TERMS OF REFERENCE DATED 26 JANUARY 2021

COOMBE WOMEN & INFANTS UNIVERSITY HOSPITAL ("COOMBE") TERMS OF REFERENCE FOR EXTERNAL REVIEW

- FINAL -

1 BACKGROUND AND SCOPE

- 1.1 The Board of the Coombe has been concerned to learn that on Friday 8th January in the course of the Covid-19 vaccination program carried out at the hospital, sixteen family members of staff received the vaccine.
- 1.2 Against this background, the Board has decided to commission an external review to establish the facts in relation to this occurrence (the **Review**) and has appointed Brian Kennedy SC (the **Reviewer**) to undertake this Review. This document dated 26 January 2021 sets out the Terms of Reference for the Review.
- 1.3 The scope of the Review is to carry out a factual review into the commissioning, planning and execution of the Vaccine Programme at the Coombe having regard to but not limited to the following key themes:
 - The guidelines that were available to the vaccination team in terms of the selection of vaccine participants and the extent to which those guidelines were followed.
 - Where no guidelines were available, what was the selection criteria adopted and by whom in terms of selection of vaccine recipients and what information was available to them to inform those decisions?
 - If remnant vaccines were available after the completion of the vaccine roll out on Wednesday 6th January to whom were these vaccines administered. Who were the decision makers in identifying those recipients and what information was available or sought to inform those decisions?
 - On Friday 8th January when was it determined and by whom that there would be excess vaccines beyond the requirement of Coombe staff?
 - What was the process by which the recipients of these excess vaccines were identified and selected and how was their data shared with the Coombe? Who made the final decision?
 - When was it determined and by whom that there would be remnant vaccines on Friday night?
 - What options and information was available in terms of identifying potential recipients (other than family members) of the remnant vaccines on Friday night and what efforts were made to explore those other options?
 - Who made the decision to select family members for vaccination on Friday night?
 - Was consideration given to the implications of the requirement for the administration of the second vaccine to family members?
- 1.4 The Board has established a subcommittee to oversee the conduct of the Review on behalf of the Board (the **Subcommittee**).
- 1.5 If, in the course of the Review, additional relevant points arise that the Reviewer considers should be reviewed, they shall be referred to the Subcommittee by the Reviewer to consider the necessity to vary or add to the scope of the Review.

2 **REVIEW PROCESS**

2.1 Timeframe

- 2.1.1 The Review is to be completed by 15 March 2021. If the Reviewer requires additional time he will inform the Subcommittee who will consider an extension to the timeframe.
- 2.1.2 The Reviewer shall update the Subcommittee if, during the course of the Review, it becomes apparent to the Reviewer that this timeframe cannot be met. The Reviewer will endeavour to complete the Review in as expeditious a manner as reasonably practicable.

2.2 **Confidentiality**

- 2.2.1 All meetings shall take place on a confidential basis. All parties who participate in the review process will be required to co-operate with the process and respect the privacy of the parties involved by refraining from inappropriately discussing the matter with other work colleagues or persons outside the organisation, save for authorised representatives. The Reviewer will advise (and record in writing that he has so done) all employees that he speaks to in the course of his Review of the confidential nature of the Review and that they are prohibited from divulging the details of the Review or inappropriately discussing it with other workplace colleagues or persons outside the organization including the media.
- 2.2.2 Confidentiality will be maintained throughout the Review to the greatest extent possible however it may not be possible to guarantee the anonymity of any person who participates in the Review.

2.3 Interviews

- 2.3.1 The Reviewer will make such enquires, conduct such interviews, seek and be provided with such documentation and information and engage in such correspondence as he considers relevant for the purpose of the Review.
- 2.3.2 Any refusal or failure to co-operate with the Review by any party will not prevent the Reviewer from issuing a report on the information available.
- 2.3.3 All interviewees will have the right to be accompanied to an interview by a work colleague or trade union official. The Reviewer must be informed of the name of any person accompanying the interviewee at least 2 days prior to the interview.
- 2.3.4 All interviews will be voice recorded and each interview will be transcribed. Each person interviewed will be provided with a copy of the interview note in order to give each interviewee the opportunity to confirm the accuracy of the note within a reasonable timeframe. Failure to confirm the accuracy of the note does not prevent the content of the note being relied upon and forming the basis of the Reviewer's findings, although any objections will be noted as a footnote to any such findings. Interviewees are prohibited from making their own recordings of interviews.
- 2.3.5 The Reviewer may require persons who have participated in the Review process to attend follow up interviews to respond to any new information adduced or to provide clarification on any of the issues raised in the Review. The Reviewer may share aspects of interviews with other interviewees for that purpose.
- 2.3.6 Where, during the course of the Review, the Reviewer proposes to ask an interviewee questions about a document, the Reviewer will provide a copy of the document to the interviewee. The Reviewer will afford each interviewee an opportunity to submit to the Reviewer relevant facts which the Reviewer will consider. The ultimate determination as to relevance lies with the Reviewer.

