



COVID-19 Primary Care Vaccination Site Brighton Racecourse

Clinical Governance Flow

Clinical Governance responsibilities and flows for Here, Participating PCNs and GP Practices

Document Version:	1.4
Document Author:	Dr Simon Hincks
Document Owner:	Dr Simon Hincks
Approved By:	Brighton Racecourse Clinical Governance Sub-group IAS Clinical Quality Group
Approved Date:	12/01/2021 11/02/2021
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	10/01/2021	Initial draft	Dr Simon Hincks
1.1	18/01/2021	Update to list of participating PCNs	Jen De Souza
1.2	08/02/2021	Update to local incident reporting process	Jen De Souza
1.3	18/02/2021	Sussex Incident reporting flow chart and form updated	Jen De Souza
1.4	11/02/2021 23/03/2021	Update from IAS CQG Incident flow chart and form updated Complaints process added	Dr Simon Hincks Jen De Souza

Contents

1. Background.....	4
1.1 Participating PCNs / Practices	4
2. Clinical Leadership.....	4
3. Brighton Racecourse Clinical Governance Subgroup.....	5
4. IAS Clinical Quality Group.....	5
5. Brighton Racecourse GP Vaccination Hub Processes and Documentation.....	5
6. Clinical Incident & Enquiries Reporting	5
7. Local Complaints Reporting	6
8. Workforce Management & Assurance.....	6
9. Infection Prevention & Control	7
10. Anaphylaxis/Cardiac Arrest	7
11. Associated Processes/Information	7
11.1 Staff Mandatory Training Requirements	7
12. Appendix 1 – Incident Reporting Flowchart	8
13. Appendix 2 – Incident Reporting Form	9
14. Appendix 3 – Management of COVID-19 vaccination clinical incidents and enquiries	12
15. Appendix 4 – Complaints Reporting Flowchart	14

1. Background

This document outlines the Clinical Governance processes and responsibilities in relation to the running of the Brighton Racecourse GP Vaccination Hub with Here (Care Unbound Ltd) and participating Primary Care Networks.

1.1 Participating PCNs / Practices

East & Central Brighton PCN 1 – Clinical Leads Dr Tim Worthley / Dr Rachel McPherson

- Park Crescent Health Centre – PM Bret Stevenson
- St Peter's Medical Centre – PM Carol Witney
- Wellsbourne Healthcare CIC – PM Sarah Webb
- Albion Street Surgery – PM Denise Griffin
- Arch Healthcare – PM Jennie Worthley
- Ardingly Court Surgery – PM Cher Rooney
- Pavilion Surgery – PM Michelle Spicer
- Regency Surgery – PM Jeff Wood
- Broadway Surgery – PM Sonia Mulla

Preston Park Community PCN – Clinical Director Dr Craig Milne

- Stanford Medical Centre – PM Cheryl Palmer
- Preston Park Surgery – PM Janak Chauhan
- The Haven Practice – PM Sue Doyle
- Warmdene Surgery – PM Cheryl Palmer
- Beaconsfield Medical Practice – PM Amy Barratt

Brighton PCN II – Clinical Director Dr Lee Thompson

- Allied Medical Practice – PM Clare Marks
- Avenue Surgery – PM Ros Clayton
- Ship Street Surgery – PM Vida Tonna
- Saltdean Surgery – PM Sue Ward
- St Lukes Surgery – PM Murray King
- Woodingdean Surgery – PM Richard Hilder

Havens PCN – Clinical Director Dr Geraldine Vaughan

- Quayside Medical Practice – PM Karen Ford
- Chapel Street Surgery – PM Belinda Kristiansen
- HavensHealth

2. Clinical Leadership

The clinical leadership for the Brighton Racecourse GP Vaccination will sit with the IAS Clinical Lead who will be responsible for clinical oversight and day to day decisions requiring clinical input on site with support from other nominated Clinical Leads as required. This role will be supported by the Brighton Racecourse Clinical Governance Subgroup.

The Vaccination Hub will be supported by a Pharmacist Lead who will be available to support with vaccine specific information and support on site supervision and training of vaccine reconstitution.

The IAS Nurse Lead will provide input on Infection and Prevention Control.

3. Brighton Racecourse Clinical Governance Subgroup

This group will comprise of the Clinical Directors of each PCN, the IAS Clinical Lead, IAS Nurse Lead and supporting Clinical Leads and the Pharmacy Lead. PCN Management Leads will also be able to attend and will be copied into any correspondence regarding Incidents & Complaints. The group will meet when necessary to provide overall clinical direction and sign off.

4. IAS Clinical Quality Group

The IAS will review, monthly, all incidents and complaints and any other issues arising from the clinical operation of the Vaccination Hub. Members of the Brighton Racecourse Clinical Governance Subgroup will be invited to participate.

