Witness Name:
Dr Naresh Chada
Statement No. M4/NC/01
Exhibits:
Dated: 28 October 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF DR NARESH CHADA

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1. I, Naresh Chada, Deputy Chief Medical Officer, make this statement in response to the request from the UK Covid-19 Public Inquiry ("the Inquiry"), 4 June 2024 under Rule 9 of the Inquiry Rules 2006), requiring me to provide the Inquiry with a witness statement in respect of specified matters relating to Module 4.

Scope of this Statement

2. This statement is provided from the perspective of my role as Senior Responsible Owner of the Covid-19 vaccination programme in Northern Ireland, in relation to the decision-making with respect to vaccines during the Covid-19 pandemic between 30 January 2020 and 28 June 2022. I have provided my recollection of the context in which such decisions were made.

STRUCTURE, ROLE, PEOPLE AND PROCESSES

Overview of my role

3. I was appointed to the post of Deputy Chief Medical Officer (DCMO) Public Health in April 2019, having previously held the position of Senior Medical Officer in the Department (from October 2001 to March 2019) with responsibility for advising on, inter alia, planning and preparedness for a civil contingency/chemical, biological, radiological and nuclear (CBRN) emergency. I was responsible for management and policy oversight of Population Health Directorate and for providing public health advice, which includes ensuring that all necessary action is taken to protect public health and to learn lessons from outbreaks, incidents and inquiries.

4. Over the period March 2020 to October 2020, as part of my role as a Deputy Chief Medical Officer, I provided medical input for vaccination related issues in the absence of a permanent Senior Medical Officer (SMO) lead for vaccinations and health protection more generally within the Department. I was therefore involved in providing input to and clearing submissions related to the early preparatory work for the Covid-19 vaccination programme. I did not have any role or responsibility in respect of the development, manufacture, procurement or approval of Covid-19 vaccines.

5. Each of the four nations appointed a Senior Responsible Owner (SRO) for the Covid-19 vaccination programme and I was the Northern Ireland Senior Responsible Owner. The SROs were senior officials from within the respective Government health departments. Each country had a slightly different structure in place to plan and implement the Covid-19 vaccination programme and therefore the role of the SRO varied between countries.

6. As SRO, my role was to oversee the effective deployment of vaccine within Northern Ireland, as well as coordinate and align policy and communications relating to vaccine deployment across all four nations. As SRO I worked closely with the Head of the vaccination programme in Northern Ireland, Patricia Donnelly OBE, who was appointed to lead the implementation of the programme and led on the design and day to day operation of the programme in NI. I was also a member of the Department's Covid-19 vaccination programme oversight programme board. As a member of the Oversight Board, I would have taken part in meetings and discussions around planning for and responding to disparities in vaccine coverage and uptake, as well as the discussions around public messaging about the vaccines, but I had no direct responsibility for these elements of the programme.

6a. I was part of the team within the Department of Health that had discussions regarding policy decisions, while Patricia Donnelly had responsibility for operational delivery of the programme in Northern Ireland. Patricia Donnelly would also have had input into policy given the extensive scope of the programme. I do not believe there was significant overlap in our roles.

6b. I liaised with my counterparts across the UK, ensuring we all stayed aligned during the implementation of the programme, and this allowed Patricia Donnelly to focus on the day-to-day operational implementation. Moreover, as one of the Deputy Chief Medical Officers within the Department of Health during the covid response, I would have had greater strategic oversight over other aspects of the Department's response as well as the overall epidemiology of the virus which would have complemented Patricia Donnelly's contribution.

6c. The UK's SRO group initially met weekly to share our preparation plans and discuss outstanding issues. Once the programme was launched in December 2020, we monitored progress and uptake rates as well as discussed, any policy issues that arose as the programme proceeded.

Key Individuals, including government and non-government bodies:

7. The key individuals, government, and non-government bodies with whom I worked in relation to matters within the Provisional Outline of Scope for Module 4 included the following:

- the Minister for Health, Robin Swann, MLA.
- the Chief Medical Officer for Northern Ireland, Professor Sir Michael McBride and other senior officials in DoH NI;
- the UK CMO/Deputy Chief Medical Officer group;
- the 4 Nation Senior Responsible Owner Group;
- the UK Covid-19 Vaccination Programme Board;
- the Vaccine Taskforce Group;
- the Head of the Northern Ireland vaccination programme, Dr Patricia Donnelly and members of her team;
- representatives from the Public Health Agency (PHA);
- representatives from the Health and Social Care Board (HSCB) now known as the Strategic Planning and Performance Group (SPPG);
- the Executive Office's Northern Ireland Emergency Planning Group (NIEPG), which was a subgroup of the Northern Ireland Civil Contingencies Group (CCGNI) which included representatives from local councils and the Police Service for Northern Ireland (PSNI).

I am not aware of any other relevant body, agency or committee that requires to be referred to in this section.

How the relationships functioned in practice

8. Overall, I believe these relationships functioned well. This mainly involved 'Teams' video meetings but also included 'whatsapp' group chats and of course e-mail correspondences. During the preparation stages and early roll out stages of the programme, there were numerous meetings and while these undoubtedly helped to build relationships the sheer number of meetings did put us under pressure due to the size of the team in NI and the need

to cover all meetings. Also, the overall infrastructure as listed above was designed to ensure adequate communication and information flows at a local, regional and UK wide level.

9. At CMO and SRO level we developed highly productive and effective relationships that allowed us to seek advice and exchange views as and when required, while coordinating the rollout of the programme across the UK. Planning and implementing the vaccination programme was only possible because of the willingness, commitment and collaborative approach taken by a wide range of organisations at all levels within NI and across the UK. As with all relationships there were challenges at times, but these were quickly resolved due to the commitment to ensure the programme was rolled out as quickly as possible. It should be remembered this was the largest mass vaccination campaign in the history of the UK and part of a global effort so it isn't surprising that from time to time pressures would have arisen around a range of issues for example communications , deployment policy or logistics but the overall culture across all four nations was of cooperation to ensure smooth deployment of the vaccine as will be reiterated across this statement.

Overview of my role in relation to UK Government and other devolved f

10. Each country had a different structure in place in respect of oversight and deployment of the vaccine and therefore the role of the SRO varied between countries. My role in Northern Ireland was to oversee the effective deployment of the vaccination programme, as well as coordinate and align policy and communications relating to vaccine deployment across all four nations. I attended the 4 nations SRO meetings and the UK-wide Covid-19 Vaccination Programme Board, which had been established by Public Health England (PHE) and first met in May 2020. The aim of the Board was to plan for the implementation of a safe and effective Covid-19 vaccination programme to help protect the UK population from the threat of Covid-19. The Northern Ireland representation on the Board included myself as well as lead vaccination officials from the Department's Health Protection Branch. Although I did attend the UK-wide covid -19 Vaccination Programme Board on several occasions as far as I can recall it was more frequently attended by other officials in the Department. The Public Health Agency was also represented. I along with other officials kept Minister Swann informed about progress as the Board discussed the following topics: scenario modelling, vaccine characteristics, vaccine supply, vaccine usage and prioritisation, and vaccination policy development to assist with programme implementation.

11. I was the point of contact for NI for the other UK nations if they needed to discuss any issues that arose in the programme which could have implications for vaccine deployment in the other UK nations.

12. Overall, there was in my opinion a high level of collaboration and cooperation between the four countries on the implementation of the programme. This was particularly the case amongst the Senior Responsible owners at their regular meetings which was a highly effective forum for sharing progress, highlighting any emergent problems and issues and collegiate problem solving.

Chronology of key dates

13. See Annex A, attached.

Communication between advisers and the Government

14. Over the period March 2020 to October 2020, as part of my role as a Deputy Chief Medical Officer, I provided the medical input for vaccination related issues in the absence of a permanent Senior Medical Officer (SMO) lead for vaccinations within the Department. I was therefore involved in providing input to and clearing all submissions related to the early preparatory work for the Covid-19 vaccination programme. My role also included liaison with the senior staff within the Public Health Agency (PHA), who have operational responsibility for implementing all vaccination programmes in NI, in terms of preparing and planning for a vaccination programme.

15. Following the appointment of Patricia Donnelly as Head of the vaccination programme in Northern Ireland, I continued to provide input into the programme as the SRO lead for NI and as a member of the Northern Ireland Oversight Programme Board, but Patricia Donnelly provided the lead role for all day-to-day decisions and operational issues. This would have involved meetings with the Health Minister and submissions seeking approval on major policy issues. In addition, Patricia Donnelly provided updates to or attended NI Executive meetings on a number of occasions. I am not aware of any significant advice or recommendations not being accepted by the Health Minister who of course would have as part of his role subjected advice to scrutiny and challenge before accepting it.

DEVELOPMENT, PROCUREMENT, MANUFACTURE AND APPROVAL OF COVID-19 VACCINES

Role of the SRO in the development, procurement, manufacture and approval of the Covid-19 vaccines

16. The development, procurement, manufacture and approval of the Covid-19 vaccines was led by the UK government and therefore I did not have any role or responsibility in respect of the development, manufacture, procurement or approval of Covid-19 vaccines.

ELIGIBILITY AND PRIORITISATION DECISIONS

Policy decisions regarding eligibility and prioritisation

17. The Department of Health in Northern Ireland relies on advice from the independent experts on the Joint Committee on Vaccination and Immunisation (JCVI) to decide how best to use an approved vaccine and which groups or individuals should be eligible to receive it. As JCVI advice is received, this is considered by policy officials before a submission, with a recommendation, is submitted to the Minister seeking a decision.

18. In relation to the Covid-19 vaccination programme, the 4 UK Health Ministers agreed at a meeting on the 5 November 2020 that Ministers would follow a number of principles. The one relevant to vaccinations was, "We all agree to take due regard of the Joint Committee on Vaccination and Immunisation's (JCVI) advice in developing its policy position on prioritisation and utilisation of any successful Covid-19 vaccine(s)" [PM2304 - INQ000276627, and PM2305 - INQ000276628].

19. Therefore, the Department stayed in line with the advice of the JCVI on eligibility and prioritisation throughout the Covid-19 vaccination programme. Submissions were put to the Minister as updated JCVI advice was received. For example, the Minister was updated orally on developments and by submissions on 4 November and 16 November 2020 [PM2304 - INQ000276627, PM2310 - INQ000276633, and PM2311 - INQ000276634]. The Department did not introduce any other factors to determine vaccine eligibility and prioritisation criteria.

20. This process stayed the same throughout the scope of Module 4. At various points I, in my role as Deputy Chief Medical Officer with policy responsibility for vaccinations, would have been involved in approving draft submissions before they were submitted to the Minister.

21. Overall, I would have provided advice on the vaccination programme and as when required. As the Deputy Chief Medical officer, I am medically qualified with a license to practice and am on the GMC specialist register for Public Health Medicine. Therefore, as well as advising on overall strategic vaccination policy I would have provided advice on the public health aspects of the vaccination programme. This would have been in conjunction with Public Health

specialists in the Public Health agency and Dr Margaret Boyle who was seconded into the Department to assist with the programme.

Overview of liaise with counterparts in GB re eligibility and prioritisation

22. All 4 nations followed the JCVI advice on prioritisation and eligibility and while the 4 countries did not step outside the overall JCVI advice, during the early stages of the vaccination programme, each country did receive requests from various groups, and professions, such as teachers and police officers, that they should be included as a priority group. Minister Swann confirmed that NI would continue to follow JCVI advice on priority groups, to reach those considered to be at greatest risk from the effects of Covid-19.

23. In addition, queries also arose around the definition of who should be considered frontline health and social care staff or whether outside contractors working on a Trust site could be considered for vaccination. Many of these issues arose partly because of the strict handling conditions associated with the vaccines and the need to try and avoid unnecessary vaccine wastage. I liaised with my SRO colleagues to check if they had received similar queries and if so, how they had responded. I believe this enabled a largely consistent approach to be taken, while also taking into account local circumstances and where possible minimising vaccine wastage.

Differences in approach taken in Northern Ireland regarding eligibility and prioritisation decisions compared to GB

24. I do not believe there were any significant differences in approach taken in Northern Ireland in terms of eligibility and prioritisation decisions when compared with England Scotland and Wales.

Vaccines given outside of their prioritisation cohort (Messages exchanged in the "Vaccine SROs" Whatsapp group [INQ000477804])

25. The inquiry has asked for comment around the messages sent in the WhatsApp chat INQ000477804. As far as I can recall in the early months of phase one the vaccination programme there was not unreasonably a high level of interest for people to get vaccinated and protected as soon as possible. Phase one started when the programme commenced on 8 December 2020 to the 30 March 2021. On 31 March 2021, the programme moved into phase 2 when the vaccination programme expanded to the 45-49 age group.

26. In the early stages of the programme our objective was to ensure that we systematically worked our way through the priority groups as quickly as possible within the constraints of vaccine supply and according to JCVI advice on prioritization. Overall, I do not feel that significant numbers were vaccinated out of turn. As the whatsapp messages between the SROs reflect on page 17 [INQ000477804], there were various occupational groups who lobbied for early vaccination, however this was largely resisted. On occasion and in the interests of minimizing vaccine wastage small numbers of health and social care staff who were not strictly front line may have been "mopped up" by vaccinators at the end of the day and would have prevented wastage of a precious scarce resource. It is also important to note that we were seeking to protect the HSC "system" as well as individuals at a time of great stress on this sector.

Vaccination as a Condition of Deployment ("VCOD")

26a. In terms of decision making in relation to Vaccination as a Condition of Deployment ("VCOD") for health and social care staff in Northern Ireland, I cannot recall having played any role in decision making around this issue.