3 REPORT

- 3.1 A draft report will be prepared by the Reviewer and will be presented to persons considered relevant by the Reviewer in so far as aspects of the draft report are relevant to them and if appropriate suitably redacted. Recipients of the draft report will be given an opportunity to comment on factual accuracy within a timeframe of 48 hours (or such longer period as may be determined by the Reviewer).
- 3.2 Following the process in 3.1 the Reviewer will present a draft report to the Subcommittee to ensure that the Review has dealt with the scope of the Review.
- 3.3 At the conclusion of the Review, the Reviewer shall prepare an report for submission to the Subcommittee, which shall:
 - (a) outline the review process followed;
 - (b) set out a summary of the factual information gathered; and
 - (c) make findings of fact having regard to the scope of the Review.
- 3.4 The Reviewer is tasked with ascertaining (but not limited to) the key themes listed in 1.3 above. He shall not make any other findings in respect of any employee nor shall he make any recommendations. It shall be a matter for the Board to consider what, if any, actions arise from the Review and the report (including whether any further review or process is required).

4 GENERAL

- 4.1 It will be considered a disciplinary offence to intimidate or exert pressure on any person who participates in the review process.
- 4.2 The Reviewer may be provided with certain personnel to assist him in conducting the Review.
- 4.3 Documentation, including the draft and final report may be redacted in accordance with data protection and relevance and confidentiality considerations.
- 4.4 All employees are required to work as normal and maintain a professional work environment throughout the review process.

SUGGESTED PRIORITISATION OF HEALTHCARE WORKERS FOR VACCINATION IN THE CONTEXT OF LIMITED SUPPLY (DRAFT)

Covid-19 Vaccination Programme – Vaccine Process and Workflow – For Vaccination of all Health Care Workers (includes Hospitals and Community) in Large Scale Healthcare Facilities (Acute Hospitals & designated Non Acute facilities) Plan

Version: 1.0 Date = 24-12-2020

Appendix 2 Suggested Prioritisation of Healthcare Workers for Vaccination in the Context of Limited Supply (DRAFT)

(Priority levels: 1 - 3)^{Notes 1-4}

Но	(Priority levels: 1 – 3)	Priority
a)	HCWs in Covid-19 care pathways	1
b)	HCWs in High Risk service areas (examples not exhaustive):	1
	 Antenatal, perinatal, and post-natal areas including labour wards and recovery rooms and 	
	antenatal outreach programs.	
	Neonatal intensive care units; special care units; any home visiting health service provided	
	to neonates	
	Paediatric intensive care units	
	 Transplant and Oncology/Haematology wards 	
	Intensive care units /High Dependency Unit	
	Emergency Department Staff/ Pre-hospital Emergency Care Staff	
	 Operating Theatre Departments, Endoscopy & scoping departments & Departments where 	
	there is increased risk due to aerosol generating procedures inclusive of staff who may be	
	involved in diagnostics or patient transfer	
	 NAS staff involved in the transfer of Covid-19 Patients 	
c)	Vaccinators – OH/Peer Vaccinators	1
d)	Key Laboratory Staff	1
e)	Other Hospital HCWs with patient contact	2
f)	Other Hospital HCWs	3
Na	tional Ambulance Services	
a)	All NAS staff involved in the treatment, testing and transfer of Covid-19 Patients	1
b)	All NAS staff operating the 112/999 call centres, critical support staff,	1
c)	All staff responding to ambulances calls in Dublin (DFB), and support of the air craft Military,	1
	Charity and Coastguard	
d)	Irish Coast Guard Marine Rescue Co-ordination Centre (MRCC) staff	1
60	mmunity/Primary Care/Social Care Services	
a)	HCWs in Long Term Care Facilities (LTCF)	1
b)	HCWs in Covid-19 care pathways:	1
57	Public Health services	
	Home Care services	
	• GPs	
c)	Vaccinators – OH/Peer Vaccinators	1
d)	Other Community/Primary Care/Social Care (e.g. Tusla) HCWs with client contact	2
u) e)	Other Community/ Primary Care/Social Care in high risk age category or due to co morbidities	2
e) f)	Other Community/Primary Care/Social Care HCWs	3
g)	Contact Tracing staff	3
51		
NIP	: Student/Agency/Contractors to be included within each of the relevant groupings above	

