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Dated: 22 December 2023

UK COVID-19 INQUIRY

WITNESS STATEMENT OF MATTHEW STYLE, JONATHAN MARRON AND PROFESSOR LUCY CHAPPELL

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1. I, Matthew Style, Director General of the NHS Policy and Performance Group, at the Department of Health & Social Care, 39 Victoria St, Westminster, London SW1H 0EU will say as follows, and I, Jonathan Marron, Director General of the Office for Health Improvement and Disparities, at the Department of Health & Social Care, 39 Victoria St, Westminster, London SW1H 0EU, will say as follows, and I Professor Lucy Chappell, Chief Scientific Adviser at the Department of Health & Social Care, 39 Victoria St, Westminster, London SW1H 0EU, will say as follows:

2. We make this statement in response to the request from the UK COVID-19 Public Inquiry (the Inquiry) dated 16 March 2023, under Rule 9 of The Inquiry Rules 2006 (SI 2006/1838), requiring the Department to provide the Inquiry with a witness statement in respect of specified matters relating to Module 3. The Inquiry's request focuses on the period 1 March 2020 to 28 June 2022 (the relevant period). This statement builds on Sir Christopher Wormald's first statement to the Inquiry in relation to Module 3, dated 27 October 2023. In this statement, we address the Inquiry's questions relating to:

A. The clinical management of COVID-19;
B. The supply of ventilators and oxygen;
C. NHS 111;
D. Infection prevention and control;
E. Personal Protective Equipment (PPE); and
F. Protecting the vulnerable from COVID-19 infection through shielding

3. As this is a corporate statement on behalf of the Department, it necessarily covers matters that are not within our personal knowledge or recollection. Where a matter is within our personal knowledge, we have sought to make this clear. As a corporate statement involving many different areas of policy within the Department, information has been gathered from a number of sources. This statement is to the best of our knowledge and belief accurate and complete at the time of signing, in line with responding as far as possible within the Inquiry's 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. As set out above, I, Matthew Style, am the Director General of the NHS Policy and Performance Group at the Department. I first became a civil servant in 2001 and first joined the Senior Civil Service in 2008. I have been Director General of the NHS Policy and Performance Group since I joined the Department in November 2021. I am responsible for Sections A (in part), B, C and F of this statement.

5. As set out above, I, Jonathan Marron, am a Director General at the Department having first joined the Department in 1994 and have subsequently held various roles both inside the Department and across the healthcare system. I am currently the Director General of the Office for Health Improvement and Disparities, having been made a Director General in 2017, initially on temporary promotion. In my current role I am responsible for a group which includes public health, prevention, the Work and Health Unit and

the delivery of two major Government programmes (Start for Life and Drug Strategy Treatment). I am responsible for Sections D and E of this statement.

6. As set out above, I, Lucy Chappell, am Chief Scientific Adviser and a Director General at the Department. I was seconded into the Civil Service in this role in August 2021. I am responsible for the Science, Research and Evidence Directorate in the Department as well as being the CEO of the National Institute for Health and Care Research. I am responsible for clinical trials and research into COVID-19 section of this statement.

7. The roles and responsibilities of the Department's key decision makers and advisers relevant to this period are set out the first statement for Module 3.

A. Information and guidance relating to the clinical management of COVID-19

8. The following section sets out the Department's involvement in the development of clinical guidance. As in non-pandemic times, the Department did not have a role in the development of clinical guidelines and protocols for use within the NHS relating to the treatment of patients. There are several organisations, set out below, who were involved throughout the pandemic and are involved in non-pandemic times.

The Department's role in providing information and guidance

9. I am asked about the role that the Department played in the gathering and dissemination of information within the healthcare system regarding the clinical management of COVID-19 and in formulating and disseminating guidance, guidelines or protocols regarding healthcare provision and treatment for patients with COVID-19 including decisions about escalation of care and treatment.

10. In March 2020, the Department set up a Guidance Cell to help coordinate the clearance and publication of public health and behavioural guidance relating to COVID-19. The Guidance Cell played a significant role in the

clearance of the first guidance on social distancing and for vulnerable people, which was drafted by Public Health England (PHE) and published on 16 March 2020 **(MS/JM/LC/1 - INQ000348029)**. The Guidance Cell was initially part of the DHSC Operational Resource Centre (ORC) and moved in June 2020 to the new COVID-19 Programme Directorate.

11. The Department had no direct involvement in drafting clinical guidelines and protocols for use *within* the NHS relating to the treatment of patients, which was generally published on the NHSE website. The Department was, however, involved in the production and publication of *public-facing* public health and behavioural guidance relating to COVID-19, which was generally published on the gov.uk website.

12. In early May the Department's Guidance Cell worked closely with the Cabinet Office (CO) and PHE to design a process for production and clearance of public facing public health and behavioural guidance that became known as the 'Triple Lock'. This process ensured that each piece of public facing public health and behavioural guidance published on gov.uk was seen and where relevant agreed by the Chief Medical Officer (CMO) or more usually a Deputy Chief Medical Officer (DCMO) on his behalf, by the CO/No. 10 and by senior public health professionals in PHE. The Triple Lock process was not used for the clinical guidance that was produced by the NHS, or for direct communications from the CMO.