26b. I am aware that in February 2020, as part of the draft Coronavirus Bill, Westminster Ministers had suggested that it would be beneficial for powers to be introduced which allow for mandatory vaccination, on a temporary basis, of health and care staff, to reduce staff absences from vaccine-preventable infections and reduce onward transmission of viruses such as influenza. The proposal included that the provision should apply to all those employed by a health or care organisation, not just those delivering frontline care. 26d.Vaccines mandated under the Bill would have been limited to those recommended as suitable for the cohort by the independent JCVI.

26c.DHSC asked the devolved administrations if they intended to introduce similar powers, however, in early March 2020, DHSC Ministers subsequently dropped the powers re mandatory vaccination in the Bill and no further action was taken in NI to introduce its own legislation due to other urgent priorities relating to the pandemic.

26d.While the issue was considered again during the vaccination programme in 2021, in order to try and improve uptake rates, no policy decision to proceed was taken, as there were concerns the measure could have been counterproductive and lead to workforce challenges and the timeframe to introduce legislation would also have been challenging given the ongoing work pressures.

26e. From the beginning of the programme Health and Social Care staff were encouraged to take up the offer of vaccination and a letter signed by the heads of professions, Chief Medical Officer, Chief Nursing Officer, Chief Dental Officer and Chief Social Worker etc., was issued to encourage uptake. A specific vaccination leaflet aimed at staff was developed and distributed by the PHA and Trust communication teams issued regular bulletins to staff to encourage uptake.

VACCINE DELIVERY PROGRAMME AND ROLL-OUT PROCEDURES

Design, implementation and operational delivery of the vaccination programme, including arrangements on the ground and genesis of the programme.

27. At my suggestion, the Chief Medical Officer held a meeting of relevant stakeholders which led to the establishment the Northern Ireland Covid-19 Vaccination Programme Oversight Board in July 2020 [NC/0001 – INQ000485669]. The role of the Oversight Board was to set the direction for a future Covid-19 vaccination programme, oversee the progress of planning for a vaccination programme, and ultimately the implementation of the vaccination programme. [PM2308 - INQ000276631]. I was a member of the Oversight Board, which was chaired by the CMO, and was accountable directly to the Minister for Health. Recommendations concerning strategic policy issues were submitted by the vaccination team to the Minister for decision via oral briefings or written submissions, while key operational decisions were taken by CMO based on advice from the vaccination lead, which also involved my contribution.

28. As the NI Senior Responsible Owner for the roll out of the vaccination programme, I worked closely with Dr Patricia Donnelly and the vaccination team as they developed the implementation plan for the roll out of the vaccination programme, [PD0015 – NQ000496164 and PM2340 - INQ000276660] which took account of the JCVI eligibility and prioritisation advice, to ensure we would be in a position to be able to offer vaccination to all eligible members of the public.

29. Dr Patricia Donnelly was appointed by the CMO as the head of the Covid-19 Vaccination Programme in October 2020, to oversee and drive the planning and operational delivery of the programme. From that stage, my specific role was to work with the other SROs to oversee effective deployment of vaccine within each country and ensure coordination and alignment of policy and communications relating to the vaccine deployment across all four nations particularly as new cohorts of those to be vaccinated opened up in line with JCVI advice. The vaccination team worked on all policy and operational issues connected to the

Covid-19 vaccination programme and exhibit [PD/0001 – INQ000496150] shows the reporting structure for the vaccination programme.

30. I contributed to decisions on how, when and where each different type of vaccine approved for use could best be deployed in Northern Ireland, taking into account local circumstances and medicines regulatory requirements. I ensured the implementation plan, was kept under constant review and updated as and when required to maximise vaccination opportunities. Most cohorts were identified based on their age with the Department setting out the eligibility age range in HSS letters. Clinically Extremely Vulnerable (CEV) individuals were identified mainly by GPs based on their patient lists, but some CEV individuals were identified via their Trust. GPs identified their housebound patients and passed these details to Trust teams to arrange their visit and vaccination offer. Trust teams were also responsible for visiting all care homes and offering vaccination to all residents and staff.

31. Deployment decisions were heavily influenced by the handling and storage requirements for particular vaccine products as outlined in the relevant Summary of Product Characteristics, as well as the limited quantities of vaccine initially available. As a result, during the opening months of the programme the deployment plans had to be adapted to accommodate these strict vaccine handling conditions.

32. This meant that in NI, the Pfizer BioNTech vaccine could only be deployed at Trust level, while the AstraZeneca vaccine was deployed by GPs. Consequently, the Trust programme launched on the 8 December 2020 while the GP element of the programme began in early January 2021, following the MHRA approval of the AstraZeneca vaccine in late December 2020.

33. Overall, this worked well and also allowed Trusts to utilise the Pfizer BioNTech vaccine to supply their own mobile vaccination teams to bring the vaccine to all care homes (JCVI Priority Group 1) and offer vaccination to residents and staff, from the launch of the programme on 8 December 2020.

34. As it was easier to deploy the AstraZeneca vaccine at GP level, on occasions, I, via the SRO group, helped to facilitate a swop of some of the NI share of the Pfizer BioNTech vaccine for additional supplies of the Astra Zeneca vaccine with DHSC England. This ensured the optimum deployment of the vaccine amount available to NI which ensured priority groups could be vaccinated in a timely manner.

35. In terms of socio-economic determinants, during the planning of the deployment plans, location and accessibility of vaccination clinics was taken into account to help ensure good

vaccine uptake rates and reduce inequalities. Then, as the programme progressed and data became available, we were able to identify areas that had low vaccine uptake. Proposals were considered by the Covid-19 Vaccination Oversight Board, who agreed to test a number of community settings innovations, to explore the potential to increasing vaccine uptake in these areas, including in socially disadvantaged estates and workplaces.

36. In terms of marginalised or vulnerable groups, vaccination information was produced in a range of languages which could be accessed via the NI Direct and PHA websites and in June 2021, the booking system could also be accessed in various translations. [MMcB/7039 - INQ000390077]. During the roll out of the programme, the HSCB pharmacy team publicised the interpreter services in participating pharmacies as well as the available translation resources. The HSCB pharmacy team also shared service information with Integrated Care Partnerships (ICP) for dissemination to community and voluntary sector in the hope of reaching patients within "hard to reach" groups. An ICP is led by a committee with membership from the local Trust, two GP members: two community pharmacists, a local council representative, a Northern Ireland Ambulance Service (NIAS) representative as well as service users and carers and representatives from the voluntary and community sectors.

37. For those who did not have a Health and Care (H&C) number or permanent NI address, the DoH Covid-19 mailbox was used to assist with vaccination bookings. This mailbox was referenced on the booking platform and also on the NI direct page. However, the vaccination team did not have access to the booking system to directly make bookings for anyone requiring assistance, and so had to email the individuals contact information to the relevant Trust for them to make contact and a booking. Initially those with no H&C number could only attend a Trust led vaccination centre as the Trust system had the ability to use a dummy code to override the system, whereas this was not an available option in the community, where a H&C number was required.

38. The model for vaccine deployment in NI was based to some extent on the successful annual influenza vaccination programme, which every year sees hundreds of thousands of vaccines administered, mainly by GPs, between late September and mid-December. The Covid-19 vaccination delivery model was however also designed to be pragmatic, agile, and flexible to help ensure the vaccination programme was accessible for all sections of the community and importantly to ensure minimal wastage of vaccine.

39. However, the initial constraints with the Covid-19 vaccines, limited the ability to deploy the Pfizer / BioNTech vaccine within general practice during the first phase of the programme, as the vast majority of practices would not be able to use a full pack of 975 doses within the short 5-day defrosted shelf life while sticking to the JCVI eligibility priority lists, without

unacceptably high levels of vaccine waste. Therefore, it was agreed by the Oversight Board that the Pfizer BioNTech vaccine should initially only be deployed exclusively by HSC Trusts.

40. This meant all storage, preparation and administration of the vaccine came under each Trusts single corporate and clinical governance framework and applied to vaccine administration in all hospital sites, temporary premises being utilised as large Vaccination Centres, and administration by HSC Trust employees working in community settings such as Care Homes. Professional and legal responsibility for safe and secure handling of the vaccine rested with the HSC Trust Head of Pharmacy and Medicines Management.

41. Later changes to Pfizer BioNTech vaccine characteristics including longer shelf life and the approval of other vaccines such as the AstraZeneca vaccine made it easier to expand the vaccination programme to other providers outside of HSC Trust vaccination sites, including general practice and community pharmacy. Throughout the vaccination programme, vaccine wastage remained extremely low despite the challenges posed by the pharmaceutical and handling characteristics due to the stock control and handling processes developed and overseen by pharmacy teams in all settings.

Liaison between local government, Northern Ireland Executive departments and UK Government.

42. I took part in the SRO group, which initially met at least weekly, to share preparation plans discuss outstanding issues and monitor progress with vaccine roll out. Any major issues that arose were discussed and resolved at these meetings to ensure a largely uniform approach was largely taken across the 4 countries. The level of cooperation proved to be very effective, and a UK wide policy group established in relation to the Covid-19 programme has continued but has now been expanded to include other vaccination programmes as well.

43. It was via the SRO group where we coordinated a suitable start date and recommended to our respective Ministers that the 8 December 2020 should be the launch day for the vaccination programme in all 4 UK countries.

44. Along with Patricia Donnelly, I gave updates and responded to queries at the weekly meeting of The Executive's Office's Northern Ireland Emergency Planning Group (NIEPG), which was a subgroup of the Northern Ireland Civil Contingencies Group. I believe the relationships established at the NIEPG meetings proved invaluable at certain key stages of the programme for both providing and receiving information.

45. In addition to the SRO meetings, I and officials from the vaccination team had regular engagement with our counterparts throughout the UK as part of the UK-wide Covid-19

Vaccination Programme Board. These meetings discussed various issues such as deployment plans, JCVI advice and forthcoming announcements, as well as a large focus on vaccination uptake.

Factors taken into consideration when designing the vaccination deployment programme

46. Patricia Donnelly led on the detailed planning for the vaccination programme but I am aware the following factors were considered when designing the programme:
    - logistics,
    - vaccine deployment,
    - communications,
    - workforce, and
    - digital requirements

47. One of the biggest factors the programme had to overcome when designing the deployment model was vaccine characteristics such as presentations in large pack sizes with multi-dose vials, ultra-low temperature storage, and requirements for thawing and reconstitution prior to administration. In addition, considerations around the limited quantities of vaccines available in the earlier stages of rollout.

48. In terms of vaccinations generally, in Northern Ireland, the vaccination delivery model normally relies heavily on GP practices administering vaccines to eligible individuals. However, the constraints set out above limited the ability to deploy the Pfizer / BioNTech vaccine within general practice during the first phase of the programme, as the vast majority of practices would not be able to use a full pack of 975 doses within the short 5-day defrosted shelf life while sticking to the JCVI eligibility priority lists, without unacceptably high levels of vaccine waste.

49. As mentioned at paragraphs 39 and 40, the Pfizer BioNTech vaccine was initially only be deployed exclusively by HSC Trusts. Later changes to Pfizer BioNTech vaccine characteristics including longer shelf life and the approval of other vaccines such as the AstraZeneca vaccine made it easier to expand the vaccination programme to other providers outside of HSC Trust vaccination sites, including general practice and community pharmacy.

How the programme compared to other vaccination programmes and aspects that were innovative/unusual

50. As mentioned at paragraph 38, the model for vaccine deployment in NI was based to some extent on the successful annual influenza vaccination programme, which every year sees hundreds of thousands of vaccines administered, mainly by GPs, between late September

and mid-December. However, due to the sheer size of the Covid-19 vaccination programme, the delivery model was designed to be pragmatic, agile, and flexible to help ensure the vaccination programme was accessible for all sections of the community and importantly to ensure minimal wastage of vaccine. This involved the use of Trusts, GPs and community pharmacies to deliver the programme.

51. Using large vaccination centres and pop-up clinics, was a new concept for Northern Ireland. Large vaccination centres enabled the programme to maximise vaccine use and ensure eligible individuals were offered vaccination faster than could have been achieved by using a GP based model alone. The vaccination rate capacity was increased further when a mass vaccination centre at the SSE Arena, Belfast was established. The SSE Arena vaccination centre went live from the 29 March 2021 and was able to facilitate the vaccination of up to 6,000 people per day. It closed in August 2021, with over 367,000 vaccinations administered during its time.

52. As the programme continued, an innovative approach adopted was the use of Trust teams to set up 'pop-up' clinics in various locations aimed at specific groups such as young people etc. Pop-up clinics were also established within specific Super Output Areas[1] (SOAs provide a deprivation index for over 890 small localities in NI) [PD/0004 – INQ000496153]. They were set up in locations where there was high footfall, such as shopping centres and town centres and certain occupational settings. This provided vaccination options at much easier to reach locations, particularly in areas where the uptake rate had been lower than average.

Implementation of the programme, including the management of logistics and the division of labour with other organisations including the Northern Ireland Executive

53. The vaccination programme was delivered in Northern Ireland using a number of delivery models, this included Trust led clinics, GP based clinics and eventually as vaccine supplies improved, community pharmacy clinics, to administer the vaccines. The programme also involved vaccination in care homes, as well as mobile teams vaccinating house bound patients or setting up 'pop-up' clinics in areas with low uptake or high footfall density. At one stage in the autumn of 2021, a school-based vaccination programme, was implmented by Trust school nursing teams, to offer a first dose of vaccine to all those aged 12-15 years of age.

