**COVID-19 VACCINE INCIDENT REPORTING PROCEDURE**

*Please Note: Incidents should be reported as soon as possible, on the day of the incident.*

***Do not wait until the end of the working day to report.***

**Purpose:**

This document provides locally adapted guidance based upon the [Nationally agreed NHSE/I reporting requirements](http://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/) and [government guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors).

This procedure ensures:

* Collation of incidents across the system to encourage a learning culture
* Local co-ordination of communications following COVID- 19 vaccination related incidents.
* Timely and appropriate dissemination of applicable learning, and implementation of agreed actions, across the system.

**Reporting Procedure Overview:**

**PROVIDER / SITE**

* Escalate identified Covid Vaccination incident as directed in SOPs below.

**DERBYSHIRE VOC**

* Ensure incidents requiring fast track reporting have been escalated to Regional VOC (CARS) marked “*URGENT: ACTION REQUIRED- FAO CARS*”.
* Signpost site team/provider to COVID-19 vaccination incident report form where required.
* On receipt of Appendix A: Incident report form, ensure provider/ site team are aware of investigation requirements and submission deadlines for Appendix B: Significant event analysis
* Forward initial provider incident report **and** any incidents directly notified by RVOC/CARS, to the CCG Medicines Management inbox [ddccg.meds.man@nhs.net](mailto:ddccg.meds.man@nhs.net) FAO Medicines Safety.
* Forward any responses from RVOC/CARS to the CCG Medicines Management inbox including incident reference numbers.

**CCG MEDICINES SAFETY TEAM:**

* Liaise with provider/ site lead to ensure robust incident analysis and collates any actions and learning
* Co-ordinate local dissemination of learning outcomes

**REGIONAL VOC (CARS) MAINTAIN OPERATIONAL OVERSIGHT**

**Standard Operating Procedures: According to incident type**

**Clinical Incidents**

* Please complete 'Appendix A: Incident Report' with as much detail as possible.
* Submit report to Derbyshire VOC ([ddccg.voc@nhs.net](mailto:ddccg.voc@nhs.net)); and Regional VOC ([england.midscovid19vacs.pmo2@nhs.net](mailto:england.midscovid19vacs.pmo2@nhs.net)) immediately, selecting 'High Importance' and stating “Urgent Action Required – FAO CARS” in the email subject.
* Complete 'Appendix B: Significant Event Analysis'. Submit to Derby & Derbyshire CCG Medicines Management Team ([ddccg.meds.man@nhs.net](mailto:ddccg.meds.man@nhs.net)) **within 5 working days** of the clinical incident occurring. All advice, actions taken, and outcomes must be recorded in as much detail as possible.

*Depending on the information provided, the Clinical Advice Response Service (CARS) may need to contact you for additional information. This* ***will require a same-day response*** *if the incident has been reported using the fast-track 'high importance' pathway, so please ensure you have included appropriate contact details.*

**Non-Clinical incidents**

* Please complete 'Appendix A: Incident Report' with as much detail as possible.
* Submit report to Derbyshire VOC ([ddccg.voc@nhs.net](mailto:ddccg.voc@nhs.net)); and Regional VOC ([england.midscovid19vacs.pmo2@nhs.net](mailto:england.midscovid19vacs.pmo2@nhs.net)).
* Complete 'Appendix B: Significant Event Analysis'. This must be submitted to Derby & Derbyshire CCG Medicines Management Team ([ddccg.meds.man@nhs.net](mailto:ddccg.meds.man@nhs.net)) **within 10 working days** of the incident occurring. All advice, actions taken, and outcomes must be recorded in as much detail as possible.

**Adverse Drug events /** **Defective Vaccines**

* Please complete an MHRA yellow card report via any of the suggested routes listed below:
* The [coronavirus Yellow Card site](https://coronavirus-yellowcard.mhra.gov.uk/) (preferred route).
* The Yellow Card app (download from the [Apple App Store](https://itunes.apple.com/us/app/apple-store/id990237487?pt=117756671&ct=EYC&mt=8) or [Google Play Store](https://play.google.com/store/apps/details?id=uk.org.mhra.yellowcard&referrer=utm_source%3DEYC%26utm_medium%3Dcpc%26anid%3Dadmob)) (preferred route).
* The embedded Yellow Card link in clinical IT systems (EMIS/SystmOne/Vision/MiDatabank).
* Can also call 0800 731 6789 for free. Monday to Friday between 9am and 5pm.
* Complete 'Appendix A', including the MDR# reference from your yellowcard report, and submit to Derbyshire VOC ([ddccg.voc@nhs.net](mailto:ddccg.voc@nhs.net)); and Regional VOC ([england.midscovid19vacs.pmo2@nhs.net](mailto:england.midscovid19vacs.pmo2@nhs.net)) as per the usual incident reporting process.

