Report of the HSE Review of the COVID-19 Vaccination Programme at the Beacon Hospital

29th July 2021

Contents

1. Introduction

1.1 On the 26th March, a report in the media identified that 20 teachers from a school in Co. Wicklow (the School) received vaccinations at the Beacon Hospital COVID-19 Vaccination Centre (BHVC) on the 23rd March 2021.

1.2 In response to this report the Beacon Hospital identified that, though not in line with the sequencing guidelines, the vaccination of the teachers was carried out to avoid the wastage of vaccines remaining at the end of a clinic and the use of these vaccines was time-bound. In the press statement issued by the Beacon Hospital on the 26th March 2021 the reason cited for vaccines remaining at the end of the clinic, was that there were *'over 200 HSE no shows to scheduled vaccine appointments as a result of people being double booked at the Aviva* [vaccination centre]*'*.

1.3 Following consideration of the events of the 23rd March 2021, the Minister for Health requested, on the 27th March 2021, that the HSE suspend vaccine operations at the Beacon Hospital and requested the HSE to appoint an external reviewer to establish the facts of how this occurred.

1.4 In April 2021, the HSE commissioned an external Review of the COVID-19 Vaccination Programme at the Beacon Hospital. A Terms of Reference[1] was established to govern the Review. Ms Cornelia Stuart, a retired HSE Assistant National Director was appointed by the HSE to carry out the review (the Reviewer).

1.5 In establishing the Review, it was recognised from the outset that categories of personal data, defined as special category under the General Data Protection Regulation and Data Protection Act, would be processed in the course of the review. Arrangements were therefore made for the Review's data management to incorporate data protection by design and default. For that reason, the commencement of the Review was delayed until the 16th April. A further delay occurring during the course of the Review arising from the cyberattack experienced by the HSE limiting the Reviewer's access to HSE email and shared folders.

1.6 The Reviewer considered a wide range of documentation/information provided by the Beacon Hospital and relevant HSE departments/services, and during the course of meetings with staff from the Dublin Midlands and Ireland East Hospital Groups, Community Healthcare Organisations (CHOs) 6 & 7, the School and the Beacon Hospital.

[1] See Appendix 1 *'Terms of Reference HSE Review of Vaccination Programme at the Beacon Hospital'*

1.7 As operations at the Beacon Hospital Vaccination Centre were at the time suspended, a site visit was conducted to CityWest Vaccination Centre by the Reviewer to gain an understanding of the operations required of a vaccination centre. It is acknowledged that the CityWest vaccination centre is considerably larger than BHVC and therefore this visit was being done for the benefit of the Reviewer and not for any direct 'like for like' comparison.

1.8 An analysis of the information gathered was carried out in line with the objectives for the Review set out in the Terms of Reference. This Report sets out the methodology applied, the analysis and the findings made.

1.9 During the Reviewer's interactions with Hospital Group and CHO staff there was a consistent positive acknowledgement of the professional manner in which Beacon Hospital staff engaged with them both in terms of the organisation of the clinics and from the staff who attended the clinics. It was also evident that a significant level of effort by Beacon Hospital staff was put into both the establishment and throughout the weeks that the vaccinations took place in the BHVC.

1.10 The Reviewer would like to acknowledge the level of co-operation and engagement with all parties in the conduct of the Review.

2. Background to the National Vaccination Programme and the establishment of the Beacon Hospital Vaccination centre.

2.1 Ireland's COVID-19 vaccination programme (the programme) commenced on the 29th December 2020.

2.2 To support the rollout of vaccines the Department of Health published the COVID-19 Vaccine Allocation Strategy (the Strategy) which set out a provisional priority list of groups for vaccination once a safe and effective vaccine(s) had received authorisation from the European Medicines Agency (EMA).

2.3 The Strategy was developed by the National Immunisation Advisory Committee (NIAC) and Department of Health. It was subsequently endorsed by the National Public Health Emergency Team (NPHET) and approved by Government on 8 December 2020.

2.4 Given the limited supply of vaccines at this stage of the programme, a number of groups were prioritised for receipt of vaccine on the basis of the epidemiology of COVID-19, preliminary information on vaccines, and in line with the ethical principles set out by the Department of Health[2].

2.5 The initial rollout focused on Provisional Allocation Group 1 i.e. 'people aged 65 years and older who are residents of long-term care facilities (likely to include all staff and residents on site). The second priority group were frontline healthcare workers (HCWs) in direct patient contact roles (including vaccinators) or who risk exposure to bodily fluids or aerosols.

2.6 At this point Comirnaty (BioNTec/Pfizer) and Moderna vaccines were approved for use in the vaccination programme. On the 29th January 2021, the European Commission authorised Astra Zeneca (AZ) for use across Member States including Ireland. The roll-out of AZ vaccines was scheduled to get underway after the arrival in Ireland of the first supplies in early February.

2.7 In January 2021, each Hospital Group in partnership with the relevant Community Healthcare Organisation(s) (CHO) was required to establish an Integrated Governance Steering Group (IGSG). A key objective of the IGSG was to oversee the establishment of the vaccination locations within the geographical catchment of the Hospital Group and CHO. At this time, these vaccination locations provided for the administration of the vaccine to all healthcare workers in that region who work in acute hospitals, primary

[2] See Appendix 2 'Provisional Vaccine Allocation Groups'

care, community services, private hospitals and other healthcare settings. Some of these vaccination locations would also in time provide facility for public vaccinations in line with government sequencing and guidelines.

2.8 The DM IGSG was established in respect of the Dublin Midland Hospital Group (DMHG) and Community Healthcare Organisations (CHOs) 7 & 8. The DM IGSG noted that whilst vaccinations were progressing well in respect of acute hospital HCWs that progress was less advanced in relation to CHO HCWs. This was largely due to existing vaccination centres being located in acute hospitals and the large volume of acute hospital staff requiring vaccination. Whilst the vaccination centres at Citywest and the Aviva Stadium were at this time at a planning stage they were not due to come on stream in the short term.

2.9 On the 5th January the Deputy CEO of the Beacon Hospital, who was a member of the DM IGSG at the time, raised on a call with the group, the possibility of using the foyer of the recently acquired Beacon Hotel as a vaccination centre for the hospital. It was proposed that this vaccination centre could then be used to vaccinate both Beacon Hospital staff and staff from CHO 7. The Beacon Hospital proposal was considered an attractive option as it was co-located on an acute hospital site with access to an emergency response if this was required.

2.10 In considering this proposal the DM IGSG requested the Beacon Hospital to also consider providing vaccination to staff from the Hermitage clinic and UPMC Clane private hospital which were also in the DM catchment area. The Hermitage and UPMC Clane subsequently confirmed that their preference would be to vaccinate their staff on site, and this was agreed to.

2.11 The Beacon proposal offered the use of the Beacon facility and its staff at no cost to the HSE, with the HSE agreeing to provide the vaccine and consumables required for vaccination. This proposal was forwarded by the Chair of the DM IGSG to the HSE's Office of the Chief Clinical Officer (OCCO) for consideration. The OCCO deemed that, at the time from a clinical governance perspective, the Beacon proposal represented a viable option.

2.12 The decision was then made to implement the proposal and the vaccination centre at the Beacon Hospital was established. The Reviewer was informed that the establishment of the BHVC was not subject to a formal service level arrangement between the HSE and the Beacon Hospital; rather it was by way of a verbal agreement. It operated in accordance with an agreed communication structure between the Beacon Hospital and the DM IGSG and their related CHOs and in line with relevant guidance issued by the Department of Health, NIAC and the HSE.

2.13 The BHVC was purpose-built and had 10 vaccination booths with a planned capacity to provide 100 vaccines per hour. This is in line with the HSE's vaccination clinics operating model in which it is identified that 10 vaccination booths working 10 hours (2 x 5) would deliver 1000 vaccines per day. The BHVC commenced operations on the evening of the 12th January 2021.

2.14 On the 12th January 2021, the OCCO published guidance on the order of sequencing of frontline healthcare workers for access to vaccination[3]. This guidance was updated on the 19th January to include, reference to Vaccine Moderna[4], the introduction of the term 'provisional allocation group' to align the document with the language of Government policy and to indicate that where practical to do so it is appropriate to use the vaccine for people in allocation group 3 as well as allocation group 4 when frontline healthcare workers are not available and where the only alternative is that the vaccine dose is wasted.[5]

2.15 A further set of guidance was issued by the HSE on the 5th February 2021[6]. This guidance provided detail on sequencing of Health Care Workers Priority Groups 2 & 4 with examples for each group. Instructions for registration on the portal and detail of the requirement to present photo ID and acceptable workplace credentials were also included in this guidance.

2.16 The HSE's National Immunisation Office developed a set of clinical guidance the purpose of which was to provide clinical guidance to all clinicians implementing the National COVID-19 vaccination programme. The version of this guidance that the BHVC identified was in use and upon which the Beacon Hospital's COVID -19 *Vaccine Receipt, Supply and Reconstitution Policy* was based, was the HSE's Guidance for COVID-19 Vaccination (Version 5.0). Though there were subsequent versions of the national guidance developed, the guidance relating to the preparation and administration of the Astra Zeneca vaccine contained in this guidance remained consistent during the time to which this review relates.

2.17 The Reviewer has confirmed that the DM IGSG forwarded all guidance received to the vaccination centres in its catchment area including the BHVC.

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[3] See Appendix 3 'Sequencing of COVID-19 Vaccination of Frontline Healthcare Workers Version 1.0 January 12 2021'

[4] See Appendix 4 'Updated Sequencing of COVID-19 Vaccination of Frontline Healthcare Workers Version 1.1 January 19 2021'

[5] Group 3 refers to those aged 70 and over starting with those 85 and over. Group 4 refers to other HCWs not in direct patient contact. See Appendix 2 'Provisional Vaccine Allocation Groups' for further detail.

[6] See Appendix 5 'GUIDELINES FOR SEQUENCING AND REGISTRATION PROCESS FOR HCW COVID VACCINATION FEBRUARY 5TH 2021'

3. Review Methodology

3.1 It was recognised from the outset that categories of personal data categorised as special category under the General Data Protection Regulation and Data Protection Act would be processed during the Review. Therefore, arrangements were made for the Review's data management to incorporate data protection by design and default. This included the development of a joint controller framework and relevant privacy notices. IT arrangements were put in place to ensure all documentation and information gathered for the purposes of the review were held securely and only accessible to those involved in the conduct of the review. For that reason, the Review's commencement was delayed until the 16th April 2021.

3.2 In order to best meet the Review's terms of reference, a methodology was established whereby the Reviewer sought documentation, records and correspondence in relation to the COVID-19 vaccination programme in general and the operations of the BHVC in particular. Documentation/Information requests were therefore made to the Beacon Hospital, the School and to the relevant sections of the HSE i.e. Office of the Chief Clinical Officer, Dublin Midland IGSG, CHOs 6 & 7 (the CHOs whose staff were vaccinated at the BHVC). A report was requested from CoVax[7] that listed all vaccinations logged to CoVax as completed at the Beacon Hospital ('Location Name'). All documentation provided was logged and stored in line with the identified data protection requirements.

3.3 Given that by the time this Review commenced the BHVC had ceased operation and in order to gain an understanding of the operations of a COVID-19 vaccination centre, a site visit to the Citywest COVID-19 vaccination centre was arranged. This allowed the Reviewer to consider all aspects of the operation of the centre from scheduling attendance, the registration and vaccination of persons attending and also to consider the processes applied to ensure effective medication management of vaccine supplies.

3.4 Once an understanding of COVID-19 vaccination centre operations was established, the Review focused on the vaccination programme at the BHVC. This commenced with meetings with the relevant staff from the School, the DMHG CEO who chaired the DM IGSG and those within DMHG and CHOs 6 & 7 who were responsible for co-ordinating the vaccination programme at a service level. Further information and documentation were requested arising from these meetings.

[7] CoVax is the end-to-end digital solution developed to support the delivery of Ireland's COVID-19 vaccination programme

3.5 It was notable that in meetings held with the CHOs the high level of satisfaction that was expressed in relation to the professional manner by which the BHVC engaged with them in the planning of clinics, on the day of clinics and in the provision of data to them following clinics.

3.6 Meetings were subsequently also held with the CEO IEHG, who chaired the IE IGSG and relevant staff from the Beacon Hospital.

3.7 Notes of formal meetings held with individuals were drafted and provided to all persons interviewed for the purpose of factual accuracy checking and finalised following this process.

3.8 The Review Report was drafted and extracts were then provided to parties potentially adversely affected by the draft findings for their review and comment. The Report was subsequently finalised taking account of feedback received and submitted to Mr Damien McCallion as the Commissioner of the Review.

4. Compilation of lists of HCW requiring vaccinations

Beacon Hospital

4.1 The Beacon Hospital initially identified that it had a total of 1338 staff requiring vaccination. The deputy medical director and lead microbiology consultant were asked to develop priority sequencing for these Beacon Hospital personnel. The sequencing document looked at the risk weighting based on exposure to COVID-19 of personnel in different disciplines of the hospital. Personnel were categorised into priority 1-14 with priority 1 being persons delivering vaccinations through to priority 14 which was office-based staff. This list was provided to the BHVC to guide the order in which personnel were to be sequenced for vaccine.

4.2 On the 4th February, the Beacon Hospital emailed the DM IGSG in response to a request for updated figures of numbers vaccinated up to that date. In replying to this email, the Beacon Hospital identified a further 416 HCWs at the hospital along with 116 staff relating to Beacon Fertility and Renal. The addition of these increased the total number for vaccination to 1870 HCWs.

4.3 On 5th February, the HSE issued further guidance on sequencing of health care personnel for vaccination. At that point, all personnel in Beacon Hospital were re-sequenced in accordance with the HSE guidance and the new re-sequenced list was given to the BHVC. The Beacon Hospital has confirmed that personnel were called for vaccination in order of indicated sequence and operational considerations allowing on the vaccination days.

CHO 7

4.4 CHO 7 nominated their Head of Service, Primary Care as their CHO vaccination lead (CHO 7) in early January. The Vaccination Lead developed a template for other Heads of Service to gather details of eligible frontline workers in their area of responsibility for submission to a central point in the CHO. This template was therefore confined only to frontline healthcare workers in direct patient contact roles i.e. Category 2 workers.

4.5 Eligible staff included on this list was reflective of both HSE staff and staff of Section 38 and 39 agencies[8] with service level arrangements in the catchment population of the CHO. As a result, CHO 7 identified that it had approximately 16,000 frontline staff requiring vaccination. HSE services and Section 38 and 39 agencies submitting lists

[8] Section 38 and 39 Health Act 2004 – agencies funded or partly funded by the Health Service Executive

were required to categorise staff in line with the HSE's sequencing guidelines in place at that time as outlined in the published guidance from the OCCO published on the 12th January 2021.

4.6 The sequencing was updated in February in the context of the HSE Guideline of the 5th February. Due to the large numbers of staff identified, CHO 7 confirmed that a formal process for validation of categorisation applied at service/agency level was not feasible. The BHVC held the first vaccination clinic for CHO 7 on 13th January 2021.

CHO 6

4.7 Similar to CHO 7, CHO 6 designated their Head of Service, Health and Wellbeing as Vaccination Lead for the CHO (CHO 6). The Vaccination Lead requested other Heads of Service to compile lists of all staff in their area of responsibility (HSE and Section 38 & 39 agencies) on a template provided. As a result, CHO 6 identified approximately 9,000 staff requiring vaccination. Within these lists, staff were identified as frontline or non-frontline and sequenced in line with the guidance provided by the HSE's OCCO. The sequencing was updated in February in the context of the HSE Guideline of the 5th February.