[1] Super Output Areas (SOAs) of which there are 890 in NI were developed by the NI Statistics and Research Agency (NISRA) to improve the reporting of small area statistics, based on the most and least areas of deprivation.

54. The Department of Health was responsible for the policy and operational delivery of the vaccination programme. Implementation of the programme was closely monitored by the vaccination team, who adjusted the plans or redirected vaccine supplies as and when required. Regular meetings were held with the lead Trust Directors as well as representatives for GPs and eventually community pharamcies, to set out future plans and monitor progress as well as resolve any local difficulties. The Northern Ireland Executive had no role in implementing or monitoring the roll out of the programme.

55. All the vaccines used in the programme were procured by the UK Government and shared pro rata with the 4 UK countries. The Northern Ireland share of vaccine was delivered into central storage facilities in Northern Ireland, mostly via a GB hub, but sometimes directly from a vaccine manufacturer. From central stores in NI, the vaccine was distributed on request, directly to those administering the vaccine, i.e. Trust pharmacies for all Trust led programmes such as the Trust centres, mobile teams and school teams or to GPs and community pharmacies.

56. In order to be able to deliver the Covid programme it was recognised that having an expanded workforce available would be essential. Prior to the pandemic the Human Medicines Regulations (HMR) 2012 required that only "appropriate practitioners" administer vaccines. Given these limitations and capacity constraints of the available workforce eligible to administer the vaccines amendments to the HMR 2012 were taken forward on a UK wide basis. Then, authorised by the Minister, Pharmacy colleagues developed various Protocols throughout the course of the programme to facilitate the delivery and administration of the Covid vaccines by an expanded workforce. This enabled additional staff groups such as suitably trained non-registered healthcare workers to support the programme.

57. As stated previously, the overall model for deployment was heavily influenced by the handling and storage requirements for particular vaccine products, the limited quantities of vaccine initially available, how the vaccine was presented in large multi dose pack sizes, as well as restrictions on movement of a punctured vial. These large pack sizes along with their strict handling conditions dictated where vaccines could initially be deployed in NI. As a result, the Trust programme launched on the 8 December 2020 by vaccinating staff and care home residents while the GP element of the programme began in early January 2021 with patients aged 80 years and over being invited in for vaccination.

58. Generally, GPs were responsible for the vaccination of their older patients and those considered clinically extremely vulnerable (CEV) or clinically vulnerable (CV), while Trusts vaccinated all eligible staff before the centres were opened up to age cohorts too, which allowed a twin track approach. Eventually, once vaccine supply improved, we were able to

introduce a multi-track approach, which enabled those eligible for vaccination to choose where they wished to receive their vaccination. I have set out detail in relation to each element of the model from paragraph 59.

58a. The clinically extremely vulnerable (CEV), JCVI group 4, and clinically vulnerable (CV), JCVI group 6, cohorts were defined in the Green book chapter for Covid vaccination. The Green Book has the latest information for health professionals on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. GPs and Trust Consultants were asked to identify their patients that fell into the CEV definition in order to get them priortised for vaccination. GPs led the identification of their CV patients.

58b. As the programme progressed, CEV and CV cohorts were able to identify themselves as eligible by providing a shielding letter they had received earlier in the pandemic, or by a letter received from a clinician.

Care Homes

59. Trust mobile teams were used to administer vaccinations in care homes. For this to happen, it required direct engagement by Departmental Pharmacy colleagues with the MHRA on the handling of the Pfizer BioNTech vaccine. This enabled the NI vaccination programme to be the first part of the UK to deploy the vaccine in care homes from the very start of the programme. As Trusts were setting up large vaccination centres, to vaccinate health and social care staff, with pharmacy support, each Trust was able to pack down smaller quantities of the vaccine for use by their mobile teams which was transported to a care home where vaccination was offered to residents and staff. The same delivery model was used during the first booster campaign in the autumn/winter of 2021 but since the spring booster programme of 2022, a community pharmacy led programme has been used in care homes. This involves each care home being paired with a community pharmacy, who attends the home to offer vaccination to residents and staff.

Trust Vaccination Centres

60. As mentioned earlier, Trusts were tasked with establishing large vaccination centres and there were initially 7 HSC Trust-led static vaccination centres operating at the start of the vaccination programme. These centres were located either on HSC Trust sites or in council premises such as leisure centres and were initially used to vaccinate Health and Social Care workers. By February 2021 the centres were also opened to eligible age cohorts, those aged 65-69 years of age being the first to be able to book a vaccination slot at a Trust centre. As the programme developed and vaccine supply increased, the South Eastern

Health and Social Care Trust (SEHSCT) were asked to set up a mass vaccination centre to help speed up the vaccination process and offer a wider choice of location and timing to those coming forward for vaccination. This was located at the SSE Arena Belfast and operated between late March 2021 and August 2021 during which time over 367,000 vaccinations were administered.

GP Practices

61. At the beginning of the Covid-19 vaccination programme there were around 321 practices located across NI. Following agreement with the Northern Ireland General Practitioners Committee (NIGPC), all practices agreed to administer primary doses to those eligible, in line with JCVI advice. This helped ensure that many people, particularly the elderly, had easy local access to the vaccine via their own GP, from early in the programme. Each practice put in place its own particular arrangements for inviting their patients in to receive vaccination. GPs began their vaccination programmes in January 2021 following the approval of the AstraZeneca vaccine by offering vaccination to all their patients aged 80 years or older. They then continued to work down through the eligible cohorts in line with JCVI advice. Overall, GPs were responsible for a delivering around 33% of all first and second doses of all the Covid-19 vaccinations administered in NI, while Trusts were responsible for 59% and community pharmacies around 8%

Community Pharmacies

62. Following improvements in vaccine supply, community pharmacies began to offer the AstraZeneca Covid-19 vaccine from the 30 March 2021. This assisted the speed of delivery to the eligible cohorts by providing an accessible and convenient option to access vaccination in local communities across Northern Ireland. By May 2021, 347 pharmacies were providing Covid-19 vaccinations.

Mobile Teams

63. In addition to the delivery models outlined above, Trust mobile vaccination teams visited with all housebound patients. As the programme developed Trust teams were also used to set up 'pop up' clinics in various locations aimed at specific groups, specific Super Output Areas[2] (SOAs provide a deprivation index for over 890 small localities in NI) [PD/0004 – INQ000496153], or where there was high footfall, while at a later stage of the programme school nursing teams were also involved in the delivery of the vaccine in special schools and to all 12–15-year-olds via a school-based programme.

[2] Super Output Areas (SOAs) of which there are 890 in NI were developed by the NI Statistics and Research Agency (NISRA) to improve the reporting of small area statistics, based on the most and least areas of deprivation.

Role of local authorities, armed forces and voluntary sector

64. Local Authorities did not play a direct role in planning the covid-19 programme but they did facilitate some of their buildings to be used as vaccination centres to deliver the programme. In addition, they provided advice to those GP practices that chose to set up vaccination clinics outside of their normal premises. Liaison with local government took place via the Executive's Office's Northern Ireland Emergency Planning Group (NIEPG), which I attended along with Patricia Donnelly, where we provided updates and responded to queries at the weekly meeting.

65. The establishment of the large mass vaccination centre at the SSE Arena, Belfast, referred to above, was only possible following a decision to activate the Military Aid to Civil Authority (MACA) requesting military assistance to Health and Social Care in NI [PM2345 - INQ000276665, PM2346 - INQ000276666, PM2347 - INQ000276667, and PM2348 - INQ000276668]. As a result, 100 Combat Medical Technicians were stationed at the SSE Arena, from 22 March 2021 to 31 May 2021, to assist with the administration of the vaccine. Prior to the launch of the programme some Trusts took up an offer to receive advice from Ministry of Defence (MoD) personnel regarding where to locate their vaccination centre(s).

66. In terms of the voluntary sector, I was aware that the vaccination team approached Volunteer Now, British Red Cross and the Ulster Gaelic Athletic Association (GAA) to explore the idea of volunteers supporting the mass vaccination centres across Northern Ireland in a meet and greet role. I understand this resulted in volunteers being deployed at vaccination centres across Northern Ireland.

Feedback from vaccinators or other groups to the NI Executive

67. The Northern Ireland Executive had no role in the deployment of the vaccination programme and therefore I am not aware of any procedures established for Health and Social Care trusts, health care professionals, local authorities, armed forces or the voluntary sector to raise issues to the NI Executive.

68. The Department of Health was responsible for the operational delivery of the vaccination programme from the start of the programme in December 2020, until the start of April 2022, when operational responsibility transferred back to the PHA.

69. If challenges or issues arose, these were escalated to the Department via established lines of communication with the organisation in question. i.e. if an issue arose at a Trust led clinic,

this would normally have been resolved within the Trust but if necessary, it would have been raised by the Trust lead Director via the weekly liaison meetings with the vaccination team in the Department. Similar arrangements were in place for GPs and community pharamcies.

Vaccine wastage

70. For routine vaccination programmes, the usual wastage can be around 10-20%. However, as vaccine availability was lower during the initial roll out of the programme, I was aware that the vaccination team tasked those delivering the programme to meet target waste levels of under 5%. Those involved in the vaccination programme were provided with guidance on the strict handling conditions associated with the vaccines. I understand the actual waste levels achieved were around 1%, which was an excellent result, particularly given the strict handling conditions associated with the vaccines.

71. I believe this was achieved partly as a result of the enthusiasm by members of the public to take up the offer of vaccination, which avoided vaccine going to waste. It was also achieved by ensuring good accessibility of vaccination clinics and taking a pragmatic approach once a vial was opened which saw a small number of individuals vaccinated slightly earlier than they otherwise would have been under the JCVI prioritisation list.

Vaccine supply

72. The Department for Business, Energy & Industrial Strategy (BEIS) led on the procurement of all Covid-19 vaccines on behalf of the whole of the UK. The vaccines and vaccine related items were shared across the UK based on the Barnett formula[3]. The Barnett formula vaccine supply arrangements worked effectively and ensured NI, and the other 3 UK countries, had equal access to authorised vaccine supplies throughout the programme. As mentioned earlier in my statement, the Northern Ireland share of vaccine was delivered into central storage facilities in Northern Ireland and from there distributed on request, directly to those administering the vaccine, i.e. Trusts GPs or community pharamcies. Vaccine supply was a standing agenda item at SRO meetings and each country held its own bilaterial meetings with the vaccine team within BEIS.

[3] The Barnett formula is a mechanism used by the Treasury in the United Kingdom to automatically adjust the amounts of public expenditure allocated to Northern Ireland, Scotland and Wales to reflect changes in spending levels allocated to public services in England, Scotland, Wales and Northern Ireland, as appropriate. For Covid-19 vaccine supply it was agreed the 4 countries would receive the following split in vaccines: England 84.09%, Scotland 8.28%, Wales 4.78% and Northern Ireland 2.85% of the total vaccines authorised for use.

72a. I had no concerns about using the Barnett formula to divide the vaccine between the 4 nations. This has been frequently used for other vaccination programmes over the years and has worked well. I was confident that once the programme was established there would be sufficient flexibility to share vaccine across the UK as required. Given the relatively small size of Northern Ireland it has normally been possible to accommodate any increase required or to redistribute excess vaccine to other parts of the UK.

73. In advance of the programme starting, as well as during the course of the programme, I am aware that the Department's Chief Pharmaceutical Officer liaised with the Medicines and Healthcare Regulatory Agency to ensure that NI's vaccine deployment model was consistent with the regulatory requirements for medicines [MMcB/7001 - INQ000390028 and MMcB/7001a - INQ000390029].

74. At times we did face vaccine challenges, an example of this was during March 2021, the Department had expected a significant volume of the AstraZeneca vaccine to be delivered into the UK. This was mainly down to two large deliveries of short-dated AstraZeneca vaccine stock from India. The schedule had predicted that the first delivery would arrive in the UK on the 8 March while the second delivery would be received by the 26 March.

75. For Northern Ireland we were expecting around 140,000 doses from each of these deliveries and had prepared delivery plans on that basis. The first delivery of 140,000 doses was received as planned in early March however on 17 March we were informed by colleagues in England that the second delivery of the India vaccine stock was delayed, due to production issues, and would likely not be delivered until mid/late April.

76. While this had an impact on and slowed down vaccination plans for late March and early April when programme delivery was due to speed up with the opening of the SSE arena vaccination centre. However, the programme remained on track to roll out the vaccination to the remaining adult population over the following months, as planned.

77. I am not aware of any concerns raised with Northern Ireland regarding particular areas or groups not receiving sufficient supply levels, equal access or fair distribution.

Vaccine distribution

78. As previously stated, when the programme first began the overall model for deployment was heavily influenced by the handling and storage requirements for particular vaccine products, the limited quantities of vaccine initially available, how the vaccine was presented in large multi dose pack sizes, as well as restrictions on movement of a punctured vial. These large

pack sizes along with their strict handling conditions dictated where vaccines could initially be deployed in NI.

79. This meant that in NI, the Pfizer BioNTech vaccine could only be deployed at Trust level, while the AstraZeneca vaccine was deployed by GPs. This was also necessary as, unlike other parts of the UK, NI did not have a GP Federation organisational arrangement which could have allowed the large packs of Pfizer BioNTech vaccine to be legally broken down and distributed in smaller numbers to individual GP practices within a Federation. Without such a Federation GPs would require a manufacturing licence to break down and distribute such large packs of the vaccine. Therefore, the large pack size limited the utility of the vaccine to those providers capable of vaccinating large numbers of individuals within the short expiry period after defrosting, which at that point meant that only HSC Trust vaccination centres were suitable. As a result, the Trust programme launched on the 8 December 2020 by vaccinating staff and care home residents while the GP element of the programme began in early January 2021 with patients aged 80 years and over being invited in for vaccination.

