
**REPORT BY MR EUGENE MCCAGUE TO THE NON-EXECUTIVE
DIRECTORS OF THE BEACON HOSPITAL FOLLOWING THE
INDEPENDENT REVIEW OF THE VACCINATION CLINIC AT BEACON
HOSPITAL**

Contents

CHAPTER 1. INTRODUCTION.4

CHAPTER 2. GOVERNANCE STRUCTURES, OPERATING PROTOCOLS AND OVERSIGHT OF THE VACCINATION CLINIC.6

CHAPTER 3: PROCESS OF COMMUNICATION BETWEEN BEACON AND HSE.7

CHAPTER 4: SCHEDULING AND BOOKING PROCESS OF HSE, BEACON STAFF AND OTHERS..8

CHAPTER 5: MANNER IN WHICH INDIVIDUALS WERE RECORDED ON THE NATIONAL AND LOCAL HOSPITAL SYSTEMS.9

CHAPTER 6: LOGISTICS PROCESS ON THE DAY OF VACCINATIONS.10

CHAPTER 7: SUPPLY AND CUSTODIANSHIP OF VACCINE VIALS AND CONSUMABLES.11

CHAPTER 8: THE VACCINE VIAL EXTRACTION AND ADMINISTRATION PROCESS.12

CHAPTER 9: PROCESS FOR ADMINISTERING UNUSED VACCINES.....13

CHAPTER 10: THE DECISION MAKING PROCESS FOR SELECTING CANDIDATES FOR VACCINATION WITH REFERENCE TO THE HSE SEQUENCING GUIDELINES.....14

CHAPTER 11: THE COMMUNICATIONS, DECISION-MAKING AND ADMINISTRATION PROCESS FOR THE VACCINATION OF TEACHERS FROM ST GERARD’S SCHOOL, BRAY.17

CHAPTER 12: THE COMMUNICATION, DECISION MAKING AND THE ADMINISTRATION PROCESS FOR THE VACCINATION OF EMPLOYEES OF THE PARK ACADEMY CRECHE, BEACON MEDICAL CAMPUS, SANDYFORD.....23

CHAPTER 1. INTRODUCTION.

Background to Appointment

- 1.1 Arising from media, political and public commentary on the vaccination of 20 teachers at the Covid-19 Vaccination Clinic (the "Vaccination Clinic") operated by the Beacon Hospital ("Beacon"), discussed in Chapter 11, the non-executive directors of Beacon decided to commission an independent review of the operation of the Vaccination Clinic. On 29 March 2021, I was appointed to carry out that independent review (the "Review"). As a first step, a considerable amount of information was collated by Beacon to assist me in the conduct of the Review. I commenced my work on Tuesday 6 April, immediately after the Easter break.

Terms of Reference

- 1.2 The Terms of Reference of the Review are set out in **Appendix 1**.

Methodology

- 1.3 The Terms of Reference provided that I should determine the methodology of the Review in accordance with the Terms of Reference and having proper regard to the principles of natural justice.
- 1.4 I determined that I should, as a first step, review documents and correspondence, including internal emails within Beacon and between Beacon and HSE, relevant to each of the topics in the Terms of Reference and then meet with key people in Beacon to get a better understanding of the information contained in the documents. Following the review of the documents and the initial meetings, I identified other people to meet, and those with whom I should have follow-up meetings for the purposes of the Review.

- 1.5 I met with 16 people from Beacon, some on multiple occasions. I had a telephone conference call with six representatives of HSE and corresponded and spoke by telephone with one person from St Gerard's School, Bray.
- 1.6 I shared redacted extracts from a draft of my report with certain individuals. I considered any comments I received and revised my draft report, as necessary.
- 1.7 I received full co-operation from everyone whom I approached in the conduct of the Review for which I am grateful.
- 1.8 The Review was conducted in the context of the constraints imposed both by GDPR and by Beacon's duty of confidentiality to its patients. I did not have access to the vaccination data on the national COVAX registration system.

Structure of Report

- 1.9 At the end of each chapter, I have summarised my findings in relation to the matters addressed in that chapter.

Legal Advice

- 1.10 I received legal advice and administrative support from Mr JP McDowell, Ms Julie Austin and Ms Aisling Ray of Fieldfisher, Solicitors.

