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COVID-19 vaccination programme

Standard operating procedure

Management of COVID-19 vaccination clinical incidents and enquiries

Contents

Glossary

- CARS: Clinical Advice and Response Service (Part of Screening and Immunisation Teams)
- CRG: Clinical Reference Group
- EPRR: Emergency Preparedness Resilience and Response
- ICC SPOC: Incident Coordination Centre Single Point of Contact
- MHRA: Medicines and Healthcare products Regulatory Agency
- NHS E&I: NHS England and NHS Improvement
- NRLS: National Reporting and Learning System
- NVOC: National Vaccination Operations Centre
- PHE: Public Health England
- PMO: Project Management Office
- ROC: Regional Single Point of Contact
- RVOC: Regional Vaccination Operations Centre
- SIDD: Strategic Incident Director of the Day
- SPS: Specialist Pharmacy Service
- SVOC: System Vaccination Operations Centre

Purpose

The purpose of this document is to clarify the process by which incidents and enquiries related to the COVID-19 vaccination programme are escalated and addressed, at both regional and national levels, and to describe the audit and governance process for this. This is not intended to replace existing local investigation and risk management processes, in accordance with NHS England's Serious Incident framework.

Responsibilities

- It is the responsibility of everyone involved in the Covid-19 vaccination programme to ensure that any incidents or enquiries are identified and escalated appropriately, in accordance with the agreed regional and national framework outlined in this document.
- All sites must have a designated staff member responsible for ensuring that the procedures in this document are adhered to.
- Any incidents that are deemed to require a fast track response should be escalated urgently and as a priority through designated fast track pathways.
- Escalation pathways at every level require appropriate governance processes to be in place – including assignment of reference numbers, appropriate logging, audit and closure.

Procedure

1. Key principles

- Providers (hospital hubs, vaccination centres and local vaccination services) must report all clinical incidents, as soon as possible after the event, using the frameworks outlined in this document.
- The MHRA Yellow Card, PHE reporting form and NRLS eForm reporting and local risk management system (eg Datix, Ulysses) upload to NRLS should not be solely relied on for reporting significant incidents – these must also be escalated to RVOC/CARS via the agreed escalation process (Appendix 1). The fast track incident response pathway should be used if urgent.
- A unique reference number must be assigned by RVOC when the incident is reported and this reference must be quoted in the incident report, notification to NVOC, and all subsequent correspondence. If an MHRA Yellow Card or NRLS eForm report has already been completed before reporting to RVOC occurs, these reference numbers should be provided to RVOC/ CARS so that all sources of information can be linked.

- Providers using NRLS eForm reporting and local risk management systems (eg Datix, Ulysses) that upload to the NRLS should add 'COVIDVACC' to free text descriptions of what happened before submitting/uploading. This helps to rapidly locate incidents that the national vaccination team will review.
- **The fast track incident response pathway follows the same route described in Appendix 1, but the subject line should begin 'URGENT: ACTION REQUIRED'. All team members are required to urgently act (within one hour during normal service operating hours) on these requests.**

2. Provider enquiry or incident management

Provider (Hospital Hub, Vaccination Centre or Local Vaccination Service) identifies an immunisation query or incident

OR

Incident identified at a later time, within NHS trusts, NHS 111, 119 or 999

Adverse Reaction Following Immunisation (allergic or non-allergic)

- Complete MHRA Yellow Card
- If a significant adverse event (see section 2.1) report to RVOC/CARS

  CARS will advise which additional forms to complete as appropriate

Potential Defective Product

- Complete MHRA Yellow Card
- Escalate to RVOC / CARS for further advice

Other Incident eg vaccine storage, handling, administration

- Complete NRLS report eg Datix, Ulysses, eForm or equivalent, and include the term 'COVIDVACC'
- Escalate to RVOC/CARS for further advice

Vaccination Enquiry

- Contact RVOC/CARS for further advice

Enhanced Surveillance eg vaccination in pregnancy, COVID-19 infection post-vaccination

