



COVID-19 Primary Care Vaccination Site Brighton Racecourse

The Use of Patient Specific Directions for Vaccination for patients who fall outside of the National Protocol for giving COVID-19 Vaccinations.

Document Version:	1.0
Document Author:	Dr Simon Hincks
Document Owner:	Dr Selma Stafford
Approved By:	
Approved Date:	
Review Date:	As required during the COVID-19 pandemic
Review Cycle:	As required during the COVID-19 pandemic

Version	Date	Summary of Change	Reviewer
1.0	22/03/2021	Initial draft	Dr Simon Hincks
1.1	13/05/2021	Updates	Pippa Halley

Contents

1. Background.....	4
2. Process for Vaccinating an Individual who falls outside of the National Protocol.....	4
3. COVID Vaccination, Pregnancy and National Monitoring.....	5
4. Associated Documents	5
5. Appendix 1 - PSD AstraZeneca	6
6. Appendix 2 – PSD Pfizer BioNTech.....	8

1. Background

All injectable medicines are Prescription Only Medicines (POM). Therefore, they must be prescribed prior to administration or administered under an alternative legal mechanism.

1.1 National Protocol

This is the primary mechanism for the majority of deployment models. It can be used by a single registered healthcare professional undertaking all stages of the vaccination process, or by up to four registered or non-registered persons undertaking different stages. It has been introduced specifically to support the vaccination programme and is a new legal mechanism following amendment of the Medicines Regulations.

Hence, the protocol allows a wider range of suitably trained and competent persons to deliver the vaccination programme. The operational stages of activity that can be undertaken by registered and non-registered persons, are detailed in:

AstraZeneca: <https://www.gov.uk/government/publications/national-protocol-for-covid-19-vaccine-astrazeneca-chadox1-s-recombinant>

Pfizer: <https://www.gov.uk/government/publications/national-protocol-for-covid-19-mrna-vaccine-bnt162b2-pfizerbiontech>

This means there is no requirement for individual signed paperwork by a Registered Prescriber and data entry is done on the Pinnacle IT System which is then uploaded to the Patient's GP Electronic Record.

Most COVID-19 Vaccinations given at the Brighton Racecourse Site will be given under the National Protocol:

1.2 Patient Specific Direction (PSD)

Where an individual falls outside the inclusion criteria stated in the National Protocol or PGD, they need to be clinically assessed on an individual basis to receive vaccine by a prescriber. If this results in a decision to vaccinate, a PSD should be used.

Registered healthcare professionals that can write a PSD for COVID-19 vaccination. In line with the advice contained in NHS England's [Summary of the legal mechanisms for administering the COVID-19 vaccine\(s\)](#) only doctors, independent nurse prescribers or independent pharmacist prescribers can write PSDs for COVID-19 vaccinations. Other non-medical prescribers cannot prescribe unlicensed or medicines authorised under Regulation 174.

Questions about PSDs: <https://www.sps.nhs.uk/articles/patient-specific-directions-qa/>

2. Process for Vaccinating an Individual who falls outside of the National Protocol

2.1 Individual is identified as not suitable to be vaccinated under the National Protocol

2.2 Alert On-Site Clinical Lead

2.3 The On-Site Clinical Lead will be responsible for consenting the patient following current guidelines

2.4 The On-Site Clinical Lead will obtain the correct PSD for the Vaccine that is to be given these are available on the IAS website under Brighton Racecourse GP Vaccination Site

- PSDs can be found on the [website](#) or in Appendices 1 & 2.

2.5 The On-Site Clinical Lead will undertake the following as outlined in the PSD:

- Complete the Risk assessment
- Where yes is answered to any questions then clarify and discuss risks and benefits from proceeding with vaccination and record a summary of the discussion in the Risks & Benefits Discussed section
- Advise the patient that the Vaccinations is to be given outside of MHRA Temporary Authorisation/National Protocol and record this
- Discuss possible side effects and how to manage these and record that this has been completed
- Date the PSD at the top of the second page
- Add your name to the PSD and then Sign the adding your professional Registration Number and the date.

2.6 The PSD can then be given to the vaccinator who can proceed with the vaccination

2.7 The Vaccinator will add their name, sign that they have given the vaccination and add the date the vaccination was given

2.8 The completed form will then be given to the Site Support Team for scanning and storing in a secure folder on the S Drive and emailing to the patient's registered practice.

3. COVID Vaccination, Pregnancy and National Monitoring

3.1 Inadvertent Vaccination – Patient unaware that they were pregnant and the time of their first vaccination: if any woman presents for her second vaccination who was unaware she was pregnant at the time her first dose was given, these will need to be reported to Public Health England for ongoing monitoring.