See Notes overleaf

Covid-19 Vaccination Programme – Vaccine Process and Workflow – For Vaccination of all Health Care Workers (includes Hospitals and Community) in Large Scale Healthcare Facilities (Acute Hospitals & designated Non Acute facilities) Plan

Version: 1.0 Date = 24-12-2020

Note 1:

Priority 1: Healthcare workers employed in an area where there is high risk of acquiring or transmitting infection *Priority 2:* Healthcare workers employed in an area where there is medium risk of acquiring or transmitting infection *Priority 3:* Healthcare workers employed in an area where there is low risk of acquiring or transmitting infection **Note 2:**

Vaccinators have been included as Priority 1 in accordance with the *Provisional Vaccine Allocation Groups* notified by the Department of Health.

Note 3:

WHO SAGE* Roadmap For Prioritizing Use Of Covid-19 Vaccines In The Context Of Limited Supply

(https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-contextof-limited-supply) provides further guidance which may assist in the prioritisation of healthcare workers. *Strategic Advisory Group of Experts on Immunization (SAGE)

Note 4: Healthcare worker (HCW) includes all of those involved in the planning, management and delivery of care.

PRIORITISATION OF HEALTHCARE WORKERS FOR VACCINATION IN THE CONTEXT OF LIMITED SUPPLY

Covid-19 Vaccination Programme – Vaccine Process and Workflow – For Vaccination of all Health Care Workers (includes Hospitals and Community) in Large Scale Healthcare Facilities (Acute Hospitals & designated Non Acute facilities) Plan

Version: 1.0 Date = 24-12-2020

Appendix 2 Prioritisation of Healthcare Workers for Vaccination in the Context of Limited Supply

Priority 1

Uncontrolled environment

Staff involved in direct patient care. This includes staff who have frequent face-to-face clinical contact with patients and who are directly involved in patient care in either secondary or primary care/community settings. This includes doctors, nurses, midwives, healthcare assistants, social care workers, students on face to face clinical placements, dentists, paramedics and ambulance drivers, pharmacists, optometrists, occupational therapists, physiotherapists and radiographers. It should also include those working in independent, voluntary and non-standard healthcare settings such as hospices, and community-based mental health or addiction services. HCWs working in High Risk Clinical Areas as follows;

- a. Vaccinators administering the vaccinations
- b. In very High Risk Clinical Areas e.g. ICU staff, Residential Care Facility Staff
- c. with frequent/ prolonged essential uncontrolled face to face contact with patients or clients in acute and community settings and patient/client homes,
- d. Temporary staff, including those working in the COVID-19 vaccination programme, students, trainees and volunteers who are working with patients must also be included in:
 - i. Antenatal, perinatal, and post-natal areas including labour wards and recovery rooms and antenatal outreach programs (as these women will be unlikely to access a vaccine).
 - ii. associated community settings whose usual clients include infants, pregnant women, transplant, or oncology/haematology patients,
 - iii. required to work in a variety of areas or change location on a rotating basis or who may be required to work in very High Risk areas
 - iv. who are posted to or frequently work in very High Risk clinical areas
- e. Other High Risk clinical areas
 - i. Neonatal intensive care units; special care units; any home visiting health service provided to neonates

Controlled environment

Line managers at local care delivery will make determinations on whether the following are prioritised in line with points above;

HCWs working with;

- a. Laboratory and pathology staff Hospital-based laboratory and mortuary staff who frequently handle SARS-CoV-2 or collect or handle potentially infected specimens, including respiratory, gastrointestinal and blood specimens should be eligible as they may also have social contact with patients.
- b. deceased persons, blood, body parts/substances or infectious material or surfaces/equipment that might contain these or contact that would allow acquisition and/or transmission of a specified Infectious disease by respiratory means.
- c. Frontline funeral operatives and mortuary technicians / embalmers.
- d. Non-clinical staff who may have social contact with patients but are not directly involved in patient care. This group includes receptionists, ward clerks, porters and cleaners where their normal work location is a clinical area such as a ward, outpatient clinic; or who frequently throughout their working week are required to attend clinical areas, e.g. persons employed in food services who deliver meals and maintenance workers

Covid-19 Vaccination Programme – Vaccine Process and Workflow – For Vaccination of all Health Care Workers (includes Hospitals and Community) in Large Scale Healthcare Facilities (Acute Hospitals & designated Non Acute facilities) Plan

Version: 1.0 Date = 24-12-2020

Priority 2

Includes HCWs who:

- 1. Do not have face to face contact with patients/clients, deceased persons, blood, body substances or infectious material or surfaces/equipment that might contain these.
- 2. Normal work location is not in a clinical area, e.g. persons employed in administrative positions not working in a ward environment, food services personnel in kitchens
- 3. Only attends clinical areas infrequently and for short periods of time e.g. visits a ward occasionally on administrative/ICT technical duties; is a maintenance contractor undertaking work in a clinical area. Necessity of priority to vaccinate will be determined on a local basis by lead manager of area.
- 4. Incidental contact with patients no different to other visitors to a facility (e.g. in elevators, cafeteria etc

Prioritisation of Covid 19 Vaccination for HealthCare Workers 27th December 2020

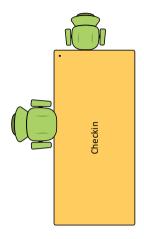
Dr Susan Kent & Dr Kevin Kelleher

AND National HR AND Office of Chief Clinical Officer

DIAGRAMS SHOWING A MOCK-UP OF THE VACCINATION CENTRE

Check-in

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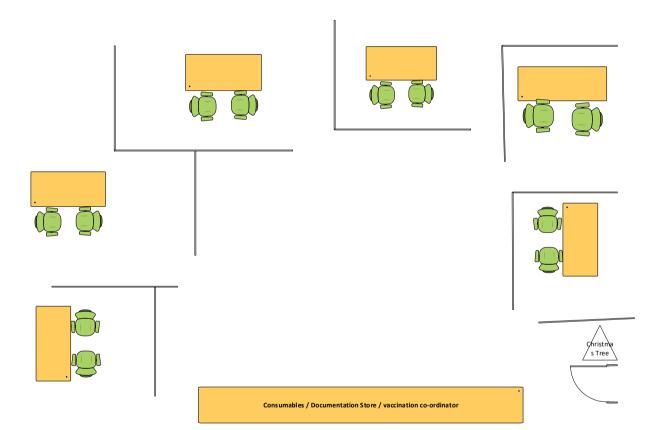




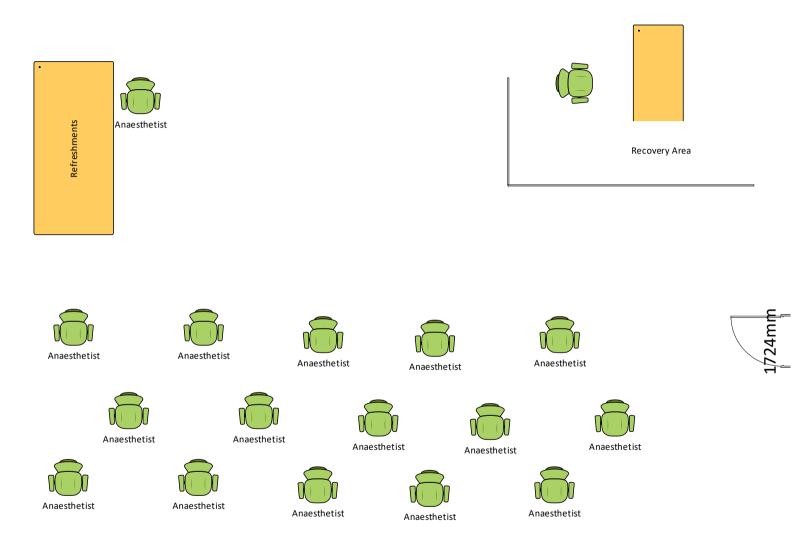




Vaccination Room



Observation Room



EMAIL FROM TO ALL COOMBE STAFF DATED 18 JANUARY 2021

Subject:	[Fwd: Message from] [ALG-MAIN.100809.01435785.FID2992960]
Original Me Subject: Message from From: Date: Mon, January 18, 2021 9 To: allstaff		

Dear Colleagues,

You may by now be aware of an article in this morning's Irish Times with regard to the COVID-19 vaccination programme here in the Coombe on Friday 8th January.

This morning's story relates to 16 doses of the vaccine that remained unused across a number of open vials when the vaccination of external GPs and healthcare workers had been completed shortly before 9pm on the Friday night. At this point over 1,100 vaccines had been administered to frontline staff, GPs and local community health workers. If the remaining vaccines were not used that night, they would have had to have been discarded.

At that time, the HSE booking system and portal was not live, as it came online the following morning (Saturday 9th), and so it was not possible to pre-book vaccinations and therefore be certain of the number of vaccinations required. It is important to note that the HSE booking system and portal is now live.

The hospital worked throughout the Friday, reconstituting the vials. At the time five vaccines were expected from each vial, however throughout the day it was possible to get six doses out of most vials, and in some cases seven. As a direct result of this operational efficiency, over 120 additional vaccines, over and above what had been anticipated, were made available. The team at the hospital proactively contacted the HSE to inform them of the additional available doses and actively sought out front-line workers to vaccinate both within and outside the hospital.