- Contact RVOC/CARS for further advice, if required

- These escalation systems are to monitor the vaccination programme and identify potential learning or adjustments. They are aimed at reducing the burden on providers and regions while ensuring all the reporting requirements are met.
- Significant incidents must be escalated via the agreed escalation process (Appendix 1), using the fast track incident response pathway if urgent.
- Significant incidents must be reported on the same day of the incident and, where possible, escalated within one hour.
- Significant incidents include, but are not limited to:
    - Significant adverse events (section 2.1)
    - Incidents with significant or critical impact
    - Incidents which may impact on the vaccination programme continuing at the affected site
    - Incidents with potential for significant vaccine wastage
    - Concerns regarding potential defective vaccine(s) or products
    - Incidents where there is potential for significant shared learning.
- **If in any doubt, escalate the incident.**

2.1. Adverse reaction following immunisation

- COVID-19 vaccines are ‘black triangle’ medicines. MHRA encourages the reporting of all suspected adverse reactions (side effects) to newer drugs and vaccines, which are denoted by the Black Triangle symbol.
- All suspected adverse reactions, even minor, should be reported via the MHRA Yellow Card Scheme.
- An MHRA Yellow Card should be routinely completed to report all acute clinical events where symptom onset is within 72 hours of immunisation or any other events that are potentially related to the administration of the vaccine.
- Many adverse events post vaccination are known side effects of the vaccine. Where these are reported but are minor and transient, the only action is to complete an MHRA Yellow Card report.
- Some adverse events are more significant and these should be escalated to RVOC/CARS for further investigation and advice. These include, but are not limited to:
    - Any side-effect / reaction that is not already noted in the manufacturer’s SPC and that the clinician considers to be possibly linked chronologically to the vaccination
    - A known side-effect / reaction noted on the SPC but that the clinician considers to be an extreme or severe form of this known side-effect, eg fever that lasts for more than an expected number of days and for which there is no other cause; an urticarial reaction that affects a much larger area than just the injection site etc.

    - An acute clinical event linked in time to the vaccination for which the clinician does not consider there to be any other clinical cause.
- RVOC / CARS will advise on which additional reporting should be completed following initial review of the information provided about the event/incident (Appendix 3). This may include completing the PHE allergy / acute clinical event form https://cutt.ly/covid-ae. This reporting system is a collaboration between Public Health England, NHSE&I and MHRA. PHE is the data owner and controller, but the information will be shared with NHSE&I to ensure that all appropriate action can be taken to develop advice and guidance to mitigate against future events. Once the form is completed, the system will generate a summary which can be copied into the MHRA Yellow Card form (and other reporting systems as necessary).
- Once submitted, data will be reported to PHE and shared via an automated process with NHS E&I (which ensures consistency of data between NHS E&I, PHE and MHRA)
- Significant adverse events must be escalated via the agreed escalation process (Appendix 1), using the fast track incident response pathway if urgent.
- RVOC will allocate a unique reference number when the incident is reported. This will be used to log the incident at regional level and will be provided to NVOC. This reference should be quoted in further correspondence.

2.2. Potential defective product

- If there are concerns regarding a potentially defective vaccine, they should be escalated to RVOC/CARS and reported via the MHRA Yellow Card Scheme.
- CARS will advise on any further actions required and will escalate to NVOC for further advice and guidance where significant.

2.3. Other clinical or non-clinical incidents

- This refers to all other vaccine-related incidents, including cold chain, storage, preparation and administration.
- These incidents should be reported to RVOC/CARS as soon as possible to ensure prompt identification and management of any patients who may be affected, and so effective risk assessments are carried out to enable the service to be maintained and vaccine wastage minimised.
- All these incidents, including ‘near-misses’, should be routinely reported to NRLS eForm reporting or local risk management system (eg Datix, Ulysses) upload to the NRLS. “COVIDVACC” should be included in the description.
- Advice on responding to errors in vaccine storage, handling and administration are in PHE’s Vaccine Incident Guidance

