

Ref: FOI/GS/ID 7063

**Please reply to:**  
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19 October 2022

## **Freedom of Information Act 2000**

I am writing in response to your request for information made under the Freedom of Information Act 2000 in relation to Trust procedures and reports to MHRA yellow card.

*You asked:*

*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.*

*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.*

*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.*

*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

Trust response:

1. There is no specific MHRA training for staff – It is included within Patient Group Directions training.
2. Procedures for identifying and reporting Covid-19 Vaccine Injuries/deaths (suspected or confirmed) to the MHRA Yellow Card Adverse Events Reporting System can be found in the Trust's Medicines Policy and Procedure. The relevant section is copied below and a copy of the complete policy is attached to this email.

#### **11.8 Adverse drug reactions / interactions**

Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Where there is a serious or unusual reaction i.e. an adverse reaction to the administration of a medication, this must be reported to the doctor and no further doses of that medicine should be given. The reaction should be documented in the patient's healthcare record and on the allergies section of the prescription chart, and on the allergies section of the eDN. Consideration must be given to reporting the incident to the Medicines Healthcare products Regulatory Authority (MHRA) using the Yellow Card System. Blank yellow cards are attached to each copy of the BNF. These are also accessible online via the MHRA website. Doctors, nurses or hospital pharmacists can complete these cards. All suspected reactions to new medicines (indicated by a black triangle in the BNF) and any serious suspected reactions to established medicines, even if well recognised or causal link uncertain should be reported.

3. The process for reporting suspected/confirmed Covid-19 Vaccine Adverse Reactions/deaths to the Government's MHRA Yellow Card System can be found in the Trust's Medicines Policy and Procedure. The relevant section is copied below and a copy of the complete policy is attached to this email.

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4. We are not able to provide you with Trust wide information as it is possible to submit individually and directly.