IN THE MATTER OF THE INQUIRIES ACT 2005

AND IN THE MATTER OF THE INQUIRY RULES 2006

UK COVID-19 INQUIRY

EIGHTH WITNESS STATEMENT OF CLARA SWINSON

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1. I, Clara Swinson, Director-General for Global Health and Health Protection at the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU, will say as follows:

INTRODUCTION

2. I make this statement in response to a request from the UK COVID-19 Public Inquiry (the Inquiry) dated 20 July 2023 made under Rule 9 of the Inquiry Rules 2006 (the Request) asking for a corporate statement on behalf of the Department of Health and Social Care (the Department) providing an overview of the role of the Department in vaccine delivery in England, Wales, Scotland and Northern Ireland; including roll-out procedures; barriers to vaccine uptake, including vaccine confidence and access issues and the effectiveness, timeliness and adequacy of Government planning for and response to inequalities relevant to vaccine uptake; vaccine safety issues, including post-marketing surveillance, Vaccine Damage Payment Scheme (VDPS) eligibility and payment limits and VDPS reforms and lesson learning in the period between 30 January 2020 and 28 June 2022.

3. As this is a corporate statement on behalf of the Department, it necessarily covers matters that are not within my personal knowledge or recollection. As a corporate statement involving many different areas of policy with the Department, information has been gathered from several sources. This statement is to the best of my knowledge and belief accurate and complete at the time of signing, in line with responding as far as possible within the Inquiry deadlines. Notwithstanding this, it is the case that the Department continues to prepare for its involvement in the Inquiry. As part of these preparations, it is

possible that additional material will be discovered. In this eventuality the additional material will of course be provided to the Inquiry and a supplementary statement will be made if need be.

4. I have provided two other statements in this Module. The first (my Sixth Witness Statement) provides an overview of the Department's role in the development and deployment of vaccines **(CS8/1 - INQ000474334)** and the second (my Seventh Witness Statement) covers development and use of antivirals and therapeutics **(CS8/2 - INQ000474335)**.

5. This statement refers to several departmental officers and agencies, boards and committees, executive non-departmental public bodies, arms-length bodies (ALBs), executive agencies, advisory non-departmental public bodies who were all involved in the matters addressed by this statement. Details of the duties, functions and composition of these individuals and entities are set out in detail in my First Statement of this Module **(CS8/1 – INQ000474334)** at paragraphs 32 - 111 and in my second Statement of this Module **(CS8/2 – INQ000474335)** at paragraphs 25 – 57. For the purposes of this statement, these roles, responsibilities and functions are the same.

6. A list of key decision makers in the Department in respect of the topics outlined in the Provisional Outline of Scope for Module 4 was provided to the Inquiry on 10 November 2023 **(CS8/3 - INQ000399472)** and a further list was provided on 22 December 2023 **(CS8/4 - INQ000474257)**. Changes to ministerial roles during this period are outlined at paragraph 12 in my First Statement of this Module.

7. While the COVID-19 pandemic presented novel issues, including, the speed with which the vaccines were developed and deployed, and the scale of the roll-out, the Department and wider health system have a great deal of institutional knowledge and experience in vaccines programmes. Therefore, the Department already had in place practices, procedures and approaches to communications, uptake, disparities and safety which we were able to adapt to respond to COVID-19. At paragraphs 116 – 122 of my First Statement of this Module **(CS8/1 – INQ000474334)** I set out the considerable amount of work which had been done by the Department in preparation for the rapid development of vaccines to counter an emerging infectious disease; there were also large scale routine programmes and work on uptake. The Department was able to build on this very effectively.

8. The deployment of vaccines was a whole health and care system endeavour in which the Department played a leadership role, including between the four UK nations. I outline the early stages of supporting, planning for and delivering the roll-out of the vaccine and the establishment of the Vaccine Deployment Directorate in my First Statement of this Module in paragraphs 18 – 31 **(CS8/1 - INQ000474334).**

9. In paragraph 18 of my First Statement of this Module I set out the role of the Department in the development of vaccines and therapeutics. I would highlight the following areas for this statement in particular:

    a. **Research and development:** Commissioned, funded and delivered research, using new and existing National Institute for Heath and Care Research (NIHR) infrastructure which was scaled up.

    b. **Deployment:** Led preparation for, and then facilitated planning and vaccine deployment at scale, building on existing arrangements for the annual flu programme, expanded and scaled; setting an expectation on NHS England and Improvement (referred to in this statement as NHSE) readiness for roll-out; and relevant ministerial decisions, including a dedicated minister for large parts of this time period.

    c. **Campaigns and communications:** The Cabinet Office (CO) led on paid marketing campaigns and communications on vaccine uptake and published regular data on gov.uk. The Department led on vaccine communications, this includes strategic communications, media relations, external affairs, social media via owned channels etc. The Department had its own dedicated team to lead delivery of the vaccine communications strategy.

    d. **Vaccine uptake:** Real-time NHS data fed into regular ministerial vaccines meetings and as part of the Bronze/Silver/Gold meetings which included identifying areas and groups with low uptake and helping develop strategies to tackle this.

    e. **Cross-UK collaboration:** The Department coordinated with the other nations and overseas territories on relevant planning and preparation.

f. **Holding the health system to account:** Sponsorship of relevant ALBs including their prioritisation of the vaccine programme, especially Medicines and Healthcare products Regulatory Agency (MHRA), Public Health England (PHE), UK Health Security Agency (UKHSA), NHSE), the Health Research Authority (HRA) and working with the Vaccine Taskforce (VTF).

g. **Briefing ministers:** There were frequent and regular meetings between the Secretary of State and officials and the relevant ALBs to ensure alignment and fast decision making. There were also numerous written submissions for decision and information.

10. Further information on the research and development of COVID-19 vaccines and the role of the NIHR is covered by a statement to the Inquiry by Professor Lucy Chappell.

11. This statement covers the following:

a. **Section 1: Public messaging** sets out the roles and responsibilities of the Department, and those of its key partners, regarding public messaging on vaccines. It sets out the evidence-based strategy for addressing uptake, sets out the wide range of approaches used and examples of key messaging. It explains how communications were inclusive and how the Department evaluated the effectiveness of communications efforts.
b. **Section 2: Disparities in vaccine coverage and vaccine uptake, drivers and confidence** covers the disparities in vaccine coverage and uptake and the Department's approach to addressing this. It includes data on uptake, drivers, confidence and key trends over time. It covers specific groups including pregnant and breastfeeding women, black women and women living in deprived areas, and children as well as myocarditis, the educational impacts of COVID-19 vaccination and the rollout in schools. It also reflects on lessons learned in relation to particular groups and the relationship with the devolved administrations.
c. **Section 3: Tackling misinformation and disinformation** covers the Department's approach to addressing misinformation and disinformation and how it tailored this approach to address specific issues in different communities.
d. **Section 4**: **Vaccine safety** sets out the Department's role in assuring vaccine safety, monitoring risks and identifying side effects and on communications about these issues.

e. **Section 5: The Vaccine Damages Payment Scheme (VDPS)** covers the background to the Scheme, the movement of policy responsibility and administrative responsibility of the Scheme from DWP to the Department and NHSBSA respectively, and the inclusion of COVID-19 vaccines within the Scheme and associated challenges. It also sets out the Scheme's payment limits, the applications process and reform efforts to address in recent years.

SECTION 1: PUBLIC MESSAGING

Roles and Responsibilities for Public Messaging

12. In this statement, I focus on how the tools the Department used relate to the role, function and responsibilities of the Department with regards to public messaging on vaccines and how our strategies underpinned key success in deployment.

13. The Department, in partnership with the Department for Business, Energy and Industrial Strategy (BEIS)(which was split in 2023 to form the Department for Energy Security and Net Zero, the Department for Science, Innovation and Technology, and Department for Business and Trade), MHRA, PHE and the Department for Digital, Culture, Media & Sport (DCMS), led on communications about vaccine safety and confidence and to explain the vaccine approval process. It also led, in conjunction with NHSE and PHE, communications regarding vaccine deployment and delivery to support operational work, inform eligible groups when a vaccine was ready and to provide safety information and the process of vaccination and aftercare **(CS8/5 - INQ000502091)**. The Department also published regular data on vaccine uptake on the gov.uk COVID-19 dashboard.

14. As set out in paragraph 9 of this statement, the CO led paid marketing campaigns on vaccine uptake.

15. As set out in my First Statement of this module at paragraphs 64 - 70, PHE and then UKHSA provided public health advice on all aspects of vaccination, including updates to 'Immunisation against infectious disease (the "Green Book") and the development of patient group directions (PGDs) for the administration of COVID-19 vaccines. Additionally, PHE/UKHSA put complex scientific information in the public domain, which they then translate into accessible language, more information on this can be found at paragraph 26 of this statement.

16. As set out in the Government's revised 2021-22 mandate to NHS England and NHS Improvement, NHSE's role was "rolling out the national vaccination programme, prioritising those at most risk is vital. It is also essential that NHS organisations communicate effectively with patients and the public on the continuing Covid response".

Responding to COVID-19

17. From January to February 2020, the Department led on all Government communications about COVID-19, working closely with PHE and NHSE as well as CO/No.10. The Department's communications team was responsible for the communication of Government health and social care advice, policy and implementation of decisions made by departmental ministers. This included data published in the Department's public daily tweet which began on 25 January 2020 and recorded the number of positive cases **(CS8/6 - INQ000107097)**. The data referenced within the daily tweet was increased over time to include deaths and testing rates.

18. In March 2020, the Government's COVID-19 response moved from a health sector led to a whole of Government response. In April the Government created the COVID-19 Taskforce based in the CO which included a COVID-19 communications hub whose role was to coordinate a whole of Government communications response and deliver joined up communication campaigns across channels to increase awareness and behaviour change and counter misinformation. The CO took on responsibility for all paid advertising that was developed and deployed for the messaging on vaccines.

19. The COVID-19 hub worked closely with the Department, PHE, NHSE and No.10. The Department and PHE rapidly seconded a range of expertise into the CO COVID-19 Communications hub to work as part of a cross-government team, this included staff with specialist marketing, behaviour change, research/insight, evaluation, and media skills. (**CS8/7 - INQ000106257; CS8/8 - INQ000106258**). This helped the hub communications team include specialists in health communications who were able to join-up and collaborate with the Department effectively. The Department's communications team continued to support ministers, the CMO and officials with media requests, briefing new developments in the COVID-19 response, and contributing to the wider cross-government and health system COVID-19 campaign. When COVID-19 moved to a whole of

Government response, the Department's communications teams provided briefing to support all Government departments and the daily Downing Street press conferences.

20. BEIS managed the communications for the VTF. As the vaccination programme moved from planning and procurement to implementation and delivery, the Department played a significant role in the cross-government work on COVID-19 vaccine communications, working closely with the COVID-19 hub, BEIS, NHSE, the MHRA and PHE (which led all communications for the Joint Committee on Vaccination and Immunisation (JCVI)). A cross-government Deputy Director group met daily from 16 November 2020 to 7 June 2021 to drive implementation of the communication strategy, including the Department, BEIS, NHSE, PHE, CO and the Ministry of Housing, Communities and Local Government (MHCLG) which later became the Department for Levelling Up, Housing and Communities (DLUHC) liaising closely with No.10. Its work was overseen by a Communication Directors group from the Department, BEIS, CO, NHSE and PHE. The vaccine communications team produced a forward look grid to provide oversight and approval of all announcements, events, and briefings. I exhibit an example of the grid from 3 December 2020. **(CS8/9 - INQ000399254; CS8/10 - INQ000411765)**

21. On 22 September 2020, the Department and BEIS brought a paper to the COVID-O Committee on vaccine deployment which asked the Committee to '*note the unified communication planning across Whitehall to promote the uptake of Covid-19 vaccines, and to mitigate vaccine hesitancy and counter anti-vaccination publicity.*' **(CS8/11 - INQ000234020)**. The paper sets out the cross-government and health system's role in working together on vaccine communications:

> *"DHSC, working with the health marketing and communications professionals in PHE and NHSE/I, lead deployment communications. This will complement the work led by BEIS on comms relating to manufacturing, research and development, for example announcements relating to new clinical trials. The Cabinet Office manages a XWH narrative on vaccines, covering both domestic and international policy, which is regularly updated by the relevant departments.*
>
> *DHSC is also developing a communication plan to mitigate 'anti-vaccination' activity around a Covid-19 vaccine and maintain public confidence in vaccination. This is being done in close collaboration with DCMS as the overall government lead for countering misinformation and dis-information online."* **(CS8/11 – INQ000234020)**.

22. In November 2020, as we moved towards the roll out of vaccines, as I mention above at paragraph 8, the Department set up a new directorate. Antonia Williams took up the role of COVID-19 Vaccine Deployment Director, with responsibility for providing advice to the Department's ministers and strategic coordination across responsible bodies to enable the safe and effective roll out of the vaccine programme.

23. In September, considering the progress on vaccines, the Department created a new senior dedicated role of a Deputy Director for COVID-19 vaccine communications. James Sorene held this role from September 2020 until October 2021. He worked closely with the COVID-19 Vaccine Deployment Director on public messaging about the vaccines and tackling disparities in vaccine coverage and uptake. The Department had the lead role in setting the policy framework for vaccine roll out, leading on messaging and the vaccine uptake strategy and was responsible for delivering the strategy through other bodies. The Department used NHSE data to track uptake and to provide accurate daily reporting to ministers.

24. As set out in the Department's UK COVID-19 Vaccine Uptake Plan, published on 13 February 2021 **(CS8/12 - INQ000087230)**, it was important to act on knowledge from previous vaccination programmes and survey evidence in a timely manner without delaying interventions. Previous vaccination programmes indicated that uptake was likely to be lower for some minority ethnic groups and this was being confirmed by emerging local and national evidence, the reasons behind this are discussed further in Section 2 and 3, paragraph 117, 208 and 211.

25. As mentioned at paragraph 15, PHE/UKHSA were responsible for putting complex scientific information in the public domain and translating the information into accessible language. This was important for confidence and uptake. That took the form of weekly COVID-19 vaccine surveillance reports first published in April 2020 then published monthly from April 2022 and published quarterly from April 2023 **(CS8/12 - INQ000087230)**.

26. In March 2021, PHE with the University of Warwick (part of Scientific Pandemic Influenza Group on Modelling, Operational sub-group (SPI-M-O)) published the first estimates of the number of deaths prevented by vaccination in England between the start of the vaccination programme and the end of February 2021, UKHSA continues to monitor the effectiveness of the COVID-19 vaccines as set out in the COVID-19 vaccine surveillance strategy **(CS8/13 - INQ000411688)**. This showed that the first two months of the programme alone had averted around 6,500 deaths. The Department and the ALBs (see paragraphs 18 and

318 of my First Statement in this Module **(CS8/1 – INQ000474334)** were directly producing and publicising the evidence of the effectiveness of vaccines to encourage vaccine uptake. This information went rapidly into the public domain as part of the communications strategy, rather than following the usual slower process for publishing scientific information.

Strategy for Addressing Uptake

27. The Department was keen to use the most effective evidence-based approach for addressing uptake. Recognising internationally recognised methodology, the Department's view was that it would be appropriate to base its approach on the internationally recognised World Health Organization's (WHO) three Cs: complacency, convenience and confidence **(CS8/14 - INQ000411678)**. Slides titled "COVID-19 vaccine communications strategy", dated 15 November 2021, which were shared with the Secretary of State, justified the appropriateness of the considered approach, setting out that its implementation was:

    a. Driven by insight: developing deep knowledge about target audiences.

    b. Delivering as one team: supporting, sharing, amplifying across channels, problem solving within daily meetings.

    c. Expert led: public facing communications with medical experts providing clear reassuring messaging and answering lots of questions on TV and radio.

    d. Open and transparent: being up front about accurate information about vaccine impact based on data from clinical trials and later from PHE vaccine surveillance data.

    e. Evaluation and learning: examining daily and weekly polling and adapting messages and tactics and trying new creative routes and innovative use of channels **(CS8/15 - INQ000411734)**.

28. The strategy that the Department viewed as appropriate (as is referred to throughout this document) stemmed from other previously successful vaccine roll-out campaigns and was

based on the fundamental responsibility for delivering vaccines resting as much as possible at local level. As I explain in my First Statement of this Module **(CS8/1 - INQ000474334)** at paragraph 4, local level roll-out is a matter for NHSE. I explain how Integrated care systems (ICSs) and Clinical Commissioning Groups (CCGs) were involved in vaccine deployment in my First Statement of this Module at paragraph 309.

29. The Vaccine Uptake plan published in February 2021 set out that "o*ur collective aim is to improve vaccine uptake across all communities"* **(CS8/12 – INQ000087230)**. The Vaccine Uptake Plan was an important tool in our approach that stressed the importance of work at the national and the local level and set out how this would be done. Responsibility for vaccine deployment and uptake was for Directors of Public Health (DoPH) and the local NHS. The Uptake Plan is described in more detail in Section 2 (paragraphs 76, 107-108 and 117).

30. As well as basing our strategy to maximise uptake on recognised, evidence-based methodology, the Department also based its approach to individual informed consent for the COVID-19 vaccination programme on the same principles that had been used successfully in other programmes to improve vaccine coverage and uptake. Public messaging, including the COVID-19 vaccine campaign, set out the health and wider benefits (including to family and to key workers) of getting the COVID-19 vaccine. An individual would give their consent before receiving their vaccine. Additionally, the individual received information on the COVID-19 vaccine and the possible side effects of the particular vaccine given to the individual.

Delivery of Messaging

31. The Department uses a wide range of approaches, as appropriate, to communicate health issues to the public and this continued for the Department's work during the pandemic. These approaches include producing press notices for national and regional newspapers; providing interview and video/audio opportunities for TV and radio broadcasters; using departmental social media channels including Twitter, Facebook and LinkedIn; and providing a mixture of content including graphics and videos (created internally or for health campaign activities). The Department also publishes articles, guidance, and consultations for the gov.uk website, works with key stakeholders to share and spread the main details to their members, and develops and delivers paid-for marketing campaigns on key health topics for use across different channels including print, broadcast and social media.

32. For example, in preparation for the vaccine rollout the Department gave a presentation on vaccine roll-out at a meeting of the local resilience forum chairs in November 2020. Following that presentation, the MHCLG continued to pass on queries from Local Resilience Forum (LRF) chairs about COVID-19 vaccines, which the Department would answer. During January 2021 the Department held a series of ad-hoc meetings/calls with MHCLG about local authority concerns that there needed to be better collaboration locally between local NHS commissioners, service providers and local authorities. This resulted in a joint letter going out from the Secretaries of State for Housing, Communities & Local Government and Health and Social Care to all local authorities on 2 February 2021 **(CS8/16 - INQ000411683)** setting areas of collaboration, as well as advising local authorities on how to access funding for vaccine related costs.

33. At national, regional and local level the Department worked in partnership with local authorities, the voluntary and community sector, local resilience forum, communities, staff and patients to ensure that simple accessible advice and information was available to everyone and that local implementation plans are tailored to support uptake in all communities. Local DoPH were crucial to the national vaccination effort. They and their teams brought deep experience of immunisation and screening programmes and played a critical role in understanding the whole population of an area, empowered through two-way communication at national and local levels. Core to the role of local DoPH is leading work to improve local population health by understanding the factors that determine health and ill health, and how to change behaviour and promote health and wellbeing in ways that also reduce health inequalities. The Department supported these efforts at a local level by ensuring that local authorities and DoPHs had the data they needed to understand uptake in their local areas and to tailor efforts to reach those who had not taken up the offer of a vaccine appointment **(CS8/14 - INQ000411678; CS8/12 - INQ000087230)**.

34. From early December 2020, a detailed set of information used to answer questions about vaccine effectiveness, vaccine approval, vaccine eligibility, vaccine ingredients, adverse events and side effects were compiled together in one Q&A document produced by the Department's vaccine communications team. The content came from a variety of sources and organisations including the office of the CMO, NHSE, PHE, MHRA, JCVI and the Department's policy teams. The document was reviewed and approved every afternoon by the Department's Deputy Director of Communications for COVID-19 Vaccines and was shared every day across Government and partner organisations. An example of the Q&A distributed on the 25 June 2021 is exhibited **(CS8/17 - INQ000502113**).

35. Content from partner organisations was provided by working level communications officers and approved by officials and medical experts where appropriate. The clearance process for new content was overseen by the NHSE Director of Communications Simon Enright, MHRA Director of Communications Rachel Bosworth, and PHE, and later UKHSA, Director of Communications Lee Bailey. UKHSA, NHSE and the Department's senior communications leaders met every day to discuss all live COVID-19 issues. The Deputy Director of Communications for COVID-19 Vaccines chaired a vaccine communications' call every morning with working level communications officers in the Department, PHE/UKHSA, NHSE and MHRA and a call with senior communications leaders at BEIS, the Department for Education (DfE), DLUHC (previously MHCLG) and the CO.

36. Key statements about the safety and effectiveness of vaccines were approved by the office of the CMO, PHE and MHRA where appropriate. As the vaccine programme continued in late 2020 and into 2021 the Q&A document and messages included statements and Q&A from press conferences and media interviews undertaken by the MHRA CEO Dr June Raine, Chair of JCVI Professor Wei Shen Lim, and the Deputy Chief Medical Officer (DCMO) Professor Sir Jonathan Van-Tam.

37. Inclusive messaging (i.e., messaging designed to reach as many groups as possible within society) was developed by sharing content with partners and organisations across the NHS and social care sector and with local government and civil society organisations. Clinicians and communications leaders held multiple regular briefing calls with these sectors to answer detailed questions and break down complexity into simple language, addressing concerns that could drive low vaccine confidence. As is illustrated by the specific campaigns and initiatives which I will refer to below, messaging was aimed at addressing specific concerns which were held by communities, and this enabled the broadest range of government and public sector organisations to deliver communications in support of vaccination. For example, in order to address misinformation in the Black African community that vaccines affected fertility, the Department produced social media Q&A and other materials to address this, fronted by medical professionals from Black African communities. Another example was the incorrect claim that vaccines contained pork, which was being spread in some Muslim communities. MHRA published vaccine ingredients with vaccine approvals **(CS8/18 - INQ000502095)**, and the Department set out the facts on this issue in weekly Q&A briefings sent to over 500 organisations and stakeholders including faith and community organisations. The Department also made this point at regular community leaders meetings convened by DLUHC and collaborated on a

video of Dr Amir Khan specifically aimed at reassuring Muslims over vaccine ingredients, where he explained how the COVID-19 vaccine is suitable for people from all faith groups. This video was made available as part of a communications toolkit that was developed to support uptake among staff in the adult social care sector **(CS8/19 - INQ000059914; CS8/20 - INQ000502147)**.

Figure 1: Example of a YouTube video the Department collaborated to produce, where Dr Amir Khan addresses concerns that the COVID-19 vaccine contains pork products and explains how the vaccine is suitable for people from all faith groups.

38. Department advice to ministers on 19 April 2021 **(CS8/21 - INQ000502106)** stated *"our positive vaccine narrative programme will continue with targeted activity – including outreach initiatives – to under-represented communities. Wider targeting, messaging and content strategies will evolve to align with eligible cohorts and the latest audience insight with the addition of new initiatives, including: … Tailored partnerships targeted at women, to tackle issues such as AstraZeneca blood clots, fertility and pregnancy."* It further states that *"In driving vaccine confidence amongst multicultural communities, specifically, Black, South Asian, Muslim, Polish and Orthodox Jewish communities, we led a 'by community for community' strategy and delivered across three tactical pillars: expert Q&A sessions, media relations and content creation."* **(CS8/22 - INQ000502107).** The advice details that this included over 50 Q&As with over 100 organisations and influencers, 1,000 pieces of coverage across ethnic and mainstream media and co-created content with over 200 community organisations, faith, and health and care practitioner groups.

39. Public messaging was delivered across government-owned channels and proactively through media, external affairs, social media, partnerships and paid communications. Paid-for communications conformed to Government standards of accessibility to reach diverse audiences. Content was produced in multiple languages and paid-for communications included many press partnerships with community papers in multiple languages and with overseas broadcasters to reach diverse communities in the UK, such as Pakistani and Indian channels to broadcast segments on their programmes about the UK vaccine programme. A visual example of the communications utilised is provided at Figure 23.

40. Paid campaign activity on vaccines was paid for and delivered by the CO COVID-19 hub marketing team. Activity focussed on maximising vaccine uptake and a key element of this was maintaining public confidence in vaccine safety and efficacy. Delivery of all paid for activity was aligned to operational roll-out (reflecting eligibility) and informed by the latest uptake data and qualitative audience insight research.

41. The Department remained involved in delivering the messaging, working closely with the CO COVID-19 Communications Hub. A range of Department and PHE Clinicians, such as the DCMO Professor Sir Jonathan Van-Tam and the CMO, participated in public health communications. Departmental policy officials and clinical leads (DCMO/CMO) were engaged as part of assurance and approval of CO COVID-19 hub public health activity (ensuring clinical accuracy and alignment with policy) and Departmental ministers were responsible for approval of all major CO COVID-19 hub public health campaigns.

Examples of public messaging

42. Figures 2 to 8 over the next three pages illustrate some of the social media messages used by the Department to target vaccine take-up. I am including examples of tweets, including those with video footage of key figures and Snapchat to aimed at younger audiences.