5. Brighton Racecourse GP Vaccination Hub Processes and Documentation

All relevant governance documentation and processes will be held on the IAS Website under:

<https://www.improvingaccessservices.co.uk/ehs-staff-resources/brighton-racecourse-gp-vaccination-hub/vaccination-handling-documentation/>

This will include information on both local and national guidelines and will be updated as processes/guidance changes.

This allows visibility and easy access for all participating staff and practice/PCNs.

6. Clinical Incident & Enquiries Reporting

6.1 National Reporting:

All Clinical incidents relating to the vaccine must be reported nationally as per SHCP Sussex COVID-19 Mass Vaccination Incident Reporting Process:

<https://www.improvingaccessservices.co.uk/wp-content/uploads/2021/03/Sussex-Covid-19-Mass-Vacc-Incident-Reporting-Process-V4-14.02.21.pdf>

This is based on the national SOP:

[Standard operating procedure Management of COVID-19 vaccination clinical incidents and enquiries](#)

Key Principles:

Providers must report all clinical incidents using both the [MHRA Yellow Card system](#) and the reporting process described in this document, resulting in escalation via Sussex CCGs to national level via the National Incident Coordination Centre Single Point of Contact (ICC SPOC).

- All clinical incidents requiring treatment should be reported as soon as possible after the event (providers should not wait until 5pm to report these) using the fast track incident response pathway.
- The reporting process for regional and national enquiry or incident management and escalation is shown in [Appendix 1](#).

- The fast-track incident response pathway follows the same route described, but the subject line should begin 'URGENT: ACTION REQUIRED'. All team members are required to urgently act (within one hour) on these requests.

- All Incidents should be reported on the Sussex COVID-19 Mass Vaccination Program Incident Reporting Notification Template: [Appendix 2](#)

- [Appendix 3](#) outlines the Clinical Escalation Triggers

6.2 Local Clinical Incident Reporting

- 6.2.1** All clinical incidents must be reported to the onsite Clinical Lead immediately.
- 6.2.2** The site Clinical Lead will escalate all Incidents to the Here Board and the PCN Clinical Directors immediately where there is a significant or critical impact on the running of the service. Moderate Impact Incidents will be reported within 24hrs. (See [Appendix 3](#) for definitions). All other incidents will be provided in a summary report on a two weekly basis to the Here Board, PCN Clinical Directors & PCN Management Leads.
- 6.2.3** All incidents must be logged on the Datix database and with the CCG following the incident reporting flow chart in [Appendix 1](#)
- 6.2.4** Clinical Incidents will be forwarded to the PCN Clinical Director of the patient's practice and the patient's practice manager.
- 6.2.5** Once the incident investigation is complete the reports will be forwarded to the PCN Clinical Director and patient's practice manager.
- 6.2.6** If a clinical incident is raised that does not relate to the operation of the Brighton Racecourse GP Vaccination Hub, these will be forwarded to the patient's practice for logging and investigating.

7. Local Complaints Reporting

- 7.1.1** All clinical complaints must be reported to the onsite Clinical Lead immediately.
- 7.1.2** The site Clinical Lead will escalate all Complaints to the Here Board and the PCN Clinical Directors immediately where there is a significant or critical impact on the running of the service. All other complaints will be provided in a summary report on a monthly basis to the Here Board, PCN Clinical Directors & PCN Management Leads.
- 7.1.3** All complaints must be logged following the local complaints reporting process flow chart in [Appendix 4](#).
- 7.1.4** The complaints investigation procedure will follow the local Here complaints procedure.
- 7.1.5** Once the complaint investigation is complete a copy of the response will be forwarded to the PCN Clinical Director and patient's practice manager.
- 7.1.6** If a complaint is raised that does not relate to the operation of the Brighton Racecourse GP Vaccination Hub, these will be forwarded to the patient's practice for logging and investigating.

8. Workforce Management & Assurance

All Staff working at the site will be registered on the IAS Workforce platform. This will allow for rota planning and financial monitoring.

All staff will need to be up to date with required training as outlined here:

<https://www.improvingaccessservices.co.uk/ehs-staff-resources/mandatory-training-covid-vaccination-sites/>

Participating practices via the GP Vaccination Hub Subcontract will give assurance to Here that all other relevant training is up to date for staff choosing to work at the site.

9. Infection Prevention & Control

This will operate via local policy based on national guidance and will be overseen by the IAS Nurse Lead who leads on Infection Prevention & Control and will undertake an IPC Risk Assessment prior to opening.

The site is designed to ensure that Social Distancing is always maintained where possible.

Lateral Flow Testing will be available to all staff.