13. There are a range of organisations involved in providing information and guidance to the healthcare system.

NHS England

14. NHSE was responsible for providing operational guidance to NHS organisations. As Sir Christopher Wormald explained in his first witness statement for Module 3 at paragraph 69, NHSE operationally merged with NHS Improvement (NHSI) in 2018. Throughout the relevant period, the two bodies functioned as one integrated organisation, albeit they retained their

individual legal and financial responsibilities. They were referred to jointly as NHSEI, though for the purposes of this statement I sometimes refer to them by their separate titles.

15. NHSE, previously known as the NHS Commissioning Board, was established as a non-departmental body to lead and oversee the NHS. Amongst its powers was the power to issue guidance (s.14Z8 of the NHS Act). Consistent with their statutory duties, NHSEI provided operational leadership to the NHS throughout the pandemic, which involved gathering information within the healthcare system regarding COVID-19 and issuing guidance in relation to treatment for patients. NHSE collected and published data on activity related to COVID-19, including data about numbers of patients in hospital, numbers of patients in mechanical ventilation, and numbers admitted, diagnosed and discharged from hospital. NHSE's COVID-19 Post-COVID Assessment Service contains information on activity and demographics of patients who have been referred to a Post-COVID (Long COVID) assessment clinic in England.

16. Other bodies also played important roles in relation to the gathering and dissemination of information and the provision of guidance within the NHS and these are set out in more detail below.

Chief Medical Officer (CMO)

17. Professor Sir Chris Whitty FRS FMedSci is the current CMO for England, Chief Medical Adviser to HM Government and professional head of the public health profession. He took up this post in October 2019 and remains in post.

18. From January 2016 until August 2021 Professor Whitty was the Chief Scientific Adviser (CSA) to the Department and head of the National Institute for Health Research (NIHR), the UK's largest funder of clinical and public health research. The Department CSA has overall responsibility for the Department's research and development, including the NIHR. Professor Whitty held the role of CMO and CSA concurrently for most of the early

pandemic. In August 2021 Professor Lucy Chappell FMedSci assumed the Department's CSA/NIHR role reporting to the CMO. Further details will be covered by the Office for CMO (OCMO) Module 3 corporate statement and any CMO Module 3 personal statement.

National Institute for Health and Care Excellence

19. The National Institute for Health and Care Excellence (NICE) was responsible for developing guidance on clinical pathways for patients with COVID-19. Amongst the key guidelines that NICE produced relating to COVID-19 were the following:

    i. NG164: COVID-19 rapid guideline: hematopoietic stem cell transplantation **(MS/JM/LC/2 - INQ000339134)**, first published on 1 April 2020.
    ii. NG187: COVID-19 rapid guideline: vitamin D **(MS/JM/LC/3 - INQ000339279)**, first published on 17 December 2020.
    iii. NG188: COVID-19 rapid guideline: managing the long-term effects of COVID-19 **(MS/JM/LC/4 - INQ000272222)**, first published on 18 December 2020.
    iv. NG191: COVID-19 rapid guideline: managing COVID-19 **(MS/JM/LC/5 - INQ000339283)**, first published on 23 March 2021.
    v. NG200: COVID-19 rapid guideline: vaccine-induced immune thrombocytopenia and thrombosis (VTT) **(MS/JM/LC/6 - INQ000339287)**, first published on 29 July 2021.

20. Beyond the guidelines referred to above, NICE also conducted a range of other work relating to COVID-19, including:

    i. Rapid evidence studies (see e.g. ES23 published on 14 April 2020, relating to the acute use of non-steroidal anti-inflammatory drugs (NSAIDs) for people with or at risk of COVID-19 **(MS/JM/LC/7 - INQ000339147)**

ii. MedTech briefings (see e.g. MIB217 published on 21 May 2020, relating to Cytokine absorption devices for treating respiratory failure for people with COVID-19 **(MS/JM/LC/8 - INQ000339200)**; and

iii. Technology appraisal guidance (see e.g. TA900 published on 14 June 2023, relating to tixagevimab plus cilgavimab for preventing COVID-19 **(MS/JM/LC/9 - INQ000339319)**.

Public Health England / UK Health Security Agency

21. Public Health England (PHE)/the UK Health Security Agency (UKHSA) also produced guidance on the investigation and initial clinical management of COVID-19, which was published on 10 January 2020 on GOV.UK **(MS/JM/LC/10 - INQ000339109** (withdrawn on 5 April 2022) and which contained links to a variety of other relevant resources, including NICE guidance **(MS/JM/LC/5 - INQ000339283)**. UKHSA also produced a range of guidance from 10 January 2020 onwards **(MS/JM/LC/11 - INQ000339103; MS/JM/LC/12 - INQ000339111; MS/JM/LC/10 - INQ000339109; MS/JM/LC/14 - INQ000074966; MS/JM/LC/15 - INQ000339112; MS/JM/LC/16 - INQ000339108; MS/JM/LC/17 - INQ000339107; MS/JM/LC/18 - INQ000339105; MS/JM/LC/19 - INQ000339106; MS/JM/LC/20 - INQ000339102)** to provide information and advice for health professionals on the assessment and management of suspected UK cases of COVID-19. This was updated throughout the relevant period, most frequently in 2020, to include further guidance on a number of specific topics such as: terminology, self-isolation, advising the public, PPE, and testing and taking swab samples.