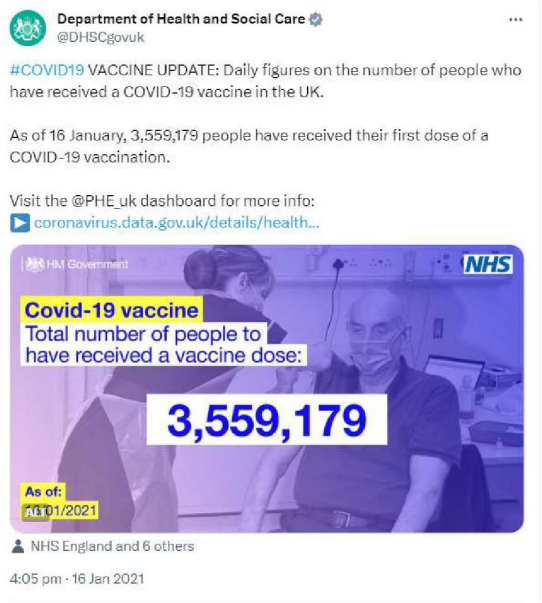


Figure 2: Example of a daily vaccine update tweet published by the Department on 16 January 2021 **(CS8/23 - INQ000411679)**

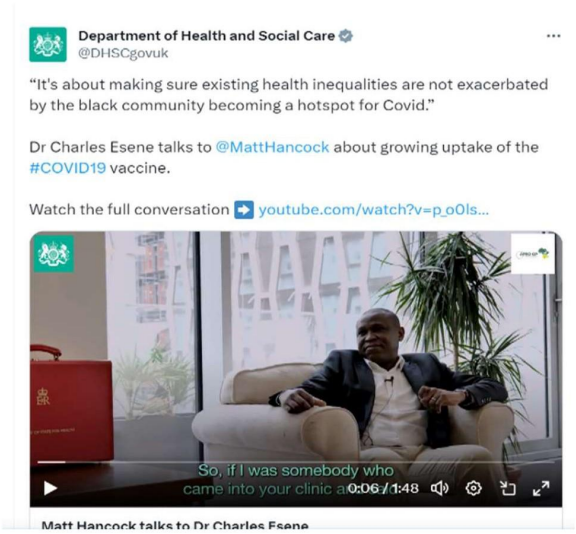


Figure 3: Tweet published by the Department of a video of Dr Charles Esene encouraging the public to get a second dose of the COVID-19 vaccine **(CS8/24 - INQ000502104)**

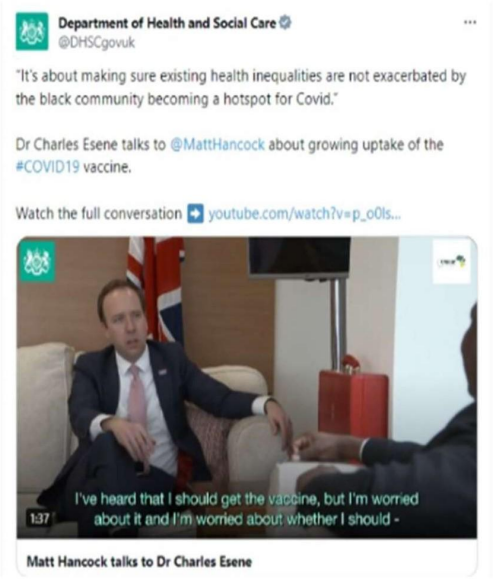


Figure 4: Tweet published by the Department of Matt Hancock speaking to Dr Charles Esene about growing uptake of the COVID-19 vaccine **(CS8/25 - INQ000411689).**

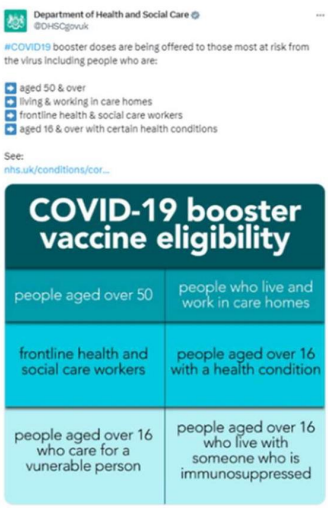


Figure 5: Tweet from the Department with information on eligibility for a COVID-19 booster vaccine **(CS8/26 - INQ000411731).**

Figure 6: Government partnered with social media app Snapchat to introduce new filter to drive vaccine uptake amongst younger audiences **(CS8/27 - INQ000502115).**

Figure 7: 2 July 2021 tweet from the Department with a video of the DCMO (Professor Sir Jonathan Van-Tam) explaining why you should get the COVID-19 vaccination even if an individual had the COVID-19 **(CS8/28 - INQ000502114).**

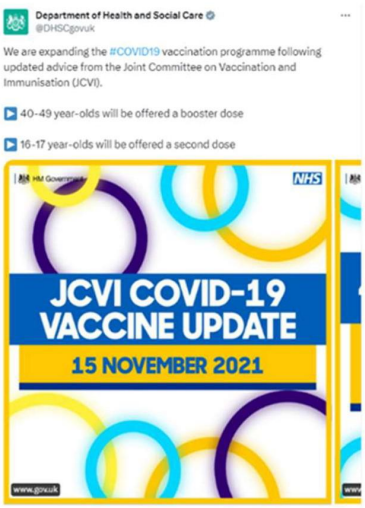


Figure 8: Example of a daily vaccine update tweet published by the Department on 15 November 2021 **(CS8/29 - INQ000411733).**

Key Paid-for Campaigns

43. Paid-for campaigns were delivered by the CO, but for context and completeness I outline some examples of the key campaigns that target uptake included:

    a. December 2020: A 'vaccine deployment' campaign to support the early stages of vaccine roll out. This predominantly paid-for social campaign addressed false narratives by mobilising trusted voices and delivering a vast range of content focussed on positive facts about regulatory approvals, robust development processes and the protection offered by COVID-19 vaccines.

    b. April 2021: The 'Every Vaccine Gives Us Hope' campaign was launched to support vaccination of those aged 50 and under. This mass broadcast campaign also included activity tailored to a wide range of less confident audiences **(CS8/30 - INQ000411696)**.

    c. July 2021 to September 2021: 'Vaccines: Don't Miss Out.' From October 2021 to December 2021, CO led on autumn/winter protective behaviours (this included guidance on testing, ventilation, and face coverings) **(CS8/31 - INQ000411717)**.

    d. November/December 2021: The mass broadcast 'Get Boosted Now' campaign, supported by individual SMS texts, was mobilised rapidly to respond to the rapid spread of Omicron and consequent expansion of vaccine eligibility **(CS8/32 - INQ000411735)**.

44. Campaign materials and messaging were reviewed by policy teams and CMO/DCMO's office for clinical accuracy and to ensure alignment with policy.

45. In addition, in September/October 2021, the mass broadcast 'Winter Boost' campaign launched to support booster vaccination amongst eligible groups as autumn/winter approached. This was a combined COVID-19 and Flu vaccination campaign. This was part-funded by the Department and PHE, with PHE providing budget to enable integration of Flu vaccination; and the Department providing funding to extend and scale planned paid-for activity in response to rising virus levels. This was a regular programme which the Department undertook every year to encourage uptake of the Flu vaccine. In 2021, it was combined with messaging about COVID-19 vaccines. The CO was responsible for end-to-end campaign development and delivery including strategic campaign planning and

development, audience definition and insight generation, campaign implementation, and evaluation.

46. Mass broadcast campaigns comprised a vast range of paid-for activity spanning:

    a. Multimedia TV, radio, outdoor posters, social and digital;
    b. PR and partnerships with influencers, charities and commercial organisations; as well as
    c. Grassroots street teams and engagement with community and faith organisations.

47. All paid for campaigns included tailored activity to groups with low vaccine confidence and low uptake (when eligible) including multicultural communities, young people, people with ongoing health conditions, pregnant women and parents of young children **(CS8/33 - INQ000502105)**.

Evaluation

48. The effectiveness of communications was measured through a range of evaluation tools. Research to monitor effectiveness was centrally commissioned, coordinated and delivered by the COVID-19 hub communications team in the CO. Data was routinely shared between CO, the Department, PHE and NHSE to allow teams to adjust communications activity accordingly. The Department made use of live NHS uptake data, quantitative and qualitative research delivered by the CO, and community engagement to monitor the impact of communications and fine tune its messaging.

49. As set out in the Third Witness Statement of Sir Christopher Wormald at paragraph 242, key data included a weekly campaign evaluation tracker (c. 2,000 UK adults, nationally representative) a daily public sentiment tracker (c. 2,500 UK adults, nationally representative) a weekly coronavirus health behaviours tracker (c. 2,000 UK adults, nationally representative) a vaccines tracker measuring attitudes, behaviours and campaign evaluation (c. 2,000 UK adults and/or specific audience groups) and weekly bespoke qualitative research to assist campaign and policy development, testing, understanding behaviours and actions **(CS8/34 - INQ000144792)**.

50. Behavioural insight and expertise were provided by CO's in-house behavioural science consultancy and through specialist agencies such as Decode. Learnings were routinely shared for use by teams.

51. The effectiveness of social media content was assessed in daily evaluations that measured content performance, including sentiment analysis, to inform future content creation and refinement. Weekly content evaluation was delivered as part of a wider communications evaluation tracker. Specific evaluation, including social media analysis of the impact of key announcements, took place to support priority audience communications e.g., communications to ethnic minority communities.

52. Evaluations assessed many aspects of media coverage (print and broadcast), including the number of reactive statements carried, prominence of the Department and Government's statements, and the number of appropriate rebuttals to inaccurate claims. Rolling monitoring of coverage was undertaken to ensure relevant government messaging was carried and if follow-up briefings were required. Daily internal media coverage updates were produced in the morning, afternoon and evening; an example from the morning of 31 December 2020 is exhibited. **(CS8/35 - INQ000399255)**

53. Social media content teams applied CO behavioural insights within the social media engagement and content strategies. Comments were monitored across the Department's social media channels to allow any confusion to be addressed and clarified. Media relations teams applied the latest behavioural insights and public opinion research data to statements, interview briefings and overall public health messaging.

54. Analysis conducted by CO about the impact of COVID-19 vaccinations on uptake demonstrated that paid campaigns played a critical role in positively influencing vaccine demand. For example, it suggested that between 10 December 2020 and 8 July 2021 vaccine demand of 9.9 per cent of the UK adult population was associated with the Government and NHS campaign's advertising and public relations (PR) activity. It found that advertising and PR activity was associated with 13.1 percent of vaccine demand for younger people (18-39yrs) during the relevant period **(CS8/36 - INQ000399277)**.

SECTION 2: DISPARITIES IN VACCINE COVERAGE AND VACCINE UPTAKE, DRIVERS AND CONFIDENCE

55. This section sets out the Department's approach to addressing disparities in vaccine uptake, how it used its existing knowledge and expertise from previous vaccination campaigns, how vaccine hesitancy was defined and how the Department used data to

increase vaccine confidence, improve vaccine uptake and reduce disparities over time. It also covers vaccine communications for specific groups including ethnic minorities, pregnant and breastfeeding women, and black women and women living in deprived areas. It covers how the Department considered disparities in coverage and the approach to improving coverage and uptake for children and support vaccine confidence in parents including communication and guidance on myocarditis (inflammation of the heart muscle), the importance of vaccines to avoid education disruption and the COVID-19 vaccination rollout to schools. Finally, it discusses the lessons learned for public messaging and the relationship with devolved administrations.

Departmental Approach to Disparities

56. I have already set out in my First Statement **(CS8/1 - INQ000474334)** of this Module how the Department led vaccine development and deployment that was globally recognised. Additionally, in order to make best use of the world-class response to development of vaccines, the Department worked on vaccine coverage and vaccine updates from the planning stage and throughout deployment. As I will set out in this section, the Department took a robust and evidence-based approach to building public confidence in vaccine uptake and addressing disparities in vaccine coverage.

57. Overall, the Department provided appropriate strategic direction to the health and social care system to increase vaccine uptake by:

    a. Putting research into place and reviewing successful interventions;
    b. Working cross government to reduce online harms from mis/disinformation;
    c. Encouraging collection of and access to timely data to inform decision making;
    d. Monitoring the health and social care system's approach to vaccination programmes and holding it to account for improved delivery;
    e. Promoting accessibility for the public to receive vaccines; and
    f. Making improvements to the vaccination service included within annual negotiations for the GP contract.

58. I have mentioned above at paragraphs 27 to 30 in Section 1 above that the Department used a range of strategies at both national and local levels. At a national level, the national campaigns and work with DLUCH were more extensive than the Department would normally undertake, in order to respond to the scale and pace of the task to reach as much of the population as possible. We appreciate the knowledge of local demographics and

needs that local health leaders contribute to informing the most effective approaches to improving coverage. In particular, local DoPH and local commissioners played a vital role in supportive effective coverage to their local vulnerable populations. DoPH and their teams are independent advocates for the health of the population and provide local government and health system leadership for its improvement and protection (for example, see paragraphs 33, 112 and 119 below).

59. The starting point for the Department's approach to ensuring the most effective vaccine coverage and in managing disparities was in very early identification of groups in the population that were the most vulnerable. When the JCVI prioritised the nine groups, as set out in my First Statement of this Module, paragraph 200 to 216 **(CS8/1 - INQ000474334)**, this was on the basis of their assessment of what characteristics were likely to make people more vulnerable to COVID-19. These vulnerabilities were addressed by prioritising them, for vaccine deployment. For example, a submission to the Minister for Vaccines and Public Health on 12 June 2020 **(CS8/37 - INQ000106484)**, which informed them of an interim statement from the JCVI. The JCVI's advice was as follows:

> *"Frontline health and social care workers are at increased personal risk of exposure to infection with COVID-19 and of transmitting that infection to susceptible and vulnerable patients in health and social care settings. The Committee considered this group to be the highest priority for vaccination. Vaccination of frontline health and social care workers will also help to maintain resilience in the NHS and for health and social care providers. The next priority for vaccination is those at increased risk of serious disease and death. Current evidence strongly indicates that the risk of serious disease and death increases with age and is increased in those with a number of underlying health conditions... Therefore, after health and social care workers, the Committee advises the prioritisation of vaccination using a mortality risk-based approach."* **CS8/38 - INQ000106485)**.

60. Uptake and disparities were at the forefront of discussions. The Department held daily Secretary of State vaccine briefing meetings to discuss live and emerging issues on the vaccination programme, including on deployment and uptake, from Autumn 2020. These meetings were attended by senior officials in the Department, NHS, PHE/UKHSA and the VTF, according to the phase of development and deployment including the CMO/DCMO, the Senior Responsible Officer (SRO) for Vaccine Deployment (from October 2021) and the Deputy SRO for the NHS COVID-19 Vaccination Programme for NHSE, me in my role as the Director-General of Global Health and the Director of COVID-19 Vaccine

Deployment at the Department and the Deputy Director for COVID-19 communications. The NHSE Medical Director of Primary Care Dr Nikki Kanani was often also in attendance. Her role leading a dedicated team to support effective communication with ethnic minority healthcare workers h(jointly with the NHS Chief People Officer Prerana Issar) on COVID-19 vaccines, and as a practicing GP, meant she was effectively able to update and advise ministers.

61. Even before COVID-19, equality and improving health and wellbeing across the whole population has been at the core of the Department's functions. The Department is committed to ensuring that resources are maximised for the benefit of the whole community, making sure that nobody is excluded, discriminated against or left behind, this aligns with the principles and values that guide the NHS and sets the framework for the delivery of social care. This approach is reinforced by the duties set out in the Equality Act 2010 (EA 2010) and the Human Rights Act 1998 (HRA) and the duty in section 1C of the National Health Service Act 2006 (the Act), as inserted by the Health and Care Act 2012, which in part reflects the 2008 Report and the Marmot Review, to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS. Section 1C of the Act places a duty on the Secretary of State to have regard to the need to reduce inequalities between the people of England. This is in respect of both access to health services and the outcomes achieved, including any benefits that may be obtained by them.

62. These principles and values, which are reflected in the WHO's August 2008 Commission on Social Determinants of Health report, '*Closing the gap in a generation: health equity through action on the social determinants of health'* (the 2008 Report) **(CS8/39 - INQ000184077)** and the February 2010 Sir Michael Marmot review, '*Fair Society, Healthy Lives*' (the Marmot Review) **(CS8/40 - INQ000184071)**, can be seen, for example, in the medical practice of clinical prioritisation, i.e., identifying who is most vulnerable and taking the necessary steps to protect them, and are perhaps best illustrated in the context of the pandemic by the prioritisation of the giving of vaccines to those most in need first.

Building on Our Knowledge & Experience

63. The Government is committed to improving vaccination uptake rates to fully protect the public from preventable diseases because there has been a decline in vaccine uptake, for example the measles, mumps, and rubella (MMR) vaccine, over the last 10 years. This

section will outline what the Department did specifically in relation to COVID-19 vaccine uptake and vaccine confidence.

64. The Government has a role to play in improving public confidence in the safety and effectiveness of vaccines and of vaccination programmes. The Department works with UKHSA and NHSE to improve immunisation delivery, capacity, and uptake for all including increasing efforts to reach under-served communities. NHSE has responsibility for commissioning immunisation services that are accessible to all members of the population. UKHSA publishes quarterly data and commentary on coverage achieved and ensures commissioners, providers, and relevant healthcare professionals have access to the necessary resources to maintain confidence in the national vaccination programmes. The medical and scientific community also have a role to play in improving confidence in vaccines, as do schools (as part of the science curriculum) and the pharmaceutical industry.

65. Prior to the pandemic, the Department was prioritising work to increase vaccination uptake due to an increase in measles cases. The NHS Long Term Plan published in January 2019 committed to improving immunisation coverage **(CS8/41 - INQ000113233)**. In early 2019, the Secretary of State was concerned about the ongoing decline in vaccine uptake and commissioned advice on a wide range of options to improve this, and on proactive proposals to tackle the challenge of anti-vaccination campaigners. The green paper "*Advancing our health: prevention in the 2020s*" that was published in July 2019 set out that a Vaccination Strategy would be launched in response to the gradual decline in vaccine uptake in recent years and to maintain and develop our world-leading immunisation programme (**CS8/42 - INQ000411668**). In August 2019, the Prime Minister set out a number of urgent actions to boost the number of children and young people receiving vaccinations, including updating the advice on NHS.uk to give people NHS-approved, evidence-based and trusted advice on vaccines including through a new website and calling a summit of social media companies to discuss how they could promote accurate information about vaccination **(CS8/43 - INQ000411671)**.

66. Building on the extensive knowledge and experience of working with vaccines gained prior to COVID-19, we were able to respond at pace to the unprecedented scale of the COVID-19 vaccination programme. By the end of October 2021 85 per cent of adults had received two doses of COVID-19 vaccines, which is substantially higher than the uptake for single-dose flu vaccines in 2019-2020 (which was 72 per cent for people aged 65 and over and 45 per cent for people under 65 in a clinical at-risk group). Comparison of these two

vaccination programmes shows that the COVID-19 vaccination programme generally achieved high uptake compared to other vaccination programmes **(CS8/44 - INQ000256987; CS8/45 - INQ000502077)**.

67. The Department learned lessons from previous vaccination programmes through an iterative process, often involving the Department, its ALBs and Parliamentary institutions such as the National Audit Office (NAO) and the Public Accounts Committee. In order to assist the Inquiry with evidence and provide the necessary context, it is necessary for me to make reference to that process as reflecting matters of historical fact. In particular, the Department prepared and submitted material and evidence to Parliamentary committees as part of their investigations, as well as by considering the content of such committees' reports and recommendations. These reviews are listed in the Second Witness Statement of Sir Christopher Wormald at paragraph 9. This enabled the Department to reach reasoned conclusions about how the COVID-19 vaccination programme compared with previous vaccination campaigns. I do not make reference to the evidence provided to any Parliamentary committees, or the reports of such committees or other bodies protected by Parliamentary privilege, in order to rely on the truthfulness of the content of that material or the accuracy of the opinions expressed, but because it is impossible for me to explain, or for the Inquiry to understand the Department's learnings from previous vaccination campaigns without reference to it **(CS8/46 - INQ000065228)**.

Definition & Data on "Vaccine Hesitancy"

68. The principles that underpin the Department's focus on population wellbeing and supporting building an evidence base to maximise health benefits to the whole community apply as well to vaccine uptake, including COVID-19. The Department's preference is to avoid using the term "vaccine hesitancy" to move the emphasis of messaging to persuasion rather than implications of personal failing. In this section, I will refer to "vaccine hesitancy" when it was used in research, for example the ONS studies.

69. During the pandemic, the Department was keen to learn more about what messages are most likely to influence confidence in uptake. As part of this, attitudinal surveys were commissioned. For example, we worked with UKHSA to draft questions for surveys which would provide evidence of the public's attitude to the vaccination campaign. ONS surveys, which were carried out for the period from January to July 2021, **(CS8/47 - INQ000410485)** provided some of the data on which Health Protection Analysts team within the

Department, relied upon to monitor vaccine coverage and “vaccine hesitancy. The ONS defined "vaccine hesitancy" as adults who[1]:

a. have been offered a vaccine and decided not to be vaccinated;
b. report being very or fairly unlikely to have a vaccine if offered; and
c. responded "neither likely nor unlikely", "don't know" or "prefer not to say" to the question "if a vaccine for the coronavirus (COVID-19) was offered to you, how likely or unlikely would you be to have the vaccine?

70. "Positive sentiment" was defined as adults who[2]:

a. have received a vaccine;
b. have been offered a vaccine and are waiting to be vaccinated; and
c. report being very or fairly likely to have a vaccine if offered.

71. In the ONS ‘Opinions and Lifestyles Survey (OPN)’ vaccine hesitancy varied by age. For each period measured from 28 April to 18 July 2021 the youngest age group had the highest level of vaccine hesitancy when comparing with other age groups for the same period. Vaccine hesitancy amongst those aged 50 or over ranged from 1 per cent to 2 per cent, for those aged 30 to 49, it ranged from 5 per cent to 8 per cent and for those aged 16 to 29 it ranged from 8 per cent to 13 per cent.

72. Over the same period, similar proportions of men and women reported vaccine hesitancy in the general population (4-7 per cent for males and 4-6 per cent for females). From 23 June to 18 July 2021, vaccine hesitancy was highest amongst unemployed (12 per cent) and economically inactive (9 per cent) people (for reasons other than retirement) and lowest amongst those who had retired (1 per cent). From 28 April to 23 May 2021, vaccine hesitancy was higher amongst those in elementary occupations (12 per cent) than those in professional occupations (3 per cent). Over the period of 28 April to 18 July 2021, Black or Black British adults had the highest rates of vaccine hesitancy (18-21 per cent) compared with White adults (4-6 per cent).

1 It should be noted that a small number of respondents in the survey reported "prefer not to say". This response is considered to represent those unsure about the vaccine.

2 The ONS survey did not include adults living in care homes or other establishments so will not capture vaccinations in these settings.

Using Data to Improve Vaccination Uptake

73. Unlike routine immunisation campaigns, the pandemic-specific approach meant the time period between vaccine delivery and the Department receiving uptake data was much shorter. Coupled with high levels of resourcing and funding, this meant that this data could be acted upon much more effectively during the roll-out.

74. Data was used to inform decisions through the Bronze, Silver and Gold structures. The Third Statement of Sir Christopher Wormald at paragraph 77 explains that:

> '*Gold was implemented on 11 June 2020 to provide oversight of the local containment aspects of the Test and Trace programme, and escalated issues requiring national decisions. Weekly Gold meetings (also known as Local Action Committee meetings) were chaired by the Secretary of State and covered the latest epidemiological briefing and assessment; assurance for containment action underway; discussed the implications of any trends identified; and proposed issues to raise with the Cabinet Office and Prime Minister on a weekly basis* **(CS8/48 - INQ000106468**; **CS8/49 - INQ000106471** and **CS8/50 - INQ000106469)**.
> *Final decisions were taken by ministers following recommendations to COVID (0) and COVID (S)'.* **(CS8/34 - INQ000144792)**

75. From 27 January 2021 date, Gold meetings took into account vaccine uptake as part of its decision-making process. The Department used NHSE data to internally track uptake and to provide accurate daily reporting to ministers **(CS8/51 - INQ000119834); CS8/52 - INQ000502098)**.

76. Vaccine uptake data was also regularly published. The Vaccine Uptake Plan published on 13 February 2021 noted:

> "*At a national level, the NHS publishes daily data on the number of first and second doses administered, now broken down by region. Weekly publications share data on the number of first and second doses broken down by age category, ethnicity and STP/ICS. Local authority Directors of Public Health receive daily updates on vaccine uptake in their areas…*" **(CS8/12 - INQ000087230)**.

77. From 13 January 2021, the ONS regularly published estimates of vaccine sentiment with breakdowns by different population groups. Analysis was based on the Opinions and Lifestyle Survey data from this is discussed below at paragraphs 82-83, 90.