2.3.1 Preventing vaccine wastage

- If there are concerns about whether vaccine(s) are suitable for use, eg a potentially defective vaccine vial, **do not discard it.** The vaccine should be quarantined in accordance with storage requirements and may need to be sent for further investigation.
- In deciding whether a vaccine is suitable for use CARS will consult the regional Chief Pharmacist and further advice may be provided by the Regional Quality Assurance Pharmacist and the Specialist Pharmacy Service (SPS).
- If an incident occurs where it is believed that more than 100 doses may need to be discarded, or where the temperature excursion may be ambiguous, this must be urgently escalated to national level for a decision to be made and **national authorisation through NVOC is required**. This is to minimise any potential vaccine wastage, as further information may be available at a national level or special dispensation may be granted in particular circumstances in conjunction with manufacturers and technical experts. While awaiting a national decision the vaccine must be quarantined in accordance with the storage requirements.
- Incidents that require escalation should include the following information:
    - Vaccine type
    - Batch number
    - Number of vials affected
    - Expiry date (fridge and frozen, if applicable). For the Pfizer vaccine transport time must be included in the expiry
    - Description of current condition and location of the vaccine
    - As much detail as possible regarding the incident (including any uncertainty around specific details).

2.4. Vaccination enquiries

- All vaccination enquiries should be escalated via the agreed route to RVOC/CARS – see Appendix 1.
- The fast track pathway should be used if an urgent response is required.

2.5. Enhanced surveillance

- PHE has published details of the COVID-19 vaccine surveillance strategy. This includes:
    - Reporting cases of COVID-19 post-vaccination. Further information, including criteria for reporting is here
    - Routinely notifying PHE about COVID-19 vaccination in pregnancy (VIP)

- Any questions about COVID-19 vaccine surveillance should be escalated to CARS.

3. Regional enquiry or incident management

- Once a provider has escalated an enquiry or incident, the RVOC will then forward to CARS who will consult with the relevant regional leads, as required, to address it.
- If CARS requires further capacity to address the enquiry or incident, regional mutual support networks can be used.
- If the CARS team requires urgent advice, they may contact the PHE National Immunisation Team directly. If this occurs, the interaction must be logged appropriately by the CARS team and reported into the RVOC.
- If required, a provider or SVOC may contact CARS directly. If this occurs, this should be logged and reported to the RVOC for audit and governance purposes. Any telephone advice given should be logged using a telephone advice proforma (Appendix 2, or equivalent).
- Most incidents and enquiries will be resolved at a regional level, however, all significant incidents must be reported to the National Clinical Team via ICC SPOC, as described in Appendix 1.

4. Regional enquiry or incident escalation processes

- If an incident or enquiry requires immediate escalation, the preferred route is via RVOC requesting that the Regional Single Point of Contact (ROC) send a message to the ICC SPOC.
- It is RVOC's responsibility to ensure that a single reference number has been assigned to the case. This reference must be quoted in the incident report, notification to NVOC, and all subsequent correspondence. If an MHRA Yellow Card or Datix report has already been completed before reporting to RVOC occurs, this information should be included in the report to enable all sources of information to be readily linked.
- All incidents requiring escalation should be reported **as soon as possible after the event.**
- The PHE National Immunisation Team can escalate an issue directly through the ICC SPOC. In this case, procedures must be in place to ensure duplicate requests are not made through ICC SPOC under different case reference numbers.

5. National enquiry or incident management and escalation processes

- The ICC SPOC will direct all COVID-19 vaccination-related cases to the NVOC.
- The NVOC will direct all clinical cases to the National Clinical Cell.
- If a case arrives at the NVOC without a reference number, it should be assigned a reference number before being sent to the National Clinical Cell.
- In the event of duplicate requests being made with different reference numbers, the PMO team and clinical cell triage lead will ensure consistency of approach by assigning a single reference for the case.
- The National Clinical Cell will provide a 7-day 08:00-20:00 clinician run triage service.
- The National Clinical Cell will address the incident or enquiry, liaising with the regional CARS team via RVOC to obtain further information if required, and with PHE, MHRA Yellow Card system and NHS subject matter specialists or other key stakeholders as needed.
- The responses will be collated and sent out via ICC SPOC after approval by the COVID-19 Vaccination Clinical Workstream.
- If required, significant incidents will be raised within the national COVID-19 incident response infrastructure, including directly with the National COVID-19 Vaccination Clinical Workstream and the COVID-19 National Strategic Incident Director of the Day (SIDD). This will be undertaken by an on-call member via the Vaccination Clinical Workstream lead and the Clinical Cell Triage Lead.