Clinical trials and research into the treatment of COVID-19

22. I am asked about whether the Department coordinated or otherwise contributed to the response of the healthcare system in England to clinical trials and research into the treatment of COVID-19.

23. The Department funds research through the NIHR. The NIHR focuses on early translational research, clinical research and applied health and social care research. Working in partnership with the NHS, universities, local government, other research funders, patients and the public, the NIHR funds, enables and delivers health and social care research that improves people's health and wellbeing and promotes economic growth. The NIHR is centered on England but collaborates closely with the devolved governments in Scotland, Wales, and Northern Ireland. It is also a major funder of applied health research in low- and middle-income countries, work that is principally funded through UK aid from the UK government.

24. The Department and the NIHR responded rapidly to the pandemic and commissioned a wide range of research to address different aspects of the pandemic, as well as encouraging relevant research groups to focus their work on COVID-19 related research. The NIHR commissioned research to support the development of vaccines and therapeutics, a wide range of research into the clinical manifestations and understanding of the disease in different groups, research to test different vaccine schedules to inform the national roll-out of the vaccination programme and a range of policy-related research to inform the response to and recovery from the pandemic. In 2020/2021, NIHR direct expenditure on COVID-19 research was over £108 million. NIHR infrastructure was also used by others with the costs borne by NIHR.

Joint COVID-19 research calls

25. The Department's Science, Research and Evidence Directorate (SRE) worked closely with colleagues in UK Research and Innovation (UKRI) from the Medical Research Council (MRC) and with the NIHR Central Commissioning Facility (CCF) from January 2020 to establish joint NIHR-UKRI open research calls to develop vaccines and therapeutics, diagnostics and to build the evidence base on COVID-19 more generally.

26. During the relevant period, there were two significant research calls:

i. The Rapid call was launched in February 2020, with projects commissioned in March 2020. This was the most rapid large scale research call that has ever been commissioned in the UK. Its success was a testament to the focus of the funders, the research community which developed high quality proposals in record time, and those experts and members of the public who gave their time to sit on the commissioning panels. The funded projects were expected to lead to a benefit in the UK and international public health within 18 months. A total of 26 projects were funded at a cost of approximately £26 million, including the RECOVERY trial (an international clinical trial identifying treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19) and the Oxford vaccine study.

ii. The Rapid Response Rolling call ran from April 2020 to June 2020, though some additional commissioning took place over the subsequent 3 months. The panel, which was chaired by Professor David Heymann, met weekly to consider applications. Four highlight notices on ethnicity, mental health, seroprevalence and transmission were issued during this time to seek proposals on these specific topics, aimed at research for public health benefit within 12 months. Overall, the Rapid Response Rolling call led to the commissioning of approximately 50 studies at a cost of approximately £50 million.

27. The scale of the work involved in carrying out the Rapid and Rolling calls was significant. Almost 1000 proposals were assessed across the two calls.

The Fighting Fund

28. In the March 2020 Budget, HM Treasury provided the NIHR with £30 million of new funding to enable further rapid research into COVID-19. This was colloquially known as the 'Fighting Fund'. The fund could be spent with joint agreement from both the CMO and the Government Chief Scientific Adviser. The idea behind the fund was that, given the health emergency, there would be some discrete pieces of research or related work that needed to be done

so rapidly that it was not possible to fund them through normal mechanisms, so this alternative funding was used.

Long COVID calls

29. Early in the pandemic, funders recognised the need for research on the syndrome or syndromes collectively called Long COVID. The SRE Directorate held a roundtable on research needs for this topic for the Secretary of State in July 2020, having previously commissioned a literature review on early evidence of a possible longer-term impact of COVID-19. As set out in the Fourth Witness Statement to the Inquiry by Professor Sir Christopher Whitty (INQ000251645):

"On 25 June 2020, the OCMO asked the Health Protection Research Units (part of NIHR) to undertake a literature review of the longer-term health impacts of COVID-19 (CJMW4/220 - IN0000069876). This was published in October 2020 (CJMW4/221 — INQ000236442)."

30. An expert group was set up jointly by UKRI and NIHR to identify key research needs in relation to COVID-19 patients who had not been admitted to hospital. In November 2020, a UK-wide targeted research call was launched to fund ambitious and comprehensive research into the longer-term physical and mental effects of COVID-19 among such patients **(MS/JM/LC/21 - INQ000283379)**. On 18 February 2021, the successful projects were announced, with four studies commissioned at a total cost of £18.5 million **(MS/JM/LC/22 - INQ000339117)**.