78. Department analysis, using UKHSA data from the National Flu and COVID-19 surveillance reports, are shown in figures 9 to 12 below. Figure 9 shows the percentage rate of COVID-19 vaccination uptake in England for the first, second and third vaccine between 6 December 2020 and 26 June 2022 **(CS8/53 - INQ000354600).**

Figure 9: COVID-19 Vaccine Uptake between December 2020 and June 2022

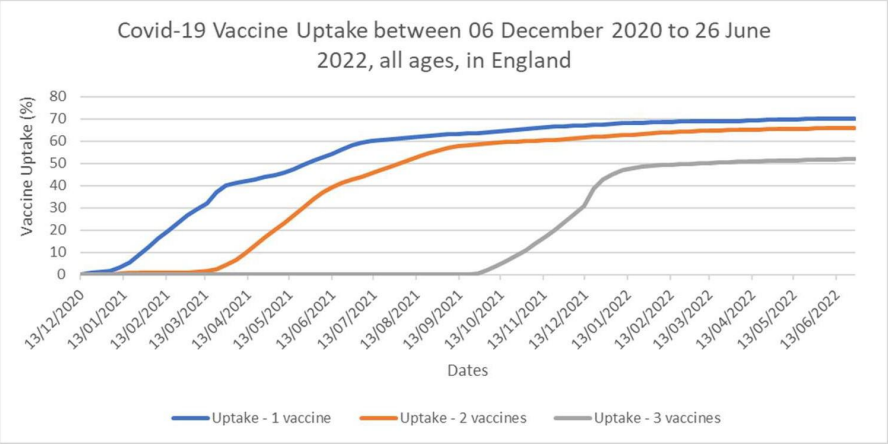
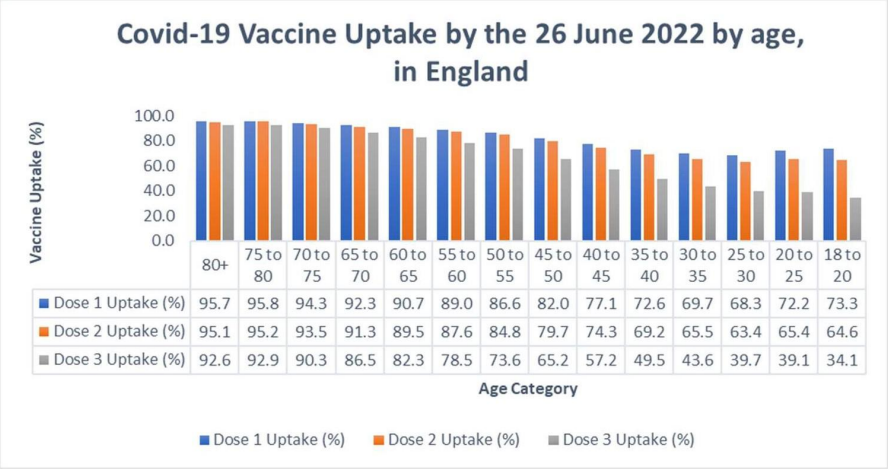


Figure 10: COVID-19 Vaccine Uptake by Age at 26 June 2022

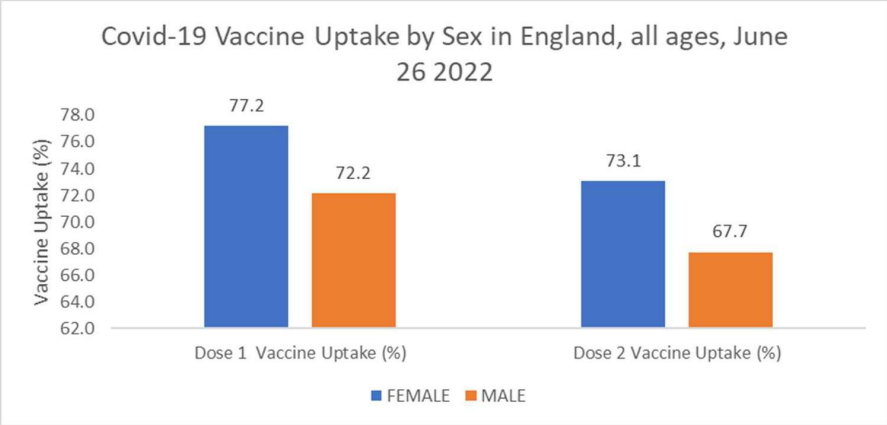


	80+	75 to 80	70 to 75	65 to 70	60 to 65	55 to 60	50 to 55	45 to 50	40 to 45	35 to 40	30 to 35	25 to 30	20 to 25	18 to 20
Dose 1 Uptake (%)	95.7	95.8	94.3	92.3	90.7	89.0	86.6	82.0	77.1	72.6	69.7	68.3	72.2	73.3
Dose 2 Uptake (%)	95.1	95.2	93.5	91.3	89.5	87.6	84.8	79.7	74.3	69.2	65.5	63.4	65.4	64.6
Dose 3 Uptake (%)	92.6	92.9	90.3	86.5	82.3	78.5	73.6	65.2	57.2	49.5	43.6	39.7	39.1	34.1

79. Within this data, there is variation in vaccine uptake according to age, sex and ethnicity. Figure 10 (above) shows vaccine uptake by age at 26 June 2022 and shows that uptake is typically lower for younger age groups **(CS8/53 - INQ000354600)**.

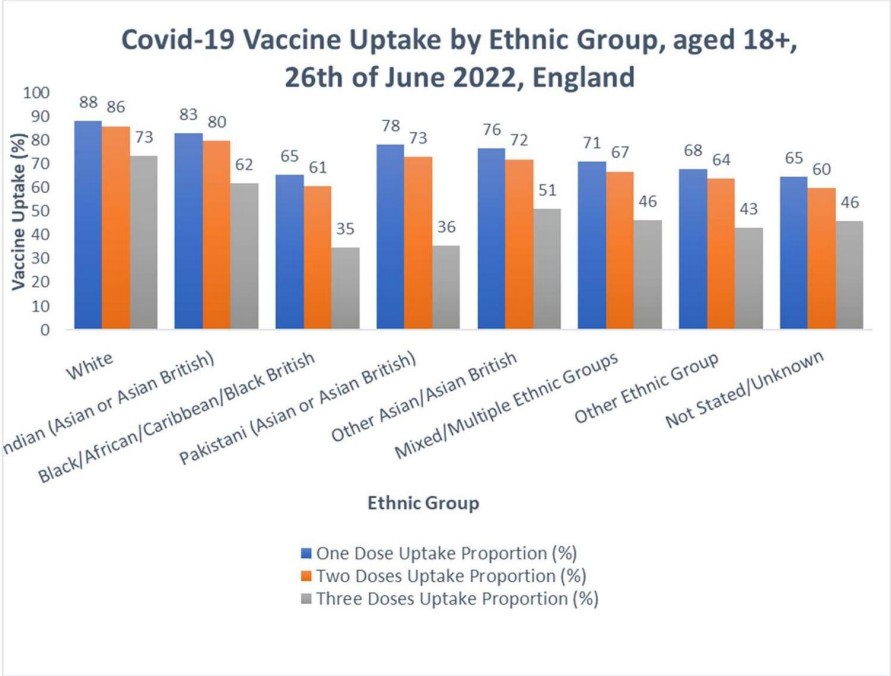
80. There is also variance by sex. Figure 11 below shows that at 26 June 2022, vaccine uptake was higher for women than men for both the first and second doses **(CS8/53 - INQ000354600)**.

Figure 11: Vaccine Uptake by Sex, June 2022



81. The data also shows variation according to ethnicity. Figure 12 below shows the breakdown of vaccination uptake by ethnic group at 26 June 2022 **(CS8/53 - INQ000354600)**. This shows vaccination uptake as highest amongst White people and lower levels amongst Black, African, Caribbean and Black British people.

Figure 12: Vaccine Uptake by Ethnic Group, June 2022



Vaccine Uptake Trends Over Time

82. By the end of May 2021, as a result of the approaches adopted by government as a whole, to which the Department contributed significantly, vaccine confidence increased with the majority of people saying that they had already been vaccinated or would be likely to accept a vaccine and there had been increases in both positive vaccine sentiment and vaccine uptake across all ethnic groups, with vaccine confidence increasing in three consecutive research periods.

83. For example, between 31 May and 31 October 2021, the percentage of over-50s who received both doses of the COVID-19 vaccine increased in all ethnic groups. The largest percentage point increases were in the Pakistani ethnic group (from 54.2 per cent to 78.8 per cent, up by 24.6 percentage points) and Bangladeshi ethnic group (from 63.7 per cent to 87.0 per cent, up by 23.3 percentage points) **(CS8/54 - INQ000354552).** Data also showed high rates of positive vaccine sentiment, with 96 per cent of adults aged 16 or over reporting a positive vaccine sentiment between 23 June and 18 July 2021 **(CS8/47 - INQ000410485).**

84. Figures 13 to 21 below show COVID-19 vaccine uptake for doses 1, 2 and 3 by geography, sex, and ethnicity, in England, for the period from December 2020 to June 2022 using UKHSA data.

85. Department analysts calculated the cumulative vaccine uptake as a percentage of the population for all ages, including those under the age of 18. Vaccine uptake for all doses was significantly lower for individuals aged under 18 because vaccination programmes were rolled out to different groups and were offered to this group later. Overall, the data shows increasing COVID-19 vaccine uptake for all doses according to geographical location, ethnicity and sex throughout the period **(CS8/55 - INQ000502146).**

Figure 13: Dose 1 COVID-19 vaccine uptake by region, England from December 2020 to June 2022

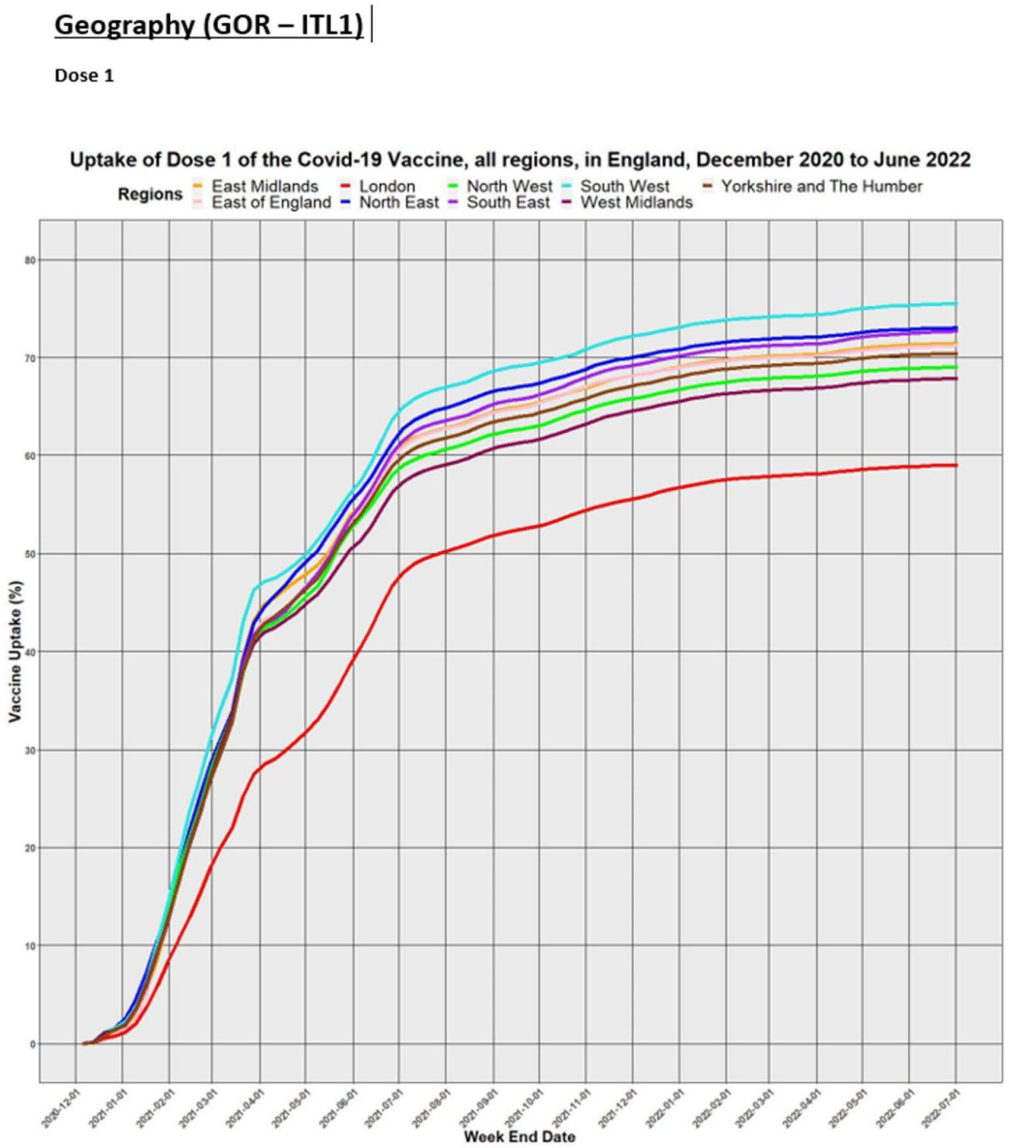


Figure 14: Dose 2 COVID-19 vaccine uptake by region, England from December 2020 to June 2022

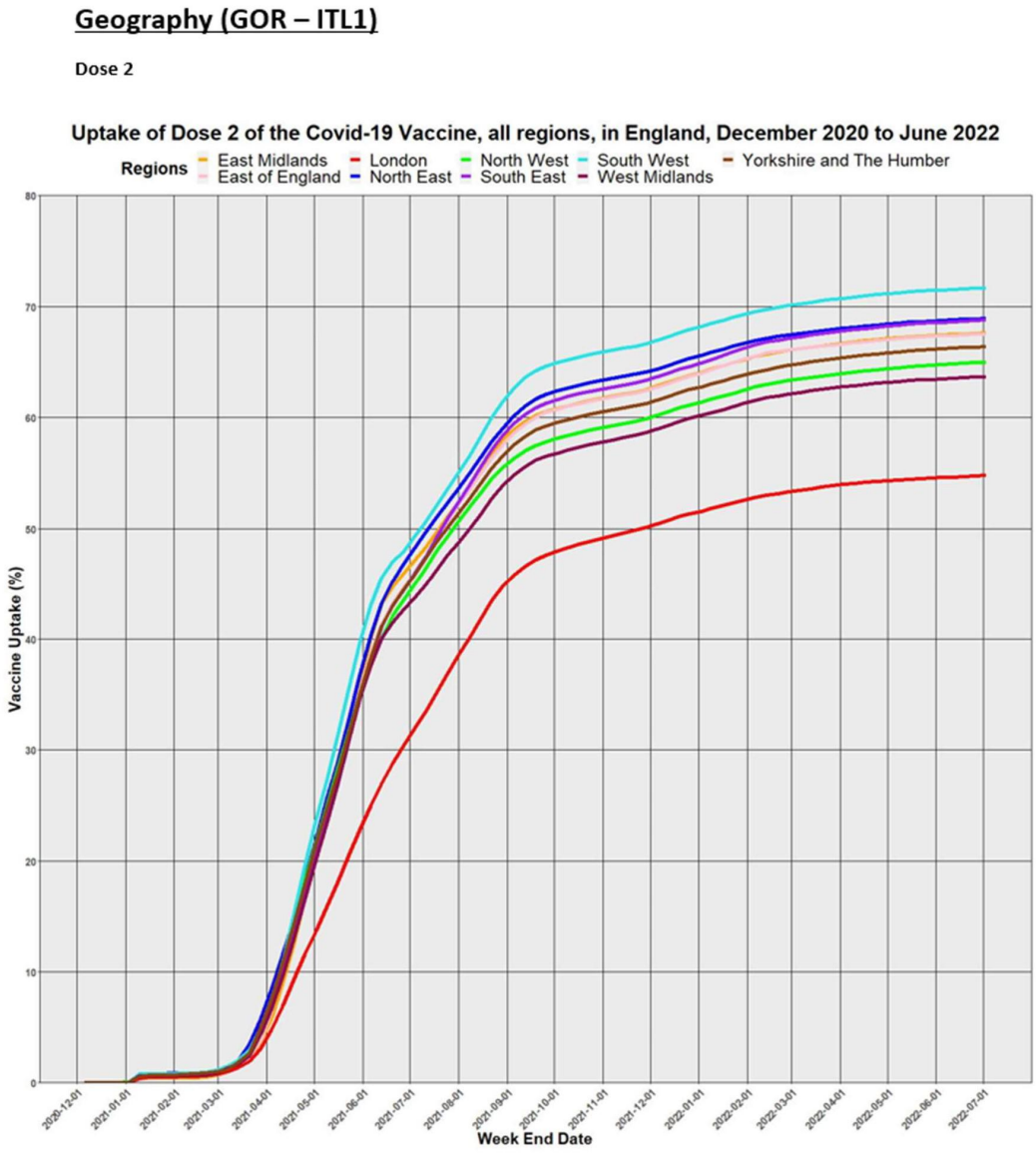
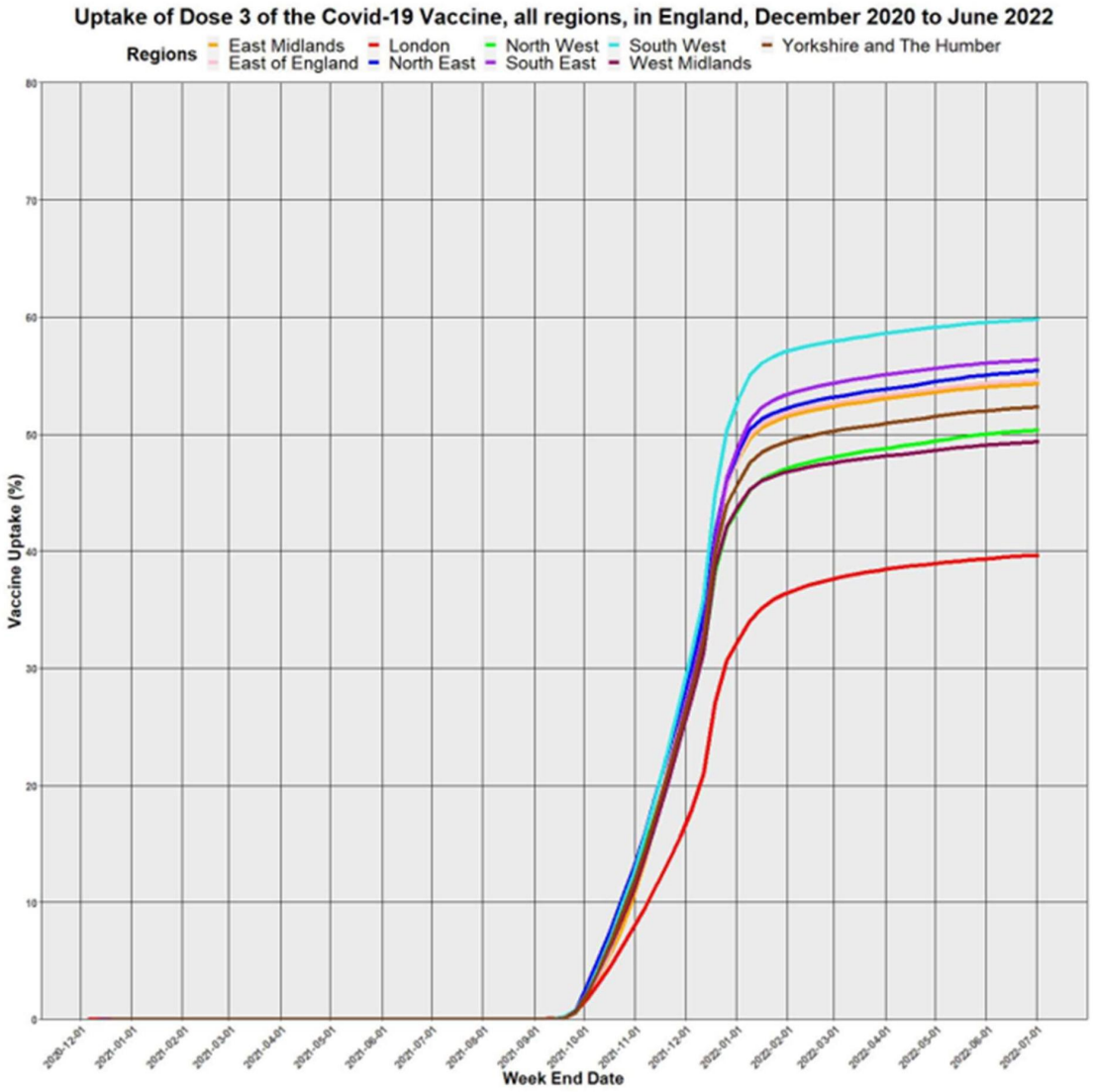


Figure 15: Dose 3 COVID-19 vaccine uptake by region, England from December 2020 to June 2022

Geography (GOR – ITL1)

Dose 3



86. The dataset highlights COVID-19 vaccine uptake for doses 1, 2 and 3 for all regions in England from December 2020 to June 2022. The Southwest had the highest and London the lowest vaccine uptake over this period.

Figure 16: Dose 1 COVID-19 vaccine uptake by ethnic group from December 2020 to June 2022

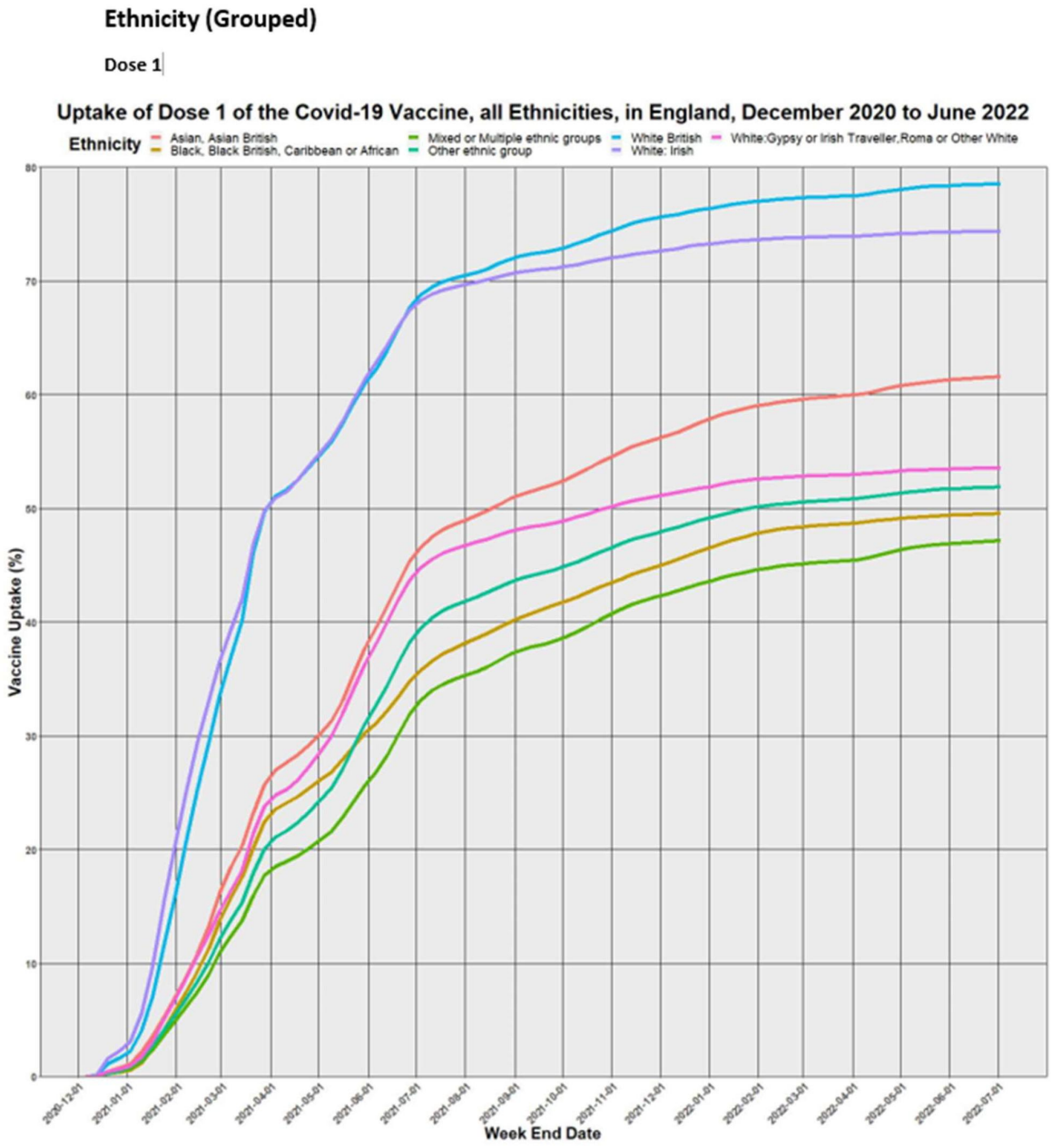


Figure 17: Dose 2 COVID-19 vaccine uptake by ethnic group from December 2020 to June 2022

Ethnicity (Grouped)