4.8 Unlike CHO 7, CHO 6 vaccination lists included all staff, rather than just Category 2 staff. The returns received from the Heads of Service were then compiled into an overall master list which could be filtered according to sequencing category. Due to the large numbers of staff identified, CHO 6 also confirmed that a formal process for validation of categorisation applied at service/agency level was not feasible. CHO 6 commenced their vaccination process with the BHVC nearly two months after CHO 7, with their first clinic held on the 2nd March 2021.

5. Organisation of CHO clinics

5.1 Vaccine supplies were allocated by the DM and IE IGSGs to the BHVC based on the number of eligible staff in the Beacon Hospital and CHOs and in line with national vaccine availability.

5.2 The CHOs were advised on a weekly basis of the quantity of vaccine being allocated to them from their respective IGSGs. The vaccine leads in the CHOs would, based on priority of need, agree with the care groups how the weekly vaccine allocation was to be shared across each group.

5.3 From the documentation reviewed, the vaccination clinic arrangements were agreed between the BHVC and the CHO in advance i.e. dates, times and slots available. The BHVC would then send a schedule template outlining the available clinic timeslots to the CHO for completion and return. The CHOs through their Heads of Service, allocated appointments to their staff and subsequently confirmed those appointments with staff. The lists of staff whose appointments to attend a clinic were confirmed, were then returned to the CHO vaccination lead who compiled the information into an overall vaccination clinic schedule using the schedule template provided by the BHVC. Completed schedules were required to be sent to the BHVC by noon on the day before the clinic.

5.4 On the day of a clinic, a direct phone line and a designated point of contact was maintained between the relevant CHO and the BHVC in the event of any questions regarding eligibility of staff attending on the day e.g. if their name was not on the schedule provided by the CHO to the vaccination centre the day before the clinic.

5.5 The day following a vaccination clinic the BHVC would return a copy of the vaccination schedule that had been provided to them by the CHO together with details of whether a staff member had received a vaccine or whether they had failed to attend for vaccination. This returned schedule was referred to as the end of day report. The end of day report was used by the CHOs to update their listings of staff identified for vaccination.

5.6 The process, from the perspective of both CHOs, worked very well and they reported having a very good working relationship with their contacts in the BHVC. From the perspective of the BHVC the working relationship with CHO 7 had evolved since the first clinic held for them on the 13th January 2021. The clinic on the 23rd March 2021 was the fifteenth clinic held for them by which time the arrangement had been optimised and was running efficiently. CHO 6 on the other hand was at an earlier stage in the vaccination process, the clinic on the 23rd being their third clinic. The

arrangements between the BHVC and CHO 6 were therefore less evolved and still in the process of ‘bedding down’.

6. Standby List Arrangements

Beacon Hospital

6.1 The Beacon Hospital confirmed, that for clinics run for Beacon Hospital staff, any unused vaccines were offered in line with the sequencing guidelines, to members of staff on duty who had not yet been given a formal appointment but who were on the list of staff for vaccination. The Beacon Hospital also confirmed that as more of their staff were vaccinated, the continuing availability of 'short notice' vaccine recipients was becoming more limited.

CHO 7

6.2 As the arrangements for vaccination clinics were only being developed between CHO 7 and the BHVC in January and early February, the need for staff to attend at short notice to avail of left over vaccines was often required from the CHO on the days that the clinics were being run for them. To minimise the need for a standby list, CHO 7, in drawing up their vaccination schedule, operated on an assumed 10% DNA rate and included a 10% buffer of scheduled additional appointments (later moving to a 20% buffer). Over time the process evened out and to further minimise the need for standby lists, an arrangement was agreed with the BHVC that as the Beacon Hospital was also in the process of vaccinating their staff, vaccine left over at the end of a CHO 7 clinic could be used by the Beacon Hospital to vaccinate those staff. The agreed understanding between the BHVC and CHO 7 of this arrangement was that any vaccine doses remaining at the end of a clinic used in this way would be reallocated from the Beacon Hospital's vaccine allocation at a subsequent CHO 7 clinic. By the 23rd March, CHO 7 was nearing the completion of the vaccination of their Category 2 staff.

CHO 6

6.3 CHO 6 advised that they were not requested by the BHVC to have a 'standby list' and that they were not contacted in relation to sending staff at short notice to clinics to avail of doses of vaccine remaining at the end of a clinic and so avoid vaccine waste.

6.4 CHO 6 did however confirm that if contacted to send staff at short notice that, due to the fact that they were at an early stage in the vaccination process, that they could have pulled staff from their listing of eligible staff awaiting vaccination.

Note

In response to the Draft Report, the Reviewer was advised that the Beacon Hospital never committed to manage or seek stand by lists from either CHO 6 or CHO 7 and that the CHOs were responsible for managing and scheduling their own staff for vaccination in the BHVC.

7. Provision of Vaccine to the Beacon for use in the Hospital and Vaccination centre

7.1 Vaccine was delivered in bulk to the BHVC via the HSE Cold Chain Delivery Service. It was received and stored in line with HSE requirements. The total quantity assigned was based on returns made in relation to the number of staff for vaccination identified and returned by two CHOs and the Beacon Hospital. This was delivered over a period of time based on the amount of vaccine available to the HSE at any point.

7.2 At the outset of the vaccination programme the vaccine supply chain was neither consistent nor assured. As a consequence of this there was significant emphasis placed on planning each vaccination clinic to maximise the number of frontline healthcare workers vaccinated and to minimise any vaccine waste.

7.3 This was of particular importance as, at that time, there was a new wave of infection occurring and the need to protect both vulnerable groups and frontline healthcare workers was both paramount and urgent.

7.4 There was also understandably considerable public interest in the programme and its deployment.

8. Operation of the BHVC Vaccination Clinic

8.1 As the BHVC was no longer operating at the time that this Review was being undertaken, the Reviewer conducted a site visit of the Citywest VC. Whilst it is accepted that CityWest VC was considerably larger than the BHVC and operated on a daily basis, the visit provided an opportunity to gain an understanding of all aspects of the operations of a vaccination centre. These included the processes in place from the reception of those attending for vaccination, the conduct of a wellness check, queuing, registration, vaccination, post vaccination observation and medication management.

8.2 In response to the Draft Report, Beacon Hospital advised that they believe that CityWest VC is not a valid comparison to BHVC. The reason cited by the Beacon Hospital was that CityWest VC was established much later than the BHVC with considerably more fulltime resources operating consistently on a daily basis. Whilst the comments of the Beacon Hospital are noted, as stated earlier, the visit to CityWest VC was done solely for the benefit of the Reviewer to gain an understanding of the operation of a vaccination centre and not for any direct 'like for like' comparison.

8.3 It would appear that the BHVC and CityWest VC operated in a relatively similar manner. Key differences related to the model for managing patient flow and vaccine preparation on the day of a clinic.

8.4 In CityWest VC, although there would always be sufficient vaccine on hand to meet the demands of those scheduled to attend, vaccine is allocated for preparation and administration on the basis of those actually attending rather than being pre-prepared for administration on a prediction of attendance based on appointments made.

8.5 At the outset of the day and prior to the commencement of the clinic, a briefing session is held with all clinic staff attending. The focus of this briefing is to outline the detail of the clinic being run e.g. the vaccine in use that day e.g. AZ or Pfizer, the number of persons on the list to be vaccinated, PPE use, procedures for clinical emergencies etc. An end of day, a de-brief is also held to review the day, identify areas for improvement and outline the numbers booked and the staffing for the next clinic day.

8.6 In City West VC, vaccine booths are provided with a tray containing an unopened vial of AZ vaccine and the syringes and other items required for its administration. Each vial contains on average 11.7 doses of vaccine. Once a vial is opened the guidelines state that the doses must be used within a 6 hour timeframe. The vaccine dose is drawn up in the vaccination booth, pursuant to the manufacturer's instructions, on a per patient basis and administered. When all available doses are administered, the vaccinator

returns to request another tray. Based on the numbers attending at the time another tray may be provided or if the numbers awaiting vaccination are slowing the booth may be temporarily closed. Both the opening of vials and the drawing of vaccine is therefore regulated on an on-going basis in response to these numbers. Towards the end of clinic, a 'hard stop' was carried out in order to accurately identify the numbers at the vaccination centre awaiting vaccination against the number of doses available from open vials. In addition to counting those registered inside the vaccination clinic, the count includes anyone at the registration desk awaiting registration and persons queuing outside the vaccination centre to be registered i.e. those outside the clinic environment. This allowed for an accurate assessment of those on site awaiting vaccination. This number was tallied against the number of doses available in open vials and additional vials would be opened only if required. It also accurately identified the actual number of doses that would be available at end of clinic ('left over doses') so that additional persons could be called at short notice. Such people if required were identified from appointments scheduled for the following day or from the portal.

8.7 The CityWest model was therefore an adaptive model which had the agility to respond to changes in the pattern of attendance on any given day.

8.8 In the BHVC, the outcome of initial clinics held, were analysed by clinic management so that they could learn from experience and use this information to refine and optimise clinic arrangements. This led increasingly to the attendances at clinics running in a predictable manner. The predictable manner of clinics assisted staff in planning the throughput of people attending for vaccination at the clinics. The premise upon which the predictive modelling was based is illustrated from the analysis of data from CoVax in the two charts below.

Chart 1 – Average Vaccination Clinic Flow in the BHVC

8.9 Chart 1 shows the flow of CHO staff across all clinics held in the BHVC from the first clinic held on the 13th January 2021 to the last clinic on the 23rd March 2021. Peaks were attained in the middle of the morning and in the mid-afternoon. The mid-afternoon peak would drop at 16:00hrs before the closure of the clinic at 17:00hrs. The average number of vaccine doses 'left over at the end of clinics (excluding the 23rd March clinic) was one.

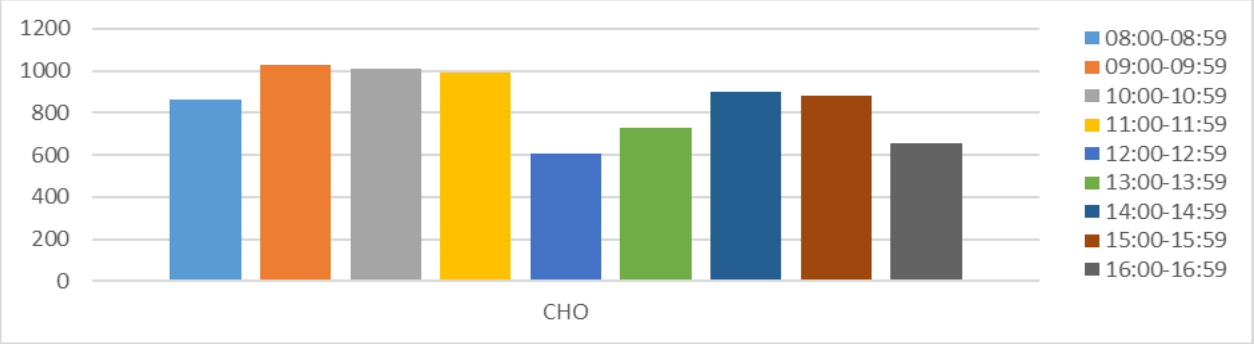


Chart 1

Chart 2 – Vaccination Clinic Flow on 2nd March 2021

8.10 Chart 2 shows the flow of CHO staff on the 2nd March 2021. Like the 23rd March, this was a joint CHO 6 and CHO 7 clinic. Similar to Chart 1, a peak is attained in the morning after which the numbers attending for vaccination steadily declines until the clinic closes. This steady rate of decline provided BHVC staff with an opportunity to stop opening vials and commence using excess doses drawn into syringes during busy periods of the day. At the end of this clinic there were no doses 'left over'.

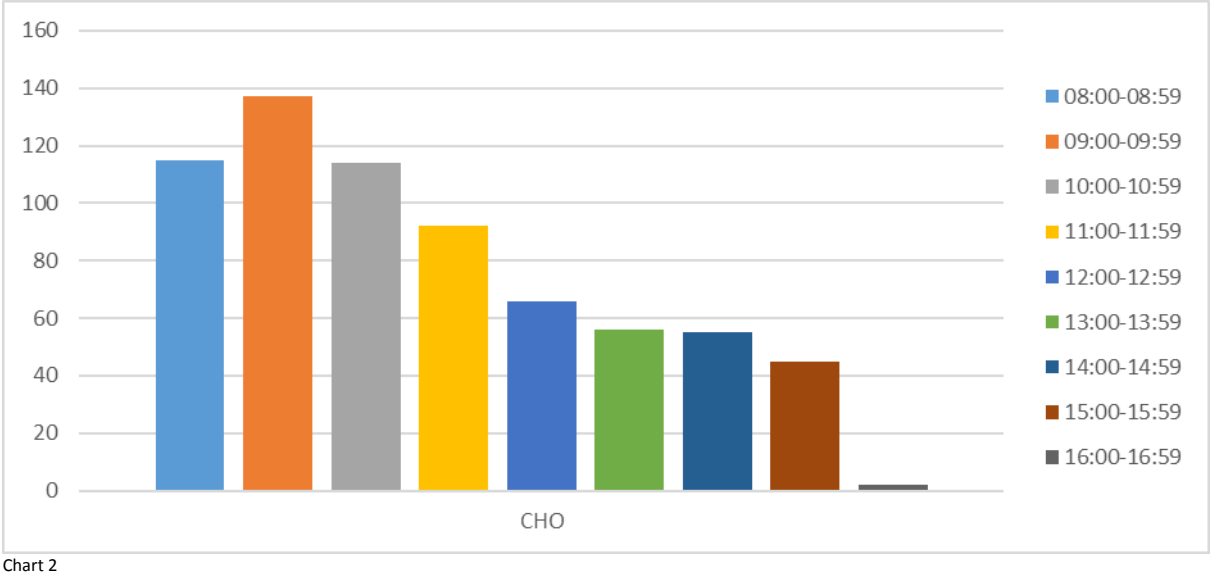


Chart 2

8.11 Clinic flow on the day of a clinic was monitored in clinic via an online vaccine tracker system developed by the Beacon Hospital. This tracker system monitored the flow of people for vaccination from the time they were checked in on the system to the time they were discharged. It allowed clinic staff to monitor flow, in real time, at all stages of the process. This model of managing flow did not take account of those people waiting to be checked in.

8.12 The BHVC's predictive modelling relied on clinics running in a predictable manner based on past performance.

8.13 The Reviewer was informed that in order to maximise throughput, rather than draw vaccine into the syringe on a per person basis at the point of administration in the vaccination booth, vaccines were drawn up in advance from vials into syringes and given on trays to each vaccination booth ready to administer. Vaccine preparation was done in this way in the BHVC throughout the day and was based on the number of people expected to attend in the following hour (taking account DNA rates). It is also interesting to note in Chart 2 that though the planned capacity of the 10 vaccination booths was 100 vaccines per hour, for three of the hours on which the clinic operated on the 2nd March 2021 that capacity was exceeded, with 138 vaccines delivered in one of the hours. In response to the Draft Report, the Beacon Hospital advised that whilst in early January they gave CHO 7 an estimate of 100 vaccines per hour, following their experience [of running BHVC], their capacity to provide more vaccines per hour was communicated to the CHOs. However, it is the opinion of the Reviewer, that the BHVC's original estimate of 100 vaccinations per hour is in line with the HSE Operating Model which was predicated on the AZ vaccine being drawn at point of administration.