**Allergic Events**

* Please complete an MHRA yellow card report via the routes listed above.
* Please also complete a PHE report ([Link Here](https://snapsurvey.phe.org.uk/snapwebhost/s.asp?k=161151977187)).
* Complete 'Appendix A' and submit to Derbyshire VOC ([ddccg.voc@nhs.net](mailto:ddccg.voc@nhs.net)); and Regional VOC ([england.midscovid19vacs.pmo2@nhs.net](mailto:england.midscovid19vacs.pmo2@nhs.net)) as per the usual incident reporting process.

NB. [UK Health Security Agency (UKHSA – formerly known as PHE) have advise](https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners)d that any adverse reaction to a vaccine should also be documented in the individual’s record and their GP should be informed.

**Cold Chain incidents**

Use the standard SPS form [linked here](https://www.sps.nhs.uk/wp-content/uploads/2021/05/Temperature-excursion-reporting-checklist-v1.1.docx) for recording cold chain issues. Sufficient information is required for resolution of all cold chain issues; when the query requires escalation for specialist pharmacy advice via the 'CARS – SPS fast-track' route they can only be accepted if a completed form is provided.

**DO NOT send cold chain incidents/ queries directly to SPS as these need to be logged and monitored by Local and Regional VOC.**

Send the completed form to Derbyshire VOC ([ddccg.voc@nhs.net](mailto:ddccg.voc@nhs.net)); and Regional VOC ([england.midscovid19vacs.pmo2@nhs.net](mailto:england.midscovid19vacs.pmo@nhs.net)) as per the usual incident reporting process.

**Appendix A – Incident Report Form**

*\*Please ensure ALL MANDATORY FIELDS ARE COMPLETED ON THIS FORM (\*)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident Details** | | | |
| **Date of incident** | \* | **Your Reference No.**  **(Datix. Etc)** | \* |
| **Time of incident** | \* |
| **Date form completed** | \* |
| **Service Provider** | | | |
| **Name and location of site, including POSTCODE** | \* | **Type of Provider** | \* |
| **Has this incident been notified to the MHRA Yellow Card Scheme? \*** | | Yes No N/A | |
| **If an allergic event, has a PHE report been completed?\*** | | Yes No N/A | |
| **Has this incident been entered on DATIX or other recording system?** | | Yes No **Ref No:** | |
| **If other recording system, please state** | |  | |
| **Has the patient’s GP been informed?** | | Yes No | |
| **Has the STP/CCG been notified?** | | Yes No | |
| **Contact Details of Reporter** | | | |
| **Name** | \* | | |
| **Site Role & Job title** | \* | | |
| **Email** | \* | | |
| **Telephone** | **\*** | | |
| **If further details are required, who should be contacted?** | | | |
| **Name** | **\*** | | |
| **Site Role & Job Title** | **\*** | | |
| **Email** | **\*** | | |
| **Telephone** | **\*** | | |
| **Incident Details** | | | |
| **Date of vaccination** |  | | |
| **Vaccine Details & Dose No.** | | | |
| **Vaccine / Manufacturer** | \* |  |  |
| **Batch No:** | \* | **Expiry date:** | Click or tap to enter a date. |
| **Dose No - 1 or 2** |  | **Expiry once reconstituted** | Click or tap to enter a date. |
| **Patient Details – *IF NECESSARY ONLY*** *Please note: We are not authorised to handle patient identifiable data. If this is required, you will be contacted by the relevant authorised bodies.* | | | |
| Sex: | ☐Male☐Female | Age: |  |
| Relevant History: |  | COVID-19 status: |  |
| Date of test | Click or tap to enter a date. |

|  |  |  |
| --- | --- | --- |
| **Incident Details** | | |
| **Describe the incident:** | \*Please provide as much detail as possible.  *What happened, why it happened, timeline etc*  *Include whether it was before or after the vaccine was given, if after, how long?*  *Relevant medical history, symptoms* | |
| **Immediate Short-Term Actions/Outcomes** | | |
| **Describe any treatment given at site.** | \*Please provide as much detail as possible. | |
| **Previous Incidents** | | |
| **Have you had a similar incident happen before/recently?** | | Yes No |
| **Has the affected patient been informed of the error?** | | Yes No |
| **If any actions are outstanding, what are these and when will they be completed?** | \* | |