Dose 2

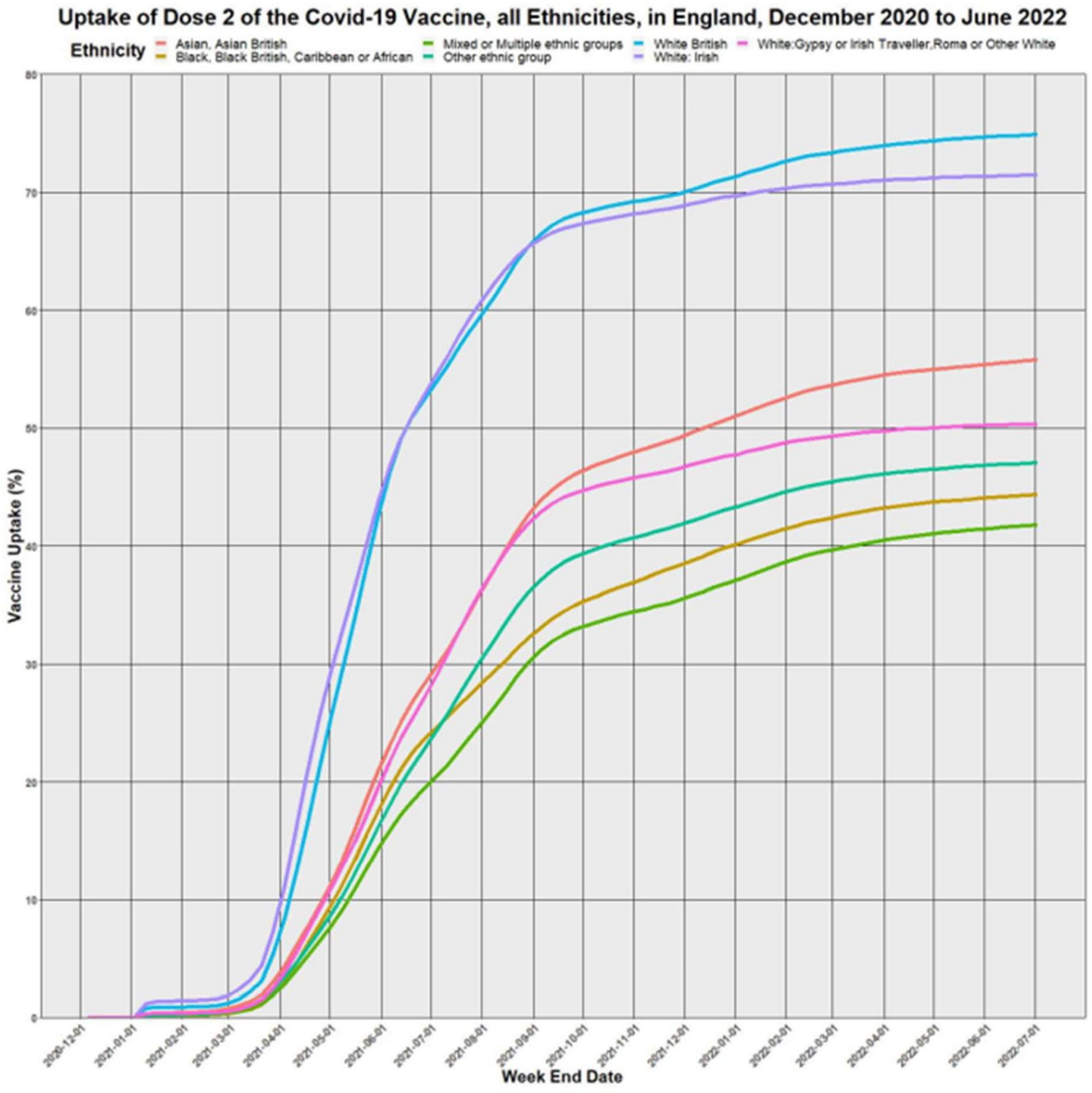
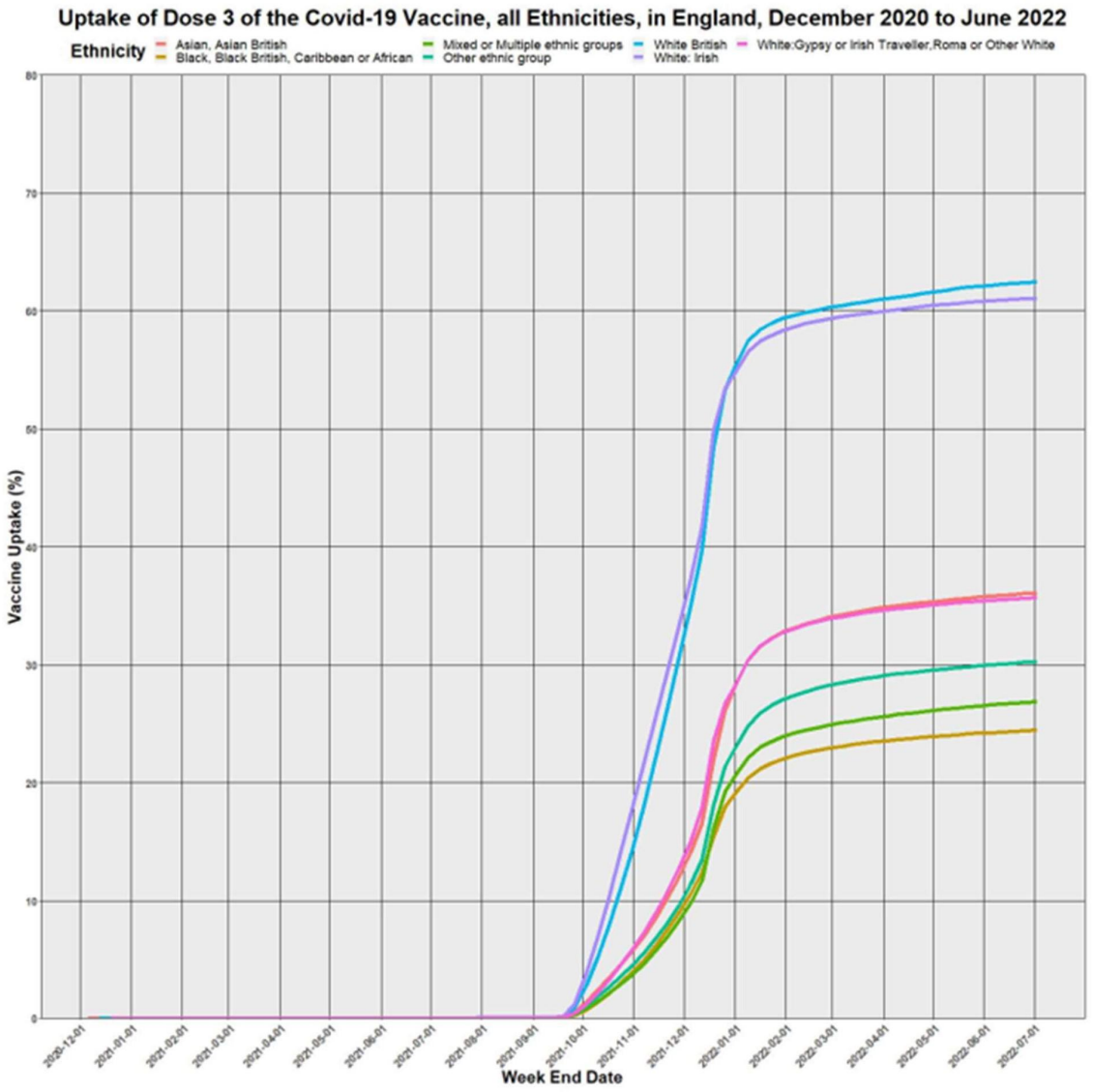


Figure 18: Dose 3 COVID-19 vaccine uptake by ethnic group from December 2020 to June 2022

Ethnicity (Grouped)

Dose 3



87. Figures 16 to 18 show vaccine uptake by ethnic group. Ethnic groupings are the same as those in the ONS ethnic group classifications given in the 2021 census. There was no record of dose 1 uptake in the first week of the timeseries for White Irish and Mixed or Multiple ethnic groups. This does not have a significant impact on the figure itself and in the following week there is recorded data. This could be a result of no vaccine uptake in these ethnic groups or a result of data collection issues.

88. The data for all doses show that COVID-19 vaccine uptake was initially highest among those with White Irish ethnicity, and subsequently amongst those with White British ethnicity. For doses 1 and 2, vaccine uptake was lowest among Mixed or Multiple ethnic groups. For dose 3, vaccine uptake was lowest among Black, Black British, Caribbean, or African ethnicities. In order to assist the Inquiry with evidence and provide the necessary context, it is necessary for me to make reference to the fact that the Department prepared and submitted material and evidence to Parliamentary committees as part of their investigations, as well as by considering the content of such committees' reports and recommendations on vaccination uptake for different groups. **(CS8/46 INQ000065228)**

Figure 19: Dose 1 COVID-19 vaccine uptake by Sex from December 2020 to June 2022

Sex (Male & Female)

Dose 1

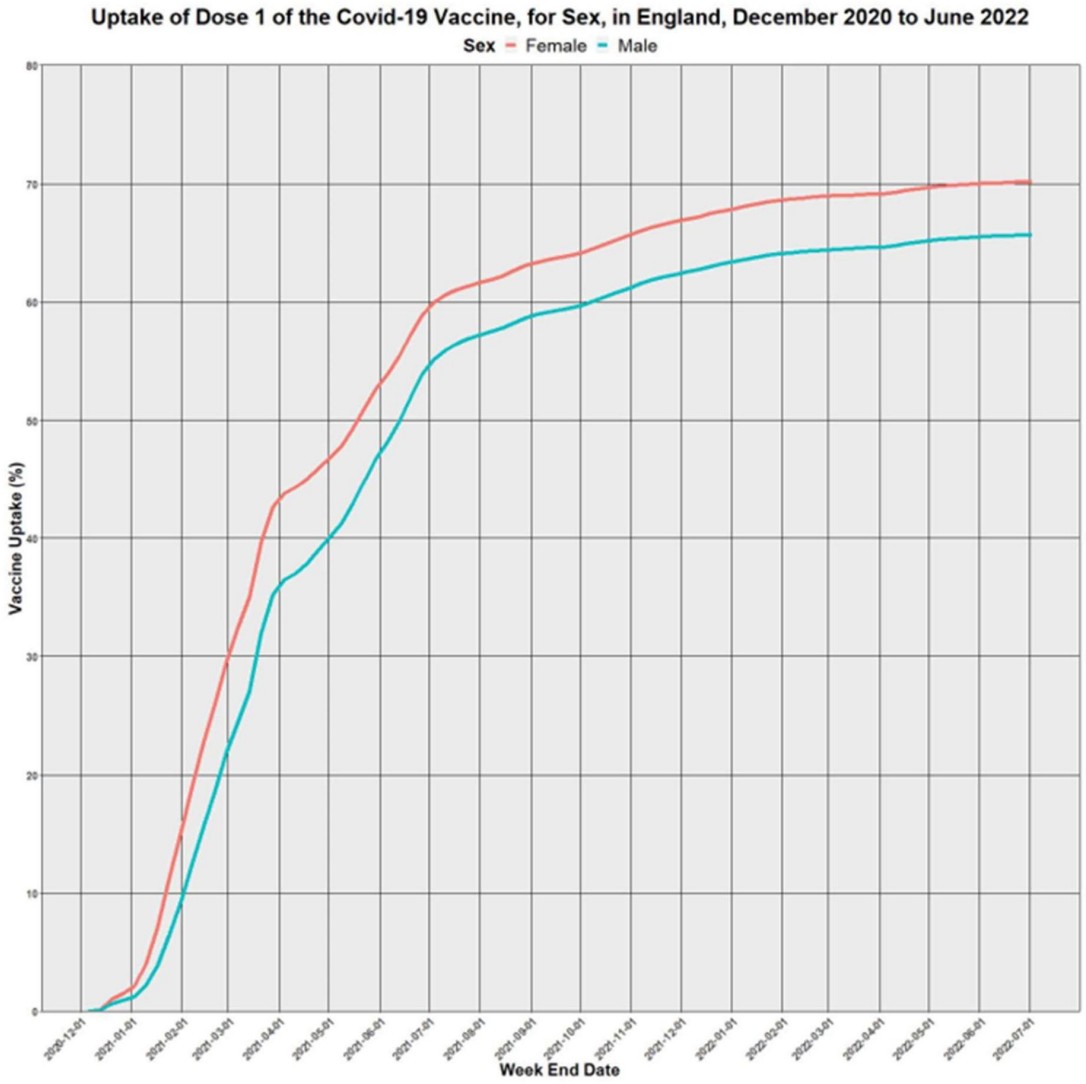


Figure 20: Dose 2 COVID-19 vaccine uptake by Sex from December 2020 to June 2022

Sex (Male & Female)

Dose 2

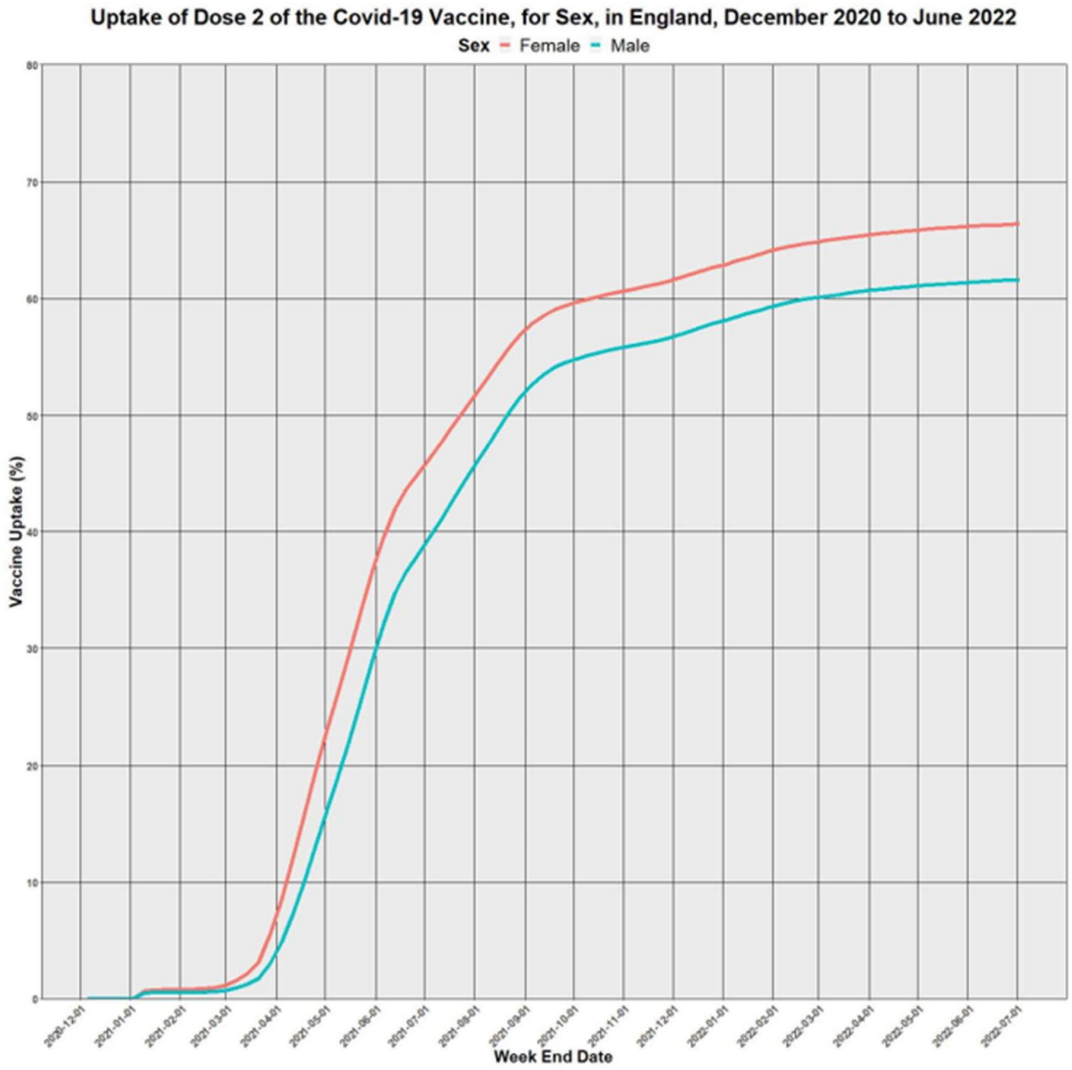
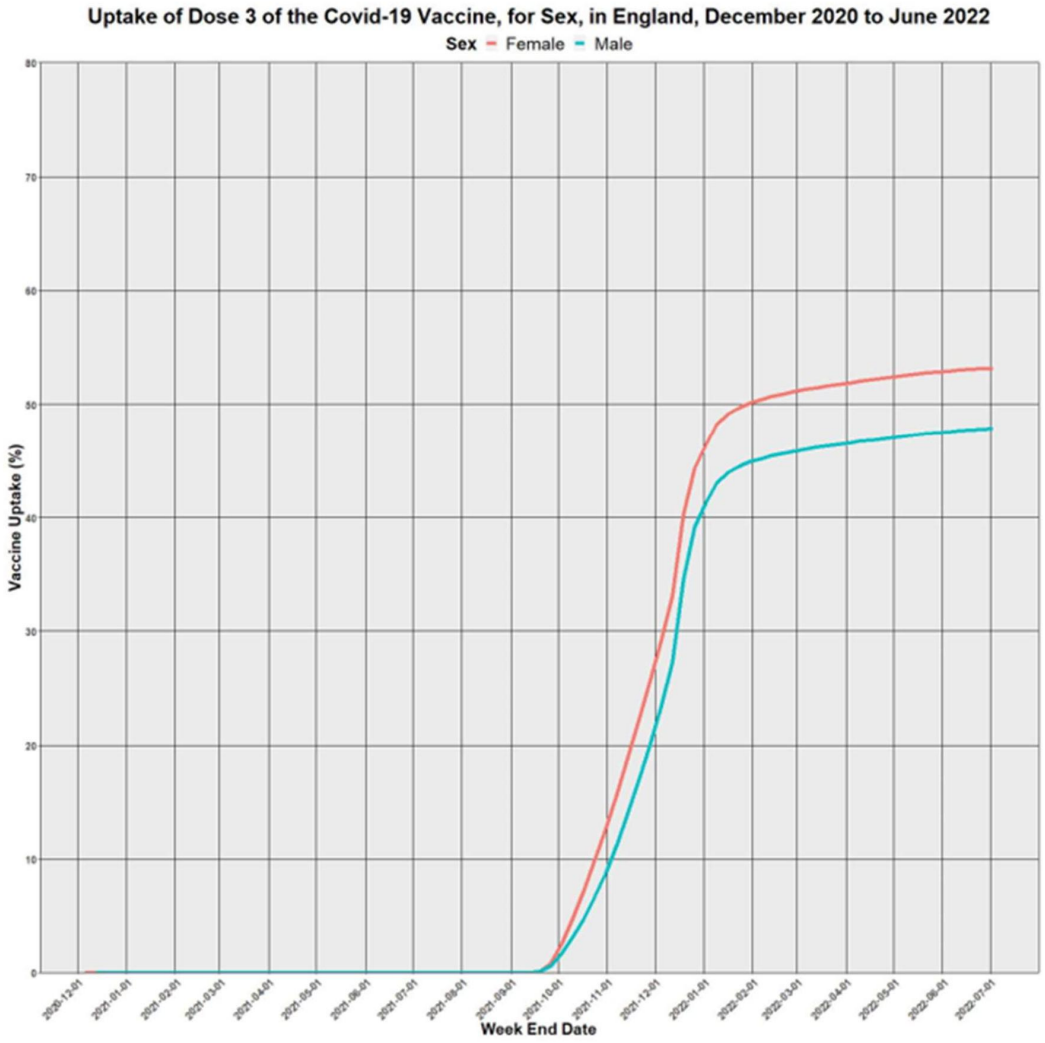


Figure 21: Dose 3 COVID-19 vaccine uptake by Sex from December 2020 to June 2022

Sex (Male & Female)

Dose 3



89. The data shows vaccine uptake was higher amongst women for all doses in England over the stated period.

90. However, while positive vaccine sentiment increased over time, residual low vaccine uptake continued to be an issue in some groups. For example, the increase in vaccine confidence amongst the Black population was substantial but it was still lower in this group than any other. The Black ethnic group reported the highest low vaccine confidence at 18

per cent compared with the 4 per cent national average. The vaccine confidence gap between Black people and people from other broad ethnic groups narrowed but was not entirely eradicated.

Disparities & Drivers of Vaccine Uptake

91. The impacts on vulnerable groups **(CS8/56 - INQ000411780)** were considered continuously by the Department during its response to COVID-19 in accordance with the Public Sector Equality Duty. In my first and second statements for this Module (**CS8/1** - Statements A and B **(CS8/2 – INQ000474335**) at paragraphs 19 and 17 respectively, I explain the introduction by the Department of the Battle Plan as an internal tool to organise the Department's programme to deliver the response to COVID-19. One of the key Battle Plan workstreams was the protection of the most vulnerable and this necessarily entailed the development of policies for their protection.

92. It was also clear that there were differences between ethnicities when it came to attitudes to the vaccines, vaccine confidence and vaccine uptake.

93. Key drivers of low vaccine confidence for all groups between 13 January and 7 February 2021 were worry about side effects, long-term effects, waiting to see how well the vaccine worked and concerns about safety **(CS8/57 - INQ000089744)**. The core Q&A and messages included detail to address all these issues with content approved by DCMO, MHRA, JCVI and PHE. These issues were also addressed at length in regular press conferences and media appearances by the main spokespeople for the vaccine programme who included the DCMO, MHRA Chief Executive Officer and Chair of JCVI.

94. When focusing on disparities between different ethnicities, in the overall period covered by the ONS surveys from 13 January to 18 July 2021 **(CS8/57 - INQ000089744)**, vaccine hesitancy (the term used in the survey) was highest amongst Black or Black British people during this period, varying from 18-44 per cent. For White people it ranged from 4-8 per cent, for 'Mixed' this was 7-17 per cent, for Asian or Asian British this was 3-16 per cent and for other ethnic groups it varied from 7-18 per cent. Taking a snapshot of the period covered by the survey, in the period 23 June 2021 to 18 July 2021, based on adults in Great Britain, the ONS found:

a. More than 9 in 10 (96 per cent) adults reported positive sentiment towards a COVID-19 vaccine, while 4 per cent reported vaccine hesitancy.

b. Vaccine hesitancy appeared to have decreased slightly among the youngest age groups compared with the previous period; vaccine hesitancy was 11 per cent among those aged 16 to 17 years (14 per cent in the previous period), 5 per cent among those aged 18 to 21 years (9 per cent in the previous period) and 9 per cent among those aged 22 to 25 years (10 per cent in the previous period).

c. Black or Black British adults had the highest rates vaccine hesitancy (21 per cent) compared with White adults (4 per cent).

d. Vaccine hesitancy was higher for adults identifying Muslim (14 per cent) or Other (14 per cent) as their religion, compared with adults who identify as Christian (4 per cent); however, there was no statistically significant difference when compared with any of the remaining religious groups.

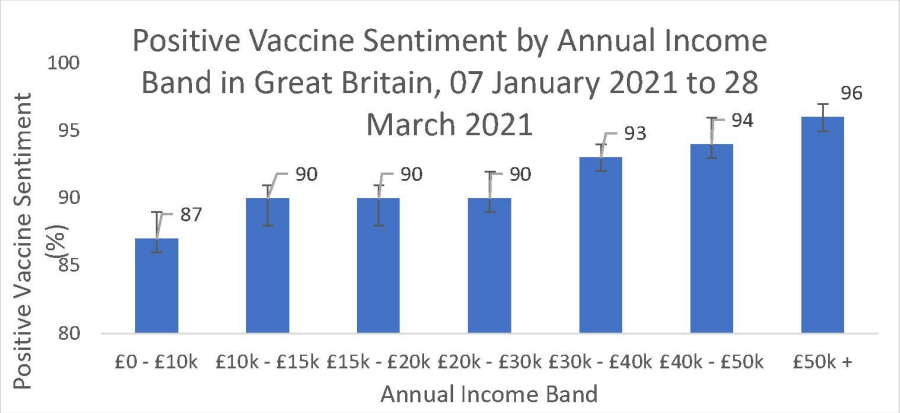
e. Adults living in the most deprived areas of England (based on the Index of Multiple Deprivation) were more likely to report vaccine hesitancy (8 per cent) than adults living in the least deprived areas (2 per cent%).

f. Adults who were unemployed (12 per cent) were more likely to report low vaccine hesitancy than those who were in employment (4 per cent) or retired (1 per cent).

g. The data in respect of COVID-19 vaccines was consistent with data from the UK Household Longitudinal study, the Office for National Statistics (ONS), and REACT-2 (an ONS surveillance study undertaken in England that examines the prevalence of antibodies in the community) which identified general lower levels of vaccine uptake among some ethnic minority groups which was not specific to COVID-19 vaccines **(CS8/47 - INQ000410485).**

95. Figure 22 below, which uses ONS data, shows vaccine confidence according to annual income from 7 January 2021 to 28 March 2021. This shows that those people with higher incomes were more likely to have positive vaccine sentiment than those people with lower incomes.

Figure 22: Positive vaccine sentiment by annual income band in Great Britain, 07 January 2021 to 28 March 2021. Data from the ONS



96. Primary care data analysed by QResearch **(CS8/57 - INQ000089744)** indicates that, in the case of several viruses, Black African and Black Caribbean groups are less likely to be vaccinated compared with White groups; over-65s from the Black Caribbean population are half as likely to have had the influenza vaccine, compared with over-65s from the White group. Furthermore, for vaccines against viruses that have emerged since 2013, all adults in minority ethnic groups were less likely to be vaccinated compared with those in White groups (by 10-20 per cent) **(CS8/58 - INQ000250215).**

97. According to the ONS **(CS8/57 - INQ000089744)**, from early December 2020 to early January 2021, fewer than half (49 per cent) of Black or Black British adults reported that they were likely to have the vaccine. Higher percentages were reported amongst people from White (85 per cent) and Mixed ethnicity (80 per cent) backgrounds.

98. This study **(CS8/57 - INQ000089744)** also mentioned that of those who said they were unlikely to have the vaccine:

    a. Over 6 in 10 adults of ethnic minority background (64 per cent) reported they were worried about the side effects of the vaccine, compared with 45 per cent of adults of White ethnic background; and

b. Around 2 in 10 adults of White ethnic background (21 per cent) reported they did not feel COVID-19 was a personal risk, compared with 11 per cent of ethnic minority background.

99. The ONS survey '*Coronavirus and vaccine hesitancy, Great Britain*' survey **(CS8/59 - INQ000410483)** conducted between 13 January and 7 February 2021 identified '*concern about side effects*', '*long term effects on health*' and '*wanting to wait to see how the vaccine works*' were the most common reasons given for low vaccine confidence. 64 per cent of Asian people and 55 per cent of Black people reporting low vaccine confidence said they were worried about side effects. The ONS published reports contain further detail.