80. The vaccination rollout plan did include a focus on vaccine equity, with the programme starting simultaneously across the NI Trusts and then simultaneously in the GP sector when the AstraZeneca vaccine became available.

81. Trusts and GPs submitted their weekly vaccination requirements and while inevitably there were some restrictions due to the overall amount of vaccine available, all Trusts and GPs received vaccine supply propionate to their overall size and previous vaccine use. I believe this system worked well. As previously mentioned, as it was easier to deploy the AstraZeneca vaccine at GP level, on occasions, I, via the SRO group, helped to facilitate a swop of some of the NI share of the Pfizer BioNTech vaccine for additional supplies of the Astra Zeneca vaccine with DHSC England.

Evaluation of decision-making on prioritisation and eligibility and other factors on the impact on the delivery of the programme

82. As previously stated, the NI programme followed the advice of JCVI in relation to all priortitisation and eligibility issues and I believe this worked well and was generally accepted and understood by members of the public. The ranking of priorities by JCVI, was a combination of clinical risk stratification and an age-based approach and JCVI had issued an interim prioritisation list on the 25 September 2020, which greatly helped the vaccination team to focus on effective delivery options. As with all vaccination programmes, having quick and clear definitions of who is eligible and who a particular vaccine should or should not be given

to, is extremely helpful. Any change of policy, such as the change to the dose interval or restrictions on who a vaccine can be given to inevitably has an impact on the delivery of the programme.

Children's programme

83. In relation to children, JCVI understandably took a precautionary approach and did not initially recommend vaccination of children. As the pandemic progressed, data accumulated on vaccine efficacy and safety, including incidence and severity of suspected adverse events, as well as on the incidence of rare complications following Covid-19 infection in children and young people (myocarditis, paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS), and long Covid).

84. Initially only those aged 16 and 17 years of age in a clinical at-risk group were recommended for vaccination and by early August 2021 this had been extended to a group of 12–15-year-old clinically at-risk children with specific conditions as well as those aged 12-15 years of age who were the household contacts of anyone who is immunosuppressed [PM/3185 - INQ000348929, PM/3186 - INQ000348930, MMcB/7016 - INQ000390048, MMcB/7016a - **INQ000348931**, MMcB/7017- INQ000390050 and MMcB/7017a - INQ000390051].

85. In order to facilitate these vaccinations special arrangements had to be put in place and they were then invited to attend a dedicated vaccination centre at either a special school or Trust vaccination centre. The expansion of the vaccination programme to some 12–15-year-olds followed on from the MHRA approval in June for Pfizer/BioNTech Covid-19 vaccine could be used in those aged 12 years and older.

86. When it came to offering vaccination to all 12 to 15 year olds, as JCVI considered harms and benefits primarily from a health perspective, the 4 UK Health Ministers sought further advice from the 4 UK Chief Medical Officers from a broader perspective (for example, considering impacts to education) on the Covid-19 vaccination of all young people aged 12 to 15. This occurred after JCVI had advised that while "*Overall the Committee was of the opinion that the benefits from vaccination were marginally greater than the potential harms…. The margin of benefit, based primarily on a health perspective, is considered too small to support advice on a universal programme of vaccination of otherwise healthy 12-15 year of children at that time.….*" [PM/3192 - INQ000348936, PM/3193 - INQ000348937 and PM/3194 - INQ000348938].

87. The joint UK CMO advice, supported by a range of expert input, found that taking into account both JCVI findings on marginal but positive health benefits alongside the likely

benefits of reducing educational disruption and the consequent reduction in lifelong public health harm from educational disruption, vaccination in this group was recommended. The offer of a single dose of vaccine was extended to all 12–15-year-olds in October 2021. In Northern Ireland it was decided by the Oversight Programme Board to make best use of limited Health and Social Care resources by implementing the one dose schedule for all 12–15-year-olds by joining in with the annual school-based Influenza programme. The flu vaccination programme requires just one dose of vaccine to be administered and the programme officially runs from October to the end of March, but the vast majority of flu vaccinations are administered pre-Christmas. The flu programme had recently been expanded to include secondary school age children and therefore on this occasion, children aged 12-15 years of age would be eligible for both a flu and Covid-19 vaccination.

88. The PHA lead on implementing this element of the programme and worked with the Trusts school nursing teams to implement a school-based programme for the first dose of Covid-19 vaccine. This was implemented over the period October 2021 to January 2022.

89. Uptake was low compared to earlier phases of the programme which had been aimed mainly at older people or those with underlying health conditions. This was also partially affected by the isolation rules in operation at that time and school testing protocols which saw large numbers of school children self-isolating as they had tested positive for SARS-Cov-2 or had been in contact with someone who had tested positive as well as a general understanding that children were at the lowest risk overall from Covid-19 [MMcB/7018 -INQ000137386].

90. By late November 2021, JCVI advised that a second dose could be offered to all healthy 16- and 17-year-olds, with and extended dose interval of 12 weeks or more [PM/3196 - INQ000348940]. By early December, JCVI then advised that all 12–15-year-olds could receive a second dose at least 12 weeks after the first dose [PM/3197 - INQ000348941].

91. It was agreed by the Oversight Board that second doses would be made available via Trust led clinics. This was because, the seasonal influenza school-based programme would be completed shortly and 12-15 year olds would only start becoming eligible for a second dose from late January 2022 onwards, therefore it would not be an efficient use of resources to ask Trust teams to revisit all secondary schools again to administer second Covid-19 doses.

92. Overall, the uptake rate in children remained low and I believe this was partly to do with the perceived delay in reaching a decision on vaccination.

<u>Limiting the use of Oxford AstraZeneca vaccine</u>

93. In early April 2021, following emerging concerns raised about a rare risk of thrombosis / thrombocytopenia with the AstraZeneca vaccine, JCVI announced that the vaccine should not be given to anyone under 30 years of age. This was further revised in early May 2021 to include anyone aged under 40 years of age.

94. The Health Minister was informed of this in the submissions exhibited [PM2351 - INQ000276671, PM2352 - INQ000276672, PM2353 - INQ000276673, PM2354 - INQ000276674 and PM2355 **INQ000305132** This development had a major impact on the community pharmacy element of the programme which was at that stage unable to deploy the Pfizer / BioNTech vaccine due to the handling constraints outlined above. It was considered likely that it would also have an impact on the pace at which the programme could be delivered, affecting the timescale for completion, as the majority of vaccinations in for those remaining would have to be completed using the Pfizer / BioNTech vaccine alone. It was anticipated at that stage that all first doses would not be completed for everyone aged 18 years and over until the end of July 2021, while it could be mid-September 2021 before all second doses were completed [PM2356- INQ000276676, PM2357 - INQ000276677 and PM2358 - **INQ000303627** . Despite the restrictions on the use of the AstraZeneca vaccine, the vaccination programme continued to quickly move down through the remaining cohorts and by 27 May 2021, the programme was opened to all adults, aged 18 and over [PM2359 - INQ000276679].

Data collection and how this was processed, stored and shared.

95. Prior to the Covid-19 pandemic, there was no single IT system that captured vaccination data in Northern Ireland. Most vaccinations are given to children and uptake information is recorded on the Child Health Information System (CHIS) but these only record vaccinations for those aged 18 years or under. Vaccinations of adults, such as the annual influenza vaccination programme was recorded on individual GP IT systems and uptake rates were based on claims submitted by GPs. As a result, information on uptake rates only became available several months into a flu vaccination programme.

96. In order to ensure accurate and timely uptake data was available for the Covid-19 programme, the Minister approved the development of a Vaccine Management System (VMS). This information was then used to, report on population uptake by phase of the programme and other agreed data variables and to identify areas of low uptake, including at 'super out-put area'.

97. Initially, ownership of the VMS sat with the GP advisors' group within the Health and Social

Care Board, but this was then transferred to the PHA during the course of the programme. The PHA would be best placed to provide an explanation as to how the data was processed and stored including whether the data was shared. The VMS was subsequently retained and adopted by the PHA for other vaccination programmes, such as the influenza and shingles programmes, and I believe it is a valuable legacy from the pandemic.

98. The Vaccine Management System (VMS) was used to collect data throughout Northern Ireland. All vaccination details were added to the VMS when an individual was vaccinated and this data was shared with key decision makers, including the Oversight Board, and used to inform both local and national decisions within NI. For example, at a Northern Ireland wide level, the decision to extend access to vaccination down through the remaining JCVI priority groups was informed by the assessment that the majority of an earlier cohort had been vaccinated/invited for vaccination, based on uptake data and vaccination slots booked. Uptake data from NI was also fed into JCVI meetings.

99. The vaccination team used the VMS data to identify any specific cohort or groups with lower uptake. Reviews of the NI Vaccine uptake data in March 2021 identified a number of geographic areas, such as Mid Ulster Council area, parts of Derry and Strabane Council area as well as parts of inner-city Belfast, as having below average uptake, this coincided with areas with a high migrant worker population or high levels of deprivation. Various initiatives were implemented to improve uptake in these areas and within these groups.

Vaccine Targets

100. I am not aware of any specific vaccine uptake targets being set for Northern Ireland, however it was hoped to achieve high uptake rates and I believe overall this was achieved, particularly in the older cohorts.

Equality analysis of uptake data

101. I was not directly involved in monitoring this aspect of the programme, but I was aware the vaccination team closely monitored vaccine uptake data from the beginning of the programme to identify any cohort, group, or geographical area that had low Covid-19 vaccine uptake. In the early stages of the programme uptake was very high in the older adult population but data from March 2021 onwards identified several geographical locations and ethnicities which were below the NI average vaccine uptake rates.

102. I was also aware that the Department asked the PHA, who were the experts on this issue, to set up a Covid-19 Vaccine Low Uptake Working Group to further support a number of key

cohorts which had been identified through vaccine uptake data as having lower than average uptake of the Covid-19 vaccine. This involved the work and expertise of the Health Improvement team within the PHA working closely with their Behavioural Science team as well as liaising with their colleagues from across the UK to try and identify trends or issues that would affect uptake rates. [PD/0002 – INQ000496151]

Deviation from vaccine delivery plan

103. Given the availability of vaccination slots at Trust led clinics, and the logistical issues with deploying the Pfizer / BioNTech vaccine by general practices, Department decided to make best use of all available vaccines by introducing a twin track approach in late January 2021. This had not been in the original vaccine delivery plan; however, the plan was designed to allow flexibility to adapt to the needs of the local population and availability of vaccine. The twin track approach started after priority group 4, i.e., those aged 70 to 74 years of age as well as those considered to be clinically extremely vulnerable (CEV), had started to be invited for vaccination by their GP.

104. Taking on board feedback from the HSCB GP advisors and NI GPC representatives the Department agreed to allow priority 4 group to continue to be solely vaccinated by their GP, while the opportunity to book a vaccination slot at one of the Trust led centres was extended to everyone aged 65-69 years of age [PM2333 - INQ000276655, and PM2334 - INQ000276656]. This was communicated to the public via press release and media reports. As additional cohorts became eligible, careful planning, and agreement between HSC Trusts and HSCB GP liaison leads, and later HSCB pharmacy leads, was essential to try and avoid duplication of effort.

105. A further deviation was allowing the option to walk-in to a Trust vaccination centres, to be vaccination without an appointment. The SSE Arena ran a pilot walk-in clinic on Sunday 27th June 2021, which vaccinated almost 400 individuals on the first day. While this was open to any age group it was a particularly aimed at younger cohorts as research indicated that while they were content to receive the vaccine, they were less inclined to book an appointment. This was communicated to the public via press release and media reports. [MMcB/7159 - INQ000390195]

106. The Department announced publicly via media communications any major developments such as approval of a vaccine or the opening of a new cohort eligible to be vaccinated and worked closely with the PHA communications team who tailored social media messages for example to particular cohorts in order to keep them updated on vaccination related developments.

Differences between the vaccination programme in Northern Ireland and the rest of the UK

107. I believe that the Department of Health in Northern Ireland had sufficient flexibility and autonomy to tailor roll out procedures to meet the needs of the local population. The Northern Ireland delivery model was similar to the models used in England and Wales, in that all 3 models used a combination of Trust led clinics and vaccination centres, GPs and community pharmacies to administer the vast majority of vaccinations. However, the model used in Scotland was different to the rest of the UK, in that the GP element in the Scottish model was much smaller. This was mainly due to the Scottish Government introducing a Trust led vaccination model for routine vaccinations prior to the pandemic.

108. A difference between the model used in England compared to NI was the use of Primary Care Networks (PCN) in England. These are created by GP practices working together with community, mental health, social care, pharmacy, hospital and voluntary services in their local areas in groups of practices. In Northern Ireland, GP practices work collaboratively in GP Federations, which are community interest bodies registered under the Companies Act 2006, towards the common objective of improving the health and wellbeing of local communities. However, the HSCB only commissions vaccination services from individual GP practice providers, and vaccines are subsequently delivered under extant distribution arrangements to individual contracted GP practice providers who assume ownership of the vaccine at the point of receipt from the distribution partner, and so it was not feasible to develop a mechanism for movement of vaccines between vaccine providers within GP Federations that provided clarity around medicines governance and accountability arrangements and which was consistent with the general requirement for organisations undertaking such movement to hold a Wholesale Dealers Authorisation (WDA).