I **matching**, having considered the options, made the decision to use the vaccines that had already been made up to ensure that not a single reconstituted vaccine dose was wasted. The 16 were administered to family members of employees of the hospital. The remaining 3 unopened vials which had not been reconstituted were administered to staff on Monday 11th January.

Every effort was made to prioritise and identify additional front-line workers and follow all measures available to us at the time.

Yours sincerely,

SEQUENCING GUIDANCE DATED 12 JANUARY 2021 AND SEQUENCING GUIDANCE DATED 19 JANUARY 2021

Sequencing of COVID-19 Vaccination of Frontline Healthcare Workers

Version 1.0 January 12 2021

This document is subject to regular review and update as required in the context of changing evidence, circumstances and feedback

Authored by HSE Clinical Advisor on Vaccination Programme

Approved by Chief Clinical Officer

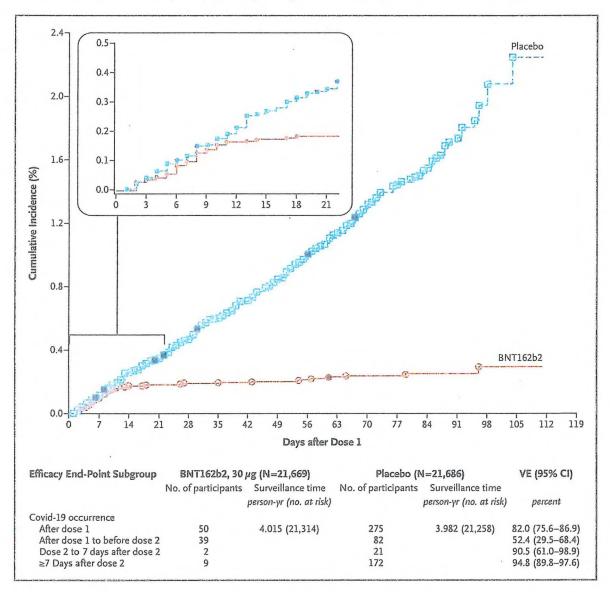
Context

There is sound scientific evidence that COVID-19 vaccine is safe and effective in protecting people against infection with COVID-19. Vaccination is based on administration of *"two doses (0.3 mL each) at least 21 days apart"* as the evidence for efficacy is based on this two dose schedule (Summary of Product Characteristics available at the link below).

https://ec.europa.eu/health/documents/communityregister/2020/20201221150522/anx 150522 en.pdf

The published evidence indicates that substantial protection is afforded to many people from about 12 days after the first dose of vaccine.

Figure 1: From Polack FP et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. https://www.nejm.org/doi/full/10.1056/NEJMoa2034577



"Shown is the cumulative incidence of Covid-19 after the first dose (modified intention-to-treat population). Each symbol represents Covid-19 cases starting on a given day; filled symbols represent severe Covid-19 cases. Some symbols represent more than one case, owing to overlapping dates. The inset shows the same data on an enlarged y axis, through 21 days."

Provisional Vaccine Allocation Groups developed by the National Immunisation Advisory Committee (NIAC) were published by Government on 8 December at the following link <u>https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/</u>

Under that strategy "people aged 65 years and older who are residents of long-term care facilities (likely to include all staff and residents on site)" are the highest priority therefore this paper will not address healthcare workers in long-term residential care facilities as they are accorded the highest priority as per Government policy.

There are various definitions of a healthcare worker. The WHO defines a healthcare worker (HCW) "as one who delivers care and services to the sick and ailing either directly -- or indirectly"-- ¹. This includes both frontline healthcare workers and other healthcare workers not in direct patient contact.

Under the Government policy "frontline healthcare workers" are listed as second in order of priority for vaccination while "other healthcare workers not in direct patient contact" are listed as fourth in order of priority. The category of "other healthcare workers not in direct patient contact" are a lower priority than "people aged 70 and older" in the provisional vaccine allocation groups. This document primarily addresses the sequencing of vaccination of frontline healthcare workers in accordance with that order of priority.

Healthcare workers, like all members of society are at risk of acquiring COVID-19 infection in the course of everyday life. In general, it is accepted that the nature of their work places many healthcare workers at a higher risk for acquiring infection with COVID-19 compared with the general population who do not work as healthcare workers. Protecting healthcare workers is also essential to ensure that healthcare services can be sustained for all members of society who need those services during the pandemic. Now that a safe and effective vaccine is available the ideal would be to offer the vaccine to all healthcare workers (and indeed all members of society) immediately however this is not possible because of practical challenges of acquiring and administering the vaccine.