31. A second open call, this time funded just by the NIHR and also relating to longer term effects of COVID-19 in non-hospitalised patients, was launched in March 2021, following a meeting of another expert group, and focused on treatments, interventions, diagnostics and service delivery **(MS/JM/LC/23 - INQ000283429)**. This resulted in a further 15 studies being funded, at a cost

of £19.6 million. These were announced on 18 July 2021 **(MS/JM/LC/24 - INQ000283460)**.

Vaccine research to support delivery of national programme

32. The National Immunisation Schedule Evaluation Consortium (NISEC) was commissioned in 2017 by the NIHR Policy Research Programme to conduct clinical trials evaluating vaccine schedules. These studies informed the work of the Joint Committee on Vaccination and Immunisation (JCVI) and national policy on vaccination.

33. During the pandemic, NISEC rapidly pivoted to focus on evaluating COVID-19 vaccines through several key trials. The research and priorities for the work were codeveloped with the Department, the Vaccines Taskforce (VTF), UKHSA and JCVI.

NIHR Health Protection Research Units

34. NIHR funds the NIHR Health Protection Research Units (HPRUs) as partnerships between universities and UKHSA. HPRUs rapidly switched to working on COVID-19 related studies, revamping their work programmes from April 2020.

35. HPRUs took on research on priorities identified by the Department. These included a study on the Assessment of Transmission and Contagiousness of COVID-19 in Contacts (ATACCC), which provided some of the first real-world information on how long people with COVID-19 were infectious.

36. The research conducted by the HPRUs supported major policy decisions. For example, the NIHR HPRU in Modelling and Health Economics provided insights to the UK government, including the devolved administrations, via the Scientific Pandemic Influenza Group on Modelling (SPI-M) and the Scientific Advisory Group for Emergencies (SAGE). They produced real time modelling on hospital demand forecasts, cases, and deaths; estimates for

the effectiveness of interventions, including how and when to lift them, and exit strategies; and short-term projections of cases, hospital demand and deaths.

Pandemic preparedness: sleeping contracts

37. NIHR and SRE also supported a variety of pandemic preparedness research. Following a review of the 2009 Swine Flu outbreak, the NIHR commissioned a portfolio of eight studies. All but one were put on stand-by in a maintenance-only state, awaiting activation in the event of a new influenza pandemic. The portfolio included modelling, surveillance, communications, triage, and clinical management. NIHR reviewed the studies regularly, and in 2018 research teams were asked to consider how their projects could be adapted for a non-flu pandemic.

38. When COVID-19 was declared a pandemic, four studies were repurposed and activated for COVID-19 by the DCMO at the time, Professor Sir Jonathan Van Tam.

Research to inform policy

39. Very early in the pandemic, the NIHR Policy Research Programme set up a rapid prioritisation process to manage research offers submitted to programme managers from the policy research community, and to address research requests received from policy teams within the Department and its arm's-length bodies (ALBs). Research supported was expected to aid policy development and implementation in response to the pandemic.

40. The rapid prioritisation process resulted in 27 projects, the majority of which were supported through the pre-existing NIHR Policy Research Units. The Policy Research Units typically carried out research in a wide range of topic areas including social care, domestic violence, cancer screening, end of life care, health disparities, pregnancy and neonatal care, disability care

provision, obesity and air pollution, and pivoted their research to COVID-19 topics in the pandemic

41. The NIHR Policy Research Programme also ran a 'Recovery, Renewal, Reset' (RRR) call in July 2020 to support the recovery of the health and care system from COVID-19. Topics included: new ways of accessing services; new ways of working; and new ways of organising healthcare services. In total, 27 projects were commissioned, at a total cost of £6.5 million.

NIHR Learning and Recovery call

42. The NIHR Learning and Recovery (L&R) call was launched at the same time as the RRR call run by the NIHR Policy Research Programme. The L&R call was run by the NIHR Evaluation Trials and Studies Coordinating Centre (NETSCC).

43. The call invited research to better understand and manage the health and social care consequences of the global COVID-19 pandemic beyond the acute phase. This was an important part of NIHR's response to provide high-quality and timely evidence to support system recovery, specifically on health outcomes, public health, social care, and health service delivery across the UK and to mitigate the impact of subsequent phases and the aftermath of the pandemic.

44. The selection panel was held on 22 July 2020. A total of nine projects were commissioned.

Research in low- and middle-income countries

45. In partnership with the MRC and UKRI, the NIHR launched the Global Effort on COVID-19 (GECO) Health Research, focused on four of the priority research topics highlighted by the WHO Coordinated Global Research Roadmap: epidemiology, clinical management, infection prevention and control, and social sciences in the outbreak response.

46. A total of 21 awards were made between October 2020 and February 2021, with a duration of up to 18 months, investing £8 million across 21 developing countries in five regions.