3.2 Process for Reporting Inadvertent Vaccination during pregnancy

- This is the responsibility of the On-site Clinical Lead to report inadvertent vaccinations
- Send email to phe.vip@nhs.net
- Include the following details: DOB, NHS Number, GP Practice, dates, batch numbers and names of vaccines given.
- Copy email into Overall Racecourse Clinical Lead and Racecourse Governance Co-ordinator
- Link to VIP reporting form is found on the Onsite Clinical Lead Document.

3.3 MHRA Vaccine Monitoring: All pregnant women Should be invited to sign up with the MHRA Vaccine Monitoring at the time of vaccination see:


[Monitor COVID Vaccination in Pregnancy Invitation Letter](#)

This link is also found in the Onsite Clinical Lead Document.

4. Associated Documents

PSDs for Pfizer and AstraZeneca can be found on the [website](#).

5. Appendix 1 - PSD AstraZeneca

 <p>COVID-19 PRIMARY CARE VACCINATION SITE BRIGHTON RACECOURSE</p> <p>East & Central Brighton, Brighton II, Preston Park Community, The Havens PCNs</p>	<p>Individual Patient assessment to assist the creation of Patient Specific Direction for the administration of COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant]) V 1.0</p>
---	---

First Name		Date of birth	
Surname			
Home Address			
		Postcode	

Risk Assessment by prescriber	Yes	No
Has the individual ever had a severe anaphylactic reaction to any drug?		
Is the individual under the age of 18?		
Is the individual pregnant?		
Has the individual had any vaccination in the last 7 days?		
Has the individual been in a trial of a potential coronavirus vaccine?		
Is the individual taking anticoagulant medication, or do they have a bleeding disorder?		
Is the individual at high risk of developing serious complications from Covid-19?		
Does the individual's occupation expose them to a higher risk of infection from Covid-19?		
Is the individual a primary carer?		
Does the individual have capacity for informed consent?		

<p>Risks and benefits discussed:</p>

Advised vaccination to be given outside MRHA temporary authorisation / National Protocol:	
Potential and management of side effects discussed:	
Patient Specific Direction (PSD) for the administration of COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant]) to individuals by Prescribers /Non- Prescribers suitably trained in Vaccination	
Date of PSD:	

The patient named below is eligible to receive **COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant]) 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.

First Name		Date of birth	
Surname			
Home Address			
		Postcode	

ONE DOSE OF COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant]) 0.5mls by Intra-Muscular (IM) Injection


Name of prescriber: (Doctor / Independent Nurse Prescriber / Independent Pharmacist prescriber only)	Registration/PIN Number:
Signature:	Date:

This PSD will expire within 7 days of signature

Name of vaccinator:	Date:
Signature:	

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

6. Appendix 2 – PSD Pfizer BioNTech

 <p>COVID-19 PRIMARY CARE VACCINATION SITE BRIGHTON RACECOURSE</p> <p>East & Central Brighton, Brighton II, Preston Park Community, The Havens PCNs</p>	<p>Individual Patient assessment to assist the creation of Patient Specific Direction for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2</p> <p>V 1.0</p>
---	--

First Name		Date of birth	
Surname			
Home Address			
		Postcode	

Risk Assessment by prescriber	Yes	No
Has the individual ever had a severe anaphylactic reaction to any drug?		
Is the individual under the age of 16?		
Is the individual pregnant?		
Has the individual had any vaccination in the last 7 days?		
Has the individual been in a trial of a potential coronavirus vaccine?		
Is the individual taking anticoagulant medication, or do they have a bleeding disorder?		
Is the individual at high risk of developing serious complications from Covid-19?		
Does the individual's occupation expose them to a higher risk of infection from Covid-19?		
Is the individual a primary carer?		
Does the individual have capacity for informed consent?		

<p>Risks and benefits discussed:</p>
<p>Advised vaccination to be given outside MRHA temporary authorisation / National Protocol:</p>

Potential and management of side effects discussed:	
Patient Specific Direction (PSD) for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2 to individuals by Prescribers/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 Book) and JCVI recommendations for the purpose of protection against COVID-19.

First 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.

Name of prescriber: (Doctor / Independent Nurse Prescriber / Independent Pharmacist prescriber only)	Registration/PIN Number:
Signature:	Date:

This PSD will expire within 7 days of signature

Name of vaccinator:	Date:
Signature:	

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