8.14 The increased capacity achieved by the BHVC in February was directly linked to the adoption of a practice of the pre-preparation of syringes. Although the approach sought to maximise throughput, this practice ran contrary to the HSE's Clinical Guidance for COVID-19 Vaccination developed by the HSE National Immunisation Office[9]. The HSE's Guidance was referred to in Appendix 8 of Beacon Hospital's own COVID-19 Vaccine Receipt, Supply and Reconstitution Policy ('the Beacon Policy')[10]. In relation to the process for preparation of the AZ Vaccine the Beacon Policy states that *'Doses should not be drawn up in advance per the manufacturer's instructions. <u>There is no information on the stability of vaccine in pre-prepared syringes.'</u>* With regard to administration of the vaccine, the Beacon Policy states that *'Each dose should be drawn up and immediately administered to the patient'.*

[9] See Appendix 6 'Section 4.3 Clinical Guidance for COVID-19 Vaccination Version 5.0 5 February 2021'
[10] See Appendix 7 Beacon Hospital 'COVID-19 Vaccine Receipt, Supply and Reconstitution Policy'

8.15 In response to the Draft Report, the Beacon Hospital informed the Reviewer that in order to determine how best to approach the preparation of syringes for BHVC they reviewed the policies and procedures from both the HSE and internationally and carried out a risk assessment to determine a plan of action. In line with their analysis of these guidelines, the Beacon Hospital conducted a risk assessment and concluded that pre-prepared syringes provided a safe option for BHVC. However, despite this the Reviewer remains of the view that the BHVC was required to operate in line with guidance issued from NIAC, the HSE and the relevant regulatory bodies.

9. The BHVC clinic on the 23rd March 2021

9.1 The clinic held on the 23rd March was unlike clinics held previously for a number of reasons.

9.2 The first of these was that the clinic on the 23rd March was a rescheduling of a clinic originally planned for the 16th March. The clinic on the 16th March had been due to administer the AZ vaccine but was cancelled, arising from a decision taken on the 14th March by National Immunisation Advisory Committee to suspend the use of AZ in Ireland. This decision arose from concerns over blood clots identified in Norway which the European Medicines Agency was investigating.

9.3 On the evening of Friday 19th March, the National Public Health Emergency Team confirmed that the use of the AZ vaccine could recommence following advice from the NIAC. On Monday 22nd March, a decision was made to reschedule the clinic cancelled on the 16th March to the 23rd March.

9.4 The BHVC consequently reallocated the 16th March appointment slots to the CHOs - 360 slots to CHO 7 and 1008 slots to CHO 6 (a total of 1368 slots). Based on a review of the end of day report provided by the BHVC to CHO 7 and 6, the clinic on that day was scheduled to run from 08:00hrs to 16:00hrs. CHO 7 advised the BHVC that 310 staff had confirmed attendance and CHO 6 advised that 600 staff had confirmed attendance. CHO 6 also advised the BHVC that due to the short notice and reduced timeframe available to reschedule staff to attend, that staff had been sent a text message (as opposed to a phone call). It was anticipated therefore that more staff may turn up to the clinic on the day than the number who responded to the text. To address this CHO 6 provided the BHVC with the full schedule of staff who had been due to attend the clinic on the 16th March (1008 staff). This was provided on the basis that if anyone turned up who was on the schedule, the vaccination could proceed without the need to revert to the CHO. CHO 6 had indicated to the BHVC that 600 staff had confirmed their attendance by responding to the text message, however, in the schedule of 1008 staff provided by CHO 6 to the BHVC there is no indication which of these staff had confirmed their attendance.

9.5 Secondly from the perspective of the on-line vaccine registration portal, the staff who had not attended for vaccination on the 16th March (due to the postponement of the clinic) were listed as 'unvaccinated' and therefore from the perspective of the HSE's vaccine registration portal appeared to be awaiting vaccination appointments. A number of these staff were consequently allocated appointments to attend the Aviva VC. This issue became apparent on the 22nd March when the BHVC reported that they received a considerable number of queries from staff scheduled to attend the

BHVC on the 23rd, advising that they had also received appointments to attend the Aviva VC. The Reviewer was advised by CHO 6 that they also received a small number of similar calls. Whilst the BHVC requested these staff to attend at the BHVC as originally planned, this situation further left a degree of uncertainty about numbers that would attend the BHVC on the 23rd March.

9.6 Finally, as both the Beacon Hospital and CHO 7 were nearing the end of the vaccination of their eligible staff, the availability of staff to attend at short notice was becoming an issue. Though this was an issue that would need to be addressed in the medium term there were still enough staff available that could be called in the context of expected levels of vaccine being 'left over' at the end of a clinic. At this point and from their prior experience of standby lists with CHO 7 the BHVC had at this point not requested CHO 6 to have a standby list arrangement in place.

9.7 On the 23rd March, 271 CHO 7 staff and 763 CHO 6 staff attended (1034 total). This, though greater than the 910 confirmed to attend, was less than the number planned for the original clinic on the 16th March where 1368 clinic slots had been made available. The pattern of attendance on the day was also unlike clinics held previously and therefore did not conform to the usual predicted pattern. This is illustrated in Chart 3 below.

Chart 3 – Vaccination Clinic Flow on 23rd March 2021

9.8 Chart 3 shows the flow of CHO staff attending for vaccination on the 23rd March 2021. In comparison to Charts 1 and 2, the clinic is consistently busy until it was due to close at 16:00hrs with over 100 CHO staff vaccinated per hour until then. On this day, the peak of 141 staff vaccinated per hour occurred between 14:00hrs and 15:00hrs as opposed to the morning which happened on previous occasions. The planned capacity of the 10 vaccination booths was to administer 100 vaccines per hour. On the 23rd March, this capacity was exceeded in every hour due to the BHVC's practice of pre-preparing syringes.

9.9 The Lead Pharmacist BHVC informed the Reviewer that sometime between 15:30hrs or 15:45hrs she entered the clinic area and noticed 'a reduced activity'. She brought the issue to the attention of the CNM3 in charge of the vaccination centre. In her meeting with the Reviewer the Lead Pharmacist said that the real difficulty was that CHO staff stopped arriving at around 15:30hrs when they had expected to be drawing up until 17:00hrs.

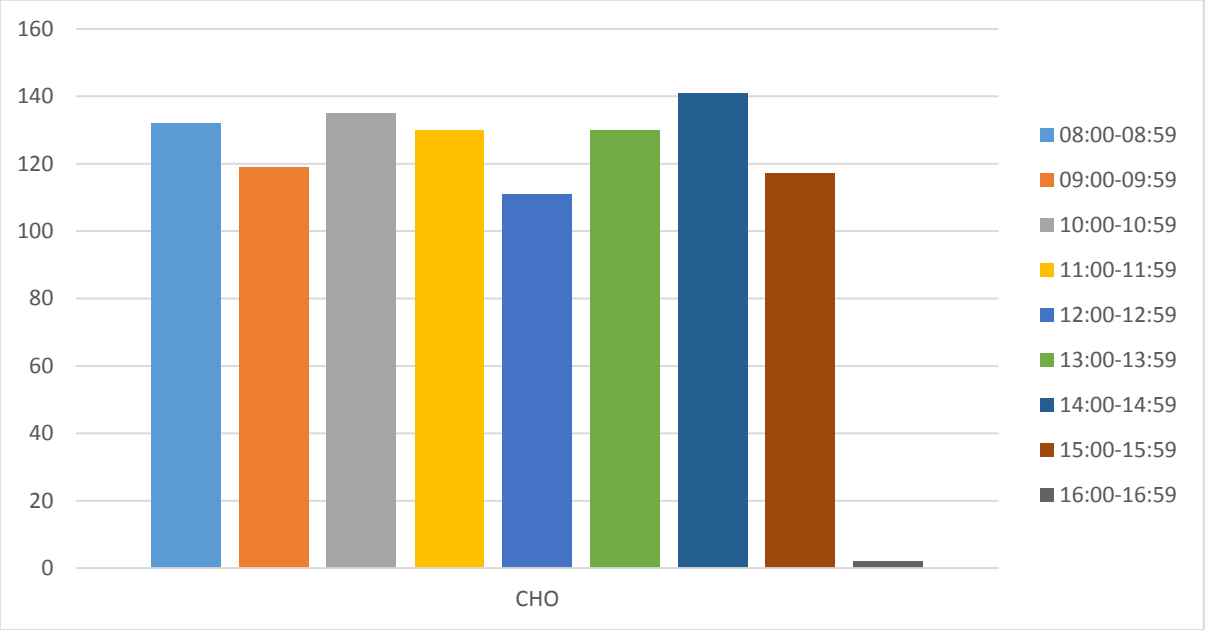


Chart 3

9.10 The total number of additional doses at the end of clinic appears to have been 52[11] as this was the number of people vaccinated identified on CoVax after 16:00hrs, who could not be reconciled with a CHO after the time the issue was identified.

9.11 The CNM3 on duty in the vaccination centre raised the issue with the Director of Clinical Operations, Quality and Patient Safety who had just arrived in the vaccination centre. It was agreed that given the number of excess vaccines which had to be used there was an urgent need to identify individuals to avail of these.

9.12 In meeting with Beacon Hospital staff, the Reviewer was advised that once a vial was pierced, due to issues relating to vaccine stability the doses needed to be used within a period of six hours in accordance with the manufacturer's instructions. The Reviewer was further advised in these meetings that once drawn into a syringe this six hour time period reduced to one hour. The Beacon Hospital therefore considered it was necessary to identify people who could attend within that timeframe as beyond an hour the vaccines would need to be disposed of.

9.13 The Reviewer was informed that the Director of Clinical Hospital Operations, Quality and Patient Safety that this situaton had never arisen before and any unvaccinated Beacon staff were identified for *'the majority of remaining vaccine doses drawn into syringes.'* The Director of Clinical Hospital Operations, Quality and Patient Safety proceeded to make a number of phone calls to the management team including to

[11] The Beacon Hospital identified this number as 62

the CEO who at that time was off site to apprise them of the situation relating to the 'left over' vaccines.

9.14 The CEO informed the Reviewer that he received a call from the Director of Clinical Hospital Operations, Quality and Patient Safety about the issue. The CEO advised the Reviewer that by the time he received the call '*all available Beacon staff had been exhausted*' and that BHVC had been told by the HSE that day not to give vaccine to oncology patients or other Category 4 patients (Aged 16-69 with medical conditions that put them at very high risk of disease). When asked by the Reviewer about the possibility of asking CHO 6 for staff to be vaccinated, the CEO responded to say that *'he had not considered that but that he was not involved in this element of the day-to-day clinics, rather he had been called by* [Director of Clinical Hospital Operations, Quality and Patient Safety] *when all options had been exhausted.'* When the CEO was asked about groups higher on the prioritisation list e.g. transport, food industry workers etc who could have availed of the vaccine, he agreed that there were a number of other options that could have been considered with the benefit of hindsight but in the moment, he thought the teachers were a viable option that could be used within the very short timeframe available.

9.15 The need for vaccines to be used in the following hour was emphasised in the phone-call with the CEO. It would also appear, from evidence subsequently provided by the Headmistress of the School, that the exact number of vaccines that would be 'left over' was not apparent at this time.

9.16 In response to the Draft Report the Beacon Hospital advised that they did vaccinate a considerable number of Category 2 people with left over doses prior to vaccinating the teachers. In addition, they do not believe that they could have found other suitable individuals from the groups referenced at such short notice and, in any event, all of the alternative groups suggested would also have been out of sequence. While the Reviewer accepts that the BHVC did seek to identify and vaccinate a considerable number of the Beacon Hospital's Category 2 staff and the alternative groups suggested would also have been out of sequence, nonetheless, those groups were all higher on the Sequencing List than the teachers.

9.17 The CEO informed the Reviewer that his thoughts then went to how to identify a group of people at short notice. As he felt it would not be practical to identify and call individuals within the short timeframe that he had understood to be available. He was familiar with the School and knew that they were running afterschool sports programmes. He also knew that the primary school was running these programmes until 17:00hrs and the secondary school until 18:00hrs. He was therefore confident that, if he contacted the Headmistress, that she could assist in identifying staff

members who would be able to avail of the vaccines. For legitimate family reasons the CEO had the Headmistress's mobile number and knew he could therefore contact her directly.

9.18 The Headmistress of the Primary School confirmed to the Reviewer that she received a phone call from the CEO at the Beacon Hospital at approximately 16:12hrs. She stated that this phone call was both unsolicited and unexpected. She outlined that the CEO had said the BHVC had run a clinic for HSE staff that day but that due to a scheduling error by the HSE, the Beacon Hospital now had five surplus vaccines that needed to be used by 18:00hrs which would otherwise be wasted. The Headmistress informed the Reviewer that the CEO had assured her that this was in line with the HSE's zero-wastage policy, he also stressed the urgency of the situation, and asked if they could get 5 staff to the Beacon Hospital by 18:00hrs.

9.19 The Headmistress of the Junior School apprised the Headmaster of the Secondary School of the situation.

9.20 At 16:18hrs the Headmistress received a text from the CEO confirming that there were now ten vaccines available.

9.21 At 16:22hrs a text received by the Headmistress from the CEO of the Beacon Hospital provided her with further assurance that the provision of the excess vaccines to the teachers was legitimate and above board and with the permission of the HSE.

9.22 Relying in good faith on the assurances from the CEO of the Beacon Hospital, their desire to ensure that vaccines would not go to waste, their belief that this afforded them with an opportunity to enhance the safety of the school community and that this was not being done at the expense of any other group, the Headmistress and Headmaster agreed to begin contacting staff.

9.23 At 17:00hrs the CEO phoned the Headmistress to confirm a further ten vaccines were available. The total number of vaccines was therefore by this time twenty. The Headmistress and Headmaster divided these equally between teachers in the primary and secondary school i.e. ten for each school.

9.24 The twenty teachers for vaccination were mobilised and their names provided via three texts from the Headmistress of the Junior School to the CEO of the Beacon Hospital. The teachers were advised to bring their PPS numbers to the Beacon Hospital Vaccination centre for registration purposes.

9.25 At 17:15hrs the first of the teachers arrived at the BHVC.

9.26 On arrival at the Beacon Hospital Vaccination centre the teachers attending were asked by the reception staff on duty if they were staff from St Gerard's.

9.27 As they arrived each of the teachers attending was registered on the CoVax system. CoVax shows that they were registered as healthcare workers with the Beacon Hospital noted as their Primary Healthcare Facility. Following registration, they were vaccinated per the normal process.

9.28 At 18:00hrs the last teacher to receive a vaccination was registered on CoVax.

10. Discussion

10.1 It was evident that there was significant effort required to plan, schedule, and run vaccination clinics. This required a high degree of teamwork within the BHVC and CHOs and cooperation between the BHVC and the CHOs. As CHO 7 came on stream first, by the 23rd March, the processes in place with the BHVC were well established with the processes between the BHVC and CHO 6 at a relatively early stage at that time.

10.2 As previously stated, the operating model which was ultimately deployed was a predictive one. The predictions were based on past patterns of attendance and the assumption being that clinics would continue to run in a predictable manner and that any excess vaccine available at the end of a clinic could be used to vaccinate Beacon Hospital staff awaiting vaccination.

10.3 In response to the Draft Report, whilst the Beacon Hospital confirmed to the Reviewer that the BHVC operated a predictive model for preparation of vaccines, they however advised that an adaptive model was used for the day to day operation of the clinic. The significant amount of doses of vaccine remaining at the end of the clinic on the 23rd March does not however support the use of an adaptive model.

10.4 The Reviewer was advised both in written submissions provided by the Beacon Hospital and in meetings with Beacon Hospital staff that the clinic on the 23rd March was extraordinary with the DNA numbers being unprecedented, resulting in a large number of excess vaccines being available at the end of day.