Other initiatives

47. There were also a range of other relevant research initiatives:

i. Platform trials: Many treatments which are widely used in other conditions, and were thought likely to help, were given to people with COVID-19. NIHR, co-funded with UKRI and MRC, supported the set-up or further development of several platform trials, which allowed them to test several of these drugs within a single study and were crucial to delivery of rapid results which were then implemented into standard clinical practice.

ii. Genomic studies: Several important genomic studies were commissioned or co-funded by NIHR. The UK genomic sequencing and variant-tracking capacity was world-leading.

iii. Impact of lockdowns and other interventions: NIHR also supported research to help academics and policymakers understand how the public were responding to the pandemic in terms of their behaviours, and what impact official communications and policies were having. NIHR research and evidence informed SAGE, SPI-M, the Scientific Pandemic Influenza Group on Behaviour (SPI-B), the JCVI, and the Government's response to COVID-19. NIHR-funded researchers also played an important role as members of SAGE, SPI-M, and SPI-B, among other advisory groups.

iv. Specific groups and settings: A range of further research was commissioned in relation to the following areas:

a. COVID-19 and ethnicity;
b. COVID-19 and mental health;
c. COVID-19 and clinically vulnerable groups; and

d. COVID-19 in social care.

v. Other support for vaccine research: the NHS COVID-19 Vaccine Research Registry, developed by NIHR, the government's Vaccine Taskforce and NHS Digital (NHSD), was launched in July 2020 for people across the UK to sign up to be contacted in taking part in COVID-19 vaccine trials. The registry was important in recruiting participants to over 14 vaccine trials, targeting different demographic groups at different stages of the pandemic. The Department and NIHR also supported the establishment of a regional model of vaccine research delivery hubs across the UK to support the concurrent delivery of multiple large scale vaccine trials.

COVID-19 and ethnicity

48. I am asked to summarise the research being conducted in the area of COVID-19 and ethnicity. A number of research calls were issued during the COVID-19 pandemic to address evidence gaps, which were funded jointly between NIHR and UKRI.

49. In addition, a joint highlight notice between the two funders was launched as part of the organisations' Rapid Response Rolling Call to COVID-19. The highlight notice specifically invited proposals to investigate evidence of an association between ethnicity and COVID-19 incidence and adverse health outcomes. Specifically the notice invited research proposals on the impact of COVID-19 and:

- association between ethnicity and COVID-19 generally, and;
- on people working in health and social care from black, Asian and minority ethnic (BAME) backgrounds.

50. All of the projects funded through the Rapid Response Rolling Call are publicly available online(**MS/JM/LC/24a – INQ000372797**). Seven projects specifically looked at ethnicity and COVID-19, and other studies in the

portfolio had components relevant to ethnicity and COVID-19. The list below draws out three example projects which had a specific focus on ethnicity:

- Intersections of ethnicity, gender, poverty, and mental health in adolescence in the context of COVID-19 (£320, 000) (**MS/JM/LC/24b INQ000381141**)
- Developing and delivering targeted SARS-CoV-2 (COVID-19) health interventions to Black, Asian and Minority Ethnic (BAME) communities living in the UK (£370, 000) (**MS/JM/LC/24c – INQ000381142**)
- Investigating incidence, severity and risk factors for COVID-19 in BAME and Migrant groups to inform public health action (£1.4 m) (**MS/JM/LC/24d – INQ000381143**)

Coordinating the research system

51. In relation to how the research response was coordinated, in March 2020 the Department's SRE Directorate asked the Clinical Research Network (CRN) to develop a national review and prioritisation system for COVID-19 studies across the UK. The Urgent Public Health (UPH) panel was set up to prioritise access to NIHR CRN resources for key COVID-19 projects. The aim was to ensure that during the early phase of the pandemic the CRN resources were used to support the most important projects, prevent duplication and to ensure that the capacity of the NHS to support research was not overwhelmed.

52. The UPH panel was chaired by Professor Nick Lemoine, Medical Director of NIHR CRN. Subject matter experts were invited to join UPH meetings as required. The panel had over 50 members across specialties, including patient and public contributors.

53. Once a study was designated as meeting UPH criteria, regulatory approval from the Health Research Authority (HRA) and where required the Medicines and Healthcare Products Regulatory Agency (MHRA) was expedited and access to CRN support prioritised.

54. The CRN received approximately 1,600 applications in total, with 101 studies UPH approved.

Care Quality Commission review of DNACPR orders

55. I am asked about the Department's commissioning of the Care Quality Commission (CQC) to undertake a special review of practice regarding the use of Do Not Attempt Cardio-Pulmonary Resuscitation (DNACPR) orders for COVID-19 patients.

Background to the review

56. During the early stages of the pandemic there were various communications from different sources counselling against the inappropriate use of DNACPRs.