100. A further study, the NIHR funded UK-REACH from 4 December 2020 to 19 February 2021, of vaccine uptake **(CS8/60 - INQ000411770)** among all staff at University Hospitals of Leicester NHS Trust found that ethnic minority healthcare workers were far less likely to take up COVID-19 vaccination than those of White ethnicity. This had implications for delivery of the COVID-19 vaccination programme.

101. Research from REACT-2, undertaken from 26 January 2021 to 8 February 2021 **(CS8/60 - INQ000411770)**, suggested that 72.5 per cent of Black adults would accept a vaccination; an increase on the ONS estimate but still lower than the figures for adults from the Mixed, Other, Asian and White groups (83.1 per cent, 84.4 per cent, 87.6 per cent and 92.6 per cent respectively). Both found vaccine confidence among Black people was the lowest of all ethnic groups.

102. Lower COVID-19 vaccine uptake was evident for some ethnic minority groups in vaccines administered to over 80s as of 4 February 2021 **(CS8/60 - INQ000411770)**. The vaccine rates for eligible Black African, White and Black African, Other Black, Bangladeshi and Pakistani people were notably low (45.1 per cent, 51.5 per cent, 53.4 per cent, 54.6 per cent and 55.2 per cent respectively). This compares to 82.8 per cent of eligible White British people having received a vaccine.

103. The REACT-2 cross-sectional community survey also identified particular concerns regarding the effect of the vaccine on pregnancy, future fertility and allergies. An additional source of concern among some communities was the ingredients of the vaccines.

104. Findings from the Cabinet Office Race Disparity Unit's (RDU) analysis of Understanding Society data (collected in January 2021) suggested that motivations to get

vaccinated were largely individual-focused. The analysis categorised reasons for getting vaccinated in 3 ways: individual-focused (such as "to stop me catching the coronavirus or getting very ill from it" and "to allow me to get the help or care I need at home"), family or work-focused (such as "to allow me to return to my workplace" and "to allow my social and family life to get back to normal") and society-focused (such as "because the vaccine won't work unless most people in the UK take it" and "to protect other people from catching the coronavirus") **(CS8/61 - INQ000411703)**.

Tackling Disparities

105. As outlined above in paragraphs 9, 13 and 17, the Department had a much greater role in vaccine uptake at a national level than routine immunisation programmes. The priority at both a local and national level was to work with partners to maximise uptake and ensure disparities were tackled. The context of the pandemic and the impact of other measures on the population meant that the national importance of roll out was paramount.

106. On 26 February 2021 the JCVI published an interim statement on Phase 2 of the vaccination programme. This advised deployment teams to actively promote vaccination uptake with people who are: male, those who were from an ethnic minority background, have a body mass index (BMI) of 30 or more, and those from areas of high socio-economic deprivation **(CS8/62 - INQ000354488)**. In response to this advice, the Department along with NHS and PHE worked to provide advice and information, including working closely with ethnic minority communities, to support those receiving a vaccine and to anyone who has questions about the vaccination process.

107. In February 2021, the Government published its Vaccine Uptake Plan, which set out a comprehensive approach to maximising uptake across all communities through cross-system and partnership working **(CS8/12 INQ000087230)**. The approach adopted in the plan was to improve vaccine uptake across all communities and was underpinned by four enablers at national, regional and local level. These were:

a. working in partnership
b. removing barriers to access
c. data and information
d. conversations and engagement.

108. The Plan provided extensive information on the approach to tackling uptake, including:

a. explaining the benefits of the COVID-19 vaccine through a multi-million-pound national communications campaign, led by the Department and the CO, supported by multi-lingual and more focussed communications activity;

b. It explained the COVID-19 vaccine was delivered via a range of delivery models – including mobile, pop-up, and roving sites – thereby ensuring convenient access, particularly in more deprived communities where the cost of travel can be a practical barrier. There was also sustained engagement and collaboration with community and faith leaders, who were encouraged to act as ambassadors for the vaccine – thereby building trust and rapport with communities who may be mistrustful of government or less receptive to public health messaging.

109. As part of its approach to tackling disparities and facilitating better coverage, meetings were also held internally to ensure effective planning. For example, following on from a previous meeting on 16 December 2020, the Permanent Secretary chaired a meeting with senior civil servants (including the Chairs of the Battle Plan Oversight Board and the Recovery, Renewal and Recalibration programme - "3 Rs Board") on 23 February 2021. The SRO for Workstream 7B 'Supporting other disproportionately affected groups and volunteering' was asked to report back on a review of the 'Road Map' released by the Prime Minister on 22 February 2021 to ensure that equalities were adequately covered and to inform further assessment of whether this activity was making a difference to people from minority ethnic communities **(CS8/63 - INQ000502103).**

110. The Department worked at a national level to support work done by local teams in addressing vaccine coverage in ethnic minority groups. NHSE led work to which the Department and PHE contributed to provide advice and information, including working closely with minority ethnic communities, to support those receiving a vaccine and to anyone who has questions about the vaccination process. The Department acting on the JCVI advice referred to above, prioritised the promotion of vaccinations to those at greater risk and ethnic minority communities who were disproportionately impacted.

111. A Red Team Challenge session on health inequalities and the impact of COVID-19 took place on 29 April 2021, focusing on vaccines, social distancing, and Test and Trace and how health inequalities were considered **(CS8/64 - INQ000411697)**. Mitigations identified, to be included in the workstreams were:

a. improved identification of vulnerable groups/areas;
b. better use of data;
c. closer work between national programmes and local public health leaders and
d. a need to conduct pilots where interventions have been increased in certain areas.

112. The Department did not just focus on improving processes and reach at a national level. Close engagement with specific communities, local leaders, and local health officials also helped to tackle uptake disparities. This was often led by local partners such as DoPH and local commissioners. We engaged with qualitative research undertaken by the Department and the Association of Directors of public health to review hyper local interventions to drive vaccine uptake. This led to a report which, although unpublished, was circulated to all Directors of Public Health to disseminate successful local interventions that could be adopted to increase vaccine uptake in March 2022 **(CS8/65 - INQ000411787).**

113. Concerns about the vulnerability of rough sleepers during a third wave (during autumn/winter 2021/22) were reported on 16 July 2021, including low rates of vaccine uptake (NHSE data indicated that about 26 per cent of the population of rough sleepers had received two doses) and having to live in settings with a high risk of transmission. Key actions to address this concern were focused on PHE and MHCLG guidance for hostels and night shelters, vaccination uptake and test and trace **(CS8/66 - INQ000287648)**.

114. Public health messaging was informed by insight, research and feedback from diverse community and faith leaders. An important initiative was the "Evergreen" strategy which was championed by the Minister for Vaccine Deployment. The Department and NHSE developed the Evergreen approach (the principle that everyone should still be able to come forward for their vaccine alongside later cohorts) to help tackle health inequalities. This was agreed with the Department's ministers through discussions and NHSE led the implementation of this approach by making sure everyone continued to be able to book a first vaccine. The aim of this strategy was to encourage individuals to receive the vaccine regardless of whether the broader public campaign had moved on from the first dose or second dose or to the boosters. People who may have missed out on the first dose or second dose when this was the focus of public campaigning were encouraged to nevertheless come forward to be vaccinated.

115. As part of this effort, the Vaccine Uptake Task Force, chaired by the Vaccine ministers, was set up to encourage the public to receive their first and second doses of the vaccine in advance of the effort to promote the booster programme. The Vaccine Uptake Task force brought together and strengthened collective efforts to drive vaccine uptake. This included national and focussed COVID-19 vaccine comms campaigns, deployment interventions, support for local NHS delivery systems and explored all possible policy and operational levers to increase uptake. Meetings were initially chaired by the Minister for COVID-19 Vaccine Deployment, then the Minister for Vaccines and Public Health, and the secretariat was provided by the Vaccines Policy team, with support from the Minister for Vaccines and Public Health's Private Office. Membership included representatives from NHSE, JCVI, CO, UKSSA, Association of Directors of Public Health and DHSC the Department. The meetings ran from August 2021 to December 2021.

Ethnic Minority Groups

116. The Government worked with over 200 community, faith and health care professionals, organisations, community and social influencers, including 20 Black-majority church leaders to encourage vaccine uptake across England through tailored content creation and PR outreach. There was a continued focus on building trust among different audiences and developing deeper engagement through these community partnerships. Over 120 "trusted voices" were mobilised across events and media, with a collective reach of approximately 3 million. Some of the examples of this national and local engagement with ethnic minority groups included:

a. The Department produced and published content on departmental social media channels to help increase uptake among Black and Black African and Caribbean communities including videos featuring trusted voices from several communities such as Public Health Director Professor Kevin Fenton, GP Dr Charles Esene and public health expert Professor Tolullah Oni. The team also worked with the African Development and Advocacy Centre in London (AFRIDAC) to produce a series of videos highlighting a pop-up vaccination clinic with clips from members of local African and African-Caribbean communities encouraging others to come forward for the vaccine.

b. Around 50 places of worship were used as vaccination sites with many more working in partnership with local pharmacies to provide pop-up services. Faith leaders reported that many people felt comfortable in these familiar and accessible

environments. In addition, faith leaders and trusted medical professionals from their respective communities hosted conversations with their congregations via livestream to answer concerns on vaccine efficacy. The videos received over 10,000 views during an 8-week engagement programme. These used focussed communication (through influencers and linked to celebrations) and interventions in areas with lower vaccine uptake, Including the Bangladeshi community and Black African and Caribbean groups in London. This included a partnership with predominantly African and Caribbean churches and others to develop a series of online community dialogues to provide factual information about the vaccine and create a safe place for questions and challenge. On average 400 people joined the live online dialogue sessions, which were also recorded and shared via social media.

c. The Department worked with MHCLG, who worked closely with Gypsy and Roma Traveller representatives, to provide assurance to undocumented people that any details provided to access the vaccine would not be shared outside of the NHS. A national bank of general resources that can be used at a local level (such as translated materials and multi-media) was created on the Vaccine Equalities Connect and Exchange Hub hosted on the Future NHS Collaboration Platform. The Hub had over 2,000 members across the country and information was shared via initiatives such as lunch and learn sessions on topical areas of interest local partnership working between CCGs, local DoPH, Community Champions (also known as health champions) which are community members who volunteer to promote health and wellbeing or improve conditions in their local community **(CS8/67 - INQ000281367**) and the voluntary and community sector.

117. In an effort to address the issues identified regarding confidence in the COVID-19 vaccines in ethnic minority communities, the Department collaborated with other government departments (OGDs) to develop strategies and initiatives to communicate the benefits of the vaccines, address community specific concerns and to make vaccination easily accessible at the community level. The Department published the UK COVID-19 Vaccines Uptake Plan in February 2021, setting out the government's approach to vaccination. This was based on advice from the JCVI on prioritising the roll-out. JCVI advised that good vaccine coverage in ethnic minority groups would be the most important factor in reducing disparities in outcomes for these groups. The strategy announced that a dedicated team would support effective communication with ethnic minority healthcare workers, headed by the NHSE Medical Director of Primary Care and NHS Chief People

Officer. This was in recognition of healthcare workers' roles as advocates and leaders within their own communities.

118. In response to the lower uptake data amongst certain ethnic minority groups, the Department asked NHSE to focus its delivery efforts more closely on these groups in order to minimise people being excluded from the protection to their health outcomes the vaccine could offer (and avoid widening health inequalities). The Vaccines' Minister chaired regular forums with officials from across the system.

119. In January 2021, in response to the emerging data (discussed above in paragraphs 82 – 88) that showed lower levels of uptake among ethnic minority groups, NHSE established a Vaccine Deployment Equalities Committee. Bringing together government departments with national representatives from the Association of DoPH, local authorities, fire and police services and third sector organisations, the Committee advised and guided the vaccine deployment programme on addressing inequalities. The Department was a member of the NHSE committee and took on key government initiatives/actions. It provided policy advice, delivery, and co-ordination support to the regular forums, focused on uptake, led by the Minister **(CS8/68 - INQ000502101)**.

120. The Department worked with OGDs to hold a series of roundtables for ethnic minority healthcare professionals and religious leaders to act as ambassadors within their communities. On the 23 February 2022 the Department worked alongside the Office for Health Improvement and Disparities (OHID), community and faith organisations and support services to convene a Black African & Black Caribbean Community Ministerial Roundtable hosted by Minister Maggie Throup. The roundtable provided an opportunity to listen to the views of Black African and Caribbean community representatives, sharing their experiences and reflections of the COVID-19 pandemic, particularly regarding vaccine uptake and confidence within some of these communities. At a national level, an Equalities Board was established to ensure inclusion. Black, Asian and ethnic minority communities were disproportionately impacted by COVID-19, including the NHS health and care workforce. A dedicated team was established to support effective communication with ethnic minority staff and to ensure it was relevant, accessible and specific and the views of ethnic minority staff were heard. This was headed by Dr Nikki Kanani, NHSE Medical Director of Primary Care, who brought her direct experience as a practising GP to input into advice to ministers including vaccine delivery to hard-to-reach groups, and NHS Chief People Officer, Prerana Issar **(CS8/65 - INQ000411787; CS8/69 - INQ000502122; CS8/70 - INQ000502124)**.

121. To increase vaccine confidence among those communities with the lowest take-up, including Black, South Asian, Muslim and ultra-Orthodox Jewish groups, and consistent with the localised approach to communications using 'trusted voices', communications took a 'by the community for the community' approach, and delivered activities across 3 tactical pillars:

a. community engagement and outreach (sessions with trusted voices);

b. media relations and community media partnerships; and

c. marketing activities, including through tailored content creation.

122. Insight-based, tailored content and campaign messaging that resonated with different ethnic minority audiences drove marketing reach and frequency. The Government's approach continued to consider diverse audiences and clear language for example, information was disseminated in multiple languages, and through trusted stakeholders and media channels.

123. Attention was paid to individual groups who demonstrated the lowest levels of vaccine confidence. For example, the data identified pockets of low vaccine confidence among various Muslim populations. As of 4 February 2021, the Bangladeshi population was one of the 5 ethnic groups with the lowest uptake in those aged over 80. The low uptake among Bangladeshi communities noted in the January and February 2021 surveys was of particular concern given the disproportionate impact the second wave of the pandemic was having on this group. The lower rate appeared to be down to a range of factors including a lack of confidence in the vaccine, general complacency about the need to be vaccinated (often linked to language barriers) and an inability to access the vaccine in local areas **(CS8/54 - INQ000354552)**. The result of these activities was that uptake in the Bangladeshi population notably increased between 4 February and 14 April, uptake in Bangladeshi over-80s increased from 54.6 per cent to 81.3 per cent, and they were no longer in the five ethnic groups with the lowest vaccine uptake. By way of comparison, vaccine uptake among over-80s in the Black Other group increased from 53.4 per cent to 72.3 per cent **(CS8/61 - INQ000411703)**.

124. Short-term pilots of family vaccines (vaccinations for households) were completed in Luton, Newham, Slough, Liverpool, Sandwell, Oldham and Newcastle. These pilots were

aimed at improving local responsiveness and vaccination uptake in underserved populations with a focus on multi-generational households. The pilots tested the benefits of a locally led and clinically informed decision to vaccinate outside current cohort prioritisation to increase uptake.

125. The concept of family vaccinations was also reflected in guidance issued by the NHS on supporting vaccine uptake during Ramadan **(CS8/71 - INQ000185163)**. The guidance was published on 9 April 2021 and encouraged vaccine delivery partners to consider how to adapt vaccine delivery for maximum uptake, how to support the many Muslim members of staff working for the NHS, and how best to reach the Muslim population and disseminate vaccine messaging during Ramadan. Vaccinators went to multigenerational households and offered to vaccinate those eligible in the household, therefore vaccinating the whole household. This included vaccinating individuals out of their cohort order on occasion.

126. The Department worked with the NHS to develop specific initiatives to encourage vaccine uptake during Ramadan. This included use of leading Muslim figures working in the NHS stressing that Ramadan should not stop anyone from getting vaccinated. These measures were part of a wider drive to maintain services and promote vaccination during Ramadan, such as holding twilight clinics in Sutton for those concerned about breaking their fast. Across government, those working on communications on public health worked with Muslim faith leaders to develop messaging to encourage testing, around social distancing and to encourage vaccinations during Ramadan and congregational prayers. As a result of these relationships, communications around vaccines were continuously improved and tailored, to reflect learning and insights from communities. In collaboration with other parts of government the Department worked to tackle the low vaccine uptake in Bangladeshi and other Muslim communities through a combination of national communications and engagement efforts, coupled with local activity.

127. Other measures aimed at improving vaccine uptake among the Muslim population included pop-up, roving and temporary vaccination sites at places with a high Muslim population, extended opening hours of vaccination sites during twilight hours in places with a high Muslim population, outreach into homes to support those who were housebound and flexibility to vaccinate where needed across Muslim groups, such as vaccinating members of multi-generational households on single visits. In terms of messaging, the guidance encouraged use of local Muslim health professionals and networks to enhance trust and credibility in the vaccination programme.

128. The Government produced myth-busting content and utilised trusted platforms and messengers within communities and used focussed approaches on social media channels (such as Facebook and Instagram which allows for better targeting). The Government also used native language publisher sites and targeted specific media outlets (Asian Voice, Leader, The Nation, JC and Desi Express).

129. Translation was a priority to reach those whose first language is not English and/or who have other accessibility needs. This included the translation of videos into British Sign Language and posters into Easy Read and Large Print as well as language translation. In addition to the translation of national assets, local authorities could request translations of their own assets.

130. In addition, in an effort to improve uptake among ethnic minority communities and healthcare professionals, the Department worked with the CO COVID-19 communications hub and other government departments to host webinars and question and answer sessions with ethnic minority medics, for example, the Department's clinical leads participated in many of the briefing events. Content was produced and published on the Department's social media channels to help increase uptake among South Asian communities. This included videos from clinician influencers such as GP Dr Nighat Arif, research scientist Dr Bnar Talabani, surgeon Dr Amalina Bakri and A&E consultant Dr Ranj Singh. They collaborated with GP Dr Amir Khan on a video specifically aimed at reassuring Muslims over vaccine ingredients. The in-house team also created a video spotlighting Aashna House care home for Asian residents. Video was also sourced from a vaccination clinic at a Gurdwara in Bedford including comments from a Sikh faith leader encouraging the local community to get vaccinated.

Inclusion of ethnic minority participants in clinical trials

131. Existing experience of vaccination programmes indicated that uptake was likely to be lower amongst ethnic minorities. That is why in July 2020, well before vaccine deployment, the Government provided funding for a project testing a framework to support inclusion of ethnic minority participants in COVID-19 research. This led to development of the NIHR funded INCLUDE Ethnicity Framework, which aimed to help trial teams think carefully about which ethnic groups should be included in their trial for its results to be widely applicable, and what challenges there may be to making this possible.

132. Lower ethnic minority participation in vaccine trials was also the driver behind the Minister for Equalities and the Minister for COVID-19 Vaccine Deployment (both representing ethnic minority groups) both taking part in the Novavax vaccine trial. Their participation was highly symbolic and was reported by the media at the time and the Minister for Equalities and Business Secretary wrote to all MPs encouraging them to promote ethnic minority participation in COVID-19 vaccine trials.

Pregnant and Breastfeeding Women

133. Developing and deploying vaccines in response to COVID-19 was conducted at unprecedented pace, and benefitted from decades of research before the pandemic. The initial phases of vaccine research and clinical trials focused on those at greatest risk of adverse outcomes (i.e. older adults with other medical conditions). Due to historical concerns with clinical trials in pregnant women, this group was not included in the vaccine trials conducted in 2020.

134. As with other groups, the Department followed JCVI advice throughout regarding pregnant and breastfeeding women. Following an evidence-based approach, JCVI exercised caution at the beginning of the period of vaccine roll-out in late 2020, because of insufficient evidence to recommend vaccinations routinely to all pregnant women, prioritising its use to certain groups, in line with advice for other adults. As time progressed, however, and more data emerged, particularly around adverse impacts of COVID-19 in pregnant women and their babies, the advice changed in response to better evidence. This section describes some of the more distinct periods where deployment and vaccination coverage changed as JCVI advice evolved in response to the emerging evidence. The first period was between December 2020 – March 2021, when there was little evidence to draw on. As data emerged, particularly from the US, the JCVI advice was updated to reflect this, with significant updates in April 2021. From the summer of 2021, UK-based research facilitated stronger knowledge, impacting significant updates in in the prioritisation of pregnant women from December 2021.

December 2020 – March 2021

135. Because pharmaceutical companies do not routinely or typically include pregnant or breastfeeding women in vaccine trials, it is not uncommon that decisions about vaccine

deployment for these groups are challenging due to insufficient data. This also applied to COVID-19 at the start of the roll-out period in autumn/winter 2020/2021. On 2 December 2020, the JCVI published advice on priority groups **(CS8/72 - INQ000411676),** pointing out the following in relation to pregnant women:

'There are no data as yet on the safety of COVID-19 vaccines in pregnancy, either from human or animal studies. Given the lack of evidence, JCVI favours a precautionary approach, and does not currently advise COVID-19 vaccination in pregnancy. Women should be advised not to come forward for vaccination if they may be pregnant or are planning a pregnancy within three months of the first dose. Data are anticipated which will inform discussions on vaccination in pregnancy. JCVI will review these as soon as they become available'.

'*As trials in children and pregnant women are completed, we will also gain a better understanding of the safety and effectiveness of the vaccines in these persons.'*

136. As the Technical Report **(CS8/73 - INQ000203933)** notes in relation to the response on vaccines in pregnancy, this advice was updated as soon as further data was obtained **(CS8/74 - INQ000399139).** By 30 December 2020, the JCVI had published updated advice on priority groups **(CS8/75 - INQ000354469),** where it noted the following in relation to pregnant women:

'There is no known risk associated with giving non-live vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child. Although the available data does not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy. JCVI advises that, for women who are offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women.'

137. This advice also recommended in relation to breastfeeding women:

'There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.'

138. Ministers received a submission about the JCVI advice on Phase 1 on 29 December 2020, this is covered in Section 3 of my first Statement of this Module **(CS8/1 - INQ000474334**) on prioritisation at paragraph 211 and the Secretary of State responded on the same day **(CS8/76 - INQ000401314; CS8/77 - INQ000401318).** The submission covered the JCVI's advice on pregnant and breastfeeding women. Following this updated advice given on 30 December 2020, the Pfizer and AstraZeneca vaccines were deployed to pregnant and breastfeeding women who met the conditions set out above in the JCVI advice. **(CS8/75 - INQ000354469; CS8/78 - INQ000411677).**

April 2021

139. As further evidence on potential adverse impacts of not getting vaccinated emerged, the JCVI reassessed the risks. It published updated advice, which drew on American research on pregnant women, that was published on 16 April 2021 **(CS8/79 - INQ000376222)**. Department officials provided advice to the Secretary of State and Minister for Vaccine Deployment on 15 April 2021 ahead of the publication of the press release announcing the change in JCVI advice **(CS8/80 - INQ000111012)**. This advice informed ministers that JCVI had recommended offering routine vaccination to pregnant women and recommended that they agree to a communications plan that set out the reason for the decision and addressed safety concerns, which it advised could lead to lower confidence amongst younger age groups and ethnic minorities.

140. The press release published on 16 April 2021 described the reasons for the change in advice and noted that data showed that vaccines were effective in protecting people with COVID-19 from serious symptoms and that pregnant women who get symptoms were more likely to give birth prematurely **(CS8/79 - INQ000376222; CS8/81 - INQ000399263)**. The updated JCVI advice was added to PHE's Green Book (clinical professional guide for vaccinators in the UK) on the same day.

141. The press release also noted that the JCVI also recommended *'that it's preferable for pregnant women in the UK to be offered the Pfizer-BioNTech or Moderna vaccines where available'*. This advice was based on data from the United States that showed around 90,000 pregnant women had been vaccinated, mainly with mRNA vaccines including Pfizer-BioNTech and Moderna, without any safety concerns being raised.

May 2021 – December 2021

142. By spring 2021, there was a rapid increase in data on vaccines and particular groups, including pregnant women. In the sections on *Data on Pregnant and Breastfeeding Women* below (see paragraphs 157-161), I will describe some key studies that were launched during this period, including by the NIHR and National Immunisation Schedule Evaluation Consortium (NISEC) (which is described in my first Statement of this Module in paragraphs 52-54 and 153-154 respectively), which had the objective of informing future JCVI decisions on coverage. This period also saw increased collaboration with expert groups to improve communication to pregnant and breastfeeding women, as set out in the next section on *Communications to Pregnant & Breastfeeding Women* (paragraphs 146-157). On 3 August 2021, alongside a press release announcing the Preg-Cov study (which will be covered in further detail in Professor Lucy Chappell's statement), the Department issued up-to-date data on the impact of vaccination on pregnant women that demonstrated their safety **(CS8/82 - INQ000411714)**.

143. While not all studies launched in this time provided robust data (see below on Preg-Cov), the significant increase in outcomes gathered from routine surveillance and data linkage between December 2020 and December 2021 meant that JCVI was able to provide a significant update to advice on vaccinations for pregnant women. On 16 December 2021, JCVI advised that pregnant women of any age should be considered a clinical risk group within the COVID-19 vaccination programme, adding pregnant women to Priority Group 6 for vaccination **(CS8/83 - INQ000354556).** As noted in the Technical Report:

> *"Pregnant women were designated as a priority group in December 2021 following evidence of increased risk of complications, including maternal death and stillbirth, following COVID-19 infection in the third trimester. While this constituted an evidence-based approach to vaccine roll-out in a potentially vulnerable group, the evolving messaging was misused by some groups to undermine vaccine confidence in pregnancy"* **(CS8/74 - INQ000399139)**.

144. The UKHSA press release on 16 December 2021 that followed the JCVI announcement set out the growing evidence that women who are pregnant are at increased risk of serious consequences from COVID-19 infection and called for pregnant women to come forward for vaccination **(CS8/83 - INQ000354556)**.