6. Escalation triggers

The COVID-19 Vaccination Programme clinical escalation triggers are as follows:

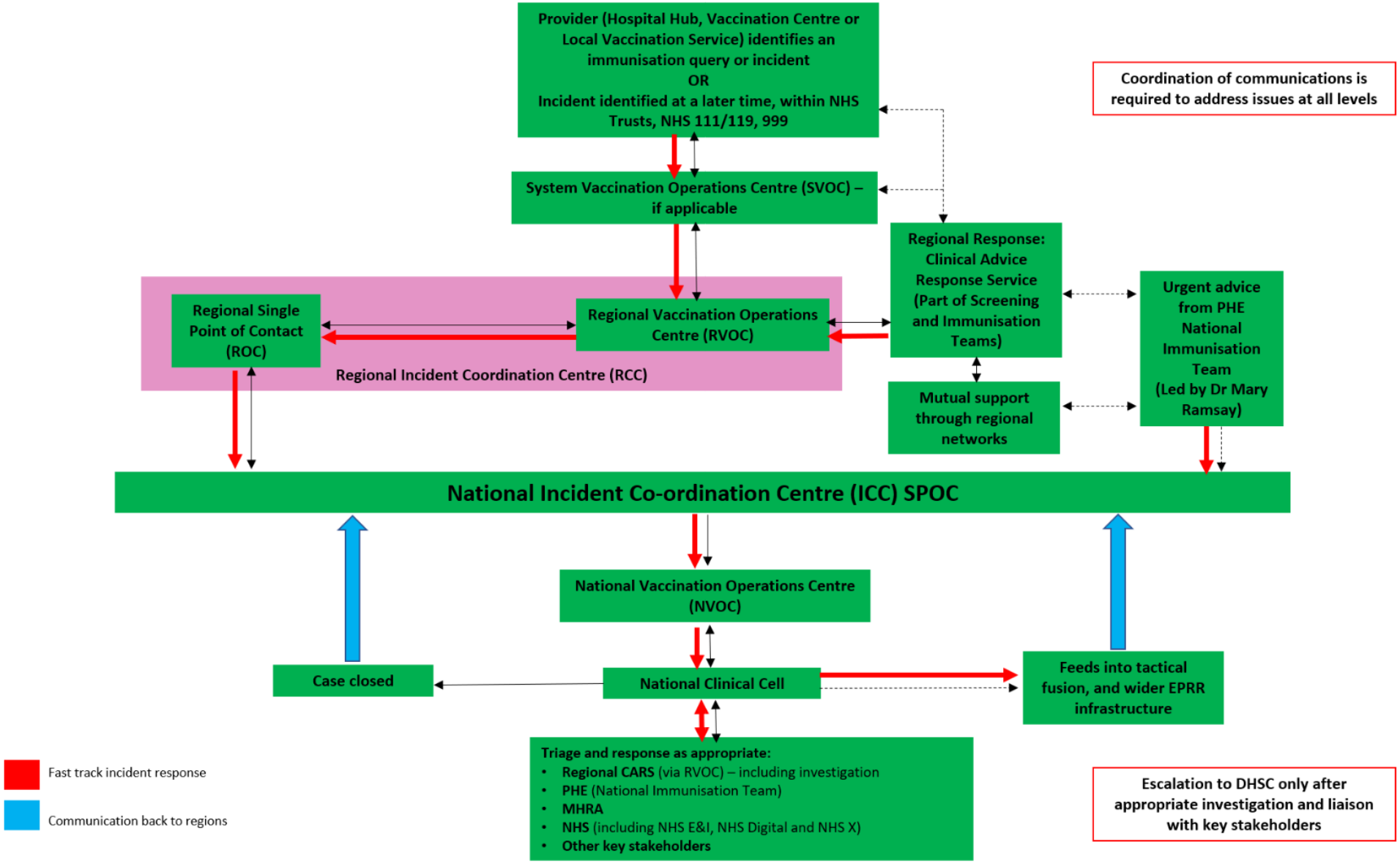
Trigger	Impact	Action	Senior leadership
Limited impact	• Issue is localised and has an expected short duration • Solutions are available within the organisation, or within the local health and care system. • No clear direct risk to patients.	• **Clinical Advice Response Service (CARS)** to lead & manage. • **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**	• 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
		Operations Centre (NVOC) of actions and outcome (weekly report).	
Moderate impact	• May result in impaired clinical outcomes **if not managed urgently** • 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	• **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.	• 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 prevention