57. There was concern that DNACPR decisions were being applied to groups of people rather than on the basis of an assessment of each individual's circumstances. The Department did not receive evidence of inappropriate and blanket use of DNACPRs. However, the Department was aware that allegations had been made. (**MS/JM/LC/24e – INQ000381137; MS/JM/LC/24f – INQ000381138; MS/JM/LC/24g – INQ000381139; MS/JM/LC/24h – INQ000381140**)

58. On 30 March 2020, the CQC, the British Medical Association (BMA), the Care Provider Alliance (CPA) and the Royal College of General Practitioners (RCGP) wrote to adult social care providers and GP practices with a joint statement on the importance of advance care planning being based on the needs of the individual. Advance care planning is a process of discussion between an individual, their family, friends, or advocates, if appropriate, and their care providers about their preferences and priorities for their future care and support. The joint statement reminded all providers that it was

unacceptable for advance care plans, with or without DNACPR form completion, to be applied to groups of people of any description **(MS/JM/LC/25 - INQ000235489**

59. On 3 April 2020, the National Director for Mental Health, the National Clinical Director for Learning Disability and Autism and the Medical Director for Primary Care wrote to all Acute Trust chief executives, Community Trust chief executives and to the Primary Care distribution list about this same issue. The letter highlighted that it was imperative that decisions regarding treatment of people with learning disabilities and/or autism were made on an individual basis (**MS/JM/LC/26 - INQ000216427**. The April 2020 letter refers to a previous letter sent by Professor Steven Powis, the National Medical Director, in May 2019 addressing the issues of learning disability, death certification and DNACPR orders. NHSE would be best placed to comment as to why that letter was issued.

60. On 7 April 2020, NHSE wrote to all NHS Trusts, Clinical Commissioning Groups (CCGs), GP practices, primary care networks and community health providers reiterating the same message (**MS/JM/LC/27 - INQ000192705)**.

61. On 29 April 2020, a pre-action protocol letter was issued to the Department regarding the lack of emergency national directions on DNACPR decisions (**MS/JM/LC/28 - INQ000339300)**. This did not progress to a judicial review as the claimant accepted an invitation to engage with the development of public-facing guidance on DNACPR.

62. On 20 May 2020, following discussions with leading thinkers from the disabled rights movement, voluntary sector organisations and specialist clinical directors, NHSEI issued a joint statement with Baroness Campbell of Surbiton, DBE, which restated that blanket application of DNACPRs "is totally unacceptable and must not happen" (**MS/JM/LC/29 - INQ000339275)**.

63. In September 2020, the Minister of State for Care, requested a submission on action being taken on the inappropriate use of DNACPRs (**MS/JM/LC/30**

- INQ000058389). The submission set out that the Department had been made aware of concerns about the inappropriate blanket use of DNACPRs. It noted the difficulties in being able to determine the scale of the problem, but nonetheless set out the various prevention plans in place, such as: revised guidance to be published by NHSEI; communications with stakeholders; the Adult Social Care Winter plan which reinforced the guidance; and pointing to powers available to CQC to raise instances of inappropriate use of DNACPR with relevant bodies, including professional regulators and to take action where registered providers are responsible.

64. An Oral Parliamentary Question was tabled for 1 October 2020 in the House of Lords to address the question of what assessment had been made of the use of DNACPRs in hospitals and nursing homes since March 2020 (**MS/JM/LC/31 - INQ000339273)**. At the debate, Lord Bethell informed the House that the Minister for Patient Safety and Mental Health would be writing to the CQC requesting that it investigate and report on DNACPR issues (**MS/JM/LC/32 - INQ000339272)**.

Commissioning of the CQC review

65. In On 7 October 2020, the Department commissioned the CQC to conduct a special review, under s48 of the Health and Social Care Act 2008, of DNACPR decisions during the COVID-19 pandemic. An interim report was published on 3 December 2020 (**MS/JM/LC/33 - INQ000235491**

The CQC's interim report

66. In the interim report, the CQC identified that:

i. There was confusion and miscommunication about the application of DNACPRs at the start of the pandemic, and a sense of providers being overwhelmed;
ii. There was evidence of unacceptable and inappropriate DNACPRs being made at the start of the pandemic;

iii. There was a quick response from multiple agencies to highlight the issue. There were differing views on the extent to which people were then (i.e., in November 2020) experiencing positive person-centred care and support in relation to the issue; and

iv. It was possible that in some cases inappropriate DNACPRs remained in place.

Subsequent communications and guidance

67. On 4 March 2021, NHSEI wrote to all CCG, Trust, and primary care leads to reiterate the position that people should not have a DNACPR on their record just because they have a learning disability, autism or both (**MS/JM/LC/34 - INQ000339282)**.

68. On 10 March 2021, NHSEI published public-facing guidance on DNACPR decisions on NHS.UK **(MS/JM/LC/35 - INQ000339118)**.