December 2021 – July 2022

145. Prioritising vaccination of pregnant women from December 2021, helped reduce the risk to women and their babies. While there are lessons to be learned around what might be done to reduce the time taken to vaccinate this cohort (because of limited clinical trial data) the Department's strong history in vaccine development and research, and the corresponding strong research infrastructure, as I set out in Section 1 of my first Statement of this Module **(CS8/1 - INQ000474334)**, was instrumental in building the evidence base.

Communications to Pregnant and Breastfeeding Women

146. The Department was mindful of how important it was to communicate with groups, such as pregnant and breastfeeding women, who were likely to be particularly anxious about adverse impacts, and who might be subject to misinformation. As the Technical Report pointed out, *"evolving messaging was misused by some groups to undermine vaccine confidence in pregnancy."* **(CS8/74 - INQ000399139)**.

147. As I set out in Section 1 of this statement (see paragraph 47), paid-for campaigns were tailored to groups with low vaccine confidence and uptake, including pregnant women. I have also set out in the paragraphs above, that JCVI advice was updated and published as soon as the evidence base informed changes to risk calculations. The paragraphs above also give examples of specific information for pregnant women that was published in relevant press releases during this time, either by the Department or one of its agencies, and disseminated in the press **(CS8/83 - INQ000354556; CS8/84 - INQ000411737; CS8/85 - INQ000411736)**.

148. The Department's social media team produced and published a wide variety of content for DHSC channels to help increase uptake among pregnant and breastfeeding women, including a series of infographics. Communications included focussed information and advice via television, radio and social media, which was translated into 13 languages including Bengali, Chinese, Filipino, Gujarati, Hindi, Mirpur, Punjabi and Urdu. The

Department worked with UKHSA and NHS to ensure communications targeting this cohort encouraged uptake and provided information to alleviate concerns about vaccination, with a range of pamphlets in different languages. An example is illustrated in Figure 23.

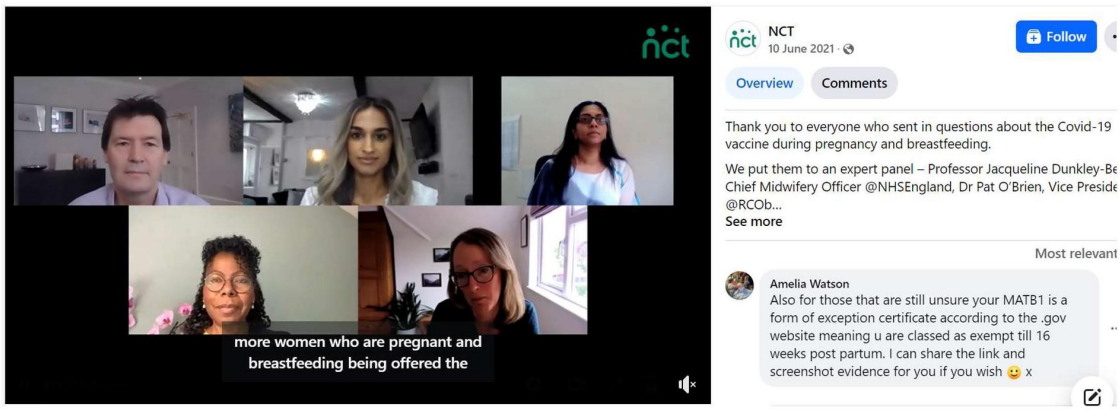
149. The content included a series of infographics and videos from medical experts and information was published on the Department's gov.uk website. This included, for example, a blog on 25 June 2021, listing frequently asked questions on COVID-19 vaccines that were answered by the DCMO Professor Jonathan Van-Tam. **(CS8/86 - INQ000411707)**. The topics covered included fertility and pregnancy concerns, including the question: *Can pregnant women have the Pfizer/BioNTech or AstraZeneca (Oxford) vaccines?* As well as providing useful links to Royal College of Obstetricians and Gynaecologists (RCOG) advice on vaccination, pregnancy and breastfeeding, PHE advice, and gov.uk advice, the published answer provided by Professor Van-Tam explained:

> *"The latest advice from the Joint Committee on Vaccination and Immunisation (JCVI) is 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.*
>
> *It is preferable for pregnant women to be offered the Pfizer-BioNTech or Moderna vaccines where available. This is because data in the US shows that around 90,000 pregnant women have been vaccinated, mainly with mRNA vaccines including Pfizer-BioNTech and Moderna, without any safety concerns being raised.*
>
> *There is no evidence, however, to suggest that other Covid-19 vaccines are unsafe for pregnant women. Women who are planning pregnancy, are in the immediate postnatal period, or are breastfeeding can be vaccinated with any vaccine, depending on their age and clinical risk group.*
>
> *The JCVI has recommended that the vaccines can be received whilst breastfeeding. This is in line with recommendations from the US and the World Health Organization."*

Figure 23 showing a series of infographics developed for pregnant women, and translated into Bulgarian. The department worked closely with UKHSA on all advice and publications. The infographics reflect the work to hone the clinical advice and turn it into simple infographics.

150. As well as working closely with its relevant ALBs and internal expertise, the Department also engaged closely with a range of external partner organisations and experts to improve messaging and targeting of pregnant and breastfeeding women. For example, the Department worked closely with RCOG and the Royal College of Midwives (RCM) to produce bespoke materials and worked with senior clinicians and healthcare professionals to produce information leaflets and social media content to address concerns of this cohort. The Department also worked with a number of organisations to ensure accurate medical advice was published on websites of a large number of relevant mother and baby and parenting organisations. For example, in 2021 the Department promoted a video with the Chief Midwifery Officer, Professor Jacqueline Dunkley-Bent, the National Childbirth Trust, and midwives around the country addressing pregnancy and infertility concerns **(CS8/87 - INQ000411783**). I have already outlined in Section 1 in this statement how inclusive messaging was particularly important in addressing fertility concerns in some Black and minority ethnic groups.

Figure 24: Example of Extensive Campaigns to target Pregnant Women



151. Figures 23 and 24 give examples of some of the extensive campaigns to target this cohort and increase uptake.

152. The Department also worked with partners and senior medical professionals as "trusted voices" aimed at the relevant audiences. For example, in August 2021, we worked with the social medial forum Mumsnet to provide a Q&A session for its members and users. Hosted by Mumsnet, it featured Dr Nikki Kanani, Dr Kate Wiles and Dr Oge Ilozue answering questions specifically on COVID-19 vaccines and women's health **(CS8/88 - INQ000411721)**.

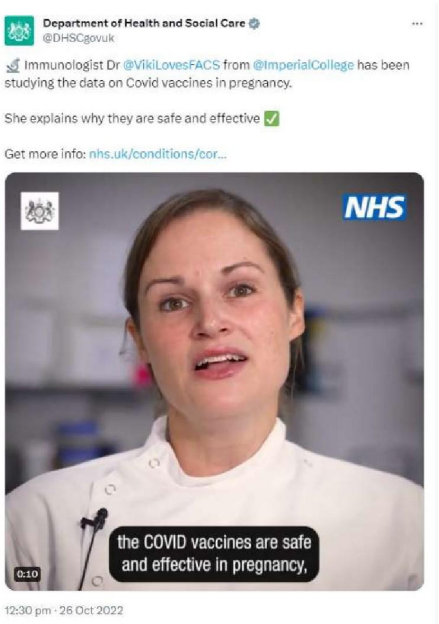
153. In December 2021, NHSE wrote to chief nurses, chief midwives, medical Directors, and all GP and pharmacy contractors in the following terms:

> "*We write to ask all healthcare colleagues to make every contact count this winter with pregnant women — and those planning pregnancy — to advise them of the benefits of COVID-19 and flu vaccination; and to signpost acute physicians to best practice guidance on the management of COVID-19 infection in pregnancy, including medication*" **(CS8/89 - INQ000257144).**

154. The Department also collaborated with the RCOG to produce videos featuring their spokespeople including Professor Lucy Chappell (prior to her appointment as Chief Scientific Adviser), Dr Jennifer Jardine, Dr Fatima Hussain and Dr Edward Morris between March and November 2021. The team also produced video content with Dr Viki Male, an immunologist from Imperial College, focusing on the various studies carried out on pregnancy and COVID-19 vaccination. This content was shared on DHSC channels in October and November 2022.

155. From August 2021, Professor Lucy Chappell was appointed as the Department's Chief Scientific Advisor. Professor Chappell is also Professor of Obstetrics at King's College London, Honorary Consultant Obstetrician at Guy's and St Thomas' NHS Foundation. The Department has been able to benefit from her expertise in our response to helping to protect pregnant women from COVID-19 complications. Prof Chappell worked with the Department to create informational videos for pregnant women, posted between November 2021 and February 2022.

Figure 25: (Left) Departmental tweet from the 3 April 2021 featuring a video of Professor Lucy Chappell from the RCOG discussing vaccines and fertility. Figure 26 (right) Departmental tweet from the 26 October 2022 featuring a video of Dr Viki Male discussing COVID-19 vaccines.



156. The Cabinet Office's *Get Boosted Now* campaign at the height of the Omicron variant involved collaboration with experts at the RCOG and the RCM to highlight the serious risks of COVID-19 infection and the benefits the vaccines bring to protecting both women and their babies. Additional operational responses included co-locating vaccination clinics within antenatal services, mirroring some pre-existing services for flu and pertussis programmes within pregnancy, together with making access easier for pregnant women to mass vaccination centres.

157. The Department worked with JCVI on specific advice and with UKHSA to issue guidance to pregnant women reassuring them of the safety of the authorised COVID-19 vaccines. The press release issued on 27 January 2022 stated that the latest data from UKHSA shows that vaccinated women who gave birth between January and October 2021 had "a very similar low risk of stillbirth, low birthweight and premature birth compared to women who were not vaccinated in pregnancy" **(CS8/90 - INQ000411741)**.

Data on Pregnant and Breastfeeding Women

158. As has already been set out above, pharmaceutical companies are often cautious about including pregnant and breast-feeding women into clinical trials. This can make it challenging to make decisions about deployment of vaccines in the absence of safety data. Above, I set out the timeline of how the emerging evidence base allowed advice to be updated. There is always a balance in considering benefits and risks of protecting against COVID-19 and associated adverse outcomes (through deploying vaccination) against vaccination itself in the initial phases of vaccine development. The Department worked with its partners, NIHR, NHSE, and UKHSA, particularly from summer 2021 onwards, to collect and publish more systematic and robust data from routine uptake. NIHR-funded and supported vaccine studies will be covered in further detail in Professor Lucy Chappell's statement

159. Previous studies had shown that the risk of being severely ill with COVID-19 was higher for unvaccinated women. One such study, the UK Obstetric Surveillance System (UKOSS), used a descriptive, case-control and anonymised cohort methodology to conduct a prospective study that collected case data monthly. Analysis of data indicated that out of 235 pregnant women who were admitted to intensive care with COVID-19 between January and September 2021, none had received 2 doses of vaccine. The UKOSS methodology uses descriptive, case-control and anonymised cohort studies conducted through a prospective, monthly case-collection scheme **(CS8/91 - INQ000411698)**.

160. Later analysis from UKHSA routine surveillance of health outcomes in the NHS published in January 2022 showed that women who had received at least one dose of COVID-19 vaccine during their pregnancy and gave birth between April and October 2021 were more likely than women who had not been vaccinated in pregnancy to give birth without any of the reported adverse outcomes associated with pregnancy and serious COVID-19 symptoms (92.9 per cent compared with 91.6 per cent). This difference was more apparent in those aged 30 years and older **(CS8/90 - INQ000411741)**.

161. Another finding from the UHKSA analysis was that data indicated that vaccine coverage had been increasing overall – in August 2021, 22.5 per cent of women giving birth had received at least one dose of vaccine. This increased to 32.1 per cent of women who gave birth in September, and 41.3 per cent in October 2021, almost doubling in 2 months. This indicates that the messaging targeting pregnant women had an impact, particularly as the evidence base for this cohort became more robust.

Black Women and Women Living in Deprived Areas

162. As already set out in this statement, the Department and Government used a number of specific approaches to communicate effectively with Black and ethnic minorities, and different socio-economic groups. This also applied to pregnant and breastfeeding women from these groups, which has already been set out above in paragraphs 146-157 on *Communications to Pregnant and Breast-feeding Women*. The Department responded to evidence as it emerged, including, for example through methods of message delivery and inclusive messaging (see paragraph 37) when, for example, it was made clear that misinformation among some Black African communities about fertility and pregnancy was influencing uptake.

163. Despite overall improvements in coverage for pregnant women, women of Black ethnicity and women living in the most deprived areas in England were least likely to have been vaccinated in pregnancy. For women giving birth between August and October 2021, a total of 13.3 per cent of pregnant Black women and 18.3 per cent of pregnant women living in more deprived areas of England had a first dose of a COVID-19 vaccine by time of delivery **(CS8/90 - INQ000411741; CS8/92 - INQ000120675)**. This was up from 5.5 per cent and 7.8 per cent respectively in the published statistics for the period from June to August 2021 **(CS8/93 - INQ000354625)**. However, just 6.8 per cent of pregnant Black women and only 10.2 per cent of pregnant women living in more deprived areas of England, giving birth between August and October 2021, had 2 doses. This compared with 23.4 per cent of White women and 34.8 per cent living in less deprived areas during the same period.

Children

164. Having already set out the decision-making process, the purpose of this section is to illustrate the extent to which the Department considered disparities in coverage and the approach to improving coverage and uptake for children and support vaccine confidence in parents. As set out in my first statement of this Module at paragraphs 250 to 269, the Department considered it appropriate that decisions in relation to the vaccination of children, defined as those under the age of 18 for the purposes of this statement, were taken in the same way as other vaccine roll-out and prioritisation decisions. There were no paid communications to improve COVID-19 vaccine coverage and uptake targeted at children. Communications to improve COVID-19 vaccine coverage and uptake in children

was aimed at parents. The same principles used in other programmes regarding consent were applied to the COVID-19 vaccine rollout, such as the Gillick Principle, which is explained further at paragraph 185.

165. I also set out in paragraphs 200 to 223 of my first Statement of this Module that JCVI's advice on Phase 1 prioritisation on 30 December 2020 included the decision that it was appropriate to prioritise those aged 16-64 who had conditions that put them at increased clinical risk for COVID-19, and children under 16 who were at very high risk of serious outcomes.

166. However, as the Technical Report points out, children are not routinely included in many vaccine trials. There was limited information for JCVI to draw on in relation to the risk-benefit calculation for advising on coverage for children. The Technical Report points out:

> *"In December 2020 there were very limited data on adolescents, with no data on vaccination in younger children, and population data showing almost all children who were infected having asymptomatic infection or mild disease."* **(CS8/74 – INQ000399139).**

167. JCVI's advice changed incrementally as the evidence base developed. Adverse impacts of *not* being vaccinated (such as, for example, premature birth was for pregnant women) were not emerging in the data as a significant risk for children. The Technical Report explains:

> *"JCVI made incremental recommendations in response to expand inclusion groups for vaccination to children aged over 12, and then offer (rather than recommend) the vaccine for 5 to 11 year olds. Decision-making regarding this group was much slower than for older age groups due to the finer benefit–risk balance as a result of the comparatively very low risks associated with COVID-19 infection in children compared with adults."* **(CS8/74 – INQ000399139).**

168. My first Statement of this Module (paragraphs 250-269) sets out the decision-making around extending the vaccination programme to children and young people. This sets out the incremental changes to advice, with JCVI initially limiting recommendations on coverage to very specific groups of children **(CS8/94 - INQ000411711)**.

169. During their considerations of vaccinations of children, two of the considerations that JCVI described in their published advice included were ***myocarditis*** and ***indirect educational impacts.*** These are particularly relevant in illustrating the Department's approach to improving coverage in children and in tackling misinformation. Over the course of the summer and into the autumn in 2021, communications across government worked to combat misinformation (see Section 3 of this Statement) and building confidence (see paragraphs 63 -67 above on vaccine confidence), including campaigns aimed at parents, to tackle concerns about myocarditis. Publications from OGDs such as DfE also emphasised the non-clinical benefits of vaccinations for children, particularly around education **(CS8/95 - INQ000061242).**

Myocarditis

170. When the JCVI was considering health risk-benefits of vaccinating children in summer 2021, its advice noted *"emerging reports from the UK and other countries of rare but serious adverse events, including myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart), following the use of Pfizer-BioNTech BNT162b2 and Moderna mRNA-1273 vaccines in younger adults".* At that time, it concluded that data on the incidence of these events in children and young people were limited, but that MHRA and JCVI were closely monitoring reports **(CS8/96 - INQ000354522).**

171. Research has shown that the risk is very low and also that it needs to be balanced against risks of serious disease when decisions about coverage are being assessed. A retrospective study showed that 5 per cent of patients developed new onset myocarditis and 1.5 per cent developed new onset pericarditis following COVID-19 infection. (It should be noted, however, that this data is general and not specific to children under 18) **(CS8/97 - INQ000411719).**

172. When this advice was published, the media picked up on myocarditis and pericarditis as potential adverse impacts of vaccination for children and young people, which risked uptake in this age-group. To build confidence in parents to improve uptake, it was imperative to understand the risks of adverse outcomes against the risks of COVID-19 infection.

173. UKHSA guidance (last updated on 9 January 2023) reported that as of 23 November 2022, for those aged under 18 years, the reported rate for heart inflammation (including

myocarditis and pericarditis) was 13 per million following first doses and 8 per million second doses of the monovalent Pfizer/BioNTech vaccine; the report noted that these are lower than the reporting rates seen in young adults. Across all age groups, the reporting rate for myocarditis is 10 reports per million doses and 6 reports per million for pericarditis **(CS8/98 - INQ000411756)**.

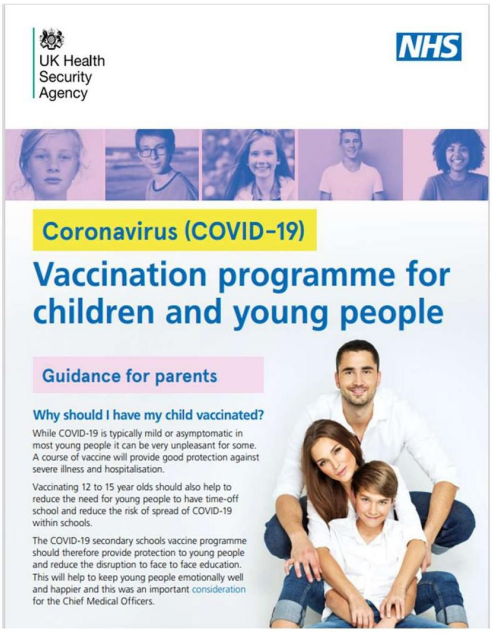
174. MHRA guidance (updated on 8 March 2023) notes:

> *"the experience with COVID-19 vaccines reported in individuals under 18 years old is similar to that identified in the general population and to date no additional safety topics specific to this age group have been identified."* **(CS8/99 - INQ000502137)** Updated JCVI advice, published in February 2022, further substantiated this, noting that *"Serious adverse events following vaccination are extremely rare in this age group. In the United States, less than 2 cases of vaccine-related myocarditis have been reported per million doses."* **(CS8/100 - INQ000257288)**.

175. As well as the rarity of the condition, the Technical Report **(CS8/73 - INQ000203933)** noted that an increased incidence of myocarditis and pericarditis in younger people following COVID-19 infection was observed several months into the pandemic. The risk of myocarditis as an outcome of COVID-19 itself, rather than vaccination, is a significant consideration that impacts this risk assessment. The WHO statement on COVID-19 vaccination for children, first published in November 2021 (later updated in August 2022), noted *"the risk of myocarditis/pericarditis associated with SARS-CoV-2 infection is higher than the risk after vaccination."* **(CS8/101 - INQ000502134).**

176. The Department worked with UKHSA and NHSE to develop guidance for parents **(CS8/102 - INQ000411800)** as vaccines for young people started to be rolled out; while this was transparent about the risk or myocarditis, it emphasised that it was rare. A blog published by UKHSA on 11 October 2021 titled *"Key questions on the children and young people's COVID-19 vaccination programme",* which included a specific question on heart problems associated with the vaccine in young people, and again emphasised how rare it was **(CS8/103 - INQ000411730).**

Figure 27: showing guidance for parents that the Department worked with UKHSA and NHS to develop. This guidance was transparent about the risk of myocarditis, emphasising that it was rare.



UK Health Security Agency

NHS

Coronavirus (COVID-19)

Vaccination programme for children and young people

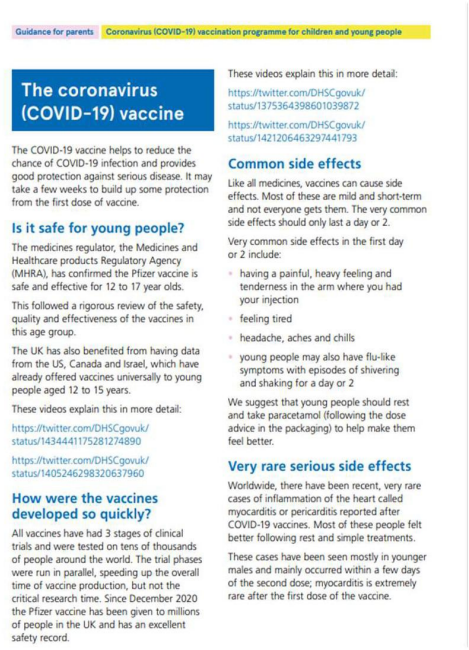
Guidance for parents

Why should I have my child vaccinated?

While COVID-19 is typically mild or asymptomatic in most young people it can be very unpleasant for some. A course of vaccine will provide good protection against severe illness and hospitalisation.

Vaccinating 12 to 15 year olds should also help to reduce the need for young people to have time-off school and reduce the risk of spread of COVID-19 within schools.

The COVID-19 secondary schools vaccine programme should therefore provide protection to young people and reduce the disruption to face to face education. This will help to keep young people emotionally well and happier and this was an important consideration for the Chief Medical Officers.



Guidance for parents | Coronavirus (COVID-19) vaccination programme for children and young people

The coronavirus (COVID-19) vaccine

The COVID-19 vaccine helps to reduce the chance of COVID-19 infection and provides good protection against serious disease. It may take a few weeks to build up some protection from the first dose of vaccine.

Is it safe for young people?

The medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), has confirmed the Pfizer vaccine is safe and effective for 12 to 17 year olds.

This followed a rigorous review of the safety, quality and effectiveness of the vaccines in this age group.

The UK has also benefited from having data from the US, Canada and Israel, which have already offered vaccines universally to young people aged 12 to 15 years.

These videos explain this in more detail:

https://twitter.com/DHSCgovuk/status/1434441175281274890

https://twitter.com/DHSCgovuk/status/1405246298320637960

How were the vaccines developed so quickly?

All vaccines have had 3 stages of clinical trials and were tested on tens of thousands of people around the world. The trial phases were run in parallel, speeding up the overall time of vaccine production, but not the critical research time. Since December 2020 the Pfizer vaccine has been given to millions of people in the UK and has an excellent safety record.

These videos explain this in more detail:

https://twitter.com/DHSCgovuk/status/1375364398601039872

https://twitter.com/DHSCgovuk/status/1421206463297441793

Common side effects

Like all medicines, vaccines can cause side effects. Most of these are mild and short-term and not everyone gets them. The very common side effects should only last a day or 2.

Very common side effects in the first day or 2 include:

- having a painful, heavy feeling and tenderness in the arm where you had your injection
- feeling tired
- headache, aches and chills
- young people may also have flu-like symptoms with episodes of shivering and shaking for a day or 2

We suggest that young people should rest and take paracetamol (following the dose advice in the packaging) to help make them feel better.

Very rare serious side effects

Worldwide, there have been recent, very rare cases of inflammation of the heart called myocarditis or pericarditis reported after COVID-19 vaccines. Most of these people felt better following rest and simple treatments.

These cases have been seen mostly in younger males and mainly occurred within a few days of the second dose; myocarditis is extremely rare after the first dose of the vaccine.

Educational Impacts

177. Another key factor that received media attention was the interface between COVID-19 and education. Over the summer of 2021, JCVI, while recognising that vaccination may have a potential non-health benefit on education, made clear in its advice that in-depth analysis of wider non-health impacts was not within its remit. Advice published on 3 September 2021 noted:

> *"JCVI is constituted with expertise to allow consideration of the health benefits and risks of vaccination and it is not within its remit to incorporate in-depth considerations on wider societal impacts, including educational benefits. The government may wish to seek further views on the wider societal and educational impacts from the chief medical officers of the 4 nations……."* **(CS8/104 - INQ000257024).**

178. The decision-making process to extend the offer of vaccines to children aged 12-15 is set out in my first Statement of this Module **(CS8/1 – INQ000474334)**. The consideration of the UK CMOs in reaching the decision was set out in a letter to the Secretary of State, that was published on 13 September 2021. This letter made it clear that the risks of further disruption of education was a key consideration. In particular, the advice notes:

"Evidence from clinical and public health colleagues, general practice, child health and mental health consistently makes clear the massive impact that absent, or disrupted, face-to-face education has had on the welfare and mental health of many children and young people."

"The negative impact has been especially great in areas of relative deprivation which have been particularly badly affected by COVID-19. The effects of missed or disrupted education are even more apparent and enduring in these areas. The effects of disrupted education, or uncertainty, on mental health are well recognised. There can be lifelong effects on health if extended disruption to education leads to reduced life chances." **(CS8/105 - INQ000257035).**

179. As well as the considerations set out in the UK CMO's letter (above), the Department aimed to provide clear reasons to the public and to parents as to why these decisions were being taken, and the risk/benefit considerations. Unlike content aimed at adults, communication campaigns on children's vaccines were aimed at their parents and guardians as well as children and young people themselves.