As defined above healthcare worker is a broad category. It includes people at very different levels of increased risk related to their work. In the context of the available volumes of vaccine and the practicalities of administration it is necessary to consider

¹ WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng (1).pdf

the sequencing of vaccination of frontline healthcare workers. This is inevitably disappointing and frustrating for those who see colleagues have the benefit of vaccine while they have to wait. The purpose of this paper is to outline an approach that can be accepted by most healthcare workers as consistent with Government policy and based on principles that are reasonable and fair.

Although it would be ideal that the order in which healthcare workers have access to vaccination should be based entirely on the sequencing outlined below this may not always be achievable because administration has to be organised in a practical way.

The following are guiding principles for the sequencing of vaccination of healthcare workers by the HSE

- 1. The sequencing process needs to be practical and transparent
- 2. Sequencing should be based on the best practical estimate of exposure risk
- 3. Sequencing should not be based on where people work (community or acute hospital), who they work for (public sector or private sector), category of worker or grade.
- 4. Vaccine allocated to frontline healthcare workers should be administered as promptly as possible to ensure that the maximum possible number of frontline healthcare workers are protected as quickly as possible
- 5. The vaccination programme has to be practical to administer
- 6. No dose should be wasted

High level sequencing for vaccination is outlined below. Please note that examples are illustrative and are not comprehensive lists. The sequencing makes no distinction between healthcare workers based in the community and those in the acute hospital system.

Sequence group 1 (provisional vaccine allocation group 2 frontline healthcare workers)

Healthcare workers whose work involves direct physical contact with people who use healthcare services (frontline healthcare workers)

Sequence group 1a Healthcare workers who are working in a congregated care setting (unit/ward/service) where there is current active transmission of COVID-19

Sequence group 1b healthcare workers who deal with unscheduled care patients on a daily basis in an uncontrolled environment (for example paramedics and others who respond to emergency calls to deliver healthcare to non-triaged individuals in non-healthcare settings)

Sequence group 1c healthcare workers who deal with unscheduled care patients in a semi-controlled environment on a daily basis (for example patient facing staff who

work in COVID-19 assessment hubs or who work in or are called to attend to patients in an emergency department or similar setting)

Sequence group 1d healthcare workers who deal with unscheduled care patients in a controlled environment on a daily basis (for example patient facing staff who work in in-patient/residential care areas that provide care for unscheduled care patients and community settings providing walk in access for patients)

Sequence group 1e healthcare workers who occasionally deal with unscheduled care patients (for example GPs/Practice Nurses who mainly see patients by appointment but who may from time to time need to see urgent unscheduled patients or hospital staff who are occasionally called to attend to people in an Emergency Department)

Sequence group 1f healthcare workers who deal with scheduled care patients in an uncontrolled environment on a daily basis (for example delivery of care by appointment in a patient/service user's home)

Sequence group 1g healthcare workers who deal with scheduled care patients in a controlled setting on a daily basis (for example deliver scheduled care by appointment in a clinic, GP surgery or hospital)

Sequence group 1 h all other priority 1 healthcare workers

Sequence group 2 (provisional vaccine allocation group 2 frontline healthcare workers)

Healthcare workers that whose work does not involve direct contact with people but does involve contact with potentially infectious blood or body fluids or human remains in a controlled environment.

If healthcare workers have to deal with infectious material in uncontrolled environment such workers should be considered as sequence category 1c).

Sequence group 3 (provisional vaccine allocation group 4)

"Other healthcare workers not in direct patient contact"

Practical Considerations

The vaccination programme needs to be organised around locations where the vaccine can be received, safely stored and administered. In the early stage of the vaccination programme, to reach high numbers of healthcare workers quickly the vaccination centres were based at locations that have access to sufficient numbers of staff to ensure that the vaccine is used (no doses wasted) and use of vaccinators time is efficient. This raises issues of geographical equity and equity of access for people who work do not work at large centres.

Every effort should be made to ensure that vaccine should be made available to frontline healthcare workers in order of sequencing (as above) rather than given primarily to people later in the sequence who work in the institution that hosts the vaccination centre.

If a vaccination centre has the vaccine and the capacity to administer 200 vaccines per day (for example) they should administer the vaccine to the 200 frontline healthcare workers earliest in sequence order who are able to attend on the day. If frontline healthcare workers earlier in the sequence order are not available to attend they should proceed to frontline healthcare workers later in the sequence order (no dose should be wasted).

Centres should establish standby lists of frontline healthcare workers later in the sequence order that are available at short notice and that are randomly selected from the lists for vaccination in the event that frontline healthcare workers earlier in the sequence order do not attend or cannot receive the vaccine.