10.5 The Beacon cites a number of matters which led up to this including.

1. *The cancellation of the planned clinic by HSE on the 16th March due to the suspension of AstraZeneca, leading to an unknown effect of clinic attendance. When the clinic was rescheduled for the 23rd March, this was the first clinic after the suspension.*

2. *The short lead into the clinic, meaning that preparation time for scheduling was tight. The resumption of AstraZeneca was announced late on Friday 19th March, allowing only Monday 22nd March as the only working day to schedule the attendees.*

3. *The non-confirmation of 400 staff by CHO 6, whilst still including those 400 in the schedule for vaccination in various timeslots during the day. No effort was made by CHO 6 to identify who those 400 unconfirmed staff were, so it was not possible to track their attendance or non-attendance during the day of clinic.*

4. *The late communication of the vaccination list by CHO 6, which was sent at 2:45pm [14:45hrs] on the 22nd March, three hours past the agreed deadline. This coupled with the message that only 60% of the list had confirmed their attendance at that point was wholly inadequate for good planning and preparation.*

5. *Attendees for vaccination received texts scheduling them both for Beacon Hospital, and Aviva Stadium on the same day. This was made known to Beacon Hospital late on the 22nd March where we had to put extra staff on the switchboard to cope with the extraordinary number of enquiries that were incoming. Beacon Switchboard advised those enquiring to come to Beacon Hospital. Subsequently, we learned from attendees on the day that they were advised by the HSE to go to whichever clinic they preferred. HSE did not inform us of this decision and it is difficult to understand how that decision could have done any other than create further confusion and difficulty.*

6. *Whilst the clinic on 23rd March was busy, the dynamics of the clinic were normal until late afternoon when the attendances suddenly stopped. Whilst Beacon Vaccination Clinic acknowledges in hindsight that communication between the Clinic staff could have been clearer and we didn't contact CHO6, there is no doubt that the sudden drop off in attendees was unusual and the number of late attenders was much lower than previously experienced.*

10.6 In a response to a query as to whether the clinic on the 23rd represented a busy day the Beacon Hospital responded that:

'… whilst it was indeed a 'busy day' it was not unusual. On the 13th of March we had in fact run a clinic for 1364 attendees. Previous experience had thought us that the DNA rate was between 8-10% and we were prepared for the number scheduled to attend but not for unprecedented nature of the clinic on the 23rd of March. If the DNA rate on 23rd March had been normal and had the HSE not double booked, the issue of trying to identify sufficient numbers of people at short notice and ensure no wastage would have not arisen.

The DNA rate on the 23rd of March was in excess of 20%. It is the opinion of Beacon that this was the key contributing factor and the reason for the excess vaccine doses at the end of the clinic day.'

10.7 There was no doubt that this clinic was indeed different from the other clinics run previously for many of the reasons cited above. The assertion however that the DNA rate was the key contributory factor is however worth further consideration.

10.8 The Beacon Hospital had calculated the DNA rate for the 23rd March on the basis of the number of clinic slots made available to the CHO Areas on that day i.e. 1368. If indeed the DNA rate is calculated according to this figure, the attendance on the day would have resulted in a DNA rate of 24.4% i.e. in excess of 20%. In planning for any event, the capacity of the venue dictates the number of invitations that can be issued. However, it is not the number of invitations issued that dictates the arrangements on the day; rather it is the number of people who confirmed their acceptance of the invitation. The Reviewer would therefore assert that the DNA rate is more accurately calculated on the basis of the number of persons who confirm their intention to attend compared with the number who actually attend, irrespective of the number of clinic slots that had been made available.

10.9 If the calculation was made on this basis, by 14:45hrs on the 22nd March there were 910 confirmed attendees (310 from CHO 7 and 600 from CHO 6), albeit that there was an indication given that due to the short notice given to staff and the manner in which they had been notified i.e. by text instead of a phone call, that more may attend. Taking the 910 confirmed attendances as the basis for calculation of DNAs and considering the numbers that did attend on the day i.e. 1034 it could be argued that rather than have a DNA rate of 24.4% as identified by the BHVC on the day, that the attendance was in fact 13.6% higher than had been confirmed which means that a greater number had attended the clinic than had been confirmed to attend. That being said the Reviewer would agree that on the day there was a higher degree of uncertainty about numbers that would attend than previous clinics and that this would have increased risk for the predictive model in place for managing clinics at the Beacon Hospital.

10.10 Another issue worth considering at this point is the assertion that the *'dynamics of the clinic were normal until late afternoon when the attendances suddenly stopped'.* Beacon staff stated that they were unprepared for the sudden drop off in attendance when it was identified that there was no queue for registration at 15:45hrs.

10.11 As was seen in Chart 3 the attendances were consistently high all day until 16:00hrs when the attendances virtually stopped. In analysing the appointment slots offered to the CHOs on the 23rd March by the BHVC, the Reviewer notes that CHO 7 was offered slots between 08:00hrs and 10:00hrs with CHO 6 being offered slots between 10:00hrs and 16:00hrs. The clinic was therefore scheduled to finish at 16:00hrs and not 17:00hrs. BHVC indicated to the Reviewer that the drop off in attendances [after 16:00hrs] was sudden and unexpected and that this was the key reason given as to why the BHVC was left with an unprecedented amount of 'left over' vaccine.

10.12 The Reviewer was not provided with any information or documentation confirming that appointment slots had been allocated for any time after 16:00hrs. In addition, CHO 6 provided the Reviewer with their end of clinic report that they received from the BHVC, which confirms that the clinic was in fact due to end at 16:00hrs on that day and this would therefore explain the reason for the sudden drop off in attendances after that time.

10.13 The Reviewer was also advised during the course of the Review that in order to maximise throughput at the BHVC, doses of the vaccine were drawn *'out of vials (for the next slot of scheduled people) and given to each booth'*. This was also done *'so CHO staff would not need to wait for doses to be drawn. They had therefore prepared for staff to arrive for their allocated time slots.'*

10.14 The practice of pre-preparing the doses was confirmed to the Reviewer by a number of persons interviewed. The Reviewer was informed that one of the reasons that the clinics ran efficiently was due to having the vaccine prepared in line with the predicted flow pattern. The Lead Pharmacist described this preparation as *'…. keeping a couple of trays ahead of vaccinators in order to ensure smooth flow.'*

10.15 The Lead Pharmacist also explained that on the 23rd March, she first became aware of an issue when, at approximately 15:45hrs, *'she popped her head out of the preparation (vaccine) room and noticed a reduced activity'* in the clinic and immediately raised her concerns to the CNM3 on duty in the BHVC. The Lead Pharmacist said that *'…the real difficulty was that CHO staff stopped arriving at around 3.30pm [15:30hrs] when they had expected to be drawing up until 5pm [17:00hrs].'*

10.16 On the basis of the information provided it is the opinion of the Reviewer that the BHVC was left with an unprecedented amount of pre-prepared left over vaccine drawn up in syringes on the 23rd March because doses were being prepared in advance for the next slot of scheduled people and the Pharmacy had expected to be preparing the doses in this way until 17:00hrs, when the clinic in fact ended at 16:00hrs.

10.17 The next issue to consider is how the BHVC responded to this situation. When the excess vaccine was identified the Beacon Hospital moved rapidly to identify people 'in house' for vaccination in order to minimise the risk of waste. This is in line with HSE guidance. However, the Reviewer was informed that that there was urgency to the decision making due to issues relating to vaccine instability and when drawn up into a syringe the vaccine was required to be administered within one hour. The Beacon Hospital advised the Reviewer that some of their vaccinators reported AZ vaccine doses drawn changed colour and appeared more viscous in the syringe post 60 minutes. It

was asserted that this timeframe influenced decision making in relation to identifying recipients.

10.18 The relevant HSE Clinical Guidance and Beacon Hospital Policy in place at the time of the event identify that after first opening a multi-dose vial, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at room temperature (of up to +30°C). The product should not be returned to the refrigerator after this time. It goes on to outline that doses should not be drawn up in advance as per the manufacturer's instructions and that 'There is no information on the stability of vaccine in pre-prepared syringes.' As a result, the guideline identifies that vaccine dose preparation should be carried out at the point of administration i.e. beside the person to be vaccinated and that each dose should be drawn up and immediately administered to the patient.

10.19 If the vaccines had been drawn up in line with manufacturer's directions i.e. that they remained in the vial until administration, then it is the Reviewer's opinion that the perceived urgency to use them within an hour would not have been as great.

10.20 Since the first of the teachers attending was registered on CoVax at 17:15hrs with the last of the twenty being registered at 18:00hrs if the assertion about vaccine stability of one hour in-syringe was valid none of the 20 vaccines should have been administered to the teachers as they were, by the time the teachers had arrived, beyond the timeframe of one hour from being drawn up.

10.21 The next issue to consider is who should have been offered the excess vaccines in the absence of there being sufficient recipients identified within the Beacon Hospital staff?

10.22 The guideline issued by the OCCO in the HSE on the 19th January set out detail of the provisional vaccine allocation groups. This guideline identifies fifteen allocation groups in order of priority. Primary and secondary school staff were identified in allocation group eleven. The issue of whether the excess vaccines had been offered to the teachers out of sequence is therefore relevant to this review.

10.23 The Beacon Hospital in their engagement with the Reviewer justified the selection of the teachers on the basis that they were a distinct group that they felt could be mobilised quickly and within the timeframe of dictated by the stability of the vaccine in syringe. This was considered by the Beacon Hospital as one hour despite there being no evidence to support this.

10.24 The choice of the School was considered feasible because, for legitimate family reasons, the CEO had the mobile phone number of the Headmistress of the School. The

Beacon Hospital asserted that this was a preferable option on the basis that they could access a group of potential recipients via one phone call rather than having to identify and contact potential recipients on an individual basis. Whilst this was valid from the perspective of the Beacon Hospital, the need to contact twenty individuals was still an issue albeit it was a task that now fell to the School. The School in accepting the offer did so in good faith and on the basis of assurances received from the CEO i.e. that was legitimate and above board and with the permission of the HSE. The Reviewer sought evidence from the Beacon Hospital and HSE staff whom she met with, in relation to whom in the HSE had provided permission but was unable to ascertain any.

10.25 When asked if consideration had been given to groups higher on the allocation list than the teachers, the Beacon Hospital confirmed that such consideration had not been given. As previously stated, the focus of the Beacon Hospital at the time was on identifying and mobilising a group quickly and to have them attend within an hour and so avoid vaccine wastage.

10.26 The Reviewer has considered a range of alternative persons or groups that might have been considered viable in the context both of the location of the Beacon Hospital and the time of the day at which the issue was identified. The Reviewer is of the view that there were a number of other options available that could have been considered before the teachers taking into account the sequencing guideline in place.

10.27 Unlike CityWest VC, the BHVC did not have access to the HSE registration portal, so the most obvious option would then have been to call CHO 6, who were at an earlier stage in their vaccination programme, and request that they send staff from the master list that they had held. CHO 6 confirmed to the Reviewer that if contacted at that time on the 23rd March they could have sent staff to the BHVC within the timeframe suggested. In response to the Draft Report, the Beacon Hospital advised the Reviewer based on their experience, CHO 6 in their view would not have be able to respond to a request for staff at such short notice in a time-pressured situation. In the opinion of the Reviewer, this is not a correct assertion; the identification of excess vaccine took place within 'office hours' which meant that a sufficient number of Category 2 or Category 4 staff would have been available to fill the 20 slots. In addition, given that CHO 6 was able to book in 600 of its staff at short notice for the purposes of the re-scheduled clinic on the 23rd March, it is reasonable to conclude that they would have been able to 'pull staff from their listing' to fill the 20 slots.

10.28 In the absence of CHO 6 being considered, other alternatives included those living or working in crowded conditions where social distancing was difficult to maintain (allocation group 9) or key workers in the food supply system, public and commercial transport and other vital services (allocation group 10). Where the Beacon Hospital is

located there are a number of retail outlets within the hospital complex itself and both the Beacon South Quarter and Sandyford Industrial Estate are proximal. There is also a large Garda station less than 3km away which may also have represented a viable option at that time of day.

10.29 The Reviewer is therefore of the opinion that, had the Beacon Hospital considered the allocation of these vaccines to groups higher on the sequencing list, that this would have been feasible.

10.30 The Beacon Hospital responded to the Draft Report advising that they do not believe they could have found other suitable individuals at such short notice and in their view, all of the alternative groups suggested would have been out of sequence. In addition, the CEO acknowledged during interview that in the limited timeframe available, he did not consider other categories of workers for vaccination. However, he was aware that teachers, admin personnel and facilities staff from two schools had been vaccinated in the clinics held for CHOs in the BHVC on 23rd of March and that this goes to the CEO's thought process at the time. The Reviewer has ascertained that the two schools referred to by the Beacon Hospital are both organisations in receipt of HSE funding which provide a range of services to children with intellectual disabilities. These organisations operate on a social care model rather than a medical model, so a wide range of supports including educational supports are provided to these children. In line with the National Standards for Children with Disabilities, a focus is placed on maximising personal development and quality of life. COVID-19 placed significant constraints on the achievement of these outcomes with many intellectually disabled persons losing access to key supports. When the vaccination programme commenced, there was significant concern placed by professionals and intellectual disability groups that these vulnerable service users – many with underlying health conditions- would regain access to a normal level of service. It is therefore the opinion of the Reviewer that the comparison drawn between teachers from a private school with teachers, administration personnel and facility staff of organisations providing supports to the service users with intellectual disabilities is not a valid comparison.

10.31 Finally, the Reviewer was aware that in addition to the vaccination of the teachers on the 23rd of March that there were also reports in the public domain relating to the vaccination of a number of persons at the BHVC who were not employees of the Beacon Hospital. Whereas such instances are not the main focus of this review, the terms of reference did refer to 'identifying if there were any breaches of the HSE Guidance in relation to sequencing'. The Reviewer therefore sought assurance from the Beacon Hospital, whether apart from these cases, there were any other instances where the sequencing guidelines were breached by the Hospital. The Reviewer was assured that there were not any. The Beacon Hospital at the outset of the vaccination

programme had identified 1870 staff requiring vaccination and by the 23rd March CoVax showed that 1651 staff were registered as vaccinated, with the Beacon Hospital identified as their primary healthcare facility.

11. Conclusion

11.1 The BHVC came on stream at a critical point in the national vaccination programme. It contributed significantly to the vaccination of non-acute healthcare staff at a time when it was critical for these staff to maintain or restore the delivery of services to vulnerable groups.

11.2 The vaccination model employed however had two main weaknesses which became evident due to the nature of the clinic on the 23rd March 2021. The first of these was that the model relied on a predictable flow of persons to be vaccinated. The second was that vaccine doses were drawn into syringes in advance of persons attending for vaccination, based on attendance predications and contrary to the HSE's Clinical Guidance for COVID-19 Vaccination, the Beacon Hospital's own COVID-19 Vaccine Receipt, Supply and Reconstitution Policy.

11.3 When faced with the situation of having excess vaccine on hand they sought to utilise this by identifying all available unvaccinated staff within the Beacon Hospital. Despite having exhausted all unvaccinated staff available and citing vaccine stability issues, they moved to avoid vaccine waste by mobilising a group of people that they considered offered a viable solution. This was done without considering alternative persons or groups higher on the vaccine allocation groupings.

11.4 There is no evidence that the School had solicited the BHVC for vaccines prior to being offered the vaccines on the 23rd March. The Reviewer is therefore satisfied that on the 23rd March the School acted in good faith and on the assurances received from the CEO of the Beacon Hospital, that the offer of the vaccines was entirely legitimate, above board and with the permission of the HSE.

Appendix 1

Terms of Reference

HSE Review of Vaccination Programme at the Beacon Hospital

2nd April 2021

1.0 Introduction & Purpose

1.1 The HSE has commissioned an external Review of the COVID-19 Vaccination Programme at the Beacon Hospital following the report on Friday 26th March 2021 that individuals received vaccination outside of the national sequencing guidelines. This document sets out the Terms of Reference for the Review.

1.2 The purpose of this Review is to establish the facts in relation to this report. It will examine the vaccination process in the Beacon Hospital, to identify if there were any breaches of the HSE guidance in relation to sequencing and to establish if there are any opportunities for learning which can be implemented to improve the vaccination process.

2.0 Scope & Objectives

2.1 Scope:

The Review will examine the operation of COVID-19 Vaccination Programme at the Beacon Hospital from commencement as it relates to the sequencing and prioritisation of those to be vaccinated based on the guidance issued by the HSE in relation to the COVID-19 Vaccination Programme. This includes the sequencing and prioritisation guidelines and the guidance in relation to medication management and the creation of standby lists.