10. Anaphylaxis/Cardiac Arrest

There will be an allocated Crash Team available at all times who will receive a briefing at the start of each shift. The team will follow local protocols based on national guidance.

11. Associated Processes/Information

11.1 Staff Mandatory Training Requirements

11.2 Brighton Racecourse GP Vaccination Hub Documentation

12. Appendix 1 – Incident Reporting Flowchart

Sussex COVID-19 Mass Vaccination incident reporting process

V 7.2 (02.03.21) – Adapted with local process added

Incident Occurs **Determine if Routine / Urgent**

Sussex LVS Process:

Routine – Limited impact -- complete incident form and forward to Systems Vaccination Operations Centre (SVOC) sxccg.svoc@nhs.net

(08:00 – 20:00 availability 7 days a week)

Urgent - Moderate, Significant or Critical Impact – (1 hr response required)

Contact SVOC sxccg.svoc@nhs.net who will escalate to on call director **or** if out of SVOC hours:

- West Sussex - 07623515396
- Brighton and Hove - 07623515400

Local Process:

Incident Reporter to:

1. Complete electronically on the incident Reporting Form available on the IAS Website
2. Once completed if you have access to Here Datix then please log incident and add Datix number to Incident Reporting Form
3. If you don't have access to Datix then please ensure that one of the Here Site Support Staff completes this on your behalf
4. Send the Incident Reporting Form to sxccg.svoc@nhs.net
 - Please copy in S.Stafford@nhs.net; phalley@nhs.net;
Kathryn.steele2@nhs.net; helen.mendoza1@nhs.net
5. Do not complete paper forms and leave at Racecourse

Clinical Lead on-site will escalate to PCN Clinical Directors/Here Board as appropriate

13. Appendix 2 – Incident Reporting Form

V 7.1 (23.03.21)

Sussex COVID-19 Mass Vaccination Program incident reporting notification template (complete and submit within 24 hours of incident occurring)

Vaccination Hub		Brighton Racecourse GP Vaccination Hub	
Reporting organisation		Here	
Reporter Details			
Reporter Name:		Reporter Job Title:	
Reporter Tel No:		Reporter Email:	
Incident Details			
Date of incident?			
Type of incident: i.e. Actual/Near Miss?			
<ul style="list-style-type: none"> • Storage incident • Transport incident • Information Governance 			
What harm occurred?			
Outcome for person?			
Level of investigation expected?			
Who Was Involved – Complete if applicable			
Person involved (NO patient details please)		Patient <input type="checkbox"/> Member of Public <input type="checkbox"/> Staff <input type="checkbox"/> Volunteer <input type="checkbox"/> Other Please state:	

GP Practice person registered with?		
Gender?	Male <input type="checkbox"/> Female <input type="checkbox"/>	
Age?		
Ethnicity?		
Usual residence of person? i.e. care home, or own home (NO patient identifiable data)	Home <input type="checkbox"/> Care Home Nursing <input type="checkbox"/> Care Home Residential <input type="checkbox"/> Hostel <input type="checkbox"/> Supported living <input type="checkbox"/> No fixed address <input type="checkbox"/> Other Please state:	
Persons Notified?	Patient <input type="checkbox"/> Family <input type="checkbox"/> Carer <input type="checkbox"/>	
Degree of Harm	None <input type="checkbox"/> Low <input type="checkbox"/> Moderate <input type="checkbox"/> Severe <input type="checkbox"/> Death <input type="checkbox"/>	
Definitions of Harm defined by The National Reporting and Learning System (NRLS) Link		
Low - Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons		
Moderate - Any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused short-term harm to one or more persons		
Severe - Any unexpected or unintended incident that caused permanent or long-term harm to one or more persons		
Death - Any unexpected or unintended event that caused the death of one or more persons		
What Happened		
Description of Incident		

Immediate Action Taken			
Learning from incident			
Media interest?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Comms informed?
			Yes <input type="checkbox"/> No <input type="checkbox"/>
Externally Reportable?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Externally reported to?
Any Other Comments: e.g. multiagency incident, police and /or HSE investigation, Coroner's inquest, CQC involvement.			

Please send to Sussex CCGs within 24 hours of incident occurring.

