

From The Chief Medical Officer
Dr Michael McBride



Department of
Health
An Roinn Sláinte
Máinystrie O Poustie
www.health-ni.gov.uk

HSS(MD)38/2021

For Action:

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

Castle Buildings
Stormont
BELFAST
BT4 3SQ

Tel: 028 9052 0563

Email: michael.mcbride@health-ni.gov.uk

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Dear Colleague

VACCINATION PROTOCOL FOR COVID-19 VACCINE MODERNA

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. More than 1 million people have now had at least one dose of a COVID-19 vaccine – over 70% of our adult population – and more than 40% have now received two doses. This is a remarkable achievement which has given real hope to our population and which would not have been possible without the tremendous effort and dedication of vaccination teams within Trusts, general practice and community pharmacy settings.
2. 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 – Moderna vaccine

3. Further to our previous communication in **HSS(MD) 26/2021** and **HSS(MD) 32/2021**, the Department of Health has now developed an additional Vaccination Protocol for the COVID-19 Vaccine Moderna, 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.

4. [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.
5. This protocol provides an additional legal mechanism for administration of the COVID-19 Moderna 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.
6. 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.
7. 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.
8. 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.
9. 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.

10. 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

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