69. NHSE's 2020/2021 General Medical Services contract Quality and Outcomes Framework (QOF) guidance also included a requirement for all DNACPR decisions for people with learning disabilities to be reviewed **(MS/JM/LC/36 -** INQ000330884

The CQC's final report

70. The final report in the CQC's review of DNACPR decisions was published on 18 March 2021 (**MS/JM/LC/37** INQ000235492. The report identified that decisions made in the early stages of the pandemic, when healthcare services were under unprecedented pressure, exposed and highlighted underlying problems that were in urgent need of attention. It summarised that focus was needed on three key areas:

i. First, information, training and support: It was noted that people's experiences of DNACPR decisions varied and that the training and

support that staff received to hold these conversations was a key factor in whether they were held in a person-centred way;

ii. Second, the need for a consistent national approach to advance care planning: It was noted that there was a need for a consistent use of accessible language, communication and guidance to enable shared understanding and information sharing among commissioners, providers and the public. The report identified that many types of advance care planning were in use, each with different approaches and different types of forms and documentation. The lack of consistency could affect the quality of care received by a person; and

iii. Third, improved oversight and assurance: It was concluded that there was an urgent need for regional health and care systems, including providers, CCGs and patient representative bodies, to improve how they assure themselves that people are experiencing personalised and compassionate care in relation to DNACPRs.

71. The CQC made a number of recommendations relating to each of these three areas, identifying a lead responsible body. Those recommendations for which the Department was the lead responsible body were as follows:

- "DNACPR decisions need to be recognised as part of wider conversations about advance care planning and end of life care, and these decisions need to be made in a safe way that protects people's human rights. To do this, a new Ministerial Oversight Group must be set up to look in depth at the issues raised in our report. That group, which should include partners in health, social care, local government and voluntary community services, should be responsible for overseeing the delivery and required changes of the recommendations of this report. (*Lead responsible body: Department of Health and Social Care)*
- People, their families and/or representatives, clinicians, professionals and workers need to be supported so that they all share the same understanding and expectations for DNACPR decisions.

To do this, system partners across health and care need to work with voluntary sector organisations, advocacy services and people to establish and assure a national unified approach to policy, guidance and tools that supports a positive experience of DNACPR decisions for people. (*Lead responsible body: Department of Health and Social Care*")

72. A further recommendation was addressed jointly to the Department, NHSEI:

- "People, their families and representatives need to be supported, as partners in personalised care, to understand what good practice looks like for DNACPR decisions. This should include what their rights are and how to challenge and navigate experiences well. In addition, there needs to be positive promotion of advance care planning and DNACPR decisions, as well as a more general focus on living and dying well. To do this, there needs to be more widely publicised and accessible information available via a national campaign and in partnership with the voluntary sector and advocacy services. (*Lead responsible body: Department of Health and Social Care and NHS England and NHS Improvement")*

Formation and work of Ministerial Oversight Group

73. A Ministerial Oversight Group (MOG) was formed, with the secretariat led by officials from the Department, to oversee the delivery of the CQC's recommendations on DNACPR decisions. The terms of reference were set out in a document dated May 2021 (**MS/JM/LC/38 - INQ000339339)**.

74. The MOG brought together key bodies responsible for delivering the recommendations. It was chaired by the relevant Departmental minister, initially Nadine Dorries MP and subsequently by Maria Caulfield MP. The composition of the MOG included senior level representatives from the organisations outlined in the CQC report with responsibility for action. Membership was also extended to a range of other stakeholders:

i. The BMA
ii. The Royal College of Nursing;
iii. The Resuscitation Council;
iv. NHSD;
v. The General Medical Council; and
vi. The Local Government Association.

75. The MOG first met on 8 June 2021 and had further meetings on 20 October 2021, 9 February 2022 and 17 May 2022.

76. At the last meeting on 17 May 2022, a summary of progress was tabled which went through each recommendation, identifying the lead responsible body and setting out progress to date, along with actions that were required on an ongoing basis to ensure DNACPR decisions continue to be applied in a consistent personalised way and were recognised as part of wider conversations about advance care planning (**MS/JM/LC/39 - INQ000339341)**. Further full update papers were also provided at the 17 May meeting from each organisation responsible for delivery of the recommendations (**MS/JM/LC/40 - INQ000339340)**. NHSE is best placed to comment on the implementation of recommendations 7 and 9. All other recommendations have been implemented or continue to be implemented on an ongoing basis.

77. One of the key outputs of the MOG was the joint publication of a set of Universal Principles for Advance Care Planning, which was first published in March 2022 by a coalition of partners **(MS/JM/LC/41 - INQ000339327)**. The document – which was intended to facilitate a consistent national approach to 'what good looks like' in advance care planning in England in clear alignment with human rights law and the Mental Capacity Act 2005 – set out six high level principles for advance care planning in England, which I have been asked to list below:

1. The person is central to developing and agreeing their advance care plan including deciding who else should be involved in the process.
2. The person has personalised conversations about their future care focused on what matters to them and their needs.
3. The person agrees the outcomes of their advance care planning conversation through a shared decision-making process in partnership with relevant professionals.
4. The person has a shareable advance care plan which records what matters to them, and their preferences and decisions about future care and treatment.
5. The person has the opportunity, and is encouraged, to review and revise their advance care plan.
6. Anyone involved in advance care planning is able to speak up if they feel that these universal principles are not being followed.

78. To ensure the principles are observed in practice, the Universal Principles for Advance Care Planning were incorporated into CQC's new single assessment framework (**MS/JM/LC/42 - INQ000339328)**. This framework sets out the evidence required to demonstrate how care users' rights are being protected in relation to DNACPRs. CQC has also published new guidance to help providers manage and maintain effective oversight of DNACPR decisions.