109. Additional logistical challenges such as the requirement to take delivery of packs of the Pfizer / BioNTech vaccine stored at ULT (ultra-low temperature) storage were also barriers to the deployment of this vaccine in Northern Ireland during the early stages of vaccine deployment, as this would have required the safe handling and disposal of dry ice that was felt to be unviable within a general practice setting.

110. These factors did restrict the options for vaccine deployment in NI, had arrangements been able to be developed whereby vaccination services were contracted by GP Federations rather than individual practices then this may have allowed for the potential deployment of the

Pfizer / BioNTech vaccine to be distributed to a GP Federation acting on behalf of a number of practices. Later extensions to the thawed shelf life of the Pfizer / BioNTech vaccine allowed the development of arrangements for vaccine to be thawed at distributor level and delivered to GP providers at refrigerated temperatures, which alleviated these concerns and allowed the deployment of the Pfizer / BioNTech vaccine in general practice.

111. Another difference between the delivery of the programmes in England, Scotland and Wales and how this occurred in Northern Ireland was the use of a central booking/allocation system. In England, there appeared to be a booking system that generated vaccination slots out to individuals as the programme moved its way down through the eligible cohorts. This helped to control how the roll out occurred and individuals received details of where and when they could be vaccinated. This process may have helped persuade some individuals to come forward who otherwise would not have sought out a vaccination. However, as the programme moved into younger cohorts, a significant number of individuals did not show up for their vaccination which caused issues regarding the predicted use of vaccine and time wasted for staff.

112. In NI, a large proportion of vaccinations were carried out by GPs and each Practice put in place its own arrangements for inviting their patients such as letters, texts or phone calls. When the Trust vaccination centres were opened to the public, individuals could book a vaccination slot online (or by phone) and they could pick a date/time that suited them. Individuals had to be proactive to book a vaccination slot but the numbers who did not attend after booking a slot were relatively low overall.

113. With the introduction of the Vaccine Management System (VMS) for the Covid-19 and flu programmes in NI, it may be possible, subject to IT developments, to introduce a central allocation system if required in a future mass vaccination scenario. However, the lessons learnt in the current programme have been that older people are more likely to take up the offer of vaccine in whatever way it is offered while younger cohorts are more hesitant. The proactive allocation of vaccine slots for the younger cohorts may lead to higher levels of vaccine wastage.

Rationale for differing approach

114. As mentioned in the previous paragraphs, some of the differences, such as the use of a Trust based model in Scotland, was connected to the Scottish decision pre-pandemic to move vaccination services away from a GP setting. In NI, the Health and Social Care system has been under increasing pressure for a number of years due to an increasing elderly demographic as well as a lack of long-term health care structural reform and lack of relative

political stability. Therefore, as the system was already under strain, setting up and delivering a mass vaccination programme, at the same time as resuming those services that had been stood down during earlier lockdowns, was a difficult balancing act. While these circumstances were not entirely unique to Northern Ireland, it was an issue that had to be factored into the design of the NI vaccination delivery model.

115. Due to having no central register of 'carers' there was no definitive way for individuals in NI to produce evidence that they were a carer, and therefore flexibility was needed to ensure this group gained access to vaccination. This involved allowing individuals to self-identify as carers with no requirement to provide proof [PM2333 - INQ000276655, and PM2334 - INQ000276656)]. This differed from other parts of the UK where central registers existed and therefore proof was providable and was required.

115a. I understand that in May 2023, the Department established the Social Care Collaborative Forum. The purpose of the Collaborative Forum is to provide a formal mechanism to support opportunities for greater co-operation, co-production of guidance/policy which involves the Department and partner organisation(s) and stakeholders developing this together, and joined up working between the Department, the social care sector, and across Government, to implement the proposals arising out of the Reform of Adult Social Care Consultation.

115b. The Forum has a number of workstreams who meet on a regular basis. A Supporting Carers Workstream, co-chaired by Carers (NI) and the Department, has been established with a workplan focused on bringing forward improved supports for Carers including exploring options around the development a centralised Carers Register and improved information systems for Carers.

Consideration given to the increased morbidity and mortality rates of particular groups

116. The NI programme followed the advice of JCVI in relation to all priortitisation and eligibility issues and therefore did not introduce any additional prioritisation considerations for any particular groups. JCVI reviewed UK epidemiological and clinical data, including disease incidence, mortality and hospitalisation from Covid-19 data on occupational exposure, inequalities associated with Covid-19 mathematical modelling, and evidence from different vaccination programmes.

117. The vaccination team worked closely with the PHA communications team who tailored social media messages for example to particular cohorts in order to keep them updated on vaccination related developments.

Any particular roll-out procedures impacted on the speed and breadth of vaccine uptake

118. The Department had to take account of was the fact that all vaccines used in Great Britain must be authorised by the independent medicines' regulator, the MHRA, before they can be placed on the UK market and advertised or promoted for use by the manufacturer. However, since 1 January 2021, under the terms of the NI Protocol[4], novel and innovative medicines, including vaccines, required for use in NI are approved by the European Medicines Agency (EMA) under the EMA's Centralised Procedure.

119. This can lead to differences in the timescales for vaccine authorisation between Great Britain and NI, although in circumstances such as a pandemic, the MHRA can temporarily authorise a vaccine for use in NI or across the UK on public health grounds under Regulation 174 and Regulation 174a of the Human Medicines Regulations 2012 (as amended).

120. These provisions help to ensure that pandemic vaccines can be authorised and deployed in NI at the same time as in Great Britain, should EMA timescales for authorisation lag behind those of MHRA. In practice there was no practical delay in rollout arising from differences in approval timescales.

121. As outlined previously in my statement, the pharmaceutical characteristics of available vaccines strongly influenced the deployment model. The large pack size of the Pfizer / BioNTech vaccine, presentation as multi dose vials requiring preparation before administration, requirement for thawing and disposal of dry ice, and short shelf life upon defrosting and upon first puncturing a vial, all meant that deployment of this vaccine was most suited to HSC Trusts, in accordance with robust medicines governance processes overseen by HSC Trust Heads of Pharmacy and Medicines Management. General practices commenced the programme using the AstraZeneca vaccine, which had a number of advantages in terms of pharmaceutical characteristics including smaller pack size and storage at 2-8°C which made it more feasible to deploy in the primary care setting.

122. A positive impact on the speed of programme delivery was the introduction of the 'twin track' approach, as described earlier, which made the best use of the available Pfizer BioNTech vaccine and the availability of vaccination slots at Trust led clinics at that time.

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[4] This refers to a Protocol of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community [2019/C 384 I/01] -The Protocol on Ireland/Northern Ireland, commonly abbreviated to "the Northern Ireland Protocol".

123. The introduction of the community pharmacy vaccination service also greatly assisted the speed of delivery to the eligible cohorts by providing an accessible and convenient option to access vaccination in local communities across Northern Ireland. By May 2021, 347 pharmacies were providing Covid-19 vaccinations.

124. The approach taken by the Department to facilitate the vaccination of carers (cohort priority group 6) helped ensure they were vaccinated without creating a difficulty for individuals or a huge administrative burden on the vaccination programme. The vaccination programme team established that in Northern Ireland there was no central register of carers. After meeting with relevant stakeholders, the Department concluded that as there was no definitive way for individuals to produce evidence that they were a carer, and that flexibility would be needed. Following advice from the NI carers groups the Minister agreed to allow individuals to self-identify as carers with no requirement to provide proof [PM2333 - INQ000276655, and PM2334 - INQ000276656]. This allowed the offer of vaccination to be extended to this group in line with the rest of the UK and enabled a large number of carers to be vaccinated rapidly via Trust vaccination centres.

125. A practicality that initially had a negative impact on the roll out of the programme was the inability for community pharmacies to administer a second dose if an individual had received their first dose somewhere else in Northern Ireland. For most people this was not an issue however, as the programme extended into younger cohorts this became an issue as some people wanted more flexibility to receive their second dose of vaccine at a time and place that better suited them. Individuals did not understand why it was not possible to receive their second dose via a different provider and based on uptake data there appeared to be difference developing between the number of first doses administered and the number of second doses due to be administered 10 weeks later. By July 2021 the VMS digital team had been able to reconfigure the system to allow community pharmacy to administer second doses for individuals who received their first dose elsewhere which helped ensure a higher uptake of second doses.

Integrated Care System

126. It is important to remember that NI is unique in the UK in having an integrated Health and Social Care system in that social care is provided by health and social care trusts and not separately by local authorities. This definitely would have provided a distinct advantage in vaccinating residents of care homes and those who would have been too frail to attend GP surgeries and Trust vaccination centres and requiring vaccination in a domiciliary setting. The trust would have managed these teams directly hence making it easier to facilitate

vaccination of these high priority vulnerable groups.

Rollout of programme and needs of marginlised, disabled and those belonging to inclusion health groups.

127. The Head of the vaccination programme, Patricia Donnelly, asked the PHA to establish a low uptake group to understand and address the barriers to uptake within the Covid-19 vaccination programme. This group had their first meeting on 29 April 2021and helped identify and address these barriers by involving key community stakeholder groups and HSC partners. Analysis of the VMS data on uptake rates was available at an early stage to enable such targeting of messages and access to be planned and delivered.

128. The Community & Voluntary sector network organisations were also asked to cascade targeted information though their own memberships, which included NI Council for Voluntary Associations (NICVA), Healthy Living Centre Alliance, Rural Support Networks, Community Development & Health Network (CDHN) and Stronger Together Network. [PD/0014 – INQ000390122]

129. While planning and developing local deployment plans, the vaccination team was mindful of the location and accessibility of vaccination clinics to enable good vaccine uptake rates and reduce inequalities. Then, as the programme progressed and data became available, the team were able to identify areas that had low vaccine uptake. Proposals to address these were brought to the Covid-19 Vaccination Oversight Board, who agreed to test a number of community and workplace settings innovations, to explore the potential to increasing vaccine uptake in these areas, including in socially disadvantaged estates and workplaces.

130. Uptake data identified Ballysally Estate in Coleraine, with a population of approximately 3,000 people, as among the most disadvantaged Super Output areas with low vaccine uptake in NI. It was agreed to use Ballysally to pilot a 'pop up' approach, which resulted in 315 vaccinations carried out over 2 days in May 2021. [MMcB/7011 - INQ000390039, MMcB/7011a - INQ000390040, MMcB/7011b - **INQ000346712** and MMcB/7011c - INQ000390042. Evaluation of the project showed that it increased uptake by 20%. [MMcB/7012 - INQ000390043 and MMcB/7012a INQ000390044].

131. Uptake data also identified Strathroy in Omagh as a Super Output Area (SOA) with low vaccine uptake. The Western Health and Social Care Trust (WHSCT), in partnership with Fermanagh and Omagh District Council, the PHA and Community and Voluntary Sector (CVS) groups delivered a 'Mobile Clinic' in the local community centre. The WHSCT established a task and finish group and produced a 'Myth Busters' leaflet in partnership with PHA communications. The group worked with CVS groups to deliver leaflet to over 1500

homes and promote the clinic via social media, and 420 vaccinations were administered at the clinic.

132. In May 2021, Moy Park approached Patricia Donnelly for support to get more of their staff vaccinated, many of whom are from the Ethnic Minority & Migrant (EM & M) Communities and English would not be their first language. Moy Park senior management had concerns about the low uptake levels and hesitancy amongst their migrant workers, and the high-risk environment that their staff work in, with high numbers of staff working in close proximity.

133. The vaccination team asked the PHA to develop a pilot with they delivered working with the Northern Trust, Southern Trust, across the 3 Moy Park sites (Ballymena, Dungannon & Craigavon) in late May and early June, with local Trust vaccination teams setting up clinics on-site. Over 500 staff received a first dose across the 3 sites, with 2nd doses delivered in July. This represents 8% of the total Moy Park NI Workforce.

134. Another example of the NI programme taking into account marginalised or vulnerable groups is, at the request of the vaccination team, how the PHA, worked in collaboration with the 5 health Trusts and the NI Housing Executive, to offer vaccination to all 1,200 homeless service users from March 2021. Guidance was issued for homeless service providers which included information on where service users could receive vaccination [MMcB/7042 -INQ000390079]. Vaccinations were administered via outreach clinics and by July, approximately 720 individuals were vaccinated. Afterwards, the PHA continued to work with the Housing Executive to identify individuals still requiring vaccination.

135. In relation to inclusion health groups, the PHA were tasked by the vaccination team, with putting special arrangements in place for vulnerable groups such as Women's Aid Hostels, refugees, asylum seekers, and undocumented migrants. To help improves access, an additional clinic was set up by Belfast Trust in the Lower Ormeau Resident's Action Group (LORAG) Centre in South Belfast. Migrant Help (a support organisation helping asylum seekers, refugees, and victims of human trafficking & slavery) supported this clinic to encourage their clients to attend and helped with translation. Vaccinations were also provided to Women's Aid Hostels with the support of Trust Public Health Nursing, Adult Nursing, BHSCT Inclusion service and the Welcome Centre Mobile Health Unit.

Transparency and decision making

136. The Department of Health communications teams worked very closely throughout the pandemic with communication colleagues in the Public Health Agency. The Department was responsible for policy announcements on the various phases of the vaccination programme – confirming who was eligible at each stage and who was providing the

vaccinations, while the PHA was responsible for the public information campaign on Northern Ireland's vaccination programme.

137. Maintaining public confidence and trust was a guiding principle in a rapidly evolving environment through openness and transparency while also carefully considering any changes to advice in order to avoid confusion.

