

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



Department of  
**Health**  
An Roinn Sláinte  
Máinnystrie O Poustie  
[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

**HSS(MD)32/2021**

For Action:

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

Castle Buildings  
Stormont  
BELFAST  
BT4 3SQ

Tel: 028 9052 0563

Fax: 028 9052 0574

Email: [michael.mcbride@health-ni.gov.uk](mailto:michael.mcbride@health-ni.gov.uk)

Our Ref: HSS(MD) 32/2021

Date: 27 April 2021

Dear Colleague

**VACCINATION PROTOCOL FOR COVID-19 VACCINE BNT162b2 (PFIZER / BIONTECH)  
AND UPDATE TO VACCINATION PROTOCOL FOR COVID-19 VACCINE ASTRAZENECA**

**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 their staff working on COVID-19**

1. Firstly, we would again like to thank you and your teams again for the exceptional work that is continuing to deliver the COVID-19 vaccination programme. The Northern Ireland vaccination programme has now delivered well over 1 million doses of COVID-19 vaccines since the start of the programme in December 2020, and we have no doubt that this achievement would not have been possible without the tremendous effort and dedication of vaccination teams within Trusts, general practice and community pharmacy settings.
2. As we slowly and cautiously start to lift the restrictions that have become part of our lives there is no doubt there is much to be optimistic about. An enormous amount of planning and hard work has gone into delivering this highly complex programme and we want to place on record our sincere thanks to everyone involved in making this happen.
3. The rollout of the vaccination programme will continue to be dependent on the availability of vaccine supplies. As we move into the later stages of the programme, we will need to continue to be agile and flexible in our deployment models and ensure that

the expanded workforce required to deliver the accelerated vaccination programme are able to efficiently operate in a range of settings.

#### Vaccination protocol – Pfizer / BioNTech vaccine

4. Further to our previous communication in **HSS(MD) 26/2021**, the Department of Health has now developed an additional Vaccination Protocol for the COVID-19 BNT162b2 (Pfizer / BioNTech) Vaccine, which has been clinically approved by the Chief Medical Officer, Chief Nursing Officer and the Chief Pharmaceutical Officer and authorised by the Minister for Health.
5. [Regulation 247A](#) of the Human Medicines Regulations, as inserted by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#), allows the Minister for Health in Northern Ireland during a pandemic situation to approve protocols which allow for the supply of coronavirus and influenza immunisations by persons of the classes specified in the protocol, subject to compliance with the conditions set out in the protocol.
6. This protocol provides an additional legal mechanism for administration of the Pfizer / BioNTech vaccine by registered healthcare professionals who cannot operate under a PGD, and defined groups who are not registered healthcare professionals, to safely administer a licenced or temporarily authorised COVID-19 vaccine. The protocol allows the process of vaccine administration to be split into its component parts i.e. clinical assessment and consent, preparation of the vaccine, administration of the vaccine, and record keeping.
7. All these stages can be done by one competent person (a registered healthcare professional) but alternatively these tasks can be split with each person trained and authorised to complete their specific task as defined in the protocol. Where multiple person models are used, the service provider must ensure that all elements of the protocol are complied with, in the provision of vaccination to each patient. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol and that adequate supervision arrangements are in place. As a minimum, competence requirements stipulated in the protocol under 'Characteristics of staff' must be adhered to.
8. This Protocol does not remove inherent obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.
9. A clinical supervisor, who will be required to be a registered healthcare professional trained and competent in all aspects of the protocol, will also need to be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the drawing up of the vaccine if this can be done safely alongside their overarching role. Any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol must be recorded for

the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol.

10. The COVID-19 vaccination programme may also be provided under a Patient Group Direction (PGD) or on a patient-specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient-specific direction (PSD)). Supply and administration in these instances should be in accordance with contractual arrangements with the commissioner for the delivery of the COVID-19 vaccination programme and are not related to the protocol.

#### Vaccination protocol – AstraZeneca vaccine

11. The vaccination protocol issued for the AstraZeneca vaccine has also been updated in light of recent JCVI advice and updates to the Green Book and replaces the previous version with immediate effect. Full details of the amendments are included in the document change history. Further amendments may become necessary prior to the published expiry date, as information on COVID-19 vaccines evolves.
12. Persons must be authorised by name to work under the updated protocol, and so provider organisations must ensure that staff operating under the updated protocol meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing.
13. Again, we would like to take this opportunity on behalf of the Department to offer our thanks for your continued support and for the enormous efforts being made to ensure the safe and timely rollout of the COVID-19 vaccination programme, whilst continuing to maintain existing services, during what continues to be a very challenging time.
14. A copy of this letter and the current version of the Vaccination Protocols for COVID-19 vaccines, authorised by the Minister for Health in accordance with regulation 247A of the HMR Regulations will be published and placed on the Department's website along with the latest information relating to COVID-19. These can be accessed at the following link: <https://www.health-ni.gov.uk/coronavirus>

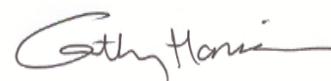
Yours sincerely



**Dr Michael McBride**  
Chief Medical Officer



**Prof. 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*)  
Medical Directors, HSC Trusts (*for onward distribution to all Consultants, Occupational Health Physicians and School Medical Leads*)  
Nursing Directors, HSC Trusts (*for onward distribution to all Community Nurses, and Midwives*)  
Directors of Children's Services, HSC Trusts  
RQIA (*for onward transmission to all independent providers including independent hospitals*)  
Medicines Management Pharmacists, HSC Board (*for cascade to prescribing advisers*)  
Regional Medicines Information Service, Belfast HSC Trust  
Regional Pharmaceutical Procurement Service, Northern HSC Trust  
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery, QUB  
Professor Sonja McIlpatrick, Head of School of Nursing, University of Ulster  
Caroline Lee, CEC  
Donna Gallagher, Open University  
Prof Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU  
Prof Colin McCoy, Head of School, School of Pharmacy, QUB  
Prof Colin Adair, Director of the NI Centre for Pharmacy Learning and Development, QUB  
Joe Brogan, Assistant Director of Integrated Care, HSCB  
Donncha O'Carolan, HSCB (*for distribution to all General Dental Practitioners*)  
Raymond Curran, Head of Ophthalmic Services, HSCB (*for distribution to Community Optometrists*)  
Trade Union Side  
Clinical Advisory Team

This letter is available on the Department of Health website at:

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