180. Additional information made available included working with UKHSA on an advice booklet for parents. The Department worked alongside DfE to ensure advice booklets were made available to schools to put on site and share with parents and emphasise the importance of vaccines to avoid education disruption. With the input of DLUHC and DCMS, James Sorene's team built a contact list of more than 500 stakeholders that included faith and community leaders, and civil society organisations, to whom we sent a full Q&A document about vaccines every week, including information aimed at improving vaccine confidence in parents and young people.

181. As already described above, communications with parents also included UKHSA's blog on gov.uk that provided key advice on *Key Questions on the children and young people's COVID-19 vaccination programme*, published on 11 October 2021 and UKHSA/NHS information leaflets setting out guidance for parents on the schools' vaccination programme **(CS8/102 – INQ000411800; CS8/103 – INQ000411730)**.

COVID-19 Vaccination Rollout to Schools

182. The rollout of COVID-19 vaccinations to schools followed the JCVI recommendations and ministerial decisions as for all other groups.

183. Following a COVID(O) on 19 July 2021, which the Department provided advice for **(CS8/106 - INQ000502116; CS8/107 - INQ000502117)**, the Government accepted the JCVI recommendation that those aged 12 and over, with specific health conditions or household contacts of the immunosuppressed should be offered vaccinations **(CS8/108 - INQ000401371; CS8/109 - INQ000502119)**.

184. The Department provided advice to ministers on 3 August 2021 **(CS8/110 - INQ000111661; CS8/111 - INQ000111662)**, recommending that the Government accepted JCVI's advice to offer one vaccination dose to all 16- and 17-year-olds. This recommendation was accepted on 4 August 2021.

185. Following JCVI advice on 3 September 2021 in relation to the vaccination of 12–15-year-olds without underlying health conditions, which recommended the Government considered wider societal and educational impacts and consulted with the CMOs, the Government accepted the CMOs recommendation to vaccinate all 12-15 year olds on 13 September 2021.

186. On 22 December 2021, the Government accepted JCVI advice to vaccinate 5–11-year-olds with specific health conditions that put them at greater risk of COVID-19 or household contacts of the immunosuppressed.

187. The vaccination programme in schools involved close collaboration between UKHSA, NHSE, the Department, and DfE. It built on considerable previous experience of effective partnership working to run school-age vaccination programmes including how to ensure parents and the public were informed about roll-out and coverage. For example, on some early concern about consent, we applied the same principles used in other programmes. Consent for people aged under 16 was approached on the basis of the application of the "Gillick Principles", with those deemed to have Gillick competence being given the vaccines if they consented, and those who did not have Gillick Competence were subject to parental consent. The Gillick Principles do not apply to people aged 16 and over who can themselves give effective consent to any surgical, medical, or dental treatment (under section 8 of the Family Law Reform Act 1969).

188. Following the universal school vaccination offer for 12–15-year-olds beginning on 22 September 2021, by 9 January 2022, 52.5 per cent of state school pupils in England in this cohort had been vaccinated with at least one dose, and 69.7 per cent of pupils aged

16-17 (vaccination began in August for this group). However, ONS data showed that uptake varied between ethnic groups, with Chinese and Indian pupils most likely to have received at least one dose, and Gypsy or Roma and Black Caribbean pupils least likely. There was also lower coverage among pupils eligible for free school meals, pupils living in deprived areas, and pupils who speak English as an additional language **(CS8/112 - INQ000411779)**.

189. These groups reflect the same disparities already outlined earlier in this section (see paragraphs 116-130). Later ONS data showed that the factor with the biggest impact on vaccine uptake of school pupils in England was parental vaccination status. By July 2022, 81.6 per cent of pupils in state schools in England, who had a parent who had received three or more doses, had received at least one dose; this compared to only 5.3 per cent of pupils where no parent had been vaccinated **(CS8/113 - INQ000411749)**.

190. The Department worked with NHSE, UKHSA, DfE and OGDs to increase awareness of the evidence on safety of vaccines for children and their importance to the child and to their families. As well as the leaflets already mentioned above, "trusted voices" helped get the message across. Figure 28 shows DCMO Professor Van-Tam giving a press conference on 4 August, following the JCVI announcement on its recommendation to offer to vaccinate 16- and 17-year-olds. During the live broadcast, the DCMO emphasised that there was "no time to waste" in rolling the vaccine out to this cohort, and said he would be "very much in favour" of his own children being vaccinated.

Figure 28: Professor Jonathan Van-Tam emphasising importance of vaccination for 16 and 17 year olds. (CS8/114 - INQ000502118)

Lessons Learned on Public Messaging for Particular Groups

191. As with all vaccine development, prioritisation can become more nuanced the more we learn about a pathogen and its impacts on different groups. As the Technical Report noted, JCVI exercised caution when giving advice on issues with evolving evidence and was able to update this as further evidence came to light.

192. The Technical Report also noted that vaccination rates were also influenced by deliberate disinformation and misinformation. I have set out further details on how the Department tackled the problems of misinformation and disinformation in Section 3 of this statement. Looking to the future, we can learn in particular from campaigns that successfully focussed on vulnerable groups, including some ethnic groups that were most at risk of being influenced by misinformation.

193. The Technical Report noted that New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) recommendations for prioritisation for clinical trials included a recommendation to explicitly consider the need to include children and pregnant women where possible because it was unknown if these are vulnerable groups at particular risk for severe outcomes. While this did not happen at the same pace as other groups, decisions were made based on the evidence available at the time. Although pregnant women and children are not usually included in vaccine trials, our experience with COVID-19 has taught us more about some of the judgements that may need to be made in calculating risk-benefits calculations for these groups. The Technical Report pointed out "*with the benefit of data available later in the pandemic the decision to encourage*

vaccination in pregnancy would have come earlier, but that is with the benefit of hindsight." The Report also remarked that both groups would likely be questions for future pandemics because they are not usually included in vaccine trials and noted that the risk-benefit calculation would depend on a future pathogen and its impact **(CS8/74 – INQ000399139).**

194. The Technical Report further reflects on the role JCVI had in public understanding by noting that independent scientific and clinical advice were particularly important "*for decision-making in areas where risk and benefit were less clear cut, or where there was more scientific uncertainty.*" It also noted "*The public understand the need for prioritisation of medical interventions such as drugs or vaccines based on clinical need. But they need to see the logic laid out, and fairness in execution.*" **(CS8/74 – INQ000399139).**

Relationship with the Devolved Administrations

195. While the procurement of vaccines was done on a UK-wide basis through the VTF and later UKHSA, **(CS8/115 - INQ000399251)** the vaccine roll out was the responsibility of the Devolved Administrations (DAs) in the same way as other health services. The Department was responsible for England and had an informal national coordinating role with the DAs to ensure as much alignment as possible. There was an ongoing dialogue at the policy and operational level with the DAs regarding vaccine roll out as at Ministerial and official level, as well as via the UK CMOs. This is covered in more detail in my first Statement in this Module at paragraphs 112-115.

SECTION 3: TACKLING MISINFORMATION AND DISINFORMATION

Approach to tackling misinformation

196. I set out above (at paragraphs 18 - 19) that from March 2020, public communications moved from health sector led to a whole Government response, with the CO COVID-19 hub coordinating a whole Government communications response, including on countering misinformation. Section 5 of Sir Christopher Wormald's Third Witness Statement to the Inquiry, sets out (at paragraph 237) that "*the overall approach to countering disinformation was not directly to rebut, but instead to deliver large quantities of positive information from a range of voices with audience credibility to provide easy access to factual information and address misperceptions and misinformation*". The former DCMO Professor Sir Jonathan Van-Tam said in his personal statement to Module 2 in paragraph 13.2 of section

13 *"my approach to dealing with misinformation was simply to highlight it as that and then refuse to engage with it. If asked about a specific view that I thought was misleading or false, I would simply say that, explain my own view and explain the evidence and rationale for it."* This reflects the overall approach we took to tackling all misinformation and disinformation. While the following paragraphs set out in more detail more specific issues relating to building public confidence in vaccines and countering misinformation, it should be considered with this underpinning principle in mind.

197. The Department was faced with two distinct issues, misinformation, and disinformation, which can be grouped under the heading of 'anti-vaccination' activity. I define misinformation as the widespread acceptance of incorrect information regarding the genesis, efficacy and effects of the vaccines. I define disinformation as the deliberate dissemination of erroneous information regarding the vaccination programme, the seriousness of disease, or side effects of the vaccines. I define anti-vaccination activity as spreading of misinformation or disinformation. The Department developed a communication plan on 23 October 2020 to mitigate 'anti-vaccination' activity around a COVID-19 vaccine and help maintain public confidence in vaccination **(CS8/116 - INQ000399249).** This was done in close collaboration with the Counter Disinformation Unit (CDU) as the overall Government lead for countering misinformation and disinformation online.

198. The government's Rapid Response Unit (RRU), based in the CO, shared information to identify trends in media and social media coverage. When 'anti-vaccination' activity, that was considered misinformation or disinformation, was identified by the RRU, it coordinated with departments across Whitehall, including the Department, to assess the effectiveness of the Government's public information. The CDU, which at the time was based in DCMS (and is now based in the Department for Science, Innovation and Technology (DSIT)), was stood up on 5 March 2020 by CO, bringing together cross-government monitoring and analysis capabilities to enable a cross-Whitehall response. Its primary function was to provide a comprehensive picture of the extent, scope and the reach of disinformation and misinformation linked to COVID-19, and to work with partners to stamp it out. This unit covered all disinformation, not just vaccines related. Given the roles of the CDU and the RRU, I would expect DSIT and CO, to be able to say more about these subjects.

199. The UK Vaccine Security Team (UKCVS), covered in more detail in my first statement in this Module at paragraphs 58 and 324-328 had a role in vaccine security including physical security and assessing mis/disinformation threats.

200. The Department had an important role at the start to ensure DCMS was aware of misinformation and disinformation as an issue and had the information they needed to tackle it. These responsibilities are now owned by DSIT. The Department used social media and news media monitoring tools to gather information about the themes of false information that could potentially reduce vaccine confidence. The Department provided weekly reports for information, including to the relevant DHSC Minister; the CO's RRU also provided weekly reports which added to this overall picture. False information about vaccines was largely variations on key themes of safety, efficacy, side effects, ingredients and size and scope of clinical trials.

201. The CDU led the cross-Government response to disinformation, including on understanding disinformation narratives. A submission to the Secretary of State on 21 August 2020 stated, regarding the intentions of those sharing mis- or dis-information, that:

> *"Most individuals that share misinformation about vaccination are well-meaning and genuinely believe vaccines cause harm and are doing so in a bid to protect the public. By attacking them, we run the risk of alienating them, making them more susceptible to misinformation.*
> *There are a proportion of individuals that profit from sharing anti-vaccination content, either via advertising revenue or by selling "alternatives" to vaccination. Working closely with DCMS to ensure that platforms take action where appropriate to reduce content that violates platforms' Terms of Service while simultaneously promoting accurate sources of information like the NHS or the WHO websites works to reduce the spread and effect of misinformation."* **(CS8/117 - INQ000502085).**

202. I anticipate that DSIT will be better placed to provide evidence as to the full role of CDU. The Department worked with them and with other partners to ensure a co-ordinated approach to messaging, I understand that CDU worked closely with social media platforms to help them identify and take action to remove incorrect claims about the virus, in line with their revised terms and conditions, and to promote authoritative sources of information:

a. Several social media platforms took positive steps to reduce the spread of harmful and misleading narratives, and to promote Government and NHS messaging.

b. The DCMS Secretary of State met with the major platforms on severaloccasions, including holding a joint roundtable with the Department's Secretary of State in

November 2020 bringing together social media companies, civil society and health experts.

c. DCMS launched a toolkit with content designed to be shared via WhatsApp and Facebook community groups, as well as Twitter (now X), YouTube and Instagram, to tackle false information spread through private channels.

203. As has been described already in Section 5 of Sir Christoper Wormald's Third Witness Statement, sets out (at paragraph 237) that "*the overall approach to countering disinformation was not directly to rebut, but instead to deliver large quantities of positive information from a range of voices with audience credibility to provide easy access to factual information and address misperceptions and misinformation*" **(CS8/34 - INQ000144792)**. This included large quantities of clear medical advice from a range of senior clinicians and healthcare professionals who could provide factual information and answer questions about safety and other vaccine concerns to build knowledge and understanding of vaccination and reassure people of safety and efficacy. An illustrative example of the focus on providing accurate, positive information was the effort to build knowledge and understanding of COVID-19 vaccines and reassure people of the safety and efficacy of those vaccines by addressing specific concerns, such as, the short time taken to develop COVID-19 vaccines and the use of new vaccine technology such as messenger ribonucleic acid (mRNA). This approach was built into all campaigns which were centrally commissioned, coordinated and delivered by CO's the National Resilience Hub communications team, working closely with the Department's and NHSE's communication teams. The Department, together with NHSE and PHE, provided advice and information at every possible opportunity to support those getting the vaccine and to anyone who might have questions about the vaccination process.

204. The Department promoted positive information on social media rather than engaging with disinformation. It supported DCMOs, media medics, scientists, experts and NHS staff to create a range of content communicating clear facts and the latest advice about how to get a vaccine, vaccine efficacy and side effects and more generally communicating clear facts in relation to clinical/government advice and vaccination. Content was created in a variety of formats, such as shareable graphics with simple, clear messaging, to reach a diverse range of audiences across the Department's social media channels and signpost sources of trusted information on gov.uk and the NHS website.

205. The Department's communications division worked with a range of influential and trusted organisations to disseminate factual information and advice to the wider public and target audiences, particularly those who were more vulnerable. Stakeholder forums and Q&A sessions were held featuring departmental, NHSE and PHE spokespeople, clinicians and ministers to improve understanding of the development of the COVID-19 vaccine so that organisations could in turn reassure their communities and members of its safety and efficacy.

206. The Department's media relations team deployed expert spokespeople across a broad range of media outlets, including clinicians from the Department, PHE and NHSE, as well as government ministers. This included coordinating with No. 10 and CO to field clinical experts such as the CMO and DCMOs for daily Downing Street press conferences that were broadcast live and reached millions of people across the UK. At the same time, the Department's ministers were regularly updating Parliament by responding to parliamentary questions and making oral statements. Spokespeople and experts were also interviewed on a range of broadcast programmes in formats that included direct questions from viewers – such as Q&A on the BBC News Channel. Other communication via news media included newspaper op-eds, ministerial quotes to accompany press notices, and ministerial broadcast clips with vital public health messaging across a wide number of outlets. Reactive media handling included provision of factual spokesperson statements to answer journalist queries. Public health messaging was designed with input from regular polling and focus group research to address themes and issues raised in social media engagement.

207. Reactive handling included provision of accurate, factual spokesperson statements to journalist queries around dis-information, amplification of government action to combat disinformation, and re-iteration of important public health messaging. The Department also engaged with social media companies to support tackling mis/disinformation. At the Department/DCMS joint roundtable on 3 November 2020 **(CS8/118 - INQ000502094)** the following principles were agreed:

a. To commit to the principle that no user or company should directly profit from COVID-19 vaccine mis/disinformation.

b. To ensure a timely response to mis/disinformation content flagged to them by public health bodies.

c. To continue to work with public health bodies to ensure that authoritative messages about vaccine safety reach as many people as possible.

d. To join new policy forums over the coming months to improve responses to mis/disinformation and to prepare for future threats.

Tackling misinformation in ethnic minority communities

208. In addition to the initiatives described in the section above which were aimed at tackling misinformation and disinformation among the general population, it was recognised that specific efforts were required to address disinformation and low vaccine uptake among ethnic minority communities. In Section 1 paragraph 37 above, I described the focus of the Department on inclusive messaging, to reach many groups in society, and the extensive collaborative work the Department carried out with stakeholders and local government to ensure messages were received as widely as possible. Examples given included social media campaigns to tackle misinformation among a small number of Black African groups about vaccines impacting fertility in women.

209. Social media toolkits continued to be developed and updated further throughout the campaign to address narratives that insight showed were being shared widely across social media at certain times, for example misinformation about not being able to take the vaccine during Ramadan, or about the vaccine being linked to infertility. Specific communication strategies were developed to address fertility concerns among women, especially from ethnic minorities, including a series of videos with midwives, health visitors and expectant mothers on the benefits of vaccination.

210. More generally, a number of prominent ethnic minority celebrities and influencers stepped forward, with calls to their communities to take up the vaccine. Communications were developed to increase COVID-19 vaccine confidence in Black African and Caribbean groups in London. This included a partnership with predominantly African and Caribbean churches and others to develop a series of online community dialogues to provide factual information about the vaccine and create a safe place for questions and challenge. An open letter from Sir Lenny Henry and a range of other high-profile celebrities encouraged Black audiences in the UK to make informed decisions about the vaccine. Supported by the NHS, the letter was turned into a short film which was aired across various channels. Another video featured Black Members of Parliament from the Conservatives and the

Labour Party, who came together to share personal stories of losing loved ones, warning against the spread of misinformation and encouraging communities to take the vaccine.

211. The Minister for Equalities, working with the Department and the CDU in January 2021, expanded work to support those most at risk from COVID-19 and boost vaccine uptake through the Community Champions scheme. This included enhancing existing communication strategies in a target group of councils and to fund work with grassroots advocates from those communities most at risk from COVID-19. The broader aim was to reduce the impact of the virus on all communities, beyond just the target areas, including promoting vaccine uptake and tackling misinformation. As mentioned earlier following an expression of interest exercise, £23.75 million in funding was released to 60 local authorities on 25 January 2021 **(CS8/119 - INQ000137114)**. An additional £22.5 million was announced for this purpose on 19 December 2021.

212. The Government implemented a tailored approach to counter misinformation, both nationally and locally, focusing on the safety and efficacy of the vaccine. Faith leaders then assisted by mitigating concerns about ingredients and the permissibility of the vaccines.

SECTION 4: VACCINE SAFETY

213. This section of the statement explains the Department's role in assuring the safety of vaccines, Including the monitoring of risks, identification of side effects and communications.

Monitoring of risks

214. Vaccine safety, as with all drugs and medical procedures, is a matter of relative risk compared to the risk of being unvaccinated. Almost no drugs or vaccines have no risks. It is important to identify the risk of the vaccine, and then to compare it to the risk of the disease the vaccine protects against, the degree of protection the vaccine affords, and the probability of getting the disease. COVID-19, especially in those who had not previously been infected or vaccinated, had significant risks and was a very common disease; the vaccines had high vaccine efficacy. The question for COVID-19 vaccines was whether being vaccinated carried fewer risks than being unvaccinated. All consideration of vaccine safely has to be judged in this context.

215. The Department's role with regard to the risk-benefit judgements associated with the vaccines was limited. The MHRA, as the independent regulator, is responsible for authorising vaccines and for monitoring vaccine safety. The Department is advised by the JCVI on vaccine deployment and prioritisation. Further information can be found at paragraph 21 in my First Witness Statement of this Module.

216. As set out at paragraphs 71 - 76 of my first statement of this module **(CS8/1 - INQ000474334)**, the MHRA is an Executive Agency which regulates medicines, medical devices and blood components for transfusion in the UK. The responsibilities of the MHRA include ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy.

217. In delivering these functions, the MHRA carries out regulatory activities such as inspecting facilities and carrying out safety tests; approving and inspecting clinical trials; monitoring the safety of medicines while on the market; regulating the importation of licensed medicines; and helping to set and enforce advertising regulations for medicines.

218. The first phase of identifying any risks associated with the vaccine is done through the licensing process where the MHRA will decide whether manufacturers should be granted licences to make, assemble or import medicines and vaccines and whether licences can be varied as information about the medicines and vaccines develop. The decisions are based on safety, quality, and effectiveness data which is reviewed by experienced scientists and clinicians. All vaccines go through a rigorous authorisation process carried out by the MHRA which is recognised as a world leader in the field of medicines regulation.

219. The safety, quality and effectiveness data must include results from the lab and clinical trials in humans; manufacturing and quality controls, product sampling, and testing of the final product. Once the MHRA have thoroughly reviewed the data, the MHRA will seek advice from the Government's independent advisory body, the Commission on Human Medicines (CHM). The CHM will critically assess the data too before advising the UK Government on the safety, quality and effectiveness of any potential vaccine. I have set out at paragraphs 74 and 93 - 97 of my first Statement of this Module **(CS8/1 - INQ000474334)**, the role of the CHM in advising the MHRA on matters relating to safety. My first Statement of this Module also set out that during the pandemic, a designated minister took the final decision as to whether to license the COVID-19 vaccines based on recommendations by the MHRA.

220. In authorising each vaccine, the MHRA provides a Summary of Product Characteristics which describes the product's properties and the conditions attached to its use. This will set out any special warnings or precautions for use and provide information on undesirable effects and adverse reactions.

221. This process was followed for the COVID-19 vaccines. While the timeframe was accelerated, the rigorous approval process was the same. Paragraph 75 of my first Statement of this Module **(CS8/1 - INQ000474334)** sets out what evidence is required to be submitted to the MHRA. Figure 1 and 2 in the 'UK COVID-19 vaccines delivery plan' sets out the development, procurement and deployment processes for COVID-19 vaccines compared to typical vaccines in England **(CS8/14 - INQ000411678)**. This illustrates that the same steps were followed in the authorisation of a non-COVID-19 vaccine as were followed for the COVID-19 vaccines. The only difference was that some steps that would have happened sequentially, were carried out in parallel on a rolling basis which helped expedite the authorisation process. Relevant data, analysis and expert committee judgements was put rapidly into the public domain to ensure transparency, which was critical to ensure public confidence was maintained. In order to assist the Inquiry with evidence and provide the necessary context, it is necessary for me to make reference to the fact that the Department prepared and submitted material and evidence to Parliamentary committees as part of their investigations, as well as by considering the content of such committees' reports and recommendations, on the process for COVID-19 vaccination approvals **(CS8/46 - INQ000065228)**.

222. A Blog by UKHSA published in December 2020 **(CS8/120- INQ000502092)** set out to the public the joint roles of the MHRA and JCVI in COVID-19 vaccinations, points out that *"both the MHRA and the JCVI are playing a critical role in getting COVID-19 vaccines approved and rolled out to the public. Safety is the number one priority."* The JCVI takes on board the rigorous evidence on safety, quality and effectiveness from clinical trials as the MHRA evaluates vaccine safety and applies this to its consideration of recommendations for coverage.

223. Following the authorisation of any vaccine, the MHRA undertakes post-authorisation surveillance. The safety of the COVID-19 vaccines was monitored continuously throughout the pandemic through the MHRA's comprehensive COVID-19 vaccine surveillance strategy first published on 11 January 2021 **(CS8/121 - INQ000223936)**. The manufacturers of the vaccines also had an obligation to carry out this surveillance in

parallel. The MHRA surveillance strategy had four main strands, further explanation of these strands can be found with the MHRA surveillance strategy:

- Enhanced passive surveillance – 'observed vs expected' analysis.
- Rapid Cycle Analysis and Ecological analysis.
- Targeted active monitoring – Yellow Card Vaccine Monitor.
- Formal epidemiological studies.

224. The MHRA encourages the reporting of any side effects via its Yellow Card scheme. Reporting an event or a potential side effect does not mean that there is causation; the Yellow Card reporting scheme is in place to collect information that can then be analysed and assessed as to whether there is a safety signal or not, and if so, the impacted groups. In responding to the COVID-19 vaccines roll out, the MHRA provided a dedicated coronavirus Yellow Card site for healthcare professionals and patients to report suspected side effects of the COVID-19 vaccines **(CS8/122 - INQ000411797)**. The scheme relies on voluntary reporting of suspected safety concerns or incidents by healthcare professionals and members of the public (patients, users, or carers). The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation.

225. Information received through the Yellow Card scheme indicating a possible new safety concern is evaluated by the CHM and, during the relevant period for this statement, its expert working group on COVID-19 vaccine safety surveillance. The JCVI secretariat has observer status at CHM meetings and receives updates from the MHRA on Yellow Card reports associated with the vaccines.

Identification of side effects

226. All medicines and vaccines have some side effects. As part of its monitoring of the safety of vaccines, the MHRA will continuously assess whether the benefits of the vaccines continue to outweigh any risks. The MHRA's Yellow Card Scheme, which collects and monitors information on suspected safety concerns or incidents involving vaccines is explained in paragraphs 224-225 above.

227. Following assessment by the CHM, the MHRA may issue additional guidance on any new safety concerns. Additional information may be included in the Summary of Product Characteristics. This information is considered by the JCVI, including through an interchange of observers between JCVI, the CHM and its Expert Working Group on COVID-19 vaccine safety surveillance (EWG), The MHRA provided presentations to the JCVI on the assessment of Yellow Card reports associated with vaccination.

228. To inform the JCVI's advice on vaccinations, which informed the advice given to Department ministers, the JCVI also considered information provided by NHSE on vaccine deployment and uptake in England, and from the devolved nations on data arising in their respective countries. PHE/UKHSA also provided evidence to JCVI on the epidemiology of vaccine preventable diseases and vaccine effectiveness in the UK, and attitudinal research on immunisation programmes.

229. On 7 April 2021, the MHRA issued updated information on the possible risk of extremely rare and unlikely to occur specific types of blood clots following vaccination with the Oxford/AstraZeneca vaccine (**CS8/123 - INQ000408453**). The MHRA's advice set out that the benefits of vaccination continued to outweigh any risks but that the MHRA advised careful consideration should be given to people who are at higher risk of specific types of blood clots because of their medical condition. The advice outlined that the overall risk of blood clots was approximately four people in a million who received the vaccine. The data suggested there was a slightly higher incidence reported in the younger adult age groups and the MHRA advised that this evolving evidence should be taken into account when considering the use of the vaccine. The MHRA then issued updated guidance for healthcare professionals on how to minimise risks, as well as further advice on symptoms for vaccine recipients to look out for four or more days after vaccination.