2.2 Objectives:

The objectives of the Review are to:

- Review the planning, scheduling and management of daily vaccination, inclusive of medication management
- Review all documentation of vaccine ordered, received and administered by the hospital, and ensure records are in compliance with the national guidelines
- Determine to what extent the national guidelines were followed and what if any deviations from guidelines occurred
- If deviations from the guidelines did occur, the review will seek to determine, how the decisions were made. These will focus in particular on;

    - Establishing if standby lists were created in line with guidance.
    - Determining if appropriate standby lists were utilised and adhered to.
    - Establishing if additional vaccine capacity resulted at the Beacon Hospital, when was it discovered and what actions were taken, how were people for vaccination identified out of sequence, and what rationale was used to provide vaccines to these people.
    - Establishing how these vaccine recipients were chosen and contacted by the Beacon Hospital.
    - Establishing who was the decision maker/s;
    - Establishing how their data was collected by or shared with the Beacon Hospital;

- Make recommendations on any learning that may apply to the wider vaccination programme.

3.0 Confidentiality

3.1 All meetings and interviews shall take place on a confidential basis.

3.2 All parties who participate in the Review process will be required to co-operate with the process and maintain the confidentiality of the process particularly with respect the privacy of any other parties involved.

3.3 While every effort will be made to maintain the confidentiality of all participants, it may not be possible to guarantee the anonymity of any person participating in the review.

4.0 Review Process

4.1 The Review will follow the 'fair procedures' process set out in the HSE's incident management framework 2020.

4.2 The Reviewer will review relevant guidelines in place at the relevant time regarding the COVID-19 vaccination process and the correspondence issued between the HSE and the Beacon Hospital.

4.3 The Reviewer will make enquiries, seek and be provided with relevant documentation, records and correspondence in relation to the COVID-19 Vaccination Programme, particularly as it pertains to the Beacon Hospital.

4.4 The Reviewer shall interview personnel associated with the vaccination programme, deemed relevant by the Reviewer.

4.5 All interviewees will have the right to be accompanied by a work colleague or trade union representative.

4.6 Subject to section 3 above, all interviews shall take place on a confidential basis. A copy of the interview notes will be provided to the interviewee for factual accuracy checking after the interview.

4.7 Follow up interviews may be required to clarify information or to respond to new information that may become available during the course of the Review.

5.0 Report

5.1 Following the completion of the Review process, the Reviewer will prepare a report setting out a chronology of events, describing the Review process followed, a summary of information gathered, the findings of fact and recommendations in relation to the COVID-19 Vaccination Programme.

5.2 The Reviewer will then provide the Commissioner with the final report.

6.0 Timeframe

6.1 The Reviewer will complete the review within six weeks from the commencement of the Review.

6.2 The Reviewer will provide regular updates of their progress to the Commissioner and notify him if any issues arise over the course of the Review e.g. unanticipated delays.

6.3 If additional time is required, an extension will be sought from the Commissioner.

7.0 Issues that need to be escalated during the review

If during the course of the Review, the Reviewer identifies any critical or urgent issues or risks, these will be brought to the immediate attention of the Review Commissioner.

8.0 Commissioner

The Minister for Health has asked the HSE to undertake the review. Damien McCallion is the commissioner in the HSE.

9.0 Support

Administrative support will be provided to the Reviewer. Any specialist expertise as deemed relevant will made available to the reviewer.

Appendix 2

Table 1. Provisional Vaccine Allocation Groups

Group	Rationale	Ethical Principles
Adults aged ≥65 years who are residents of long-term care facilities. Consider offering vaccination to all residents and staffon site.	At greatest risk of severe illness and death. In Ireland, in the first wave of COVID-19, 56% of deaths occurred in this setting.	In line with the principle of minimising harm, vaccination of this group would protect those at greatest risk of a poor outcome from infection. It adheres to the principle of moral equality and the principle of fairness in recognising the disproportionate burden this group has carried.
Frontline healthcare workers (HCWs)* in direct patient contact roles (including vaccinators) or whorisk exposure to bodily fluids or aerosols.	At very high or high risk of exposure and/or transmission. In the first wave over 30% cases werein healthcare workers.	The principle of minimising harm is realised, as benefit will accrue to healthcare workers and the patients they care for, producing a multiplier effect. Society also has a reciprocity-based duty to protect those who bear additional risks to safeguard the welfare of others.
Aged 70 and older in the following order: 85 and older 80-84 75-79 70-74	At higher risk of hospitalisationand death.	The principle of minimising harm, moral equality and fairness are relevant as this group are at greater risk of carrying disproportionate burdens from the pandemic.
Other HCWs not in direct patientcontact.	Provide essential health services, protect patients.	Maintenance of healthcare services, minimises harm by preventing injury, illness and death from causes other than COVID, and the principle of reciprocity is upheld.
Aged 65-69. Prioritise those with medical conditions** which put them at high risk of severe disease.	At higher risk of hospitalisationand death.	By protecting those at greatest risk of poor outcomes from the disease the principle of minimising harm is upheld.

Key workers (to be further refined).	Providing services essential to the vaccination programme (e.g. logistical support)	Upholds principle of minimising harm by protecting the continuing functioning of essential services. The principle of reciprocity is upheld.
Aged 18-64 years with medical conditions** which put them athigh risk of severe disease.	At higher risk of hospitalisation.	By protecting those at greatest risk of poor outcomes from the disease the principle of minimising harm is upheld.
Residents of long-term care facilities aged 18-64	High risk of transmission.	The principles of moral equality and fairness are applicable, given the higher risk of exposure to infection and the potential vulnerability of some who may not be able to adequately protect their own interests.
Aged 18-64 years living working in crowded accommodation where self-isolation and social distancing is difficult to maintain.	Disadvantaged sociodemographic groups more likely to experience a higher burden of infection.	The principles of moral equality, minimising harm (especially in the context of multi-generational households) and fairness are relevant. Prioritising this group recognises that structural inequalities make some people more vulnerable than others to COVID-19
Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19. They include workers in the food supply system, public and commercial transport and other vital services	High risk of exposure as unable to work without physical distancing.	The principle of minimising harm is upheldby reducing societal and economic disruption and the principle of reciprocityrecognises the additional risk these groups bear in order to provide essential services
Those who are essential to education and who face disease exposure - primary and second levelschool staff, special needs assistants, childcare workers, maintenance workers, school bus drivers etc.	To maintain the opening of full-time education of all children who have been disproportionately impacted from the pandemic.	Maintaining children's educational and social development and facilitating parents' employment adheres to the principle of minimising harm. The principle of reciprocity is also relevant given the potential additional risk being borne by such groups.

Aged 55-64 years.	Based on risk of hospitalisation.	The principles of moral equality, minimising harm and fairness apply.
Those in occupations important to the functioning of society, e.g., third level institutions, entertainment and goods-producing industries who work in settings where protective measures can be followed without much difficulty.	Moderate risk of exposure.	The principle of minimising harm is upheld as protecting workers needed to maintain critical infrastructure and other important services will enable social and economic activity. The principle of fairness and moral equality also apply.
Aged 18-54 years who did not have access to the vaccine in prior phases.	If evidence demonstrates the vaccine(s) prevent transmission, those aged 18-34 should be prioritised due to their increased level of social contact and role in transmission.	The principle of minimising harm is relevant should it become clear that a vaccine can impact on transmission of the virus as this would indirectly protect the most vulnerable in society as well as restore social and economic activity.
Children, adolescents up to 18 yearsand pregnant women (to be refined).	If evidence demonstrates safetyand efficacy.	The principles of moral equality, minimising harm (if vaccines are shown to be safe and effective in these groups) and fairness

*Includes health care workers who work in and out of all healthcare settings

**Chronic heart disease, including hypertension with cardiac involvement; chronic respiratory disease, including asthma requiring continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission; Type 1 and 2 diabetes; chronic neurological disease; chronic kidney disease; bodymass index $\geq$40; immunosuppression due to disease or treatment; chronic liver disease.

Appendix 3

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

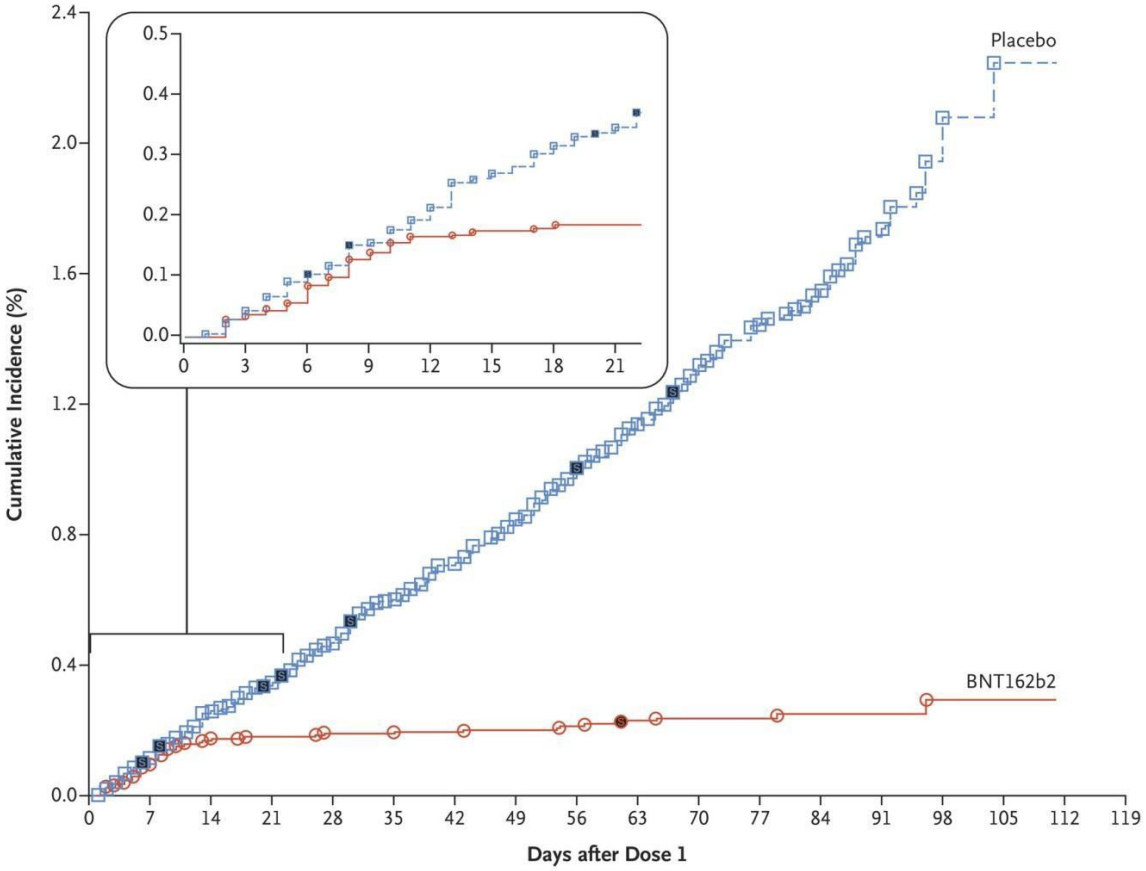
Context

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/community-register/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



Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669)		Placebo (N=21,686)		VE (95% CI)
	No. of participants	Surveillance time *person-yr (no. at risk)*	No. of participants	Surveillance time *person-yr (no. at risk)*	*percent*
Covid-19 occurrence					
After dose 1	50	4.015 (21,314)	275	3.982 (21,258)	82.0 (75.6–86.9)
After dose 1 to before dose 2	39		82		52.4 (29.5–68.4)
Dose 2 to 7 days after dose 2	2		21		90.5 (61.0–98.9)
≥7 Days after dose 2	9		172		94.8 (89.8–97.6)

"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 https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/

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

Appendix 4

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

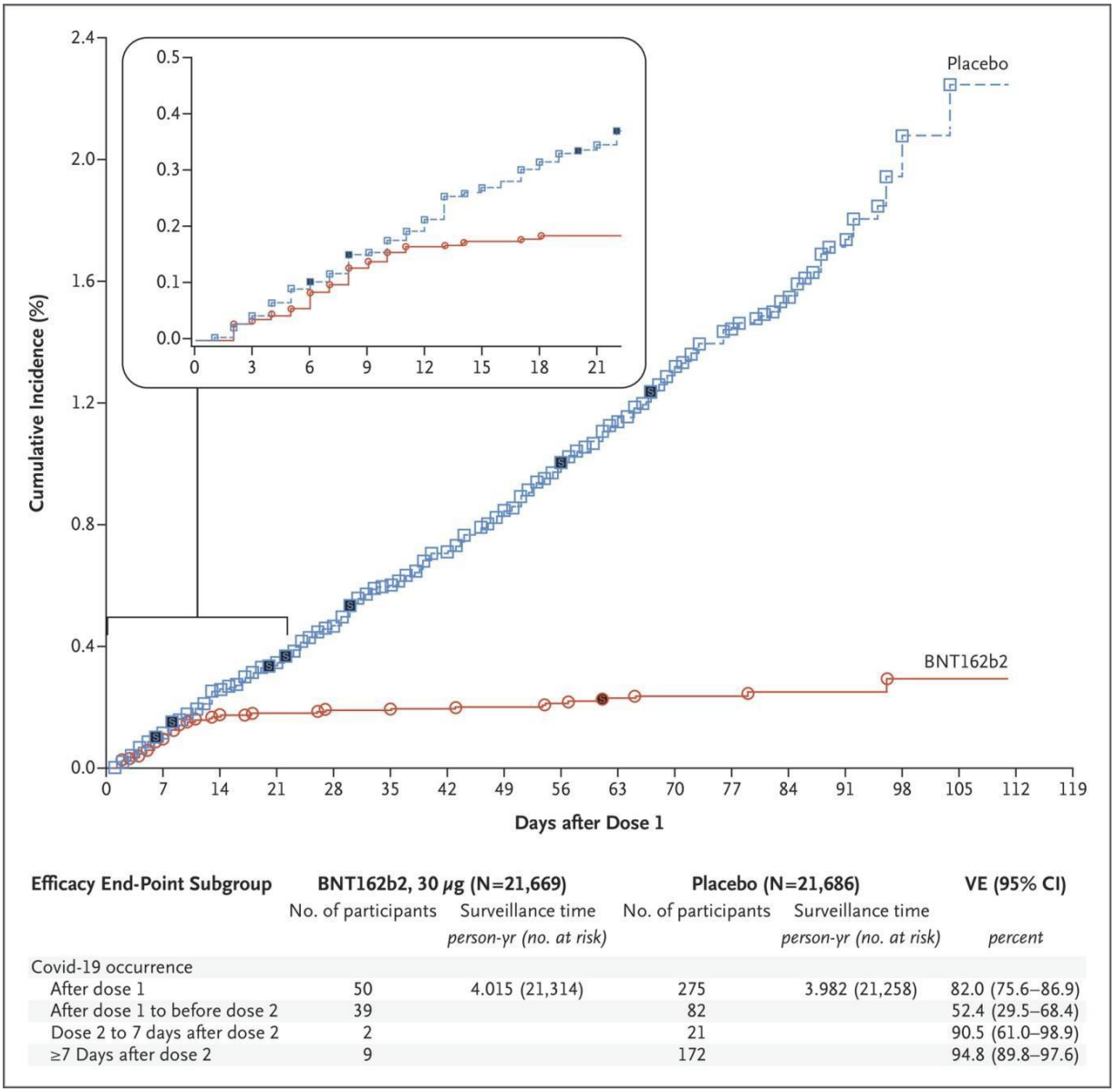
There is sound scientific evidence that COVID-19 vaccines available for use in Ireland are safe and effective in protecting people against infection with COVID-19. Vaccination is based on administration of "*two doses of the vaccine at a specified interval*" as the evidence for efficacy is based on this 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/community-register/2020/20201221150522/anx_150522_en.pdf

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-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



Efficacy End-Point Subgroup	BNT162b2, 30 μg (N=21,669)		Placebo (N=21,686)		VE (95% CI)
	No. of participants	Surveillance time *person-yr (no. at risk)*	No. of participants	Surveillance time *person-yr (no. at risk)*	*percent*
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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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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 ona 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

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

Appendix 5

GUIDELINES FOR SEQUENCING AND REGISTRATION PROCESS FOR HCW COVID VACCINATION

FEBRUARY 5TH 2021

1. Guidelines for Sequencing for Healthcare Worker Vaccination

1.1 Introduction

This sequencing process applies to HCW who have not yet had a first dose of COVID-19 vaccine and are included in the Provisional Vaccine Allocation Groups 2 & 4, as outlined on page 9 of the 'National COVID-19 Vaccination Programme: Implementation Plan' . https://www.gov.ie/en/publication/bf337-COVID-19-vaccination-strategy-and-implementation-plan/, and who work in the following:

A. HSE or HSE-funded organisations

B. Private hospitals/Clinics

C. Community based not-for-profit and private healthcare providers not directly funded by the HSE

Sequencing should not be based on where people work (community or acute hospital), who they work for (public sector, voluntary or private sector), and category of worker or grade. Instead sequencing is based on the type of work and the setting in which HCW work and maintaining a safe level of health and social care services.

