

Ref. No: 393241121 From: Public Date: 24/11/21

Subject: Trust procedures and reports to MHRA yellow card

## **REQUEST & RESPONSE**

Under the Freedom of Information Act 2000, please provide data and information regarding the reporting procedures operated within Trust Hospitals, and number of instances where the staff have reported suspected or confirmed deaths/injuries resulting from Covid-19 Vaccinations to the MHRA Yellow Card System.

Specifically, please provide the following:

1. MHRA Yellow Card Training given to hospital staff

Please provide copy of the Trust's MHRA Yellow Card Staff Training Policy (or similar internal document) outlining the Training which has been provided to nursing staff regarding how to report suspected or confirmed Covid-19 Vaccine Adverse Events to the MHRA Yellow Card System.

We do not have a Trust policy on MHRA training for staff. We have a Trust policy called COVID-19 Vaccine handling and management policy (attached), which contains the statement below:

Any serious adverse reactions are to be escalated for immediate senior clinical input; such situations are to be fully documented following the event and a record kept of relevant product batch numbers. A record of all serious adverse events is to be provided to the responsible Pharmacist. Adverse reactions will be reported promptly using the MHRA's Yellow Card reporting scheme. Incidents, including adverse drug reactions will be reported on Datix and managed in accordance with the Trust's policy for management of incidents

Please see the policy attached.

2. Trust Hospital Procedures for identifying and reporting Covid-19 Vaccine Injuries/deaths (suspected or confirmed) to the MHRA Yellow Card Adverse Events Reporting System

Please provide copy of the policy and/or written procedures/flowchart showing the steps medical staff take to diagnose cause of injury/death when a patient is first admitted.

We do not have a policy or procedure or flowcharts on the steps medical staff take to diagnose cause of injury/death when a patient is first admitted.

3. Process for Reporting Instances of injury/death to MHRA Yellow Card System for Covid-19 Vaccinations

What is the process for reporting suspected/confirmed Covid-19 Vaccine Adverse Reactions/deaths to the Government's MHRA Yellow Card System.

An adverse drug reaction is reported to the MHRA via the link below:

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

The reporting system takes a reporter through the process step by step.

4. Number of unique reports to MHRA Yellow Card Reports made by the Trust for Covid-19 Vaccinations

How many reports has the Trust submitted to the MHRA Yellow Card System relating to COVID-19 Vaccinations:

	Number of unique Reports made to MHRA Yellow Card System relating to Covid-19 Vaccinations
November 2020	
December 2020	
January 2021	
February 2021	
March 2021	
April 2021	
May 2021	
June 2021	
July 2021	
August 2021	
September 2021	
October 2021	
November 2021	
December 2021	

We do not hold this data. The MHRA would need to be contacted directly to request this information.