Email: sxccg.incidents@nhs.net

Sussex CCGs Use Only

Reviewed by:	
Date & time reviewed:	
Outcome/Action taken:	
Ref:	

14. Appendix 3 – Management of COVID-19 vaccination clinical incidents and enquiries

Trigger	Impact	Action	Senior leadership
Limited impact	<ul style="list-style-type: none"> • Issue is localised and has an expected short duration. • Solutions are available within the organisation, or within the local health and care system. • No clear direct risk to patients. 	<ul style="list-style-type: none"> • Clinical Advice Response Service (CARS) to lead & manage. • CARS to report at weekly Clinical Reference Group (CRG) governance meeting and Regional Vaccine Operations Centre (RVOC). • After governance meeting regional CARS / RVOC to advise National Clinical Cell and National Vaccine Operations Centre (NVOC) of actions and outcome (weekly report). 	<ul style="list-style-type: none"> • Regional team have direct operational oversight • Routine weekly reporting to the National Clinical Cell to identify important trends for future planning and proactive incident prevention.
Trigger	Impact	Action	Senior leadership
Moderate impact	<p>May result in impaired clinical outcomes if not managed urgently</p> <ul style="list-style-type: none"> • Solution will require new skills, procedures or training to be implemented. • Expected duration longer than short-term. • An issue is occurring at multiple sites, or across multiple geographical areas – for example if a CARS reports the same issue at different sites. • An incident with a potential lower impact but for which resourcing constraints locally mean that they require additional 	<ul style="list-style-type: none"> • CARS to lead & manage. • CARS to collate and co-ordinate information required to inform clinical decision. • CARS to report at weekly CRG governance meeting and RVOC. • After governance meeting regional CARS to advise National Clinical Cell and NVOC of actions and outcome. 	<ul style="list-style-type: none"> • Regional team have direct operational oversight • Regional team determines if it's appropriate to brief the National Clinical Cell at the time of the incident for information • Routine weekly reporting to the National Clinical Cell to identify important trends for future planning and proactive incident
Trigger	Impact	Action	Senior leadership
Significant	<ul style="list-style-type: none"> • Significant patient safety implications 	Escalation via SPOC and	<ul style="list-style-type: none"> • National Clinical Cell

<p>impact</p>	<p>if not managed urgently</p> <ul style="list-style-type: none"> • No or limited alternatives can secure same outcome. • No immediate solutions available without significant change to skills, training or procedures. • Multiple concurrent incidents occurring across multiple organisations or a wider geographical area. • Identified solutions cannot be sustained for likely duration of incident. 	<p>the approved route to the National Clinical Cell.</p> <ul style="list-style-type: none"> • National Clinical Cell to collate and co-ordinate information required to inform clinical decision. • National Clinical Cell to use established process map to determine the most appropriate response. • National Clinical Cell to use approved guidelines and expert directory list to answer questions or to brief the most appropriate national representative. • Clinical oversight provided by senior clinician in vaccine clinical workstream. • National Clinical cell to report at weekly governance meeting with Senior Responsible Officer. 	<p>has operational oversight</p> <ul style="list-style-type: none"> • The expectation would be that a regional team briefs the National Clinical Cell at the time of the incident via SPOC • Incident takes precedence over incidents of lower impact • National Clinical Cell determines if it's appropriate to brief the Incident Director at the time of the incident for information • National Clinical Cell on-call triage member can inform clinical cell triage lead and workstream lead if they deem it appropriate • Routine weekly reporting to the National Clinical Cell to identify important trends for future planning and proactive incident prevention
Trigger	Impact	Action	Senior leadership
<p>Critical impact</p>	<p>Critical implications for patients and vulnerable populations.</p> <ul style="list-style-type: none"> • No viable alternatives exist after exhaustion of all other escalation levels. • Life-threatening or life-changing impact on patients and/or ethical implications for clinicians. 	<p>Escalation via SPOC and the approved route to the National Clinical Cell.</p> <ul style="list-style-type: none"> • National Clinical Cell to collate and co-ordinate information required to inform clinical decision. • If initial contact has been made on the phone given the urgency then a telephone log should be submitted via email 	<ul style="list-style-type: none"> • National Clinical Cell has initial operational oversight • This would be taken over by the formal stand up of an incident or with Strategic Incident Director operational oversight • The expectation would be that a regional team briefs the National Clinical Cell immediately at the time of the incident via SPC

Complaint Received

Member of staff receiving complaint will

- complete the complaint reporting form

THE VACCINATION SITE CLINICAL LEAD MUST BE INFORMED OF ANY CLINICAL COMPLAINTS IMMEDIATELY

- log the complaint in Datix
- email the form and the Datix log number to the Clinical Lead s.stafford@nhs.net & Governance Coordinator copying in here.ehsbrighton@nhs.net

Governance Coordinator will

- Send acknowledgement letter to the complainant within 24 hours of receipt
- Coordinate investigation with Clinical Lead and respond to complainant within 20 working days
- If the complaint is regarding the overall vaccination programme then support in responding to the complaint is available from the CCG. Send a copy of the complaint to sxccg.complaints@nhs.net

Clinical Lead will escalate to PCN Clinical Directors / PCN Managers / Here Board as appropriate