

**From the Chief Medical Officer
Dr Michael McBride**



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

HSS(MD)84 /2020

FOR ACTION

Chief Executives, Public Health Agency/Health and Social
Care Board/HSC Trusts/ NIAS

GP Medical Advisers, Health & Social Care Board

All General Practitioners and GP Locums (for onward
distribution to practice staff)

OOHs Medical Managers (for onward distribution to staff)
RQIA

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Our Ref: HSS(MD)84/2020

Date: 10 December 2020

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

**PFIZER BIONTECH COVID-19 VACCINE - UPDATED GUIDANCE ON
MANAGING ALLERGIC REACTIONS**

ACTION REQUIRED

Chief Executives must ensure this information is drawn to the attention of all staff involved in the COVID-19 vaccination programme.

The PHA must ensure this information is cascaded to staff working on COVID-19 vaccine deployment and the health protection team.

The HSCB must ensure this information is cascaded to all General Practitioners and practice managers for onward distribution to all staff involved in the vaccination programme.

The RQIA must ensure this information is cascaded to all Independent Sector Care Homes.

INTRODUCTION

1. Since the Covid-19 vaccination programme began on Tuesday 8 December the Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of two reports of anaphylaxis, and a further possible allergic reaction, shortly after receiving the Pfizer BioNtech COVID-19 vaccine. MHRA has carried out a thorough review and has issued updated guidance.

2. It is essential this updated guidance is brought to the attention of everyone involved in the COVID-19 vaccination programme and fully implemented. The updated guidance states:
 - I. Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNtech vaccine. A second dose of the Pfizer BioNtech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer BioNtech vaccination.
 - II. Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment.
 - III. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer BioNtech vaccine is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.
3. An Expert Group, chaired by Professor Sir Munir Pirmohamed, and attended by experts in Allergy & Clinical Immunology, met on the 9 December to review the cases and advised on action to mitigate the rare risk of anaphylaxis.
4. Anaphylaxis can be a rare risk of most vaccines and it is important that health professionals are vigilant in watching for the early signs and initiate prompt treatment, as occurred in these cases. The vast majority of people will not be at risk of anaphylaxis after being administered the Pfizer BioNtech vaccine and the benefits in preventing the serious complications of COVID outweigh the risks.
5. Anyone due to receive their vaccine should continue with their appointment and discuss any concerns or medical history of serious allergies with the healthcare professional prior to administration.
6. Please report any suspected adverse reactions via the Yellow Card scheme. To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)
7. In addition to the guidance mentioned above it is important that all those involved on the vaccination programme and colleagues in the immediate environments of the vaccination sites are supported to recognise the early signs of anaphylaxis (recognition and quick early action is key).
8. Early responders should have and be prepared to give IM adrenaline, again quick action is key;

9. In the event that support from the Northern Ireland Ambulance Service is required please ensure that NIAS is contacted via 999 and not on any other call/contact number.
10. The person making the 999 call must provide clear unambiguous information about the incident and that it follows vaccination with COVID-19 vaccine.

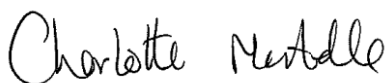
Conclusion

11. The COVID-19 vaccination programme is the best defence we have against the spread of the COVID-19. It is therefore essential that trust in the programme is fully maintained by ensuring this additional guidance is applied immediately.

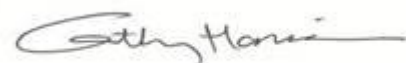
Yours sincerely



Dr Michael McBride
Chief Medical Officer



Professor Charlotte McArdle
Chief Nursing Officer



Mrs Cathy Harrison
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)
Assistant Director Public Health (Health Protection), Public Health Agency
Director of Nursing, Public Health Agency
Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board (*for onward distribution to Community Pharmacies*)
Directors of Pharmacy HSC Trusts
Director of Social Care and Children, HSCB
Family Practitioner Service Leads, Health and Social Care Board (*for cascade to GP Out of Hours services*)
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Directors of Children's Services, HSC Trusts
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Raymond Curran, Head of Ophthalmic Services, HSCB (*for distribution to Community Optometrists*)
Trade Union Side

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<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>