HCWs from all staff groupings who work in the units, wards or services, community settings day, residential and respite services, all the time, or who attend occasionally must be included. Examples of these are support staff, agency staff, students, administration staff, volunteers and other healthcare professionals (physiotherapists, PHN's, speech and language therapists, home support workers, radiologists, pharmacists, etc.)

Healthcare Workers who usually work in these roles but who are currently out of work due to, for example, sick leave, high or higher risk medical status, maternity leave etc. must be included for vaccination in the relevant groups/cohorts.

1.2. Sequencing of Healthcare Workers Priority Groups

Examples are given for each subgroup, but these are non-exhaustive.

Provisional Vaccine Allocation Group 2

2 (a) Healthcare workers who are working in a congregated care setting (unit/ward/service) in contact with a known or suspected COVID 19 patient/service user where there is potential for active transmission of COVID-19. These are patient/service user facing HCWs in units, wards or services:

- with known or suspected COVID-19 patients/service user in an inpatient clinical setting.
- with current COVID-19 outbreaks.
- 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;
- who work in COVID-19 swabbing centres with patient/service user contact.
- dealing with end of life care for the care of COVID patients/service users in an acute or home settings
- COVID-19 Vaccinators
    - Paramedics and others who respond to emergency calls to deliver healthcare to non-triaged individuals in non-healthcare settings.

2 (b) Healthcare workers who deal with unscheduled care patients/service user on a regular basis in an uncontrolled environment

- First Responders in the community.
- HCWs working in Emergency Child Protection services

2 (c) Healthcare workers who deal with unscheduled care patients/service users in a semi-controlled environment on a regular basis. These are HCWs who mainly see patients/service users by appointment but who may from time to time need to see urgent unscheduled patients/service users

- Urgent care facility clinical staff.
- GP practice staff - GPs/Practice Nurses
- Dentists and dental nurses providing urgent dental care.

Some public health nurse providing urgent unscheduled care

2 (d) Healthcare workers who deal with unscheduled care patients in a controlled environment on a regular basis

- Patient facing staff who work in in-patient/residential care areas that provide care for unscheduled care /service users and community settings providing walk in access for patients/service users. For example walk-in community services, Addiction services, homeless service, walk-in mental health facilities.

2 (e) Healthcare workers who deal with scheduled care patients in an uncontrolled environment on a regular basis where there is no known COVID- diagnosis

- Delivery of care by appointment in a patient/service user's home, for example home support, community delivered services, public health services and social care services, non-emergency patient/service user transport, residential and respite services,

2 (f) Healthcare workers who deal with scheduled care patients/service users in a controlled setting on a regular basis where there is no known COVID diagnosis

- Delivery of scheduled care by appointment in a clinic, outpatient clinic or hospital
- Provision of such therapies as physiotherapy, occupational therapy, podiatry
- Provision of face to face appointments, for example Occupational Health, Psychiatry, , Counselling/Therapy services .

2(g) All other healthcare workers without direct patient care but working in a healthcare facility with the potential to meet patients/service users, who are not captured in 2a – 2f

- Examples are Laboratory staff, pharmacists, catering, household staff, general support staff, ICT, maintenance staff.
- Statutory/Regulatory workers e.g. HIQA inspectors, EHOs and others
- Critical management posts particularly on COVID response teams who provide on-going daily support to multiple locations.

Provisional Vaccine Allocation Groups 4

All other healthcare workers, not in direct patient/service user contact, but who provide essential health services, for example, management, administration and other non-patient/service user facing personnel.

1.3 Instructions for Registration

1.31 Log into the portal by clicking on https://www.hse.ie/hcwvaccine/

1.32 Enter all your details including relevant sequencing group (2a-2f), based on the aboveguidelines. Questions or queries on this should be addressed to line management

1.33 An appointment will be sent to each HCW to attend a vaccination clinic

1.34 There will be a requirement to present for vaccination with photo ID and acceptable credentials (Workplace photo ID, Letter from employer, Certificate of current registrationstatus with relevant Irish Regulatory Body)

1.35 Credentials can be checked prior to entry to vaccine clinic

DO NOT ATTEND THE VACCINE CLINICS IF YOU ARE SYMPTOMATIC OR IF YOU HAVE BEENADVISED TO SELF ISOLATE OR RESTRICT YOUR MOVEMENTS, a later appointment will be sent to you, to accommodate this

Appendix 6

4.3 COVID-19 Vaccine AstraZeneca®

Title	Description
Type of vaccine	Replication deficient adenovirus vector*
Name of vaccine	COVID-19 Vaccine AstraZeneca
Constituents	One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S*recombinant) 5 × 1010 viral particles (vp) Produced in genetically modified human embryonic kidney (HEK) 293 cells.** The product contains genetically modified organisms (GMOs)*** L-Histidine 9 L-Histidine hydrochloride monohydrate Magnesium chloride hexahydrate Polysorbate 80 Ethanol Sucrose Sodium chloride Disodium edetate dihydrate Water for injections COVID-19 Vaccine AstraZeneca does not contain egg None of the vaccine ingredients are of human or animal origin
Presentation	Multidose clear glass vial
Number of doses in each vial	Up to 11 doses per vial
Dilution	NO DILUTION REQUIRED
Latex	The multidose dose vial has a halobutyl rubber stopper and an aluminium overseal with a plastic flip-off cap. Halobutyl rubber is a synthetic rubber. There is no latex in the vial or stopper
Preservatives	The vaccine does not contain any preservative. Standard aseptic technique should be used for withdrawing the dose for administration.
Dosage	0.5 mls
Number of doses required	2
Interval between doses	**Age under 65 years: 12 weeks** (The National immunisation Advisory Committee recommends an interval of 4-12 weeks) **Age 65 to 69 years: 6 weeks** (The National immunisation Advisory Committee recommends an interval of 4-6 weeks) **[NOTE people aged 70 years and older should be offered an mRNA vaccine]**

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.

**Please refer to FAQ section 12.21

***COVID-19 Vaccine AstraZeneca contains a genetically modified adenovirus. Two genetic alterations have been made in order to make the vaccine:
- Genes essential for adenovirus replication have been deleted.
- The coronavirus (SARS-CoV-2) spike protein gene has been added.

The result is a genetically modified organism (GMO) with a new combination of genetic material. These changes to the adenovirus allow the vaccine to deliver the spike protein genetic code to the cells without causing COVID-19.

COVID-19 Vaccine AstraZeneca® efficacy

The EMA licensed documentation states that pooled analysis of the randomised Phase 2/3 trials demonstrated a two-dose vaccine efficacy for COVID-19 Vaccine AstraZeneca® of 59.5% (95% confidence interval of 45.8% to 69.7%) in those aged 18 and above.

There was insufficient clinical data to allow reliable calculation of COVID-19 Vaccine AstraZeneca® efficacy in those aged 55 and older. However, as a similar immune response was shown in all age groups, it is expected that reduction in COVID-19 disease will be achieved in this age group. The EMA stated that the vaccine can be used in older adults.

Evidence shows that protection starts from approximately 3 weeks after first dose of vaccine and persists up to 12 weeks. Studies show 76% protection overall against symptomatic COVID-19 disease in the first 90 days. Modelling showed no evidence of waning of protection in the first three months after vaccination.

Higher efficacy of 82% after the second dose was found if the booster dose was given at 12 weeks.

COVID-19 Vaccine AstraZeneca® storage

The vaccine will be delivered by the National Cold Chain Service at +2°C to +8°C.

Unopened (unpunctured) multidose vial must be stored in a pharmaceutical grade refrigerator (+2 °C to +8°C) until the expiry date

Vials must not be frozen

Vials must be stored in outer carton in order to protect from light.

Opened multidose vial

After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at room temperature (of up to +30°C). The product should not be returned to the refrigerator after this time[1].

[1] The SmPC states: *If stored in a refrigerator (+2°C to +8°C) chemical and physical in-use stability have been demonstrated from the time of vial opening (first needle puncture) to administration for no more than 48 hours. If the vial is removed from the refrigerator and punctured, then it has to be used within 6 hours or discarded and cannot be returned to the fridge.*
The stability data for opened vials in a refrigerator at (+2°C to +8°C) applies ONLY if the vial is punctured and doses withdrawn while in a refrigerator (i.e. a walk-in refrigerator).
BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 6 HOURS OF FIRST PUNCTURE.

Table 6: Definitions of terms for expiry date and usage times of COVID-19 Vaccine AstraZeneca

	Description
Expiry date	The date the vaccine expires if stored at +2°C to +8 °C This is 6 months from the date of manufacture. The batch number and expiry date on the side of each vial should be recorded in the patient record.
***"Discard"* date and time** **Maximum time allowed from dilution to expiry**	When the vaccine is first punctured it must be used within 6 hours. Do not return to the refrigerator after this time. The *"discard"* date and time i.e. **6 hours from first puncture of the vial should** be written on the vial using a 24 hour format. This should be written onthe vial **e.g. Vial is first punctured on 01/01/2021 at 10.00. *Discard time* is 01/01/2021 at 16.00. This is the date and time that should be written on the vial.** Any unused or partially used vials must be discarded when this time has been reached.

Any expired vials need to be stored at +2°C to +8°C and sent back to the National Cold Chain Service in the original box.

Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public), is available via the EMA website https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-astrazeneca

COVID-19 Vaccine AstraZeneca® dosage, scheduling and site of vaccination

A single dose of vaccine is 0.5 ml

A vaccine course started with COVID-19 Vaccine AstraZeneca® should be completed with this product.

COVID-19 vaccines are not interchangeable.

For people aged under 65 years:

Two doses of COVID-19 Vaccine AstraZeneca are required with an interval of 12 weeks between doses.

The vaccine should be administered intramuscularly (IM). The preferred site of administration is the deltoid muscle.

The National Immunisation Advisory Committee recommends an interval of 4-12 weeks between doses, therefore the minimum interval between the first and second dose is 24 days

Table: Interval between 2 doses

Interval between 1st and 2nd doses	Action required
Less than 24 days	No further action needed
24 to 27 days	No further action needed (evidence from trial data is that this is a valid vaccine).
Longer than 12 weeks (84 days)	Give the 2nd dose at whatever interval. The course does not need to be restarted.

Preparation and administration of COVID-19 Vaccine AstraZeneca® Infection Prevention and Control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:
    - Before vaccine preparation
    - Before administering the vaccine
    - Before and after each recipient contact
    - Surgical mask should be worn as per HPSC guidance for healthcare staff.
    - There is no need to routinely check temperature either at registration of before vaccination.
- It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.
- Follow HPSC standard precautions (sharps management, healthcare waste management etc.) https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/ Check HPSC website for latest guidance on infection prevention and control for healthcare workers: https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/
- Information should be available to those attending clinics that they should not attend if they feel unwell or have any symptoms suggestive of COVID-19 (see sample clinical checklist in Appendix 5).
- Vaccine spills should be disinfected with an appropriate antiviral disinfectant.

Preparation and administration of COVID-19 Vaccine AstraZeneca®

Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person to be vaccinated.

- The same needle and syringe should be used to draw up and administer the vaccine
- Doses should not be drawn up in advance as per the manufacturer's instructions. There is no information on the stability of vaccine in pre-prepared syringes
- Each dose should be drawn up and immediately administered to the patient.
- There should be no pooling of vaccine from different vials

Requirements for administration of vaccine

- One COVID-19 Vaccine AstraZeneca® multidose vial (up to 11 doses)
- 11 x 70% alcohol swabs
- 11 x 23 gauge blue needles or 25 gauge orange needles
- 11 x 1ml syringes

Preparation and administration of one dose of vaccine

1) Check the vial

Unpunctured vials: Check the expiry date. Never use expired vaccine.

Punctured vials: Check the discard time. Never use vaccine after the discard time.

The vial should not be shaken but the vaccine can still be used if it has been shaken.

2) Examine the vaccine.

It should be a colourless to slightly brown, clear to slightly opaque suspension

The vaccine should be inspected visually prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed

3) Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully

4) Attach 23 gauge blue or 25 gauge orange needle to a 1ml syringe

Withdraw 0.5ml of vaccine

Make sure the correct dose is drawn up as a smaller dose may not provide protection

Ensure all air bubbles have been removed before the needle is withdrawn

5) Withdraw the needle from the vial

Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated

6) Administer vaccine to the patient intramuscularly (see Appendix 3)

7) Dispose of used needle and syringe in a sharps bin

Once all doses have been administered, discard the vial and record the time and date of discard.(see session report form in Appendix 1).

Checklist before administering 2nd dose of COVID-19 Vaccine AstraZeneca

Check

- dose interval
- if diagnosis of COVID-19 since last dose - delay second dose until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- no other vaccines have been given within the last 14 days
- Check if pregnant since last dose. Defer vaccination if pregnant (see section 7.1)

Appendix 7

BEACON HOSPITAL	
DOCUMENT TITLE: COVID-19 Vaccine Receipt, Supply and Reconstitution	**ACTIVE DATE: 12/02/2021**
DATE REVISED: 10/02/21	**REVIEW DATE: 12/02/2023**

1. POLICY STATEMENT AND PURPOSE

The aim of this policy is to describe the process by which Beacon receives and allocates the COVID vaccine to the vaccination clinic. It also describes process for safe dilution (if applicable) and drawing up of required dose into vaccine before supply to vaccinator, and any accountability paperwork that accompanies this. This SOP is subject to change as further vaccines may become available.

There are multiple manufacturers of Covid vaccine.

Each product has different requirements. Please ensure correct product information is used

Currently there are 2 products in use in Beacon Hospital

1 Pfizer vaccine Comiranty®

2 Astra Zeneca Covid 19 vaccine

2. SCOPE

Process of receipt, supply to clinic, reconstitution and transfer of custody to vaccinator only.

3. DEFINITION (S)

BN – Batch Number

4. PROCEDURES

4.1 ACCOUNTABILITY AND RESPONSIBILITIES

Pharmacy – it is the responsibility of the Pharmacy Department to receive and log all vaccinations received, via the Pharmacy stock and issue log and to provide the HSE with the required information on BN and Expiry as detailed in this policy. They will also decommission stock as per Falsified Medicines Directive as applicable

Pharmacy will manage vaccine stocks in the clinic - keeping records of vials dispensed and number of doses obtained from vials.

Pharmacy staff will also assist with dilution and drawing up of vaccinations as required and assist with identifying suitably competent staff for process and training, where required.