138. The Department ensured regular and prominent updates were issued to the public and media. This included announcements on which cohorts were eligible, or soon to be eligible, and any key decisions, such as the vaccination of carers and children.

Impact of handover of the programme to the PHA

139. Due to the high level of demands caused by the pandemic it was not possible for the PHA to lead on the operational delivery of the COVID-19 vaccination programme when it first began. As a temporary measure the Department of Health in Northern Ireland assumed full control of both the policy and operational elements of the programme from October 2020 through until the end of March 2022, however the Head of the vaccination team, Patricia Donnelly ensured the PHA was embedded within this structure with a view to responsibility for the programme returning to the PHA when the time was considered right.

140. Responsibility for the operational delivery of the Covid-19 vaccination programme transferred to the PHA on 1 April 2022, while the Department continued to retain control of all policy matters. Before this handover of operational responsibility, Patricia Donnelly led a number of workshops to prepare for the transfer and discuss future planning with all relevant stakeholders. These workshops were used to discuss the lessons learned, key factors attributed to the success of the programme thus far, and to plan for a future 'business as usual' model. A survey was undertaken by key participant groups ahead of the workshop and the responses collated for presentation at the workshop. [PD/0009 – INQ000496158]. A further 'Covid-19 Business As Usual Vaccination Programme' workshop was held on 22 February 2022. [PD/0010– INQ000496159, PD/0011– INQ000496160]

141. The DOH vaccination team and the PHA worked closely together to ensure a smooth transfer of responsibilities [PD/0012– INQ000496161] I therefore believe there was a very low impact with the transfer of operational responsibility from the Department to the PHA.

NI Executive and Yellow Card reporting scheme

142. The Northern Ireland Executive was not involved in arrangements related to the Yellow Card reporting scheme

143. In order to help monitor the safety of Covid-19 vaccines after they are deployed, on the 10 December 2020, the Department advised all healthcare professionals involved with vaccination programme to report all suspected adverse effects relating to the use of Covid-19 vaccines to the MHRA via the Yellow Card Scheme [MMcB/7004 - INQ000348926].

144. The MHRA is an executive agency of the Department of Health and Social Care in England, which is responsible for ensuring that medicines and medical devices work and are acceptably safe. The Yellow Card Scheme is a well-established scheme run by MHRA and is the UK system for collecting and monitoring information on suspected safety concerns or incidents involving medicines and medical devices.

145. It relies on voluntary reporting of suspected Adverse Drug Reaction (ADRs) by health professionals and/or patients. The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation. Reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market.

145a. Although voluntary, health professionals are reminded that an adverse reaction to a Covid vaccine should be reported regardless of severity, even if it is not certain that the drug or vaccine has caused it.

145b. I believe the current system has worked well and I'm not sure what additional benefit will be achieved by making it mandatory, or how a mandatory system would work in practice. There could be the risk of over reporting. All this has to be taken into consideration if we were to move away from the current voluntary reporting system.

146. On 19 February 2021, a CMO letter issued to inform the service of the weekly publication of yellow card safety data relating to the Covid-19 vaccines. The routine safety monitoring and analysis of the approved Covid-19 vaccines showed that the safety of these vaccines remained as high as expected from the clinical trial data that supported the approvals [MMcB/7007 - INQ000390035].

147. All healthcare staff involved in delivering vaccinations were trained to deliver the COVID-19 vaccine programme confidently, competently, and safely. This included e-learning sessions that consisted of a core knowledge session and separate knowledge sessions for each vaccine available for use. The core session was designed to provide essential knowledge about COVID-19 and the key principles of immunisation needed to deliver the vaccines, while the vaccine specific knowledge sessions included how the vaccine works, how it

should be stored, prepared and administered and any contraindications, precautions and potential vaccine reactions, including possible side effects.

Messages exchanged in the "Vaccine SROs" Whatsapp group [INQ000477804] in respect of the use of different types of vaccine in first and second doses.

148. The Green Book, which is an online resource from Public Health England, is regularly updated to reflect the latest evidence, guidance, and recommendations on all vaccinations for vaccine preventable infectious diseases in the UK. The Green Book Covid-19 vaccination chapter was first published on 27 November 2020 and offers guidance on storage, safety, administration dosage, priority groups and potential adverse effects [PM2322 - **INQ000257325**]. Healthcare Professionals are encouraged to consult the latest version of the Green Book prior to any vaccination.

149. The Green Book states that the same vaccine used for the first dose must be used for the second, except in very exceptional circumstances. These exceptional circumstances at the time were:

- If the first product received is unknown or if they received a brand that is not available in the UK. In these circumstances every effort should be made to determine which vaccine the individual received for their first dose and to complete the two dose course with the same vaccine.

- If the patient initially had the Pfizer vaccine in practice or clinic and has since become housebound. In these circumstances as the COVID-19 vaccine AstraZeneca can be transported, a second dose with this vaccine can be given.

- Those who experienced anaphylaxis reactions with the first dose of one brand of vaccine may be offered another vaccine if advised by an allergy specialist.

- Following MHRA guidance, patients who have experienced major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of COVID-19 Vaccine AstraZeneca.

150. If a different second vaccine was considered, a detailed informed consent process was to be followed, in line with guidance produced by Public Health England (PHE).

151. Notwithstanding the discussion on whatsapp as discussed on page 9 [INQ000477804], I do not believe there were discernible differences in the approach of the four nations when it

came to the administration of second doses. The same vaccine was utilized for first and second doses except in the rare exceptional circumstances outlined in the relevant edition of the Green Book.

Messages exchanged in the "Vaccine SROs" Whatsapp group [INQ000477804] regarding the Vaccine Delivery Plan.

152. The vaccine delivery plan was a document published early on in the vaccination campaign, on 11th January 2021, by the UK Government. It set out the overall scope of the vaccination programme in the UK and the desire to vaccinate the highest risk groups as quickly as possible. It also set out how vaccines were developed, and supply secured. As discussed on page 13 [INQ000477804], the details of deployment of the vaccines were confined to England as there wasn't time for the other Devolved Nations to contribute individualized delivery plans to the document in time for its publication. Publication went ahead and I do not believe this ultimately made much difference as the key principles were set out in the document and it was made clear this was a four-country collaborative effort. [NC/0002 – **INQ000469656**

Gillian Richardson's views of 9 January 2024, in the "Vaccine SROs" Whatsapp group [INQ000477804], that "bulldozing" was "now a pattern and at some stage risked spats".

153. It should be noted that January 2021 was very early on in the rollout of the covid 19 vaccination programme, which had only started on 8th December 2020 in terms of actual deployment of the vaccine. Although there were highly effective channels of communication across the infrastructure of the deployment of the vaccine across the UK, decisions had to be made and executed at pace. Therefore, at times colleagues may have felt there was insufficient time for the level of consultation and communication which would have been perceived as optimal.

154. Moreover, individual SROs and their teams would have had to manage the expectations of their individual Ministers in what was a highly stressed environment given that vaccines were seen as providing a viable path to normality almost a year into the pandemic. I think any such remarks, such as those on page 14 [INQ000477804] have to be considered in that context and within the overall vaccination campaign which was highly aligned and collegiate across all the devolved countries throughout its course.

BARRIERS TO VACCINE UPTAKE

Disparities in vaccine coverage between identifiable groups in Northern Ireland

155. Deprivation and ethnicity are known to have a recurrent impact on the uptake of all immunisations. The Department therefore closely monitored vaccine uptake data from the beginning of the programme to identify any cohort, group, or geographical area that had low Covid-19 vaccine uptake. In doing so, data from March 2021 identified several geographical locations and ethnicities which were below the NI average vaccine uptake rates. Reasons for the lower uptake in some communities are multifactorial, but they include concerns around safety and efficacy, given the rapid development of the vaccine. It also includes negative healthcare experiences, and distrust of doctors and vaccine developers that all contribute to vaccine uptake reluctance.

156. This information then helped to inform local planning and ensure a strong focus on vaccine equity and interventions that would address vaccine hesitancy and low vaccine uptake. To help counter hesitancy, it is important to build trust, by involving a diverse representation of stakeholders and sharing factual information about the vaccine development process and efficacy, including data on ethnic representation in trials. We need to ensure our messaging is consistent and culturally competent and engaging by participating in open and honest dialogue including on social media forums. Ideally, vaccines should be delivered in community settings that are accessible and familiar, while also using professionals who are trusted members of the local community.

157. I have set out at paras 130 to 135, examples of actions taken in NI, these local interventions, included mobile vaccination clinics that were geographically located in areas of low uptake, the engagement of senior community influencers and the translation of vaccine advice and myth busting materials. Translated materials were accessible online and disseminated through communication channels, including the regional Stronger Together Consortium of Ethnic Minority & Migrant communities support organisations. [MMcB/7066 - INQ000390107]

Vaccine Confidence

158. The PHA Health Intelligence Unit had established a monthly survey programme from November 2020, prior to the introduction of the vaccination programme, to track the public's attitudes to Covid-19 and the measures put in place to mitigate its spread. The topics included assessing intentions to getting vaccinated. The majority of respondents in each survey were positive about getting vaccinated, with positive responses rising until Jan 2021, and then reduction was seen in February and March 2021. [MMcB/7036 - INQ000390073 and MMcB/7036a - INQ000390074]. There was however a core number of respondents (circa 8%) in every survey who indicated that they would not take the vaccine, which was noted at the time to be at a higher likely refusal rate than surveys suggested for elsewhere in the UK.

159. The PHA led the work on a developing a mass media campaign and the 'every vaccination brings us closer together' campaign launched on 10 May 2021 and ran until 13 June 2021. [MMcB/7134 - INQ000382950] The rationale for implementing a mass media campaign was to build confidence in the vaccination programme and encourage those who were hesitant to get vaccinated.

Work of the NI Executive to identify those with high levels of mistrust

160. I am not aware of any work undertaken by the Northern Ireland Executive to work with local organisations to identify those with high levels of mistrust and the reasons for such mistrust.

Messages on "Vaccine SROs" Whatsapp group [INQ000477804] regarding the vaccine dashboard, vaccine inequity and hard to reach groups.

161. As far as I can recall the reference to the vaccine dashboard and "Big push on vaccine inequity and hard to reach groups," as referenced on page 31 [INQ000477804], are not connected statements. They were both intended as separate components of an update to my other SRO colleagues on what was happening in respect of the vaccination programme in Northern Ireland. It should be noted that comprehensive updates on progress were given at the weekly SRO meetings and the WhatsApp messages were never intended for that purpose.

162. The vaccine dashboard was an online resource which gave up to date figures on the number of vaccines administered at that point in time and was updated daily. It was an extremely useful resource for monitoring vaccine uptake and provided a one stop shop of information for professionals and members of the public. It received information from the Vaccine Management System (VMS). Across a number of pages, it provided information on the following;

- Total vaccination figures
- Most recent available day's figures
- Cumulative vaccination totals by dose
- 7 day moving average
- Vaccinations by age band
- Vaccination coverage rates – population figures are based on NISRA midyear estimates (MYE) for 2020.
- Vaccinations by location/provider
- Vaccinations by vaccine type
- Total vaccinations by gender
- Vaccinations by postcode and by ethnic background (when available)
- Vaccinations and coverage for Local Government Districts, based on postcode of

residence and NISRA

163. The big push on vaccine equity is covered extensively earlier in my statement. However, although not intended at the time in the whatsapp message as far as I can recall the Vaccine Dashboard was invaluable in monitoring uptake across the board but also in hard-to-reach groups as information was available as stated above which included uptake by geographical area. The data was also subject to further analysis by the PHA who would have had access to much more granular demographic and geographical information.

Measures to engage with public concerns and increase public trust in Covid-19 vaccines

164. I am no longer directly involved with vaccination programmes but I am aware that unfortunately, uptake rates have fallen in various vaccination programmes in recent years, not just the Covid-19 programme. This may be partly due to vaccine fatigue or the mistaken belief that the Covid-19 virus is no longer dangerous.

165. In terms of the Covid-19 programme the Public Health Agency now lead on the operational delivery of the programme and part of that process involves them monitoring the uptake levels and engaging with relevant stakeholders to assess the reasons for lower uptake levels as well as public trust levels in Covid-19 vaccines. I would continue to encourage anyone who is eligible to receive a Covid-19 to speak to a health care professional regarding any concerns they may have.

166. However, the current landscape is a complex one particularly in relation to social media where there are many differing views about vaccination efficacy and safety. The introduction of vaccines for covid-19 accentuated and amplified much of this debate with concomitant spreading of misinformation. Countering this, will prove to be a challenge as it is difficult to for traditional statutory health authorities to be aware of the breadth of this activity. However, the use of established good practice in public health and working with discrete groups with tailored messages and initiatives will help to improve vaccination uptake rates, such as the recent work carried out to improve uptake rates for the MMR vaccine which concentrated on particular areas where uptake rates were lowest.

Whether low vaccine uptake and disparities within particular groups and/or communities were predictable and foreseeable prior to the start of the pandemic

167. As mentioned above, the PHA Health Intelligence Unit had established a monthly survey programme from November 2020, prior to the introduction of the vaccination programme.

168. The Departmental vaccination team worked closely with the PHA, who had existing subject expert groups such as the Health Inequalities team, and also met many representatives regularly through the Implementation Group and working subgroups to discuss low vaccine uptake and disparities within particular groups or communities.