Centres should consider establishing standby lists of other healthcare workers (provisional vaccine allocation group 4) who are available at short notice and are randomly selected from the lists for vaccination if for any reason frontline healthcare workers are not available and the alternative is that vaccine dose expires.

ENDS

Updated Sequencing of COVID-19 Vaccination of Frontline Healthcare Workers

Version 1.1 January 19 2021

This document is subject to regular review and update as required in the context of changing evidence, circumstances and feedback

Authored by HSE Clinical Advisor on COVID-19 Vaccination Programme

Approved by Chief Clinical Officer

Key changes in Version 1.1

Includes reference to Vaccine Moderna

Use of term provisional allocation group throughout to align with language of Government policy

Indication that where practical to do so it is appropriate to use vaccine for people in allocation group 3 as well as allocation group 4 when frontline healthcare care workers are not available and the alternative is that the vaccine dose is wasted.

Context

There is sound scientific evidence that COVID-19 vaccines available for use in Ireland are safe and effective in protecting people against infection with COVID-19. Vaccination is based on administration of "*two doses of the vaccine at a specified interval*" as the evidence for efficacy is based on this two dose schedule. The vaccines currently in use in Ireland are Comirnaty (BioNTec/Pfizer) and Vaccine Moderna. The relevant Summary of Product Characteristics are available at these links.

https://ec.europa.eu/health/documents/communityregister/2020/20201221150522/anx_150522_en.pdf

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccinemoderna-product-information_en.pdf

The published evidence indicates that substantial protection is afforded to many people from about 12 days after the first dose of vaccine. Below is an illustration from the key publication relating to one of the vaccines currently available for use in Ireland.

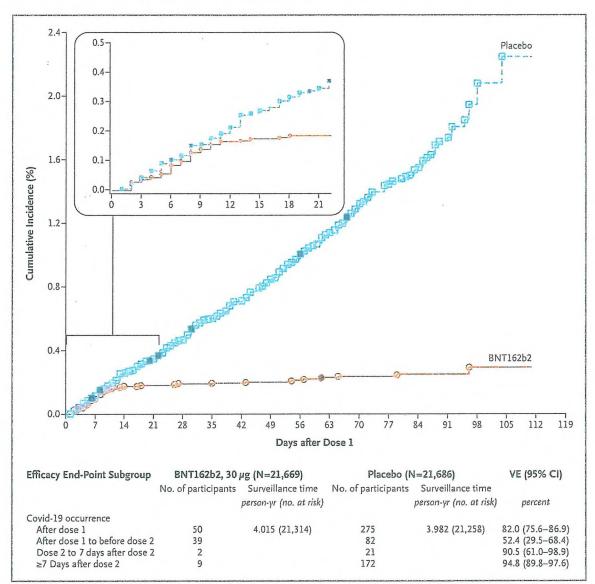


Figure 1: From Polack FP et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. https://www.nejm.org/doi/full/10.1056/NEJMoa2034577

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Under that strategy "people aged 65 years and older who are residents of long-term care facilities (likely to include all staff and residents on site)" are provisional allocation group 1 therefore this paper will not address those healthcare workers in long-term residential care facilities as they are encompassed in allocation group 1.

There are various definitions of a healthcare worker. The WHO defines a healthcare worker (HCW) "as one who delivers care and services to the sick and ailing either directly -- or indirectly"-- ¹. This includes both frontline healthcare workers and other healthcare workers not in direct patient contact.

Under the Government policy "frontline healthcare workers" are listed as the second allocation group while "other healthcare workers not in direct patient contact" are listed as the fourth allocation group. The category of "people aged 70 and older" is the third allocation group and comes before the category of "other healthcare workers not in direct patient contact". This document primarily addresses the sequencing of vaccination of frontline healthcare workers in accordance with the Government allocation groups.

Healthcare workers, like all members of society are at risk of acquiring COVID-19 infection in the course of everyday life. In general, it is accepted that the nature of their work places many healthcare workers at a higher risk for acquiring infection with COVID-19 compared with the general population who do not work as healthcare workers. Protecting healthcare workers is also essential to ensure that healthcare services can be sustained for all members of society who need those services during the pandemic. Now that safe and effective vaccines are available the ideal would be to offer the vaccine to all healthcare workers (and indeed all members of society) immediately however this is not possible because of practical challenges of acquiring and administering the vaccine.

As defined above healthcare worker is a broad category. It includes people at very different levels of increased risk related to their work. In the context of the available volumes of vaccine and the practicalities of administration it is necessary to consider the sequencing of vaccination of frontline healthcare workers. This is inevitably disappointing and frustrating for those who see colleagues have the benefit of vaccine while they have to wait. The purpose of this paper is to outline an approach that can be accepted by most healthcare workers as consistent with Government policy and based on principles that are reasonable and fair.