CHAPTER 2. GOVERNANCE STRUCTURES, OPERATING PROTOCOLS AND OVERSIGHT OF THE VACCINATION CLINIC.

FINDINGS.

- 1.** The Vaccination Clinic was established by Beacon to administer vaccines to Beacon Healthcare Workers (HCWs). Following discussion with HSE, Beacon also agreed to facilitate the vaccination of HCWs referred to the Clinic by two HSE community health organisations, CHO7 and later CHO6 and, with the consent of or at the request of HSE, certain other cohorts of HCWs, including HCWs from VHI Health and Wellbeing and MyMedical. Unlike the mass vaccination centres established by HSE, the Clinic was not a vaccination centre to which members of the public were directed for vaccination.
- 2.** The Implementation Group established to oversee the Clinic comprised senior people from each discipline required to ensure that the Vaccination Clinic was properly established and operated in accordance with its mandate.
- 3.** Given the dynamic and unique nature of the operations at the Vaccination Clinic, the Implementation Group structure adopted by Beacon was a more agile and appropriate structure than a traditional formalised committee structure.
- 4.** The governance and oversight of the Vaccination Clinic was appropriate.

CHAPTER 3: PROCESS OF COMMUNICATION BETWEEN BEACON AND HSE.

FINDINGS

1. There were no written contractual or governance arrangements in place between Beacon and HSE in relation to the operation of the Vaccination Clinic.
2. The administration of nearly 10,000 vaccines to CHO staff at the Vaccination Clinic was provided by Beacon at no cost to HSE. While not costed, the direct and indirect cost to Beacon was not insignificant.
3. Appropriate indemnities were provided by HSE as reflected in the Clinical Guidance issued by HSE.
4. Beacon was obliged to comply with a series of national and HSE guidelines and protocols in relation to a range of matters, including the Vaccine Priority List, the Sequencing Guidelines, the storage and custodianship of vials and the preparation and administration of vaccines. My findings in relation to Beacon's compliance with these guidelines and protocols are set out in subsequent chapters.
5. The relationship between Beacon and HSE was acknowledged by both Beacon and HSE as constructive and co-operative.
6. The communications between Beacon and HSE were professional and cordial.

CHAPTER 4: SCHEDULING AND BOOKING PROCESS OF HSE, BEACON STAFF AND OTHERS.

FINDINGS

1. The scheduling and booking process relating to HSE staff conformed with the requirements of HSE in that regard.
2. The Vaccination Clinic had no role in determining whether people included on lists sent by HSE were entitled to be vaccinated under the Vaccine Priority List or the Sequencing Guidelines. If a person was on a list provided by a CHO and his or her details matched those of a person attending at the Vaccination clinic, the person was vaccinated.
3. The scheduling and booking of Beacon HCWs had due regard to the rostering requirements in the Hospital and the need to avoid significant numbers of HCWs from the same service area being off work at the same time due to vaccine related side effects.
4. The scheduling and booking of Beacon HCWs conformed with the guiding principle in the Sequencing Guidelines (the “Guiding Principles”) that the vaccination programme should be practical to administer.
5. The scheduling and booking of third party contractors and franchisees working on the Beacon Campus followed the same process as used for Beacon HCWs, save that, in the case of the original list of Beacon HCWs their names were uploaded on COVAX at the outset whereas in the case of contractors and franchisees their names were uploaded at the clinic attended by them.
6. The scheduling and booking of HCWs from private health insurers as agreed with HSE followed the same process as that used for HSE staff.

CHAPTER 5: MANNER IN WHICH INDIVIDUALS WERE RECORDED ON THE NATIONAL AND LOCAL HOSPITAL SYSTEMS.

FINDINGS

- 1.** The details of every person vaccinated at the Vaccination Clinic, regardless of what cohort to which the person belonged, were registered on the national vaccine database, COVAX, in accordance with national and HSE requirements.
- 2.** Each person's details were also registered on the bespoke Beacon Vaccination Tracker. This facilitated the smooth running of the Vaccination Clinic and provided a second method of checking that those presenting at the Clinic had been scheduled to be vaccinated.
- 3.** The Vaccination Clinic faced a number of challenges from inaccurate data and from people presenting themselves at the Clinic whose details were not on the list for the day.