**Appendix B: Significant Event Analysis (SEA)**

*This document is based on the principles of Good Medical Practice and Revalidation and has been developed as a template to suit any clinical setting.*

An SEA should be undertaken to prevent recurrence of an incident or adverse event. SEAs also serve to celebrate good practice while alerting colleagues to potential pitfalls.

**Description:** *Please note that the purpose of the description section is to enable others to reflect on the case in question. Once the description is complete, the subsequent reflective analysis should not be considered complete until the cause of the event in question is fully understood.*

**Reflection:** *Thinking about something to learn from it*

**Insight:** *The degree to which both topic and outcome of reflection are considered appropriate by one’s peers*

**Significant Event:** *Any suitable topic for reflection that might benefit from a formal, structured approach either because of complexity, potential risk, or the need to involve others in the analysis****.***

1. **Title & Context:**

|  |
| --- |
| *Descriptive title of event, author of document, date of event, date of meeting, who were present. Set and record a future date to assess impact of actions agreed.* |

**2. Facts of Event:**

|  |
| --- |
| *Establish facts. The purpose of this section is to enable colleagues to understand the case sufficiently to participate fully in the analysis. Keep it simple and easy to read* |

**3. Impact of Event:**

|  |
| --- |
| *What was the (potential) impact on those involved (patient, carer, family, GP, practice)?* |

**4. Analysis:** \* *mandatory field for ALL incidents.*

|  |
| --- |
| * *What caused the event* * *Key moments* * *What was done or not done, that influenced the outcome* * *Contributing factors e.g. Human, systems, process etc*. |

**5. Lessons learned:** \* *mandatory field for ALL incidents.*

|  |
| --- |
| *Summarise what you/ your team have learned from analysing this event.* |

**6.** **Action Points:** \* *mandatory field for ALL incidents.*

|  |
| --- |
| * *What action has been taken to date?* * *What actions are planned going forward? Ensure actions are SMART and assigned.* * *What is being done to reinforce good practice and minimise the chance of any future adverse event? Consider the four areas of* [*Good Medical Practice*](http://www.gmc-uk.org/guidance/good_medical_practice.asp)*, i.e., knowledge, skills, and performance; safety and quality; communication, partnership, and teamwork; and maintaining trust.* |

**7.** **Community of practice:**

|  |
| --- |
| *Are there any solutions, learning or issues that would benefit from being shared more widely? e.g., could another service benefit from a solution you devised during this SEA or is there an issue that you could benefit from discussing with colleagues at interfacing services?* |

**References:**

[Vaccine incident guidance: responding to vaccine errors - GOV.UK (www.gov.uk)](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors)

[Coronavirus » Standard operating procedure: Management of COVID-19 vaccination clinical incidents and enquiries (england.nhs.uk)](https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/)

[Incomplete dose from vaccine leakage at the injection site – Gov.uk Covid 19 Vaccination Guidance for HCPs](http://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/965177/COVID-19_vaccination_programme_guidance_for_healthcare_workers_26_February_2021_v3.4.pdf)

[Reporting a possible side effect to a COVID-19 vaccine – a guide for Children and Young People](https://assets.ctfassets.net/58vt0wp5xpi9/1fPQotYrPRAAUMJxtGmOM3/d5331395e0f6b82a4127ecfe97d22756/2020-09-17_Children_and_Young_people_guide_to_reporting_possible_ADRs_COVID-19.pdf)

Information on known side effects of vaccines, for use by HCPs:

[Pfizer-BioNTech COVID-19 vaccines (Comirnaty)](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19); [COVID-19 vaccine AstraZeneca (Vaxzevria)](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca-regulation-174); [COVID-19 vaccine Moderna (Spikevax)](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna/information-for-healthcare-professionals-on-covid-19-vaccine-moderna)