Nursing – will provide cover for the 3 step reconstitution process or drawing up of vaccine as within the clinic, with suitably competent staff for process and training, where required.

All staff within the clinic will facilitate the provision of patient advice and reporting of any ADRs experience in the clinic.

Trained vaccinators – are responsible for the provision of accurate information via the HSE system for each patient and for adhering to the requirements of documentation within this policy to ensure the accuracy of this information.

4.2 PROCEDURES

4.2.1 Receipt of Vaccine and consumables

When a supply of vaccine is received, the amount should be checked and photographs of each box, clearly showing the QR code, should be taken. These should then be placed in the Pharmacy storage fridge immediately.

The Pharmacy Stock/Issue log (appendix 1) should be completed with the batch/expiry and quantity received. Use a new log for each delivery of vaccine to make reconciliation easier. The forms are attached to the front of the fridge in a clear plastic wallet for ease of recording.

Send the pictures of received vaccine batches, as soon as possible, to the HSE Covax group covax.batch@hse.ie, with the accompanying form (appendix 2)

The Covax Batch team also require BN/expiry of sodium chloride 0.9% 10ml amps used (applicable to Pfizer vaccine only). When these are received, send one photo per batch, making sure the QR code is clear and state the number of boxes in that batch received. This can be sent to the same email address (above)

Where possible, use the HSE supply of sodium chloride 0.9%. If using own supply, ensure the Covax team are supplied with the same information as above before issuing to the vaccination clinic.

Note – Consumables for the vaccine clinic are also delivered to the Pharmacy department – liaise with Materials Management about supplies, syringes, vaccine cards

4.2.2 Transfer to Clinic

When the clinic requests additional vaccine, a box should be transferred to the clinic. Pay attention to the time of the request and how long the clinic has left to run/estimated number of patients left to vaccinate. Towards the end of the session, supply smaller numbers of vials to ensure minimal transfer back to Pharmacy.

All supplies should be logged on the pharmacy stock/issue log (on the front of the fridge) at point of removal. Remember to enter the date and time of removal and check the expiry printed on the box (amended expiry after wholesaler removal from Freezer, if applicable) to ensure they are still viable.

The vaccination clinic fridge is centrally monitored by the Kelsius system (see PPC-PHAR-125 for detail.

If vaccine vial accountability logs (appendix 3) are requested from the clinic, these should be printed in pharmacy and supplied directly to the clinic. The Pharmacy drive contains all forms relating to the vaccination clinic (in the folder COVID vaccine docs)

Ensure log for correct product is chosen

If tray labels (see Step 1 of process for example) are requested by the clinic, these can be printed from Meditech. They are available in canned text under the mnemonic COVI or COVD

There is a folder over in the prep room in the clinic for supply of these to be stored, along with copies of the 3-step reconstitution and draw up process and policy for reference.

4.2.3 3 Step process for issue, reconstitution in the clinic (Pfizer product only)

Ideally, there should be 3-4 personnel minimum participating in the 3-step process in the prep room.

- 1 member of staff for vial allocation and oversight (can also volume check in less busy periods)
- 1 member of staff for diluting vaccine
- 1 member of staff for drawing up vaccine into syringes.
- An additional staff member for volume checks in busy periods.

Alternatively, the same member of staff can dilute and draw up and 2 personnel can do this simultaneously, but full procedure for each step should be followed every time, regardless of method.

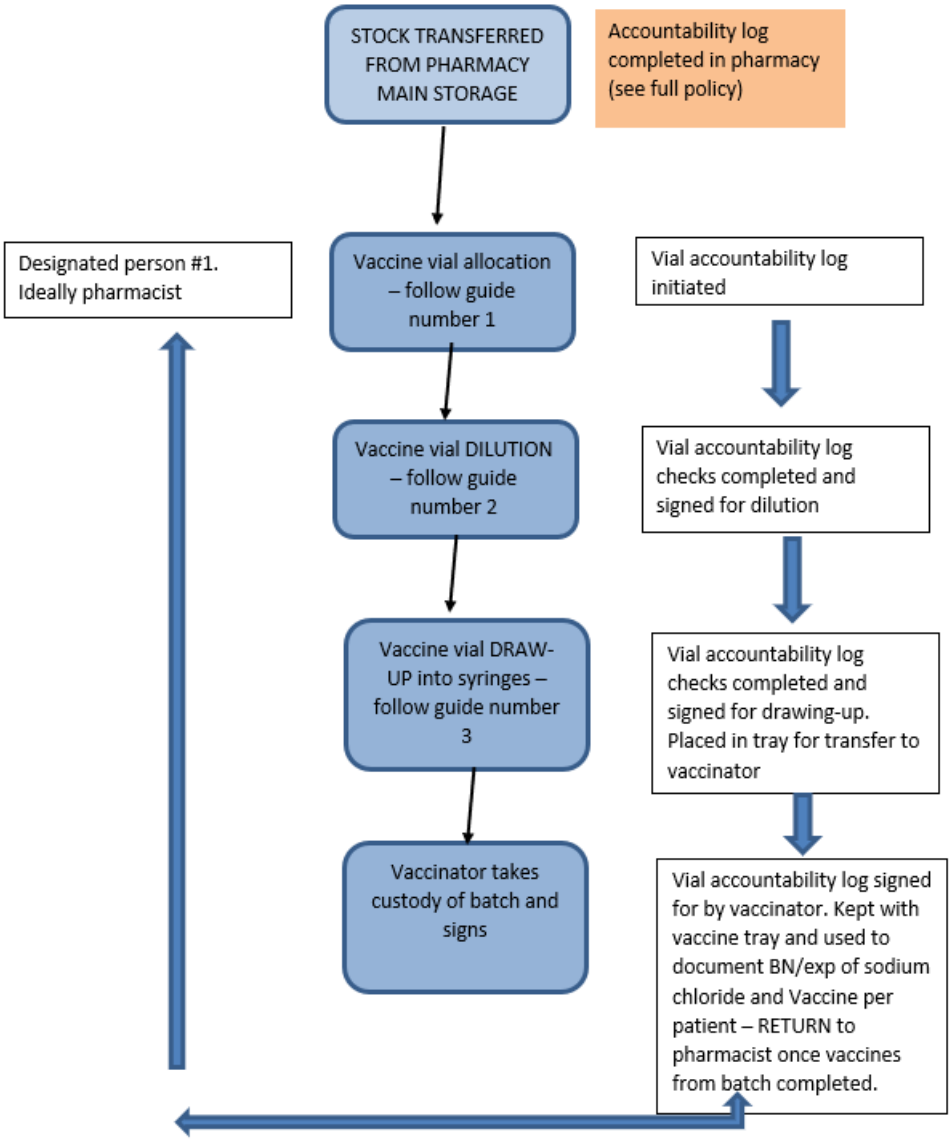
Volume checks can be carried out by anyone qualified by nature of profession (pharmacist) or by having IV administration qualification (nursing). Similarly, all nurses with IV administration qualifications can dilute and draw-up vaccines, after receiving specific guidance on this process, as can aseptically trained pharmacy technicians.

4.2.4 Process for issue and drawing up in clinic (Astra Zeneca product)

As per Pfizer product, but no dilution process. There are up to 12 doses in each Astra Zeneca vial. Astra Zeneca product should be used as soon as possible after drawing up – to facilitate this each vial may have 2 accountability logs (with 5 or 6 doses on each sheet) Use Accountability Log Astra Zeneca Vaccine

A summary of the process in clinic can be found below:

FLOW:



See appendix 4 for flow guide full page.

See appendix 5 for Vaccine vial allocation process in the clinic

See appendix 6 for vial dilution process

See appendix 7 for Vial draw-up process

4.2.4 Documentation and Reconciliation of Supply with vials used

The vaccine vial accountability log should be transferred through each stage of the 3 -step process, as per guides. As the HSE require accurate information on the BN/expiry of both the vaccine and sodium chloride used to reconstitute, the accountability log should be transferred into the custody of the vaccinator, along with that batch of drawn-up vaccines. This information should be used to ensure the most accurate information pertaining to BN and expiry is selected from the drop-downs when entering the individual patient/staff member on the system.

At the end of each session, the individual logs for that day should be returned to pharmacy. These should be counted and reconciled with the number of vials allocated/returned that day.

If a vial is wasted at the point of reconstitution or draw-up, this should be clearly indicated on the accountability form at that point and the vial returned with the part-completed form to pharmacy for log on the pharmacy stock issue log.

If vials need to be returned to pharmacy at the end of a session, this should be done via cool bag transfer, ensuring temperature doesn't exceed 8 degrees Celsius.

The HSE form should be used to track temperature of transferred boxes for all vials that are being returned to pharmacy (the transfer time to clinic from pharmacy is < 5mins before transfer to a pharmacy grade fridge so provided these are used that same day and the temperature is verified at point of transfer into clinic fridge, it can be assumed there is no excursion time) The form should be initiated for all stock transferred back so additional transport time can be documented and no excursion can be demonstrated. Any returned stock should be identifiable as the excursion form should be clearly attached. This should be used first the next day (provided excursion time not incurred)

If temperature is verified within the cool box upon transfer back to pharmacy and re-issue and does not deviate from 2-8 degrees Celsius, then the vials will have not have any recorded excursion and are fit for use.

If any excursion recorded, see HSE guidance for further action.

Maintain a record of temperature as per the guidelines
*(*https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf*)*

Temperature to be maintained between 2C and 8C	Box 1 Time	Temp	Box 2 Time	Temp	Box 3 Time	Temp	Comment on excursions
When box packed							
On return to the facility fridge							

From "HSE Clinical Guidance for Covid-19 Vaccination Version 1.0 28th December 2020"

1. CHANGES

Revision Dates	Changes Made
08/02/2021	Addition of Kelsius monitor to fridge, addition of Astra Zeneca information, update references

6. REFERENCES

HSE - Clinical Guidance for Covid-19 VaccinationV5 – available on QPulse

Pfizer medicines information: Comirnaty ▼ (COVID-19 mRNA Vaccine) Storage and Handling of VIALS Outside of Recommendations in the Product Labelling DURING and AFTER DILUTION

7. APPENDICES

Appendix 1: Pharmacy Stock/Issue Log

Beacon Hospital Pharmacy Department

Record received from supplier on one line, separate line for issues and returns

Date and time	Record number	Expiry Date & Time (if applicable)	Quantity of vials received	Vials received in good condition (Y/N)	Quantity of vials issued	Quantity of vails returned	Stock balance	Comment

Appendix 2: HSE Covax group guide for submission of BN/Expiry

Receipting Vaccine Delivery and loading vaccine delivery to the Vaccine System.

Photo and email guidelines

Guidance for photo

1. Please ensure that the information in the orange square is included in the photo
2. Please ensure photo is **good quality** and **not blurry** as the barcode is being scanned into a file to share with the vaccines administration system
3. Please send a photo of the label from EACH box included in your delivery using the below template

- **E.g. if you have received 12 vials in 1 box, you will have 1 photo of a label. If you received 195 vials each in 2 boxes, you will have 2 photos to send.**

Email template

Please email photos to covax.batch@hse.ie

Subject line: Vaccine Barcode Photos

Please include:

- Facility Name:_____
- Photos: *Please attach a Photo of the Label for each box received*
- Quantity*: Please enter the quantity of vials beside each photo*
- Confirm total number of Vaccine Vials received: _____
- Confirm number photos of labels attached: _____

Thank you very much!

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Appendix 3: Vaccine Vial Accountability Log

Beacon Hospital

Astra Zeneca COVID-19 vaccine log – complete for each individual vial

(to be retained by Pharmacy/other responsible personnel after handover to vaccinator)

VIAL DETAILS – to be completed by pharmacy/designated person		VACCINE DILUTION – to be completed by personnel diluting before handing to personnel drawing into syringes for administration.	
Batch number of vial of vaccine		Not applicable	Not applicable
DISCARD date and time of vial (see right)	_____:_____hr on _____/_____/_____		
• → Pharmacy/designated person to write **DISCARD** date and time onto the canned text label at the time of issue to dilutor, in the space provided. This should match the details on this form. • → This form should be used to track the issue to vaccinator, who should take entire tray and empty vial and recheck DISCARD time before EACH administration.			

Any wasted doses should be returned to pharmacy to be accounted for on the wastage log. →

DRAWING UP THE VACCINE INTO THE SYRINGE FOR USE BY VACCINATOR – to be completed by competent staff member (Dr/RGN/Pharmacy)						
Prepared by:	Number of doses prepared:	Volume (0.5ml) 2nd check (check all doses per vial) Initials and circle	Handed to vaccinator (time)	Vaccinator to check DISCARD date and time and sign to take over custody	Vaccinator name (print)	Number of doses wasted (if applicable)
		Dr / RGN / Ph				

Beacon Hospital

Comirnaty® COVID-19 vaccine log – complete for each individual vial

(to be retained by Pharmacy/other responsible personnel after handover to vaccinator)

VIAL DETAILS- to be completed by pharmacy/designated person		**VACCINE DILUTION - to be completed by personnel diluting before handing to personnel drawing into syringes for administration.**	
Batch number of vial of vaccine		For Sodium chloride 0.9% 10ml vial: Manufacturer | BN | Expiry 1.8ml Volume check by (initials& designation): _____ Prepared by: Checked by: • This vaccine log to be placed in an A4 clear plastic grip-lock bag along with the diluted vial for transfer to drawing up station (unless done sequentially)	Record in 24 hour clock format DATE and TIME OF DILUTION (removal from fridge): ____:____hr on ____/____/____ DISCARD TIME: (6 hours post-dilution) ____:____hr on ____/____/____ Checked by:
DISCARD date and time of **diluted** vial (see right)	_____:_____hr on _____/_____/_____		
• Pharmacy/designated person to write **DISCARD** date and time onto the canned text label at the time of issue to dilutor, in the space provided. This should match the details on this form. • This form should be used to track the issue to vaccinator, who should take entire tray and empty vial and recheck DISCARD time before EACH administration.			

DRAWING UP THE VACCINE INTO THE SYRINGE FOR USE BY VACCINATOR – to be completed by competent staff member (Dr/RGN/Pharmacy)					
Prepared by:	**Number of doses prepared:**	**Volume (0.32ml) 2nd check (check all doses per vial) Initials and circle**	**Handed to vaccinator (time)**	**Vaccinator to check DISCARD date and time and sign to take over custody**	**Vaccinator name (print)**
		Dr / RGN/Ph			

Any wasted doses should be returned to pharmacy to be accounted for on the wastage log.