CHAPTER 6: LOGISTICS PROCESS ON THE DAY OF VACCINATIONS.

FINDINGS

- 1.** The process adopted by the Vaccination Clinic for the running of clinics was very well thought out and represented an enhanced version of that recommended in the Governance Suite issued by HSE to all vaccination sites.
- 2.** The physical layout of the Vaccination Clinic ensured that there was ample space for each step in the process to be completed in compliance with national guidance on social distancing.
- 3.** The presence of 33 volunteers at each clinic facilitated a very efficient throughflow of people and the vaccination, on average, of between 110 to 120 people per hour.
- 4.** The use of the “buddy” system, whereby each vaccinator had a person with him or her in the vaccination bay who assisted in entering details on the COVAX system and preparing the vaccination card was not, I understand, a feature of other vaccination sites. It appears to have worked well in the Vaccination Clinic and was of considerable assistance to those administering the vaccines.

CHAPTER 7: SUPPLY AND CUSTODIANSHIP OF VACCINE VIALS AND CONSUMABLES.

FINDINGS

- 1.** The supply of vaccines to the Vaccination Clinic was subject to strict guidelines from HSE. The Vaccination Clinic complied with these guidelines.
- 2.** The custodianship of vaccines while in the possession of Beacon was the responsibility of Beacon pharmacy. There were detailed Standard Operating Protocols (SOPs) in relation to the storage of vaccines and procedures to ensure that the number of doses extracted from vials matched the number of doses administered. These protocols conformed with HSE guidelines and best practice and were adhered to by the Vaccination Clinic.
- 3.** A manual reconciliation between the number of doses extracted from vials and the number of doses recorded as administered on COVAX took place at the end of each clinic and was reported to HSE on the following day.
- 4.** Appropriate records were maintained of vials opened, doses extracted, doses wasted and vials held in stock.

CHAPTER 8: THE VACCINE VIAL EXTRACTION AND ADMINISTRATION PROCESS.

FINDINGS

- 1.** The extraction and administration of vaccines at the Vaccination Clinic conformed with the process outlined in the Clinical Guidance.
- 2.** There were no stability studies in relation to the Astra Zeneca (AZ) Vaccine once drawn into a syringe. The experience of the vaccinators in the Vaccination Clinic was that it became viscous or “gloopy” in the syringe. Accordingly, their professional judgement was that it should be administered within one hour or certainly no longer than two hours of having been drawn into a syringe.
- 3.** The Beacon SOPs provided that the AZ Vaccine should be used as soon as possible after drawing up.

CHAPTER 9: PROCESS FOR ADMINISTERING UNUSED VACCINES.

FINDINGS.

- 1.** Unopened vials were either used at a subsequent clinic or at a “mop-up” clinic or, if there was a risk of the vials going out of date, were transferred to HSE or to another vaccination centre.
- 2.** Beacon had permission from HSE to use vials allocated to HSE to vaccinate Beacon HCWs if the alternative was that the vaccines might otherwise go to waste. In those circumstances, Beacon would provide a similar number of doses from a subsequent allocation of vials to Beacon for administration to HCWs from the relevant CHO.
- 3.** Beacon operated a standby system so that people from the Beacon Campus could be called to a clinic at short notice to avoid doses being wasted. On two occasions, Pfizer vaccines were delivered to a local GP to avoid waste.
- 4.** My findings in relation to the vaccination of 20 teachers from St. Gerard’s School, Bray, are in Chapter 11.

CHAPTER 10: THE DECISION MAKING PROCESS FOR SELECTING CANDIDATES FOR VACCINATION WITH REFERENCE TO THE HSE SEQUENCING GUIDELINES.

SECTION 1 – FINDINGS: Period up to 5 February.

