?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
*Have you ever been prescribed an adrenaline autoinjector such as an epipen?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
Are you, or could you be pregnant, breastfeeding or planning to become pregnant in the next three months?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
Are you or have you been in a trial of a potential coronavirus vaccine?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
Are you taking anticoagulant medication, or do you have a bleeding disorder	No <input type="checkbox"/>	Yes <input type="checkbox"/>

If any of the boxes in red are ticked, then a further review by the prescriber must take place. If you or the person presenting are uncertain as to the response or counselling, they receive they must be brought to the attention of the prescriber. See later for specific advice.

Patient Specific Direction (PSD) for the administration of Pfizer BioNTech Coronavirus Vaccine to Adults by Non prescribers suitably trained in Vaccination

Date of PSD:

The patient named below is eligible to receive
Covid-19 mRNA Vaccine BNT 162b2 0.3mls Intra-Muscular (IM) Injection

in accordance with Public Health England Immunisation against infectious disease (Green Guide) and JCVI recommendations for the purpose of protection against COVID-19.

Patient Details

Name		Date of birth	
Surname			
Home Address			
		Postcode	

ONE DOSE OF Covid-19 mRNA Vaccine BNT 162b2 – 30µg in 0.3mls of the diluted vaccine by Intra-Muscular injection.

Vaccination Centre/ PCN /Hospital Hub Name and Address:

Brighton Racecourse GP Vaccination Site Brighton Racecourse Freshfield Road Brighton BN2 9XZ

Name of Prescriber	Signature of Prescriber	Date and Registration Number

This PSD will expire within 7 days of signature

Name of Vaccine Administrator (i.e. person giving the vaccine)	Signature of Administrator	Date

Notes for Prescriber/Clinician

The prescriber should be aware of the MHRA Conditions of authorisation and the vaccine's contraindications, together with the advice from JCVI regarding the avoidance of pregnancy within 2 months of the second dose of vaccine: <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>

** 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.*

Any person who has been involved in a coronavirus trial should be advised to contact the trial organisers to seek guidance on whether or when vaccination should take place.

Taking anticoagulants or a bleeding disorder is not a contraindication to intramuscular injections, but the recipient needs to be aware that they may have increased bruising and be advised to apply pressure. Those with bleeding disorders may wish to time vaccination to occur shortly after appropriate therapies. Please also refer to the relevant chapter in the Green Book – Chapter 14a. <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

9. Appendix 2 Individual assessment to assist the creation of Patient Specific Direction for the administration of the Covid-19 Vaccine AstraZeneca.

Name		Date of Birth	
Surname			
Home Address			
		Post Code	
Assessors Name Print & Sig.	GMC. NMC HCPC No		
Please ask the individual presenting for vaccination these questions and record that they have received appropriate counselling as to the purpose of the vaccine and side effects			
Are you less than 18 years of age?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Are you currently unwell with fever or have any symptoms of Covid -19 infection?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Have you tested positive for Covid in the past 4 weeks?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Have you completed a course of Covid-19 vaccinations?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Are you participating in a clinical trial of covid-19 vaccines?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Have you had any vaccinations in last 7 days?	No <input type="checkbox"/>	Yes* <input type="checkbox"/>	
Have you received a dose of Covid-19 vaccine in the preceding 21 days?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Have you had a previous systemic allergic reaction (including anaphylaxis) to a previous dose of vaccine or any component of the vaccine?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Are you pregnant?	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Are you breast feeding?	No <input type="checkbox"/>	Yes* <input type="checkbox"/>	
Are you taking anticoagulant medication, or do you have a bleeding disorder?	No <input type="checkbox"/>	Yes** <input type="checkbox"/>	

If any of the boxes in bold (red) are ticked, then the patient should be advised that a covid vaccination is not appropriate at this moment time and advice given as to when it would appropriate for them to re-present for immunisation except those marked * who may be eligible for the vaccine based on risk / benefit evaluation with the prescriber.

** Taking anticoagulants or a bleeding disorder is not a contraindication to intramuscular injections, but the recipient needs to be aware that they may have increased bruising and be advised to apply pressure.

Those with bleeding disorders may wish to time vaccination to occur shortly after appropriate therapies.

Please also refer to the relevant chapter in the Green Book – Chapter 14a.

<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

Patient Specific Direction (PSD) for the administration of Oxford Astra Zeneca Coronavirus Vaccine to Adults by Non prescribers suitably trained in Vaccination.

Date of PSD:			
The individual named below is eligible to receive			
Covid-19 Vaccine AstraZeneca Vaccine 0.5mls Intra-Muscular (IM) Injection in accordance with Public Health England Immunisation against infectious disease (Green Book and JCVI recommendations for the purpose of protection against COVID-19.			
Individual Details			
Name		Date of Birth	
Surname			
Home Address			
		Post Code	
ONE DOSE of Covid-19 Vaccine Astra Zeneca Vaccine in 0.5mls of vaccine by Intra-Muscular injection.			
Vaccination Centre			
Name: Brighton Racecourse GP Vaccination Site			
Address:			
Freshfield Road Brighton BN2 9XZ			
Name of Prescriber	Signature of Prescriber	Registration Number	Date

This PSD will expire within 7 days of signature

Name of Vaccine Administrator (i.e. person giving the vaccine)	Signature of Administrator	Date

Notes for Prescriber/Clinician

The prescriber should be aware of the MHRA Conditions of authorisation the vaccine's contraindications together with the advice from JCVI.

Please also refer to the relevant chapter in the Green Book – Chapter 14a.
<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>