Appendix 4: Vaccine Clinic Flow Chart

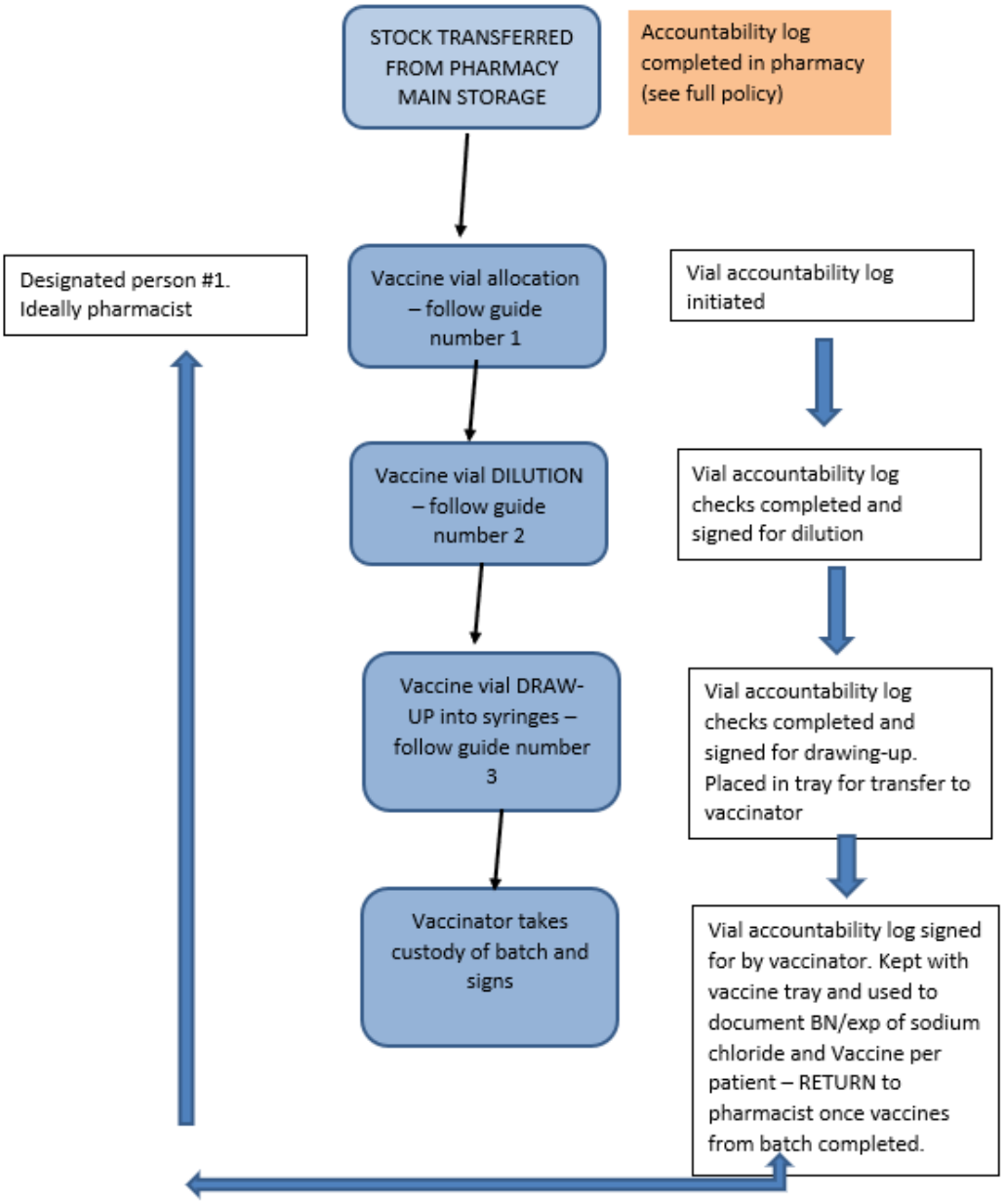
Beacon Hospital

SUMMARY OF VACCINATION CLINIC PROCEDURE FOR SUPPLY AND PREPARATION OF PFIZER COVID-19 (COMIRNATY) VACCINE

BEFORE STARTING

Check that everyone handling the vaccines is familiar with the procedures to be followed. Ensure that any deviations from the procedures are escalated as appropriate in a timely manner.

FLOW:



Prepared: 12/01/2021
Approved by: Date:

Appendix 5: STEP 1 – Vial Allocation and Oversight in the vaccine clinic

Beacon Hospital 1

INSTRUCTIONS FOR ALLOCATING VIALS AND STOCK CONTROL - VACCINATION CLINIC

BEFORE STARTING

Check that everyone handling the vaccines is familiar with the procedures to be followed. Ensure that any deviations from the procedures are escalated as appropriate in a timely manner.

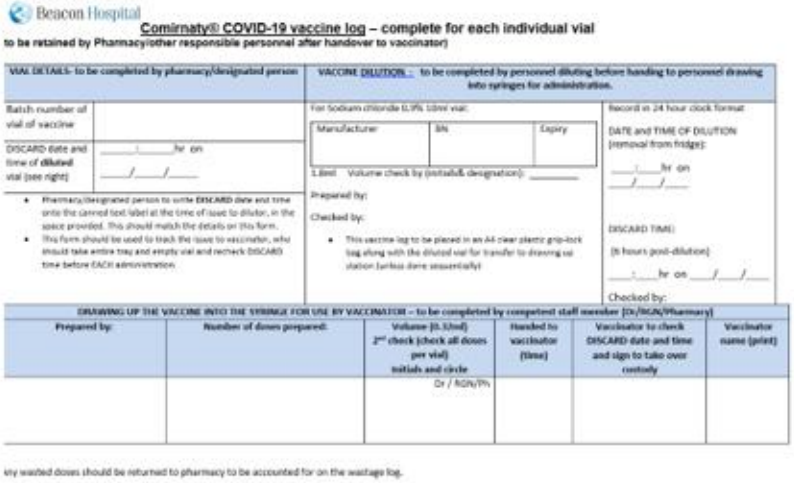
Stock will be transferred from the pharmacy fridge and logged there, prior to transfer to the clinic fridge. This process deals with the removal of stock from the clinic fridge and allocation to dilutor by designated person (ideally pharmacist)

ALLOCATING VIALS:

When a vial is requested, this should be removed at the point of need, from the clinic fridge. For simplicity, this will be used as the dilution time and the DISCARD date calculated 6 hours from this time.

STEP 1: REMOVAL FROM FRIDGE

Remove ONE vial from the fridge and check the BN and expiry. Record this on the individual vial log (as below left)



Beacon Hospital

Comirnaty® COVID-19 vaccine log – complete for each individual vial

to be retained by Pharmacy/other responsible personnel after handover to vaccinator)

VIAL DETAILS- to be completed by pharmacy/designated person

VACCINE DILUTION - to be completed by personnel diluting before handing to personnel drawing into syringes for administration.

Batch number of vial of vaccine

DISCARD date and time of diluted vial (see right)

Manufacturer | BN | Expiry

Prepared by:

Checked by:

DATE and TIME OF DILUTION (removal from fridge):

DISCARD TIME:

(6 hours post-dilution)

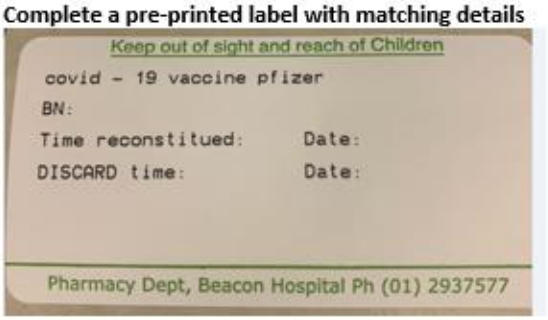
Checked by:

DRAWING UP THE VACCINE INTO THE SYRINGE FOR USE BY VACCINATOR – to be completed by competent staff member (Dr/RGN/Pharmacy)

Prepared by:	Number of doses prepared:	Volume (0.3/ml) 2nd check (check all doses per vial) Initials and circle	Handed to vaccinator (time)	Vaccinator to check DISCARD date and time and sign to take over custody	Vaccinator name (print)
		Dr / RGN/Ph			

Record the current time as the date and time of dilution and calculate the DISCARD date and time (6 hours later). Enter this on the form on the right and in the section on the left.

Complete a pre-printed label with matching details



Take a sodium chloride 0.9% vial (10ml) and transfer the BN and expiry onto the middle section of the form.

These can now be placed in a plastic gripper bag and tray and transferred to the personnel diluting the vaccine.

Prepared: 12/01/2021
Approved by: Date:

Appendix 6: STEP2 – Vial dilution (Pfizer)

Beacon Hospital 2

INSTRUCTIONS FOR DILUTION OF COVID-19 VACINE (PFIZER) - VACCINATION CLINIC

BEFORE STARTING

Check that everyone handling the vaccines is familiar with the procedures to be followed. Ensure that any deviations from the procedures are escalated as appropriate in a timely manner.

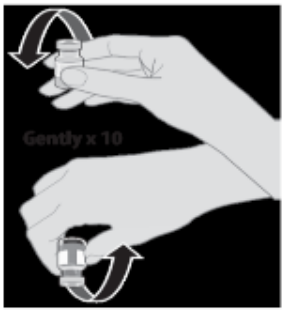
Ensure the preparation area has been cleaned recently. Ideally, this process should be done directly after vial reconstitution and area should be wiped down after maximum 5 vial reconstitutions and draw-up into individual syringes.

The vial will be removed from the fridge at the point of use and particulars such as discard date and BN will be filled in prior to receipt by dilutor.

Equipment:

- One Comirnaty® multidose vial (COVID-19 Pfizer vaccine)
- One 10ml ampoule of Sodium Chloride 0.9% solution for injection
- Two 70% alcohol swabs
- One 21 gauge green needle for reconstitution
- A 2ml, 2.5ml or 3ml syringe

STEP 1: PREPARING FOR DILUTION



Check the "DISCARD" date and time on the vial accountability form received with the vial.

Check this has been correctly transcribed onto the printed label (for tray). Sign "checked by" box on right –hand side.

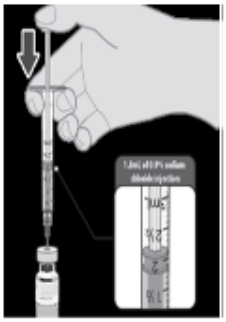
Gently invert vial 10 times prior to dilution. **Do not shake**

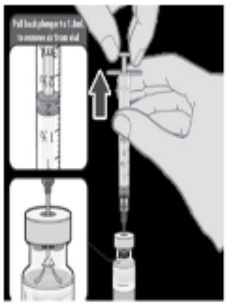
Inspect the liquid in the vial prior to dilution
(Should be an off-white solution with no visible particles visible - return to pharmacist for discarding and recording if particulates or discolouration

Remove cap

Clean with 70% alcohol swab and allow it to air dry fully

STEP 2: DILUTION





Dilute the concentrate vaccine vial by adding the 1.8 mL of sodium chloride 0.9% to the vial **(check required – checker to sign log)**.

Insert diluent slowly into the vaccine vial. You may feel some pressure in the vial as you add the diluent.

Do not remove the needle from the vial. Keeping the needle above the level of the liquid, slowly withdraw 1.8 ml of air into the empty diluent syringe to equalise the pressure.

Slowly remove the needle from the vial. Dispose of syringe and needle into a sharps bin.

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Slowly invert the vial 10 times to mix contents thoroughly, DO NOT shake. One inversion requires the vial to be fully rotated back to an upright position.

The diluted vaccine should present as an off-white solution with no particulates visible. Return to pharmacist for discarding and recording if particulates or discolouration.

Check all required areas on the form have been completed and checks signed for where necessary. Ensure the form, vial, label are placed into a plastic gripper bag for transfer to the designated person drawing into vials (if a separate person) OR proceed to instructions for drawing into syringes.

IT IS IMPERATIVE THAT IF A VIAL IS NOT FIT FOR USE, IT BE RETURNED TO THE PHARMACIST FOR RECORD OF DESTRUCTION/WASTAGE. IF THE VIAL IS DISCARDED ACCIDENTALLY, CLEARLY WRITE ON THE FORM ISSUED WITH IT THAT THIS VIAL WAS DISCARDED AND ENSURE THE FORM IS RETURNED FOR LOGGING.

Appendix 7: STEP 3 – drawing up vials into syringes

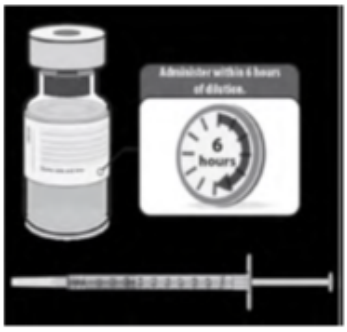
Beacon Hospital 3

INSTRUCTIONS FOR DRAWING UP COVID-19 VACCINE (RECONSTITUTED) INTO SYRINGE FOR ADMINISTRATION VACCINATION CLINIC

BEFORE STARTING

Check that everyone handling the vaccines is familiar with the procedures to be followed. Ensure that any deviations from the procedures are escalated as appropriate in a timely manner.

Ensure the preparation area has been cleaned recently. Ideally, this process should be done directly after vial reconstitution and area should be wiped down after maximum 5 vial reconstitutions and draw-up into individual syringes.



PREPARATION OF SYRINGES FOR ADMINISTRATION OF 0.3 mL DOSES OF COMIRNATY ®

Use one reconstituted vial (in clear plastic bag with vaccine accountability log)

Check the date and ***"discard time"*** has been completed and checked and is recent (allowing time for vaccinations to be given). Reconcile with printed label.

Visually inspect the vial, gently rotating it. The diluted vaccine should present as an off-white solution with no particulates visible. Do not use if particulate matter or discolouration are present. Log if wasted due to this reason.

Clean the top of the vial with a single use 70% alcohol swab and allow it to air dry fully.

Using a 23G, withdraw 0.32ml of diluted product using a low residual 1ml syringe. Consumables are supplied from the HSE and the approved syringes are:

- Omnifix-F Luer Lock Solo, 0.01ml Graduations, Total Graduated Capacity 1ml - Product Code 9167006V
- Rays - Inj/Light, 0.01ml Graduations, Total Graduated Capacity 1ml - Product Code TUB1ML
- Sol-Millennium, 0.01ml Graduation, Total Graduated Capacity 1ml - Product Code 180011LDS

Make sure the correct dose is drawn up – the 0.32ml is to allow for priming of the syringe.

Leaving the needle in place (in the vial), remove the syringe barrel and attach a new needle (using aseptic technique, do not touch the base of the needle or syringe). Repeat this step, using the needle remaining in the vial and attaching a new needle to the syringe once it contains 0.32ml of the vaccine. It should be possible to get 6 prefilled doses from each vial (potentially 7). Trained personnel preparing syringes should sign the vial accountability log in the appropriate section.
Do not prime the new needle, this will be done by the vaccinator.

Get a check for each 0.32ml withdrawn. The same checker should check ALL syringes filled from the one vial, and sign the accountability log after doing so.
Ensure all particulars of the individual vial accountability form have been completed.

Place the empty vial (so the vaccinator can check the product) into a clean tray with the form and the pre-filled syringes. Attach the label (containing discard date/time) to the tray. Cover the syringes to protect from light.

These can now be transferred to custody of the vaccinator, who is then responsible for ensuring the discard date on the tray is checked before EACH administration (and recorded in the administration record). At this stage, the corresponding section of the vial accountability form should be signed and taken in the tray with the vaccinator so they have the batch information for sodium chloride and vaccine specific to that batch. RETURN form to production area to be kept for pharmacy to complete log.

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Approved by: Date:

Appendix 8 – Astra Zeneca vaccine

Preparation and administration of COVID-19 Vaccine AstraZeneca®

Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the perso to be vaccinated.

- The same needle and syringe should be used to draw up and administer the vaccine
- Doses should not be drawn up in advance as per the manufacturer's instructions. There is no information on the stability of vaccine in pre-prepared syringes
- Each dose should be drawn up and immediately administered to the patient.
- There should be no pooling of vaccine from different vials

Requirements for administration of vaccine

- One COVID-19 Vaccine AstraZeneca® multidose vial (up to 11 doses)
- 11 x 70% alcohol swabs
- 11 x 23 gauge blue needles or 25 gauge orange needles
- 11 x 1ml syringes

Preparation and administration of one dose of vaccine

1) Check the vial

Unpunctured vials: Check the expiry date. Never use expired vaccine.

Punctured vials: Check the discard time. Never use vaccine after the discard time.

The vial shoulds not be shaken but the vaccine can still be used if it has been shaken.

2) Examine the vaccine.

It should be a colourless to slightly brown, clear to slightly opaque suspension

The vaccine should be inspected visually prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed

3) Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully

4) Attach 23 gauge blue or 25 gauge orange needle to a 1ml syringe

Withdraw 0.5ml of vaccine

Make sure the correct dose is drawn up as a smaller dose may not provide protection

Ensure all air bubbles have been removed before the needle is withdrawn

5) Withdraw the needle from the vial

Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated

6) Administer vaccine to the patient intramuscularly (see Appendix 3)

7) Dispose of used needle and syringe in a sharps bin