1. For the period up to the revision of the Sequencing Guidelines on 5 February, the Vaccination Clinic followed a guide prepared by two senior clinicians which divided Beacon HCWs into 13 separate categories (the “Beacon Guide”). The manner in which the Beacon Guide was created was in accordance with the Sequencing Guidelines that pertained at the time. The Beacon Guide was not directly modelled on the categories 1a to 1h in the Sequencing Guidelines but this does not detract from this conclusion. The categories were stated to be “high level” and the examples given were described as “illustrative” and “not comprehensive”. They were guidelines rather than prescriptive categories.
2. The principles adopted in preparing the Beacon Guide clearly reflected each of the six Guiding Principles in the Sequencing Guidelines.
3. By categorising each member of staff in one of 13 categories, the Beacon Guide provided a clear mechanism whereby the Vaccination Clinic could call on HCWs in Priority Group 2 or Priority Group 4 from the national Vaccine Priority List to attend if others higher in the sequence were unable, or failed, to do so. In other words, the Beacon Guide provided an in-built standby list of HCWs.
4. The sequence in which HCWs were actually vaccinated took account of the need to administer the programme in a practical way.

SECTION 2 – FINDINGS: Persons directly employed by Beacon

1. The allocation of staff to particular categories inevitably involved an element of subjective judgement. In the case of Beacon, this was not left to the discretion of individual staff members. From the introduction of the revised Sequencing Guidelines on 5 February, a formal process was undertaken by the Director of Human Resources to allocate Beacon staff into categories that aligned with the February Guidelines, including distinguishing between those who he believed properly came within sub-category 2g of Priority Group 2 and those who came within Priority Group 4.
2. Notwithstanding the element of subjectivity that must attach to determining the allocation of staff to particular categories, a review of the job descriptions of those allocated to each sub-category indicates to me that a very reasonable effort was made to ensure that staff were appropriately allocated.
3. The overall objective of the nation vaccine programme as reflected in the Sequencing Guidelines was to ensure that all HCWs, whether in Priority Group 2 or Priority Group 4, were vaccinated as quickly as possible.
4. The sequencing programme for Beacon staff continued to be guided by the Guiding Principles of the Sequencing Guidelines throughout the period during which the Vaccination Clinic operated and, in particular, by the requirements that no dose be wasted and that the vaccination programme be administered in a practical manner.

SECTION 3 – FINDINGS: Persons employed by third party contractors of services to Beacon or employed by third parties with operations on Beacon Campus.

1. With the exception of cleaners working in ICU who, due to their role, were vaccinated at the same time as frontline HCWs, third party contractors who attended in the Hospital and franchisees working in the integrated Beacon Campus were not vaccinated until Beacon HCWs who wished to receive the vaccine had done so.

2. The approach taken by Beacon to the vaccination of third party contractors and franchisees was in compliance with the Sequencing Guidelines and accorded with the approach taken in major public acute hospitals.

SECTION 4 – FINDINGS: VHI Health and Wellbeing and MyMedical HCWs.

1. The staff from VHI Health and Wellbeing and from MyMedical were vaccinated on the basis that they were HCWs.
2. The approach taken by Beacon to the vaccination of this cohort was in compliance with the Sequencing Guidelines.
3. The HCWs in this cohort were vaccinated with the knowledge and consent of HSE.

CHAPTER 11: THE COMMUNICATIONS, DECISION-MAKING AND ADMINISTRATION PROCESS FOR THE VACCINATION OF TEACHERS FROM ST GERARD'S SCHOOL, BRAY.

FINDINGS

The decision to open the final five vials.

- 1.** The proximate reason for the decision to offer vaccines to the Bray Teachers was the earlier decision to pierce five vials of AZ vaccine and extract a total of 64 doses so that, at that time, there was of the order of 80 doses in syringes and available for use. If this had not occurred, the decision to offer vaccines to the Bray Teachers would not have arisen.
- 2.** The decision to pierce the five vials was in line with previous practice at clinics at the Vaccination Clinic to have sufficient syringes drawn up so that vaccinators would not be delayed in moving to their next cohort of clients. In normal circumstances, it represented approximately 30 minutes' worth of vaccines at an anticipated 120/130 vaccinations per hour. There had not been an instance at any previous clinic of a dose being drawn up and not used.
- 3.** The decision to pierce the vials was done in good faith and in accordance with previous practice in the mistaken belief as to the final check-in time for the clinic that day and that there was still a sufficient number of HCWs from CHO6 expected for vaccination to justify the decision to do so. Regardless of the misunderstanding as to the correct final check-in time, as at 15.00, shortly before the decision was taken, there were 186 people still scheduled to arrive with the possibility of other people arriving who had been scheduled for an earlier time.