169. It was not unexpected that uptake rates were lower with particular age cohorts or in particular areas, for example in the annual influenza vaccination programme the uptake rates for the over 65 age cohort are normally around 75% or higher, whereas the uptake rate achieved in the under 65 'at risk' groups are normally around 50% or less, with the uptake rate lowest for the youngest 'at risk' individuals.

170. For the Covid programme, uptake rates were lowest in the youngest age cohorts. However, it is also worth noting that a vaccination programme of this scale was unprecedented and stretched the Department and the wider Health and Social Care service to breaking point. It was also impossible to predict exactly how people would react to the offer of vaccination during the pandemic. On the one hand many people were very keen to take up the offer of vaccination, while some people were hesitant or resistant to the vaccines which had been developed at pace. I believe we adapted quickly throughout the course of the pandemic as circumstances changed and learning emerged.

PUBLIC MESSAGING IN RESPECT OF THE VACCINES

171. The Department was responsible for policy announcements on the various phases of the vaccination programme – confirming who was eligible at each stage and who was providing the vaccination, while the PHA was responsible for the public information campaign on Northern Ireland's vaccination programme. The Department of Health communications teams worked very closely throughout the pandemic with comms colleagues in the Public Health Agency.

172. I had a limited role in public messaging and would largely have been copied into draft press releases etc. as part of the drafting/ clearing process within the department. However, I have recollection of occasional media appearances on BBC and with articles appearing in local media outlets [NC/0003 – INQ000503284 and NC/0004 – INQ000503285]. I also participated in a high-profile meeting between Her Majesty Queen Elizabeth and the Senior Responsible Owners in February 2021.

The approach to public messaging

173. The public messaging strategy adopted for the roll-out of the vaccination programme was designed to maintain public confidence in a rapidly evolving environment, by ensuring openness and transparency while also carefully considering any changes to advice in order to avoid confusion.

174. The Department kept the NI population updated on vaccination policy announcements by press releases, news reports, and via information on the Department's website and the NI-Direct website. These channels were used to inform people about which population cohorts were eligible and where and how they could book their vaccination [PM2323 - INQ000276646].

175. The core role of the Department communication team throughout the pandemic was to provide specialist communication support and advice to the Minister and senior officials. This meant sustained support for the Covid-19 vaccination programme, including through high-profile media interviews, press releases, speeches, articles, and visits to clinics.

176. The Health Minister, Robin Swann, the Chief Medical Officer, Professor Sir Michael McBride, Chief Scientific Adviser, Professor Ian Young and the Head of the Vaccination Programme, Patricia Donnelly, all played prominent roles in the Department's public-facing messaging on the vaccination programme. I did not play a prominent public-facing role.

177. In its co-ordinating role with the HSC Trusts, the Department also assisted with the planning and promotion of localised Trust initiatives such as pop-up clinics [MMcB/7159 - INQ000390195]. The Department also contributed to the development of specific initiatives to promote vaccination, including events like the "Big Jab Weekend" and "Jabbathon" to encourage take-up by younger people. [MMcB/7160 - INQ000383053]. The big jab weekend was an initiative at the Trust's large vaccination centres which allowed walk-in vaccination opportunities for individuals to receive their first dose of vaccine. The Jabbathon, was an initiative that saw 60 walk-in clinics across some 30 campuses established offering first dose vaccinations to students across universities and Further Education colleges.

178. During the course of the pandemic, the Department used its prominent communications channels to counter specific areas of disinformation on Covid-19. This involved the publication and promotion of fact sheets. Disinformation about Covid-19 vaccines in relation to abortion and fertility were among the areas covered [PM2324 - INQ000276656, MMcB/7078 - INQ000390118, MMcB/7147 - INQ000383225 and MMcB/7148 - INQ000390188].

179. The Department also ensured regular and prominent updates were issued to the public and media on the progress of the vaccination programme, as recorded by the public-facing vaccination dashboard.

180. The Department's press office also worked with colleagues in The Executive Office (TEO) and UK Government on broader Covid-19 advertising campaigns which included vaccination as a key call to action.

181. The PHA was responsible for the public information campaign on Northern Ireland's vaccination programme. Its work included: a public advertising campaign across TV, radio, digital and social media; provision of information online about vaccination including detailed FAQs on its website; use of behavioural science insights and social media influencers; monitoring the effectiveness of the public information campaign; targeted work for harder to reach communities eg ethnicity and socio-economic background.

182. The PHA led the work on a developing a mass media campaign and the 'every vaccination brings us closer together' campaign launched on 10 May 2021 and ran until 13 June 2021. [MMcB/7134 - INQ000382950] During the campaign development process, a number of creative concepts were pre-tested with the primary target audience. The campaign reflected insights from the tracking surveys and qualitative testing carried out by the PHA. Testing was weighted towards those in the Department of the Economy (DE) socio-economic grouping – that is those who are in semi-skilled and unskilled manual occupations, the unemployed and the lowest grade occupations.

Differences between public messaging across the UK

183. I do not believe the public messaging differed between Northern Ireland and the rest of the UK.

184. The Department of Health NI communications team worked closely with the communications teams in the Health Departments across the UK to ensure major announcements, such as the launch of the programme, were agreed and coordinated. While attending SRO meetings, we discussed progress of the programme in each country, including the capacity to open vaccination to the next cohort. In this respect, public messaging was broadly aligned across the UK, however communications were tailored to the local circumstances pertaining to the individual country. This was because each country used slightly different delivery models and so messaging needed to target how and where the local population could make an appointment.

Messages in the "Vaccine SROs" Whatsapp group [INQ000477804] regarding the announcement made by the Prime Minister about the timeline of vaccination for groups 1-4

185. The discussion on page 11 of the "Vaccine SROs" Whatsapp group [INQ000477804] was quite early in the vaccination campaign and probably refers to Prime Minister Johnson's address to the nation of 4th January 2021. At that time there was a further deteriorating picture across the UK in terms of the spread of Covid-19 and continuing increases in hospital admissions and mortality. This was because of a new variant of the virus which was more transmissible (the alpha variant) The Prime Minister also had to announce a further lockdown. The vaccination campaign was working its way through the high priority groups and the address by the PM gave a commitment, by the middle of February 2021, to offer a first vaccine dose to everyone in the four top priority groups identified by JCVI.

186. That meant offering vaccination to all residents in a care home and their carers, everyone over the age of 70, all frontline health and social care workers, and everyone who was clinically extremely vulnerable. The aim of this was to give those who were considered most vulnerable to the virus a degree of protection from the covid virus. The whatsapp discussion simply reflects the fact that as Senior Responsible Owners we were anxious that this sort of ambitious commitment may not be compatible with logistical feasibility and vaccine supply at that time. It simply reflects nothing more than real time concerns about an ambitious task set for the vaccination programme

Messages in the "Vaccine SROs" Whatsapp group [INQ000477804], regarding handling communications to the three non-English nations.

187. I am not aware of a particular issue with communications to the three non-English Ministers, as referenced on page 11 of the "Vaccine SROs" Whatsapp group [INQ000477804]. There were well established channels of communications between the devolved nations and England as are described throughout my statement. Moreover, as well as everything else which was in place, the Secretary of State for Health in England held weekly meetings with his devolved counterparts where pertinent policy related matters and communication alignment would have been facilitated.

188. On 12 April 2021, in the "Vaccine SROs" Whatsapp group [INQ000477804], I stated at 19:11:06, "... reported in press and likely to be announced by Ireland's vaccine advisory

committee tonight that [Republic of Ireland] will recommend against using AZ in the under sixties. Potential impact for us in NI in terms of public perception."

189. This discussion has to be understood within the context pertaining at the time. On 7 April 2021, the Department was advised by the MHRA that as of 31 March 2021, it had received Yellow Card reports of 79 cases of thromboembolic events with concurrent thrombocytopaenia following vaccination with Covid-19 Vaccine AstraZeneca. MHRA advised that the Commission for Human Medicines (CHM) carefully considered all available data, noting the need for further clinical details on the case reports and that data were also lacking on the need to understand the background rate of CVST, including during the pandemic because COVID-19 infection had been associated with thrombotic events. [MMcB/7049 - INQ000390086].

190. A Chief Professionals HSS letter was issued on the 8 April 2021 [MMcB/7050 - INQ000390087] to inform health Professionals that the CHM advised that the available evidence at that time did not establish a causal association between the AstraZeneca COVID-19 vaccine and these events, but investigations needed to continue. The CHM's advice remained that the overall benefits of the vaccines against Covid-19 continue to outweigh any risks in the vast majority of people, and that the evidence did not currently support excluding any age group from vaccination.

191. As a precaution, anyone who experienced cerebral or other major blood clots occurring with low levels of platelets after their first vaccine dose of Covid-19 Vaccine AstraZeneca should not have their second dose. Health professionals were reminded again at this point to report any suspected adverse reactions via the Yellow Card scheme.

192. On 7 April 2021, following concerns raised about the AstraZeneca vaccine, JCVI announced that it was preferable for adults aged under 30 years, without underlying health conditions that put them at higher risk of severe Covid-19 disease, to be offered an alternative Covid-19 vaccine, if available. JCVI advised that people may however make an informed choice to receive the AstraZeneca Covid-19 vaccine to receive earlier protection, if there was a delay in receiving an alternative vaccine [MMcB/7051 - INQ000390088].

193. The NIAC (National immunisation Advisory Committee) 12th April advice in Ireland was hence out of kilter with the advice in the UK as it advised that Astra Zeneca should not be used in the over 60s. However, the advisory and regulatory bodies in Ireland were different and carried out their own assessment of risk.

194. Northern Ireland is the only part of the UK with a land border with an EU country so it is

definitely the case that there would have been some scrutiny of the vaccination programme in the two jurisdictions. In general, it was a matter of having confidence in the robustness of the advice provided by the appropriate advisory bodies and ensuring that was appropriately communicated to the public and health professionals. It is important to remember that the two jurisdictions had entirely discrete covid-19 vaccination programmes and consistency and compatibility between the programmes was not a prime objective.

Raising awareness and addressing public concerns

195. The Department was responsible for policy announcements on the various phases of the vaccination programme. This included sharing information on vaccine availability, eligibility and prioritization as well as the arrangements for access. The vaccination plan was published on 26 November 2020, which set out how and roughly when all eligible individuals could expect to be vaccinated. Information was also issued in terms of vaccine safety which covered vaccine creation, development, manufacturing and approval process as well as the efficacy of the vaccines; and risks, safety and side effects. The PHA developed a leaflet covering the issues mentioned above, that was made available to everyone prior to vaccination.

196. Press releases, news reports, the Department's website and the NI-Direct website, were all used to inform people about all of these aspects, including addressing any known concerns that the public may have.

Public messaging and vaccine hesitancy

197. With hindsight I believe it may have been useful to take more time to clearly set out all the testing and safety procedures that had to be carried out in order to get the vaccine(s) approved. This would include, from the outset, explaining why certain conditions are initially applied to vaccines which can then be subject to change as the programme rolls out and more data is gathered.

198. Maintaining public confidence and trust was a guiding principle in a rapidly evolving environment through openness and transparency while also carefully considering any changes to advice in order to avoid confusion.

199. This was particularly important for very rare side effects which are not ordinarily detected in vaccine trials and only observed and reported once the vaccine is being rolled out to the general population. JCVI also initially took a cautious approach to the vaccination of pregnant women or those planning a pregnancy within three months of the first dose. If at the

time when this approach was announced it was made clearer that this was strictly precautionary and subject to change when more data on safety was gathered it may not have created such a reluctance among pregnant women to get vaccinated when subsequently the evidence clearly indicated the vaccines were safe.

Public communication

200. I believe, given the circumstances at the time, the public messaging was effective but as with many aspects of the overall response to Covid-19, with hindsight it may have been possible to improve on this.

201. The vaccination team did establish links with NI District Councils, Trade Unions, churches and faith groups, the inter-ethnic forum, various charities, volunteer groups, special interest groups, as well as the Commissioners for Older People and Children and Young People. These relationships proved invaluable at certain key stages of the programme for both providing and receiving information. Other initiatives included using senior influencers within the different ethnic and minority groups in targeted messaging in mainstream and social media we well as thorough local community groups.

202. Eastern European ethnic groups had the lowest uptake of the ethnic minority groups, however, it was June 2021, before the booking system allowed for translation which may have prevented some individuals from booking earlier. With hindsight, higher coverage in these groups may have been achieved if the booking system translation, and leaflets in various languages, were made available earlier.

203. As mentioned earlier, The PHA Health Intelligence Unit had established a monthly survey programme from November 2020, prior to the introduction of the vaccination programme, to track the public's attitudes to Covid-19, which included assessing intentions to getting vaccinated. Learning from the surveys was disseminated to the vaccination low uptake working group and the vaccination communications group to inform their planning and evaluation processes.

204. The Health Intelligence Unit also researched wider evidence on barriers faced by marginalised and vulnerable communities and developed a resource pack containing evidence and interventions associated with vaccine uptake in marginalised and vulnerable communities. [MMcB/7037 - INQ000390075] this information was also used to inform the work of the PHA low vaccine uptake working group and the vaccination comms sub-group to ensure public communications was sufficiently targeted.

Monitoring public messaging

205. To a large degree public messaging effectiveness was demonstrated by the numbers booking in as each cohort opened and it was evident that messaging was reaching the various age cohorts.

206. The PHA was responsible for the public information campaign on Northern Ireland's vaccination programme and they made use of behavioural science insights, social media influencers in targeted work aimed at harder to reach communities eg ethnicity and socio economic background. The PHA also monitored the effectiveness of the public information campaign.