230. Researchers at the University of Liverpool studied the mechanisms underlying the occurrence of the rare condition of blood clotting with low platelets (known as thrombotic thrombocytopenia syndrome (TTS)) following vaccination against or infection with COVID-19 **(CS8/124 - INQ000411784)**. This project:

a. Investigated the prevalence of TTS in individuals before acquiring COVID-19; following COVID-19 vaccination and in patients infected with COVID-19;

b. Aimed to understand why a very small number of those vaccinated against COVID-19, and also those with COVID-19 itself, develop blood clotting disorders; and

c. Investigated the changes in the body that lead to the unique combination of blood clots and low platelet count seen in TTS.

231. On 7 April 2021, the JCVI published a statement that recommended that those aged under 30 without underlying health conditions should be offered an alternative to the Oxford/AstraZeneca vaccine if available **(CS8/125 - INQ000354498)**. The Department acted quickly to updates from the JCVI and a submission was sent to ministers on the same day which asked ministers to note the communications and deployment implications **(CS8/126 - INQ000411692)**. The Minister for COVID-19 Vaccine Deployment noted the updates and statements and the implications for deployment on the same day **(CS8/127 - INQ000411693)**.

232. The JCVI continued to review emerging cases and concluded that in view of the favourable UK epidemiology, the success and pace of the vaccine rollout, and the supply trajectory of alternative vaccines, the age under which an alternative vaccine is preferred to Oxford/AstraZeneca should be raised to all those under the age of 40. A submission was sent to ministers on the 5 May 2021 asking them to implement the JCVI's advice and note the operational and communication implications and the Minister for COVID-19 Vaccine Deployment reviewed and said he was content with the recommendations the next day **(CS8/128 - INQ000111088; CS8/129 - INQ000411699)**. The recommendations were implemented immediately. On 7 May 2021, the JCVI published a statement extending its advice on Oxford/AstraZeneca vaccine usage relating to rare blood clotting events to include those aged 30-39 with no underlying health conditions **(CS8/130 - INQ000354505)**.

233. Another side effect that received media coverage was the risk of myocarditis and pericarditis, as I have set out in Section 2 (paragraphs 170-176). As set out in that section, UKHSA guidance gives the available data on this risk **(CS8/131 - INQ000411742; CS8/97 - INQ000411719)**.

Communications

234. The Department's role in communicating risks of the vaccines to relevant decision makers and the public was to obtain the advice from the relevant bodies, JCVI, MHRA, CHM, and PHE/UKHSA. The organisations then worked together to publish new advice and make senior clinicians available to the media to answer detailed questions to be open and transparent with the public. Individual organisations published their own statements and updated their guidance accordingly. In the case of healthcare professionals, this was the responsibility of NHSE and PHE/UKHSA.

235. The JCVI advice in relation to the Oxford/AstraZeneca vaccine advice was just one example of advice issued by the JCVI and MHRA. The JCVI also issued advice on the vaccination of children and young people covered in paragraphs 164-169 **(CS8/132 - INQ000235154)**.

236. PHE/UKHSA also published guidance for health care professionals and patients. Some examples (which are non-exhaustive) include:

a. COVID-19 vaccination: worried about having your second dose of AstraZeneca? - GOV.UK (www.gov.uk) **(CS8/133 - INQ000411708)**.

b. COVID-19 vaccination and blood clotting - GOV.UK (www.gov.uk) **(CS8/134 - INQ000411704)**.

c. COVID-19 vaccination: blood clotting information for healthcare professionals - GOV.UK (www.gov.uk) **(CS8/135 - INQ000354573)**.

d. Clinical investigation and management of COVID-19 vaccine induced thrombosis and thrombocytopenia - GOV.UK (www.gov.uk) **(CS8/136 - INQ000411695)**.

e. Myocarditis and pericarditis after COVID-19 vaccination: clinical guidance - GOV.UK **(CS8/98 - INQ000411756)**.

f. COVID-19 vaccination: myocarditis and pericarditis information for healthcare professionals - GOV.UK (www.gov.uk) **(CS8/131 - INQ000411742)**.

g. COVID-19 vaccination: Guillain-Barré Syndrome information for healthcare professionals - GOV.UK (www.gov.uk) **(CS8/137 - INQ000411739)**.

h. COVID-19: the Green Book, chapter 14a - GOV.UK (www.gov.uk) **(CS8/138 - INQ000257325)**.

237. Ministers regularly updated Parliament on the vaccine roll out and associated issues, both in proactive statements and in response to debates and parliamentary questions.

238. All the public health communications provided by the Department and as part of the whole government response highlighted that the approved COVID-19 vaccines had met the standard of safety and effectiveness required by the MHRA. Information was given on the independence of the MHRA and its role in approving vaccines. The world leading standards to which the approval process was subject and the fact that nothing was approved if it did not meet these high standards was conveyed to the public. The communications also emphasised the review of vaccine safety with people able to report to MHRA and the manufacturer any potential adverse reactions through the addition of the COVID-19 vaccines to the Yellow Card system which allowed tracking of any adverse reactions or outcomes to the administration of the vaccines **(CS8/122 - INQ000411797)**.

SECTION 5: THE VACCINE DAMAGE PAYMENT SCHEME (VDPS)

239. The VDPS was established under the Vaccine Damage Payments Act 1979 (VDPA). It provides a one-off tax-free payment, currently £120,000, for the rare cases where an individual is assessed, on the balance of probabilities, to have been severely (60 per cent or more) disabled by a vaccine for a disease specified in the VDPA.

240. The VDPS is a no-fault scheme. It is not means-tested, and it is given irrespective of the claimant's individual circumstances. It is not intended to compensate the claimant for their disablement, and it does not remove their right to pursue a claim for damages through the courts or to claim benefits should they be eligible. If an individual receives a payment under the VDPS, any damages recovered through civil proceedings must be offset by £120,000. The rationale for the fixed payment of £120,000 under the VDPS is to provide some financial support to ease the financial burden on individuals where, on very rare occasions, vaccination has caused severe disablement. The VDPS is not designed to cover all expenses associated with severe disablement, other Government support such as Statutory Sick Pay, Universal Credit, Employment and Support Allowance, Attendance Allowance, and Personal Independence Payments are available.

241. I am asked about the background of the scheme as far as historical records show. In 1973, Lord Pearson chaired the Royal Commission on Civil Liability and Compensation for Personal Injury ("the Commission"). The Commission's Terms of Reference were to undertake a wholesale review of all personal injury law as it stood in 1973. One relatively small component of this review was the legal position regarding compensation for personal injuries allegedly caused by vaccinations. In March 1978, the Commission, having completed its review, published its report and made a number of wide-ranging recommendations. With respect to vaccine injuries, the Commission recommended introducing a strict liability regime, which would make it much easier for claimants to succeed in the Courts when compared to the existing regime, under which claimants had to show fault on the part of the Defendant by reference to the ordinary principles of common law negligence **(CS8/139 - INQ000411782)**. At the time, no such claim had ever succeeded in the civil courts, and so injured people were often left without adequate, or any, compensation. Whilst this recommendation was not taken forward in full, the VDPA **(CS8/140 - INQ000377775)** (which established the VDPS) was implemented to address some of the concerns raised.

242. From the VDPS' inception in 1979 until 1 May 2014, the Department for Work and Pensions (DWP) was responsible for the VDPS. On 1 May 2014, it was agreed in a memorandum of understanding that responsibility for policy and legislation relating to the VDPS would be transferred from the DWP to the Department, initially with DWP continuing to administer and fund the scheme **(CS8/141 - INQ000281011)**. From 2014 to 2021, DWP met the costs of the scheme, with DHSC meeting any additional costs (administration and payments) as a result of any changes it made to the scheme through a transfer of funding **(CS8/142 - INQ000267760)**.

243. In March 2021, DWP questioned whether it was still the appropriate entity to oversee and administer the VDPS scheme **(CS8/143 - INQ000399256; CS8/144 - INQ000399257)**. They expressed two primary concerns: first, that the DWP team lacked expertise in causation in vaccine damage in relation to newer and more complex vaccines, such as COVID-19; and second, DWP had an insufficient number of disability assessment experts to handle the expected rise in caseload associated with COVID-19, and they anticipated difficulties in recruiting a substantially larger number of experts **(CS8/145 - INQ000399258)**. In October 2021 the Department agreed with DWP that the VDPS would move to DHSC. From 2021, the Department met the costs of the scheme.

244. After this agreement was reached, a number of potential receiver organisations were considered by the Department, such as the UKHSA, the Department, NHS Resolution and the NHS Business Services Authority (NHSBSA) **(CS8/146 - INQ000399267)**. NHSBSA was selected to be the receiver organisation for the VDPS administrative and contractual functions **(CS8/147 - INQ000411705; CS8/148 - INQ000399269; CS8/149 - INQ000399270; CS8/150 - INQ000399271)**. NHSBSA was selected on the basis that:

a. the VDPS administration aligned best with NHSBSA's extant services and functions;

b. NHSBSA had prior experience of successfully transferring and incorporating services from DWP;

c. NHSBSA had access to the capacity and skills required to ensure a safe transfer of functions; and

d. the Department sponsorship team agreed NHSBSA were the appropriate receiver organisation **(CS8/146 - INQ000399267)**.

245. DWP continued to administer the scheme until it was transferred to NHSBSA. Since 1 November 2021, NHSBSA has operated the VDPS on behalf of the Department.

246. To ensure a smooth handover process, a project steering group was established with DWP, NHSBSA and the Department. A plan defined the scope of the project and was used to manage the handover, alongside a timeline **(CS8/151 - INQ000411761)** and risk register **(CS8/152 - INQ000411762)**. A transfer team was set up within NHSBSA to conduct due diligence work for the transfer. The detailed mechanics of transferring historic and live claims was done by DWP and NHSBSA directly.

247. I set out at paragraphs 88 and 89 of my first Statement of this Module **(CS8/1 - INQ000474334)** the role of the NHSBSA: NHSBSA are responsible for the operational activities required to run it, notably: the administration of claims, payments, and mandatory reversals. The detailed responsibilities of the NHSBSA in this regard are contained within a Memorandum of Understanding between DWP, the Department and NHSBSA, and in a Service Level Agreement between the Department and NHSBSA **(CS8/142 - INQ000267760; CS8/153 - INQ000267761)**.

248. The NHSBSA is an arms-length body of the Department. The relationship between the Department and the NHSBSA is covered in more detail in my first Statement of this Module at paragraphs 87 – 92 **(CS8/1 - INQ000474334). (CS8/154 - INQ000411750)**

249. Ministers are the decision makers in respect of the VDPS, with advice from officials in the normal way. The Department has an SRO for the VDPS. At the time it was Will Jones, Deputy Director for Health Protection Policy and UKHSA Sponsorship. He reported to Emma Reed, Director for Emergency Preparedness and Health Protection at the Department, and to me (Clara Swinson), Director General for Global Health.

250. The Social Security and Child Support Tribunal (administered by His Majesty's Courts and Tribunals Service (HMCTS)) conducts appeals of VDPS decisions. The Tribunal is impartial and independent of Government.

251. Ahead of the proposed roll out of a potentially population-wide COVID-19 vaccination programme, advice was put to the Secretary of State on 5 August 2020 concerning the inclusion of COVID-19 within the VDPS. The advice recommended that COVID-19 was added to the VDPS through a negative statutory instrument which would also disapply the age limit that would otherwise prevent anyone over the age of 18 making an application following a COVID-19 vaccination **(CS8/155 - INQ000257399.**

252. Diseases have been added to the VDPS in this manner as successive governments have rolled-out immunisation programmes. The VDPS applies to the childhood immunisation programme and there have been regular amendments to the eligibility requirements for COVID-19 vaccines to include the adult population for example, for polio, rubella, meningococcal group C, HPV and meningococcal group W (up to age 26). See paragraph 255 for eligibility criteria below.

253. At the VTF Ministerial Panel on 27 August 2020, the Department was given an action to "*provide an update at the next Panel meeting on the potential to integrate COVID-19 into the Vaccine Damage Payments Act and any other options currently being explored*" **(CS8/156 - INQ000399245).** In the next meeting on 11 September 2020, the Secretary of State confirmed that the Department would be adding COVID-19 to the VDPS **(CS8/157 - INQ000497066). On** 2 December 2020, the statutory instrument was made to that effect **(CS8/158 - INQ000399253).** It was laid in Parliament on 3 December 2020, and it came into force on 31 December 2020 **(CS8/159 - INQ000502093).**

254. The rationale for including COVID-19 within the VDPS was:

a. To demonstrate the Government's confidence in the safety profile of all COVID-19 vaccines being used in the vaccination programme; and

b. To ensure that there was financial provision for the rare cases where any individual was severely disabled as a result of a vaccination against COVID-19 (separate from any civil claim for damages and government social security provision for those with a disability or long-term health condition) **(CS8/155 - INQ000257399).**

255. The detailed provisions concerning the eligibility criteria for payment under the VDPS are set out in the VDPA or in orders made under delegated powers within the VDPA. However, in general, to be eligible for a payment under the VDPS, an individual must meet the following criteria:

a. That they were vaccinated in the UK or Isle of Man[3], **and**

b. That they were vaccinated against a disease specified under the VDPA, **and**

c. That they were vaccinated after 1 July 1948, **and**

d. The claimant was 2 years old or more at the time of claim, or was at least 2 years old when they died, **and**

e. That they were under 18 at the time of vaccination unless there has been a modification to the conditions of entitlement e.g. as with seasonal influenza where the age restriction has been omitted **(CS8/160 - INQ000411774)**, **OR** that they were vaccinated at a time of an outbreak in the UK or Isle of Man of a specified disease.

256. If the eligibility criteria summarised above are met, the claim is then assessed to determine whether the claimant is or was immediately before their death severely disabled

[3] This condition does not apply to serving members of HM Forces vaccinated overseas, who are deemed in law to have been vaccinated in England.

(at least 60 per cent) and their disability was caused, on the balance of probabilities, by a vaccination against one of the diseases specified in the VDPA.

257. As is set out above, responsibility for VDPS policy and legislation was transferred to the Department in May 2014 and responsibility for its administration was transferred to NHSBSA in November 2021. Accordingly, the Department cannot speak to the original rationale for criteria which were designed and implemented by DWP. In terms of changes to the criteria that have been made since the VDPS moved to the Department's remit: vaccinations to protect against the following diseases have been included in the remit of the VDPS by the Department: rotavirus (2015); influenza other than influenza caused by a pandemic influenza virus (2015); meningitis W (2016); meningitis B (2016); and COVID-19 (2020). These changes were intended to demonstrate Government confidence in the safety profile of the vaccinations against these diseases and to ensure that there was financial provision for the rare cases where any individual was severely disabled as a result of a vaccination against these diseases (separate from any civil claim for damages and government social security provision for those with a disability or long-term health condition) **(CS8/161 - INQ000411675)**. In addition, please refer to paragraph 258b below which sets out the rationale for extending the eligibility for claims concerning seasonal influenza to all over 18s in 2021.

258. After the key criteria were established (as set out above), two changes were later made to the eligibility criteria:

a. In 2002, whilst the VDPS was still under DWP, the disability threshold was lowered from 80 per cent disablement to 60 per cent. This was in line with changes to the definition of severe disablement used by DWP for the Industrial Injuries Disablement Benefit.

b. In 2021, the eligibility for seasonal influenza was extended to all over 18s, having previously only applied to those under 18 **(CS8/162 - INQ000399260; CS8/163 - INQ000399259)**. This change was made after a judicial review claim was made in December 2017 which argued that the Specified Disease Order relating to seasonal Flu was contrary to the Public Sector Equality Duty because it was discriminatory on the grounds of age as claims for seasonal Flu could only be made by those who were vaccinated before their 18th birthday **(CS8/162 - INQ000399260).** Ministers at that time agreed to concede the claim and to review the PSED element of the seasonal Flu addition to the VDPS. After various options

had been explored, a decision was taken by ministers to extend the age range to all those over 18 for claims concerning seasonal influenza in 2021.

259. In addition, when the Act was passed in 1979 the Scheme was only open to those people vaccinated against one of the following diseases: diphtheria, tetanus, pertussis, poliomyelitis, measles, rubella, tuberculosis, and smallpox (if vaccinated before 1 August 1971). The Secretary of State is empowered to amend this list by Order, and since 1979 the following diseases have been added to the list by the Vaccine Damage Payments (Specified Disease) Orders in the following years: mumps (1990), haemophilus influenzae type b (1995), meningococcal group C (2001), pneumococcal infection (2006), human papillomavirus (2008), pandemic influenza A (H1N1) (2009), rotavirus (2015), influenza other than influenza caused by a pandemic influenza virus (2015), meningitis W (2016), meningitis B (2016), and COVID-19 (2020) **(CS8/159 - INQ000502093)**. Please see paragraph 257 above for the rationale for including the additional diseases which have been added since the transfer of the VDPS to the Department in 2014.

260. The DWP raised the payment limit to £120,000 in July 2007 (it having previously been raised to £100,000 in July 2000). Explanatory Memorandum 2007 No. 1931 records that this was done at the request of the then Parliamentary Under-Secretary of State for Disabled People Anne McGuire and the All-Party Parliamentary Group for Vaccine Damaged Children in July 2006 **(CS8/164 - INQ000411772)**. This change was requested to bring the buying power of the payment in line with the original value in 2000. For further information in relation to the reform of the VDPS payment limit, please see paragraphs 270- 271 below.

261. To apply for a payment under VDPS, applicants must submit a claim form either online or by post. Forms are available to download on the NHSBSA website **(CS8/165 - INQ000411775)**. Applicants are asked to provide personal details such as their name and date of birth, contact information, details of the vaccination(s) received and information about their healthcare providers **(CS8/166 - INQ000411777)**. Claimants are also asked to set out what happened after they received the vaccine(s) that they believe caused the disability.

262. A personal representative can apply on behalf of a deceased person **(CS8/167 - INQ000411778)**.

263. After receiving a claim form, NHSBSA check whether a claimant meets the eligibility criteria summarised at paragraph 255 (a)-(e) above, and if so, they will contact the claimant's healthcare providers to request copies of their full medical records **(CS8/168 - INQ000411764)**. Thereafter, the claim is assessed on a case-by-case basis by experienced independent medical assessors to determine whether the claimant was severely disabled (at least 60 per cent) and their disability was caused, on the balance of probabilities, by vaccination of one of the diseases specified in the VDPA. Medical assessors will consider a wide range of evidence when making a clinical assessment as to whether it is more probable than not that the vaccine caused disablement, and if so, whether that disablement is severe, including the following:

a. Clinical research;

b. Epidemiological evidence;

c. The current consensus of expert medical opinion; and

d. A claimant's application and their medical records from their healthcare providers.

264. The medical assessors are all General Medical Council (GMC) registered doctors with a license to practice and they have all undertaken specialist training in vaccine damage and disability assessments. The principles to be applied to the medical assessment of the claim are set out in full within the "VDPS Principles of Medical Assessment" document **(CS8/169 - INQ000267796)**.

265. There is no difference between the application and payment process as it relates to COVID-19 vaccine damage and damage related to other vaccines. The same application and payment process is applied to all claims irrespective of the disease they relate to.

266. Since 9 July 2023, following revised DWP regulations **(CS8/170 - INQ000502143; CS8/171 - INQ000502144)**, VDPS payments do not affect a claimant's means-tested benefit entitlement (such as Universal Credit or Housing Benefit). This is because VDPS payments are now disregarded indefinitely in the calculation of an individual's means-tested benefit payments (or their partner's). Before 9 July 2023, entitlement to means-tested benefits were affected by a VDPS payment. However, if a claimant received a payment from the VDPS before 9 July 2023, this change applies to them prospectively

from 9 July 2023 onwards and so their means-tested benefit entitlement will no longer be affected as of that date.

267. The inclusion of COVID-19 vaccinations within the VDPS posed two main challenges, namely:

a. **Volume of claims (CS8/172 - INQ000411702; CS8/173 - INQ000411701)**: It was anticipated that a significantly increased number of claims to the VDPS would be made as a result of COVID-19 vaccinations as compared to other vaccines because of the sheer volume of vaccines that were being administered.

b. **Causation** (**CS8/173 - INQ000411701)**: It was anticipated that it would take time to assess the cases severe disablement following a COVID-19 vaccination because of the novel nature of the vaccines and the lack of related research.

268. The challenges identified were addressed in the following ways:

a. **Volume of claims**: In the period leading up to the transfer of the VDPS, the Department and NHSBSA offered to: (a) provide additional administrative support to DWP; (b) process non-COVID-19 VDPS claims prior to the transfer to free up DWP staff to gather medical evidence on the COVID-19 claims; and (c) gather medical evidence on the COVID-19 claims prior to the handover (**CS8/174 - INQ000411729)**. However, this offer was not taken forward **(CS8/175 - INQ000399264)**. Following the transfer of the VDPS to the Department (and NHSBSA on behalf of the Department), NHSBSA increased the administrative team to over 80 members of staff—which was a 20-fold increase on the existing staffing levels. In addition, NHSBSA completed two major pieces of digitisation: (a) creating a digital, online application form; (b) digitising previous paper claims and placing them in a new database. This move to a principally online system enabled NHSBSA claim handlers to manage double the number of cases compared to their DWP counterparts. Furthermore, NHSBSA procured a new external provider to increase the capacity to conduct the specialist medical assessments. This was followed by a period of onboarding and establishment of an appropriate quality assurance process.

b. **Causation**: In May 2021, the Department sought advice from the MHRA and the CMO on whether it was too early to make assessments on causality for COVID-

19 cases, particularly around clotting incidents, given that the MHRA view was that whilst there was an association, no causality had been established **(CS8/176 - INQ000399265)**. The CMO's view at the time was that it was too early for an Assessor to be able to determine this in a fair way **(CS8/177 - INQ000073284)**. Thereafter, the Department continued to work closely with experts from PHE (now UKHSA) and MHRA to consider any emerging evidence which would enable medical professionals to make safe and fair causal assessments between COVID-19 vaccines and possible side effects. In October 2021, it was agreed that assessors should consider the causation of COVID-19 VDPS claims **(CS8/178 – INQ000411732)**.

269. Following the transfer of the VDPS to the Department's remit, the work undertaken by the Department (and later the Department and NHSBSA) on the VDPS largely focused on the operational changes that could be made within the existing legislation and scheme criteria. Reform efforts have focused on: (a) the scaling up the operations of the VDPS to meet claim demand; (b) improving the claim experience for claimants; and (c) the provision of VDPS decisions in a timely manner. The details of the changes that have been made in this regard are set out below:

a. **The application process:** Following the transfer of the VDPS to the Department, NHSBSA completed two major pieces of digitisation: (a) creating a digital, online application form; (b) digitising previous paper claims and placing them in a new database. Together, these actions have created an easily searchable claims database which allows for more efficient administration of the scheme, improving claimant engagement by allowing caseworkers to easily access the status of a claim, facilitating better tracking of claim progress and allowing updates to be provided at set point with greater ease. It also allows for identifying further areas for improvement through data analysis. In addition, to improve claimant experience, each claimant now has named caseworkers, they receive regular updates on the progress of their claim, and they are given a more detailed outcome response than provided previously to help them to better understand the decision made.

b. **Length of time to resolve applications:** In 2022, NHSBSA implemented Subject Access Requests (SAR) to provide robust timeframes for healthcare providers to return medical records as the process is reliant on their availability to start medical assessments. If healthcare providers do not engage with NHSBSA

within 28 days of issuing a request for medical records, NHSBSA automatically submit an SAR on a claimant's behalf **(CS8/179 - INQ000502136)**. This helps to reduce the length of time it takes to resolve applications. In addition, the Department meets weekly with NHSBSA to discuss the operation of the VDPS to ensure that processes are improved where necessary and ensure that claims are handled as quickly and efficiently as possible.

c. **Length of time to award payments to successful applicants:** Where claims are awarded, NHSBSA has a Key Performance Indicator (KPI) that 90 per cent of payments should be made to the claimant within 10 working days of receiving all the required documentation from the claimant following a decision being made. This KPI was introduced following the transfer of the VDPS from DWP to NHSBSA to help to minimise any unnecessary delays in payments being made.

270. Since the transfer of the VDPS to the Department, the Department has already made a number of reforms to the VDPS which have been summarised above. In addition, in March 2022, options for further reform of the VDPS were discussed with ministers **(CS8/180 - INQ000399272)** and on 11 May 2022, a briefing was provided to ministers setting out an overview of options for VDPS reform **(CS8/181 - INQ000399274; CS8/182 - INQ000399273; CS8/183 - INQ000399275)**. On 12 May 2022, a meeting with the then Secretary of State took place to discuss these options which included: decreasing the disability threshold to 50 per cent or lower; increasing the VDPS payment amount in-line with inflation; instituting an inflationary mechanism going forward; and instituting graduated payments based on levels of disablement **(CS8/184 - INQ000411743)**. Following this meeting, more detailed advice was provided on next steps for an option to increase the payment amount, including looking at targeting a round figure for the payment and ways to assess the costs of this option by working with financial analysts. Further advice was provided in June 2022 **(CS8/185 - INQ000411744)**.

271. There are no current plans to establish a bespoke COVID-19 compensation scheme. Any changes to the VDPS would be a matter for ministerial decisions in the normal way, including consideration of benefits, costs, implementation and legislative issues at that time. Any financial implications would need to be agreed with HM Treasury.

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: 4 September 2024