The belief that there was a short window of opportunity for use of the vaccines.

4. Shortly after the vials were opened and nearly all of the syringes drawn up, it became evident that there would be a significant wastage of doses if clients for the vaccine could not be located.
5. The steps taken to locate people on the Beacon Campus and the decision to contact the Bray Teachers, were predicated on a belief that, once the doses had been extracted into the syringes, the vaccinators had between one and two hours to use them.
6. This belief was based on the experience of vaccinators at previous clinics that, after an hour or so, the AZ vaccine became viscous or ‘gloopy”, was significantly more difficult to administer, and could be painful to the recipient.
7. Unlike in the case of the PB Vaccine, there is not, to my knowledge, any published clinical data on the stability of the AZ Vaccine once drawn into a syringe. It is possible, therefore, that in the case of the final AZ vaccines drawn up on 23 March, the timeframe during which they could have been administered was, in fact, more than one to two hours. At the time, the clinical staff present, having regard to previous experience, and using their professional judgement, formed the view that they had a limited time horizon. I am satisfied that this view was formed in good faith.
8. As with the PB vaccine, the clinical advice is that, once a vial of the AZ Vaccine is pierced but the vaccine remains in the vial, there is a six hour window in which it must be administered. At the time when the person extracting the doses was informed that there could be an issue in relation to finding clients for the drawn up vaccines, only one of the doses had been extracted from the 5th vial. In principle, if the remaining doses had not been extracted from the 5th vial, there would have been a six hour window in which to locate HCWs for the 11 doses not extracted. While that may be the case, I am satisfied that, as with the prior extraction of the doses, the extraction of the remaining doses was done in good faith.

What other options conforming with the Vaccine Priority List were available?

9. Since 3 February, a policy decision prohibited the AZ Vaccine being administered to persons aged 70 and over. As at 23 March, therefore, the AZ Vaccine could not be administered to this cohort.
10. On 4 March, a new Priority Group 4 comprising persons aged 16 years to 69 with a medical condition putting them at very high risk of disease was created. As at 23 March, Beacon had not received authorisation from HSE to administer vaccines to this cohort.
11. While it may be argued that there were other professions or categories of people who were objectively more deserving of receiving the vaccine than the Bray Teachers the vaccination of people in any such cohort would not have complied with the national guidelines.
12. The only option available which would have complied with the requirements of the Vaccine Priority List was to administer the drawn vaccines to HCWs. Significant efforts were made to locate HCWs and others on the Beacon Campus. The numbers available were very limited as, since 25 February, nearly everyone on the Campus who wished to be vaccinated had received vaccines. Of the 4168 people vaccinated in the Vaccination Clinic in the three weeks leading up to 23 March, only 87 were drawn from the Campus. While it is possible that further people on the Campus might have been located on 23 March, thus avoiding the need to approach the Bray Teachers, I am satisfied that, in the context of the urgency which was believed to exist, the approach adopted of telephoning managers on wards or of services was sensible and that every reasonable effort was made to identify people on the Campus for vaccination.
13. An option which was not explored was to contact CHO6 (for whom the clinic was being operated that afternoon) to see whether they could provide, at short notice, HCWs to be vaccinated. I was informed by Beacon that they had no experience from previous clinics of CHO6 operating reserve lists and that they did not believe that CHO6 could have directed a sufficient number of HCWs to the Clinic within the very short timeframe

which they believed existed to avoid doses going to waste. I was informed by CHO6 that it maintained a reserve list and could have provided HCWs at short notice, if requested. I am not in a position to determine whether, in the very short timeframe which was believed to exist, an approach to CHO6 would have produced sufficient people to avoid doses going to waste, but it would, in my opinion, have been appropriate to do so.

Decision to vaccinate Bray Teachers.