207. The PHA led the work on a developing a mass media campaign and the 'every vaccination brings us closer together' campaign. The rationale for implementing that campaign was to build confidence in the vaccination programme and encourage those who were hesitant to get vaccinated. The primary target audience was those aged 18- to 49-year-olds, hesitant or resistant. The Northern Ireland omnibus survey had indicated those aged 18-49 were more hesitant than those in the older age groups, with 24–34-year-olds the most hesitant within the 18 to 49 age group. The secondary audience was anyone aged 50 and over who hadn't yet received the vaccine and anyone who received their first dose and hadn't received their second dose of the vaccine.

Public Messaging and evolving advice to groups

208. The Department followed the advice and recommendations of JCVI with regards to vaccination and if the JCVI advice changed, as it did for pregnant/breastfeeding women and children, the public messaging was adapted as required.

209. With regards to evolving advice for specific age groups, such as the restriction on AstraZeneca for those aged 30, this information was shared via press release, and chief professionals' letters. This is covered in paragraphs 93 and 94 above. Similarly, the changing advice to children was shared in the same way. This is discussed in paragraphs 83 to 92.

210. A further example of changing advice relates to the advice to pregnant women, when the Covid-19 vaccination programme first launched, there was limited data on the safety of Covid-19 vaccines in pregnancy, either from human or animal studies. JCVI noted that there was insufficient evidence to recommend routine use. Women were also advised not to come forward for vaccination if they may be pregnant or were planning a pregnancy within three months of the first dose.

211. As further data was obtained, guidance was updated, initially recommending consideration of use where the risk of exposures to SARS-CoV2 infection was high, or where women had underlying conditions that put them at very high risk of serious complications of Covid-19, before moving to recommend vaccination in all women in pregnancy.

212. On 30th December 2020 JCVI updated their advice for pregnant and breastfeeding women. [MMcB/7019 - INQ000441890]. The updated information for pregnant and breastfeeding women was accepted in NI and shared via a Chief Professional's letter on the same day. [MMcB/7020 - INQ000276527]

213. Uptake was low in this group and evidence indicated that many women of childbearing age mistakenly believed there may be a link between receiving the Covid-19 vaccine and fertility issues. I believe this issue had a particular impact on health care workers and care home staff, both of which include a high percentage of young females, as they were amongst the first to be offered the vaccine in early December 2020 and January 2021.

214. On 16 April 2021 JCVI issued new advice, that pregnant women should be offered the Covid-19 vaccine at the same time as the rest of the population, based on their age and clinical risk group. This updated advice was fully accepted by the Department and shared by Chief Professionals' letter [MMcB/7021 - INQ000390055]

215. However, vaccination of this cohort remained disproportionately low compared to general population vaccination rates across all ages [MMcB/7022 - INQ000390056]. Additional measures were put in place with Trusts running specific pregnancy only clinics, in maternity units, or vaccinators being present during antenatal appointments to provide vaccination, but despite this uptake remained low overall.

216. On 2 September 2021, MHRA issued communications to an extensive range of stakeholders including patient groups, charities as well as healthcare Professionals and government bodies to reassure patients and the public regarding MHRA's position on reports of suspected side effects on breast-feeding following Covid-19 vaccination. The communications reiterated that there was no current evidence that Covid-19 vaccination while breastfeeding causes any harm to breastfed children or affects the ability to breastfeed. MHRA also explained that although they had received about 3,000 Yellow card reports from women breastfeeding at the time of vaccination, most of these women reported only suspected reactions in themselves which were similar to reports for the general population, with no effects reported on their milk supply or in their breastfed children [MMcB/7023 - INQ000390057].

217. On 10 December 2021, the JCVI Secretariat wrote to the Secretary of State for Health to inform him that data up to the end of October 2021 from national studies (UK Obstetric Surveillance System (UKOSS), and Mothers and Babies Reducing Risks through Audits and Confidential Enquires, (MBRRACE-UK), revealed that clinical outcomes following Covid-19 in pregnant women had worsened over the course of the pandemic. Six neonatal deaths were recorded during the 3rd wave, whereas no neonatal deaths had been reported in previous waves. Based on the data regarding safety, together with the increased risk from Covid-19 to pregnant women especially in relation to the wave of infection associated with the delta variant, the JCVI advised that pregnant women of any age should be considered as a clinical risk group within the Covid-19 vaccination booster programme (priority group 6).

218. The JCVI advice was shared with the Health Minister in NI prior to the JCVI statement. [MMcB/7024 - INQ000390058, MMcB/7024a - INQ000112141 and MMcB/7024b - INQ000390060]. The advice was fully accepted in NI and a Chief Professionals letter was issued to the Health Service on the 17 December 2021 informing them of this change [MMcB/7025 - INQ000390061] Despite the JCVI advice adding pregnant women into the clinically at-risk group, uptake remained low throughout the booster programme.

MISINFORMATION AND DISINFORMATION

Role in relation to handling and/or responding to mis/disinformation

219. I had no direct role in handling or responding to mis/disinformation in relation to the Covid-19 vaccines. I am unaware of the approach of the Northern Ireland Executive to address and counteract mis/disinformation.

220. Mis/disinformation about Covid-19 was widespread. In relation to the Covid-19 vaccines they included false claims about their safety, efficacy, ingredients, side effects and purpose. I was aware that Northern Ireland appeared to have a small active core of individuals who seemed to be against vaccination regardless of the information supplied.

221. Timely and targeted distribution of content to counteract 'misinformation' was of critical importance, particularly where there was a need to reach individuals, families, and communities, through sources they could trust. Efforts were made to ensure the correct and most up-to-date information from reliable resources such as JCVI or MHRA for example was available to the public via the NI Direct webpages or through press releases. With the approval of the Oversight Board, the Public Health Agency were asked to develop a Vaccine Communications Plan, and a key objective of this plan was to monitor and counter vaccine

misinformation through the provision of clear and targeted information across the most appropriate channels.

222. The Vaccine Communications Subgroup, chaired by the Head of the Communications Team in the PHA, included Trust press office representatives and DoH press office representatives as well as a representative from the Department's Covid-19 vaccination policy branch, met weekly. This group evaluated, reviewed, and planned messaging relating to key themes, including vaccine misinformation, thereby addressing any emerging issues which may negatively impact the programme roll out. The Department and the PHA issued 'myth buster' press releases and social media posts. [MMcB/7058 - INQ000390095].

223. It is difficult to say how effective these measures were but overall uptake rates for the programme were very high but there seemed to be a small hard-core number of individuals who could not be convinced to take up the offer of vaccination.

Liaison with relevant decision-makers in GB regarding the countering of vaccine disinformation / misinformation.

224. I recall this issue was raised on occasions via the SRO meetings. I and colleagues within the vaccination team also worked with the UK Covid Vaccine Security (UKCVS) group, set up within the Department of Health and Social Care in England. This group helped to coordinate and share information on disinformation/ misinformation and any anti vaccination activity. As part of that process if anyone in the Department or Trusts received letters, emails, or personal approaches for example the vaccination team were able to report it straight to a specific e-mail address. UKCVS collated all the incidents across the UK and if necessary liaised directly with PSNI in relation to any specific issues related to NI.

LESSON LEARNING

Lessons for a future pandemic

225. There are always lessons to be learned from any vaccination programme and I believe, a main lesson regarding the design of an implementation plan is to try and set out the plan and get 'buy in' from all relevant stakeholders, while keeping them well appraised of any subsequent changes that have to be made. It would also help public messaging if the plan/programme largely stayed the same as initially communicated, with regular updates provided to cover any changes.

226. In addition, due to the inevitable pressures that staff will experience in a future pandemic/health emergency, I believe using a combination model of Trusts, GPs and

community pharmacies to deliver the programme will help spread the workload across a number of sectors.

227. To help achieve high coverage I believe making the vaccination offer as accessible as possible, ideally by having multiple options available close to where people live and work is essential. Having multiple options such as GP practices, Community Pharmacies and Trust led vaccination clinics, available from as early in a programme as vaccine supplies will allow, will provide the flexibility to individuals to take up the offer of vaccination that best suited them.

228. I believe it would have been helpful had there been a mechanism that allowed every citizen in Northern Ireland to receive an individual prompt or invite to vaccination. This did occur for the first phase of the programme as GPs were heavily involved in this phase and would have invited their eligible patients in via letters, texts or phones calls. It didn't happen as much in the second phase, aimed at those aged 18 to 49 years of age and an individual prompt may have been enough to help persuade those who were slightly more hesitant to take an additional step and book a vaccination slot.

229. Having access to good data is crucial in helping to spot an issue early and thereby being able to take affirmative action quickly to help address low uptake. The Vaccine Management System (VMS) which began in early April 2021, did not start providing detailed reports until the end of April. The VMS dashboard allowed more in-depth analysis of uptake data by postcode and super output area, and had this have been available sooner, it could have helped address barriers and inequalities more quickly.

230. Having the ability to clearly identify those considered 'at risk' and allow them to be vaccinated at any of the available vaccination clinics would I believe have helped improve uptake in this cohort. At the earliest stages of the programme, these individuals were largely only identified by their GP and had no means of proving they were in a CEV/CV group in order to be vaccinated via a Trust centre or eventually a community pharmacy site. In future it would be useful if digital records could enable identification of those eligible for vaccination which would allow them to be vaccinated at a venue of their choice, rather than wait for their practice to invite them in.

231. Being able to tailor and target messages to address the various reasons for vaccine hesitancy would have been useful to try and persuade more people to take up the offer of vaccination.

232. Trying to understand qualitatively in more detail concerns about vaccination in certain ethnic minority groups would also be helpful and counteracting "myths" and misinformation in a culturally sensitive evidence-based way.

233. Having the ability to ask/make social media companies take immediate steps to tackle misinformation on their platforms, including removing or demoting misinformation, directing users to information from official sources, and banning certain adverts.

Key Challenges faced during the programme

234. Without doubt one of the biggest challenges faced by the programme was the logistical challenge presented by the first vaccine approved, the Pfizer BioNTech vaccine. As already discussed, this included the need for supply chains that allowed the vaccine to be kept at ultra-low temperatures (-90°C to -60°C), complying with requirements to defrost before use and with limitations on the number of movement-based transitions allowed in the Summary of Product Characteristics to maintain stability of defrosted vaccine.

235. In addition, the Pfizer / BioNTech vaccine initially had a 5-day shelf life once defrosted which limited the utility of the vaccine to providers capable of vaccinating large numbers in a short period of time. These significant logistical and operational challenges dictated the delivery models used in the programme.

Reducing health inequalities

236. Unfortunately, the Covid-19 pandemic has probably increased health inequalities and while substantial efforts were made to encourage vaccination by certain groups or in certain areas, by making the vaccine more assessable, these were not enough to eliminate health inequalities. In a future pandemic it would be desirable to have plans in place that could be activated quickly to try and reduce health inequalities but this would be depended on many other factors such as vaccine availability and JCVI advice on eligibility and prioritisation etc.

Inequality Issues during the programme

237. Before the vaccination programme began, an Equality Screening, Disability Duties and Human Rights Assessment (EQIA) for the vaccination policy, which at this stage was to offer every adult aged 50 years and over Covid-19 vaccination, was completed and signed off on 24 November 2020 [MMcB/7076 - INQ000390116]. All Section 75 categories of the NI Act 1998 were classed to benefit from the policy, especially older people and persons considered as clinically extremely vulnerable or clinically vulnerable. The Screening assessment was

revisited and updated when further JCVI advice was received to ensure that the initial assessment remained valid.

238. However, despite the work involved in promoting the roll out of the vaccination programme it would be fair to say that existing inequalities probably impacted uptake of vaccines between the most and least deprived areas of NI, and within Health & Social Care (HSC) Trust and Local Government District (LGD) areas. While extensive work was undertaken to try and improve uptake in these areas and ensure they had good access to vaccination clinics, uptake was lower in those areas with higher deprivation.

Innovation or unusual processes

239. As mentioned earlier in my statement, the use of large vaccination centres and pop-up clinics, was an unusual process for Northern Ireland. Large vaccination centres enabled the programme to maximise vaccine use and ensure eligible individuals were offered vaccination faster than could have been achieved by using a GP based model alone.

240. An innovative approach adopted was the use of Trust teams to set up 'pop-up' clinics in various locations aimed at specific groups such as young people etc. This provided vaccination options at much easier to reach locations, particularly in areas where the uptake rate had been lower than average.

241. Both of these measures are really only required during a mass vaccination type situation, but the pop-up style arrangement has been used again recently while trying to improve uptake rates in the MMR vaccine in certain parts of Belfast.

Retaining innovations, knowledge or lessons learned

242. As mentioned earlier, prior to the pandemic, in NI there was no single IT system that captured vaccination data. Most vaccinations are given to children and uptake information is recorded on the Child Health Information System (CHIS) but these only record vaccinations for those aged 18 years or under. Uptake rates for vaccinations of adults, such as the annual influenza programme, is based on claims submitted by GPs and information on uptake only becomes available several months into the flu programme.

243. To improve this the Minister approved the development of a Vaccine Management System (VMS). This ensured the accurate recording of the huge number of vaccinations given during the course of the programme. This information was then used to, report on population uptake by phase of the programme and other agreed data variables and to identify areas of low uptake, including at 'super out-put area'.

244. The VMS has subsequently been retained and adopted by the PHA for other vaccination programmes, including the flu and shingles programmes and is a valuable legacy from the Covid vaccination programme.

Vaccine certification / passport scheme in Northern Ireland

244a. I was not involved in any of the discussions or decisions around vaccine certification/passport scheme.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 28 October 2024