Trigger	Impact	Action	Senior leadership
	national support.		
Significant impact	• Significant patient safety implications if not managed urgently • 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.	• Escalation via SPOC and the approved route to the **National Clinical Cell**. • **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.	• National Clinical Cell has **operational oversight** • 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
Critical impact	• Critical implications for patients and vulnerable populations. • No viable alternatives	• Escalation via SPOC and the approved route to the **National Clinical Cell**. • **National Clinical Cell** to collate and co-ordinate information	• National Clinical Cell has **initial operational oversight** • This would be taken over by the formal stand up of an incident or with **Strategic**

Trigger	Impact	Action	Senior leadership
	exist after exhaustion of all other escalation levels. • Life-threatening or life-changing impact on patients and/or ethical implications for clinicians. • Multiple concurrent incidents occurring nationally.	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 • **National Clinical cell** to collate and co-ordinate information required to inform clinical decision • **National Clinical cell** to check and balance response with **Strategic Incident Director of the day** to determine if Incident team to be established and incident declared and led by EPRR	**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 SPOC • Incident takes precedence over incidents of lower impact. • National Clinical Cell briefs the Incident Director and Strategic Incident Director of the Day **at the time of the incident** • National Clinical Cell on-call triage member to also inform clinical triage lead and workstream lead • Reporting structure to involve CommsResponse and NHS England executive directors, if incident declared • Routine weekly reporting to the National Clinical Cell to identify important trends for future planning and proactive incident prevention

Appendix 1: Clinical case escalation framework



Appendix 2: Telephone advice log proforma

To: Advice Giver

From: Insert Designation

Subject: FOR ACTION: Reference number

Dear [Insert Name],

Many thanks for providing specialist advice regarding [Insert Issue], concerning……at location….

Below is a summary of our conversation and the wording that will be used to support any decisions made next.

[Summary]

If you are currently working within an NHS organisation your indemnity for this work will be covered.

https://www.nhsemployers.org/covid19/assurance/indemnity-and-litigation

If you have any concerns please do not hesitate to get in touch, and thank you for your support.

Kind regards,

[Insert name and designation]

Appendix 3: Adverse event reporting poster

COVID-19 vaccine adverse events: how to report

Significant adverse events and reactions to COVID-19 vaccines *must* be reported to:

CARS

(Clinical Advice and Response Service)

Please email CARS via your local RVOC/CARS escalation process

The following guidelines should be followed when deciding what to report:

- Any side-effect/reaction that is not already noted in the manufacturer's SPC and that the clinician considers to be possibly linked chronologically to the vaccination.
- A known side-effect/reaction noted on the SPC but that the clinician considers to be an extreme form of this known side-effect, eg fever that lasts more than expected number of days, and for which there is no other cause, an urticarial reaction that affects a much larger area than just at the injection site etc.
- An acute clinical event or hospitalisation linked in time to the vaccination for which the clinician does not consider there to be any other clinical cause.

IF IN DOUBT, REPORT IT

Following initial investigation and, if appropriate, you may be directed by CARS to complete the following online forms:

Allergic reactions and other serious immediate adverse events eg cardiac arrest, hospitalisation, etc
(event within 72 hours of vaccination)
(https://cutt.ly/covid-ae)

Yellow card reports

Please note, you should still report to the MHRA Yellow card system:

https://coronavirus-yellowcard.mhra.gov.uk/

Note: you can use the information inputted into the first online form to generate a core text which you can then cut and paste into the Yellow Card form, Datix or any other regional systems to avoid duplication of work.