Although it would be ideal that the order in which healthcare workers have access to vaccination should be based entirely on the sequencing outlined below this may not always be achievable because administration has to be organised in a practical way.

¹ WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng (1).pdf

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- 1. The sequencing process needs to be practical and transparent
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- 3. Sequencing should not be based on where people work (community or acute hospital), who they work for (public sector or private sector), category of worker or grade.
- 4. Vaccine allocated to frontline healthcare workers should be administered as promptly as possible to ensure that the maximum possible number of frontline healthcare workers are protected as quickly as possible
- 5. The vaccination programme has to be practical to administer
- 6. No dose should be wasted

High level sequencing for vaccination is outlined below. Please note that examples are illustrative and are not comprehensive lists. The sequencing makes no distinction between healthcare workers based in the community and those in the acute hospital system.

Sequence group 1 (provisional vaccine allocation group 2 frontline healthcare workers)

Healthcare workers whose work involves direct physical contact with people who use healthcare services (frontline healthcare workers)

Sequence group 1a Healthcare workers who are working in a congregated care setting (unit/ward/service) where there is current active transmission of COVID-19

Sequence group 1b healthcare workers who deal with unscheduled care patients on a daily basis in an uncontrolled environment (for example paramedics and others who respond to emergency calls to deliver healthcare to non-triaged individuals in nonhealthcare settings)

Sequence group 1c healthcare workers who deal with unscheduled care patients in a semi-controlled environment on a daily basis (for example patient facing staff who work in COVID-19 assessment hubs or who work in or are called to attend to patients in an emergency department or similar setting)

Sequence group 1d healthcare workers who deal with unscheduled care patients in a controlled environment on a daily basis (for example patient facing staff who work in in-patient/residential care areas that provide care for unscheduled care patients and community settings providing walk in access for patients)

Sequence group 1e healthcare workers who occasionally deal with unscheduled care patients (for example GPs/Practice Nurses who mainly see patients by appointment

but who may from time to time need to see urgent unscheduled patients or hospital staff who are occasionally called to attend to people in an Emergency Department)

Sequence group 1f healthcare workers who deal with scheduled care patients in an uncontrolled environment on a daily basis (for example delivery of care by appointment in a patient/service user's home)

Sequence group 1g healthcare workers who deal with scheduled care patients in a controlled setting on a daily basis (for example deliver scheduled care by appointment in a clinic, GP surgery or hospital)

Sequence group 1 h all other priority 1 healthcare workers

Sequence group 2 (provisional vaccine allocation group 2 frontline healthcare workers)

Healthcare workers that whose work does not involve direct contact with people but does involve contact with potentially infectious blood or body fluids or human remains in a controlled environment.

(If healthcare workers have to deal with infectious material in uncontrolled environment such workers should be considered as sequence category 1c).

Sequence group 3

Where a frontline healthcare worker is not available for vaccination before the vaccine expires the dose should be administered to a person in allocation group 3 or 4 in that order in so far as practical.

Practical Considerations

The vaccination programme needs to be organised around locations where the vaccine can be received, safely stored and administered. In the early stage of the vaccination programme, to reach high numbers of healthcare workers quickly the vaccination centres were based at locations that have access to sufficient numbers of staff to ensure that the vaccine is used (no doses wasted) and use of vaccinators time is efficient. This raises issues of geographical equity and equity of access for people who work do not work at large centres.

Every effort should be made to ensure that vaccine should be made available to frontline healthcare workers in order of sequencing (as above) rather than given primarily to people later in the sequence who work in the institution that hosts the vaccination centre.

If a vaccination centre has the vaccine and the capacity to administer 200 vaccines per day (for example) they should administer the vaccine to the 200 frontline healthcare workers earliest in sequence order who are able to attend on the day. If frontline healthcare workers earlier in the sequence order are not available to attend they should proceed to frontline healthcare workers later in the sequence order (no dose should be wasted).

Centres should establish standby lists of frontline healthcare workers later in the sequence order that are available at short notice and that are randomly selected from the lists for vaccination in the event that frontline healthcare workers earlier in the sequence order do not attend or cannot receive the vaccine.

Centres should consider establishing standby lists of other people in allocation groups 3 (*people aged 70 and older*) and 4 healthcare workers (provisional vaccine allocation group 4) who are available at short notice and are randomly selected from the lists for vaccination if for any reason frontline healthcare workers are not available and the alternative is that vaccine dose expires.

ENDS