- 14.** The decision to vaccinate the Bray Teachers was taken by Mr Cullen alone. No-one else participated in, or contributed to, the decision. The decision was taken by Mr Cullen quickly, without consultation, and was communicated to the Bray Teachers through the Principal of the Junior School while Mr Cullen was at home and before he returned to the Vaccination Clinic.
- 15.** The decision was taken by Mr Cullen in a time-pressured situation in the mistaken belief that the risk of doses being wasted entitled Beacon to administer the doses to anyone who was available, other than patients. This was based on his understanding that people other than HCWs, including teachers, had been referred for vaccination to the Vaccination Clinic by the CHOs and an incorrect interpretation of the extent of the discretion permitted in the Sequencing Guidelines. While the basis on which Mr Cullen made his decision was incorrect, I am satisfied that he made the decision in good faith.
- 16.** No-one aware on 23 March of Mr Cullen's decision to offer vaccines to the Bray Teachers raised any reservations in relation to the decision.
- 17.** The form of report given to HSE on the day after a clinic categorised people who had received vaccines under three headings, Beacon, CHO6 and CHO7. The 20 Bray Teachers were included under the Beacon heading on the information provided to HSE on 24 March. This was the same approach as adopted for other non-CHO cohorts such as people from VHI Health and Wellbeing and MyMedical. It was also the approach adopted in relation to the first staff from Beacon Creche although, in that case, Beacon

separately informed HSE by email of the fact that the Creche staff had been vaccinated to avoid doses being wasted.

Was the decision in accordance with the Sequencing Guidelines/ Vaccination Priority List.

- 18.** The challenge of meeting the imperative to avoid doses being wasted while, at the same time, ensuring a fair and transparent system for the administration of the vaccine is reflected in the inherent tension between the directive that no doses be wasted as set out in the Sequencing Guidelines and the rigid hierarchy of priority groups set out in the Vaccine Priority List. This tension was acknowledged by HSE in April, subsequent to the Vaccination Clinic ceasing operation.
- 19.** I accept Mr Cullen's statement to me that his motivation in offering the vaccines to the Bray Teachers was to avoid the doses being wasted. This motivation was aligned with the Guiding Principles of the Sequencing Guidelines.
- 20.** Teachers were categorised in Priority Group 11 on the Vaccine Priority List (Priority Group 10 following the amendments to the Vaccine Priority List on 4 March). It follows that Mr Cullen's decision was not in compliance with the Vaccine Priority List.
- 21.** The only circumstance in which Mr Cullen and Beacon could have complied with both the requirement of the Sequencing Guidelines that no dose be wasted and the terms of the Vaccine Priority List was if they had succeeded in identifying and vaccinating a further 20 HCWs at very short notice in addition to the 42 HCWs who were identified and vaccinated.

Did the decision have HSE permission?

- 22.** The use of the phrase "HSE permission" in the message from Mr Cullen to the Principal was unfortunate in that it may have inferred that HSE was aware of the decision and approved of it. This was not the case. I am satisfied that what Mr Cullen intended by the phrase was that, as he believed at the time, it was in line with the HSE requirement

that no doses should be wasted and that HSE supported earlier decisions to vaccinate other categories of what he viewed as frontline workers to avoid wasting vaccines. Contrary to what Mr Cullen believed and consequently represented to the Bray Teachers, the decision did not have HSE permission.

CHAPTER 12: THE COMMUNICATION, DECISION MAKING AND THE ADMINISTRATION PROCESS FOR THE VACCINATION OF EMPLOYEES OF THE PARK ACADEMY CRECHE, BEACON MEDICAL CAMPUS, SANDYFORD.

FINDINGS

- 1.** Childcare, as a profession, was included, in Priority Group 11 on the Vaccine Priority List (Priority Group 10 from 4 March). In principle, therefore, the vaccination of staff working in crèches was not in accordance with the priorities in the Vaccine Priority List.
- 2.** A distinction can be drawn in the case of the Beacon Crèche on the basis that it (1) is part of the integrated Beacon Campus and (2) provides the essential service of childcare to frontline HCWs.
- 3.** The decision to vaccinate the first nine staff members from the Beacon Crèche was made having regard to the zero wastage policy referenced in the Sequencing Guidelines and the fact that the Beacon Crèche is part of the Beacon Campus.
- 4.** Beacon informed HSE of the fact that staff from the Beacon Crèche had been vaccinated and HSE raised no issue with it.
- 5.** The final paragraph of the HSE Press Statement of 4 March implicitly confirms that the vaccination of the Beacon Crèche staff came within the Sequencing Guidelines.