

OFFICIAL

Version 2, 18 December 2020



Publications approval reference: 001559

COVID-19 Vaccination Clinical Workstream

Standard operating procedure

Management of COVID-19 vaccination clinical
incidents and enquiries

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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.

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.
- 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 case numbers, appropriate logging, audit and closure.

Procedure

1. Key principles

- Providers (hospital hubs, vaccination centres and local vaccination services) must report all clinical incidents using both the [MHRA Yellow Card system](#) and the reporting process described in this document, resulting in escalation 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.**

2. Regional enquiry or incident management

- If a provider identifies an immunisation query or incident, the preferred route of escalation is to the Regional Vaccination Operations Centre (RVOC) via the System Vaccination Operations Centre (SVOC), if applicable.
- RVOC will then liaise with the Clinical Advice Response Service (CARS), as required, to address the enquiry or incident.
- 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 Public Health England (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).
- It is envisaged that most incidents and enquiries will be resolved at a regional level, but is expected that all clinical incidents are reported to the National Clinical team via ICC SPOC, as described (**Appendix 1**).

3. 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 the responsibility of the RVOC to assign a single reference number that stays with the case.
- All clinical incidents requiring treatment should be reported **as soon as possible after the event** (providers should not wait until 5pm to report these).
- Summaries of all incidents and enquiries should be routinely reported nationally on a daily basis, using the same process described.
- 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.

4. National enquiry or incident management and escalation processes

- The ICC SPOC will direct all COVID-19 vaccination-related cases to the National Vaccination Operations Centre (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 CARS 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.
- Any 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) if required. This will be done by an on-call member via the vaccination clinical workstream lead and the clinical cell triage lead.

5. Escalation triggers

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

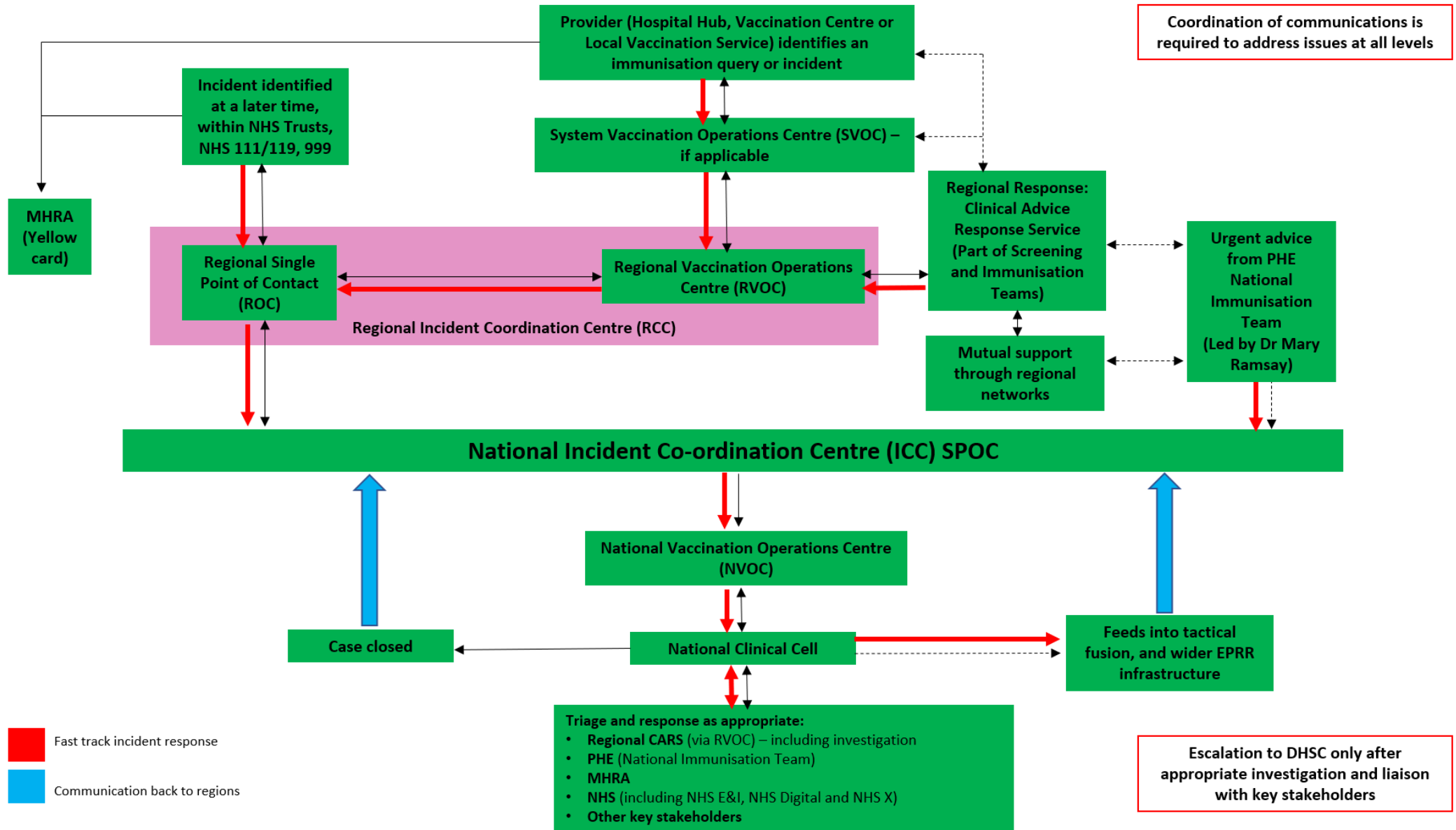
Trigger	Impact	Action	Senior leadership
Limited impact	<ul style="list-style-type: none"> • Issue is localised and has an expected short duration. • Solutions are available within the organisation, or within the local health 	<ul style="list-style-type: none"> • Clinical Advice Response Service (CARS) to lead & manage. • CARS to report at weekly Clinical Reference Group (CRG) governance meeting and Regional Vaccine Operations Centre (RVOC). 	<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
	<p>and care system.</p> <ul style="list-style-type: none"> No clear direct risk to patients. 	<ul style="list-style-type: none"> After governance meeting regional CARS / RVOC to advise National Clinical Cell and National Vaccine Operations Centre (NVOC) of actions and outcome (weekly report). 	
<p>Moderate impact</p>	<ul style="list-style-type: none"> 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 	<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 prevention

Trigger	Impact	Action	Senior leadership
	national support.		
Significant impact	<ul style="list-style-type: none"> • Significant patient safety implications if not managed urgently • 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. 	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Critical implications for patients and vulnerable populations. • No viable alternatives exist after 	<ul style="list-style-type: none"> • Escalation via SPOC and the approved route to the National Clinical Cell. • National Clinical Cell to collate and co-ordinate information 	<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

Trigger	Impact	Action	Senior leadership
	<p>exhaustion of all other escalation levels.</p> <ul style="list-style-type: none"> Life-threatening or life-changing impact on patients and/or ethical implications for clinicians. Multiple concurrent incidents occurring nationally. 	<p>required to inform clinical decision.</p> <ul style="list-style-type: none"> 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 lead by EPRR 	<ul style="list-style-type: none"> 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 comms response and TOTO formally 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]