REPORTING ADVERSE REACTIONS – COVID 19 VACCINE SOP

SETTING	Vaccination Hub (BRI and WGH)
FOR STAFF	Vaccinators and Hub staff
PATIENTS	Individuals receiving vaccinations

Adverse Drug Reactions (ADRs) should be reported in accordance with the Medicines Code Policy for Adverse Drug Reactions.

Adverse Drug Reactions Should be Reported via:

1. Yellow Card reporting system
2. Datix for moderate or major harm reactions e.g. those that require intervention or treatment.
3. PHE via SW CARS for severe reactions e.g. those reported on Datix
4. NIVS and patient/ individuals documentation record for all ADRs.

1. Yellow Card Reports
   - Should be completed for all ADRs irrespective of the severity of reaction.
   - Include the vaccine brand and batch/Lot number if available

   Reporting can be done:
   a) Online at https://coronavirus-yellowcard.mhra.gov.uk/
   b) By telephone on 0800 731 6789
   c) By App downloaded onto a smart phone for Android or IOS devices

2. Datix Incident Report
   a) ADRs requiring intervention or treatment must be reported as an incident on Datix. The report should be completed by the Clinical Lead.
   b) Report under the Category 'Medication', select the most relevant Subcategory; Adverse Drug Reaction will be the most likely subcategory but there may be a more appropriate choice, particularly if an incorrect dose or volume is administered.
   c) Ensure that the drug administered or involved names the relevant Covid vaccines administered (Covid-19 Vaccine Pfizer (Courageous), or Covid-19 Vaccine Astra Zeneca (Talent-Sceptre)).
   d) Enter the text 'COVIDVACC' within the details of the incident report, as this will help the National Reporting and Learning Centre to collate all vaccine related incidents.

3. PHE via SW CARS. All incidents reported on Datix should be copied to england.swcovid19-voc@nhs.net by the person entering the report onto Datix. You will then be asked to complete one of the following:
   - Allergic incidents https://cutt.ly/covid-allergy
   - Other serious adverse events e.g. cardiac arrest event within 72 hours of vaccination https://cutt.ly/covid-ae

4. NIVS.
   Record the ADR on NIVS and in the additional patient/ staff documentation record.

Delayed ADRs.

- If urgent, patients should seek help via normal emergency routes
- If non-urgent contact Covid vaccination site during work hours
- Clinical Lead should report to the MHRA/Datix/SWCARS/NIVs as described above

QUERIES: Clinical Lead for Shift (onsite); Medical Lead for shift (contacted on phone)