79. In June 2023, a submission was sent to the Minister for Mental Health and Women's Health Strategy recommending that the MOG secretariat write to members to formally stand down the group. The Minister agreed with the recommendation on 4 July 2023 and communications were sent to members of the MOG on 14 July 2023, thanking them for their input and standing them down from the group.

B. The supply of ventilators and oxygen

80. I set out below my understanding as to how the Government worked with health and care system partners to optimise use of existing ventilators and

oxygen supplies while, concurrently, planning for and delivering new equipment and consumables to support COVID-19 patients' care. The Department's work in this area was led by Steve Oldfield, the Chief Commercial Officer and Director General (Commercial and Life Sciences) between October 2017 and October 2022.

Ventilators and ventilation machines

81. I am asked about the number of ventilators and/or ventilation machines that were available for patients with COVID-19 across the NHS in England as at 1 March 2020 and whether this number changed over the relevant period. I am also asked about the number of staff required per mechanically ventilated patient and the level of training required for healthcare staff to operate a ventilator or care for such patients. Finally, I am asked to comment on steps taken by the Department to increase the number or availability of ventilators and appropriately trained staff during the relevant period.

82. In general, provision of equipment to the NHS is not a responsibility of the Department. Under normal circumstances, individual NHS providers are responsible for securing the equipment they need to deliver services. During the pandemic, however, the joint DHSC/NHSEI Oxygen, Ventilation, Medical Devices and Clinical Consumables programme was set up to maintain and improve access to relevant medical equipment.

83. As to the question of the number of staff required per mechanically ventilated patient and the training requirements of the same, it is not the role of the Department to determine the detail of training requirements for NHS staff or staffing requirements. These are, therefore, matters on which NHSE is best placed to comment. While it is NHSE's role to provide operational guidance to NHS organisations, guidance on staffing requirements and requisite qualifications for working on respiratory support has been published by professional bodies, such as the Intensive Care Society (**MS/JM/LC/43 - INQ000339286)**.

Background

84. By way of background, in March 2020, NHSEI modelling, based on reasonable worst-case scenario planning assumptions, assured by SAGE, indicated that nationally the NHS could require up to 90,000 adult beds with ventilators to care for COVID-19 patients (**MS/JM/LC/44 - INQ000075664**). NHSEI consulted NHS Trusts in England in late February and early March 2020 and found that the NHS only had access to a maximum of approximately 7,400 mechanical ventilators. This included some that would not normally be used to treat adult patients in a hospital bed e.g. ventilators from ambulances and paediatric departments. (**MS/JM/LC/45 - INQ000087456**)

85. In response to the immediate need for more mechanical ventilators, the Government developed a cross-departmental approach across the following three workstreams:

    a. Increased purchasing of ventilators available in the market, for use into to the NHS;
    b. Stimulating the increased manufacture of existing ventilator designs; and
    c. Partnering designers with large manufacturers to rapidly develop and manufacture new, simplified ventilator designs.

86. Workstream a. was led by the Department and NHSEI under the National Covid Oxygen, Ventilation, Medical Devices & Clinical Consumables (O2VMD&CC) Programme. Meanwhile, workstreams b. and c., which were led by the CO, became known as the 'Ventilator Challenge'. The Department and the CO ran their programmes separately but worked towards the same overall targets and exchanged data on their progress in acquiring ventilators daily.

Ventilator Challenge

87. Given the significant expected shortfall between conventional ventilation capacity and demand, the Ventilator Challenge was created with the overarching objective to produce 30,000 new ventilation units through a combination of the three workstreams identified above alongside reallocating existing stock (**MS/JM/LC/46 -** **INQ000106234**.

88. As set out above, the Ventilator Challenge was led by the CO and key activities were undertaken by the Department for Business, Energy and Industrial Strategy (BEIS) on specification, shortlisting offers to support the building and testing of devices, and the management of relationships with partners. All ventilators to be built through the Ventilator Challenge were required to meet regulatory standards, which included assessment by the MHRA.

The O2VMD&CC Programme

89. The O2VMD&CC Programme had four phases.

Phase 1

90. Phase 1 of the Programme spanned March 2020 to May 2020. In the first few months of the pandemic, there was inevitably very limited data, given that this was a novel virus. There were many unknowns and the available information and evidence evolved over time. There was also often fierce global competition for similar products as the virus spread around the world.

91. To support the initiation of the Programme, as stated above, in late February and early March 2020, NHSEI conducted an audit of baseline capacity in NHS Trusts in England, including for ventilation and oxygen. The Devolved Administrations were also consulted.

92. Seven workstreams were initiated by the Programme involving people recruited initially from the Department and NHSEI and rapidly expanding to recruitment of staff from across Government.

93. The workstreams were as follows:

Workstream Phase 1	**Objectives Phase 1**
Oxygen Production and Distribution	Ensure sufficient Medical Oxygen is produced with prioritised distribution to NHS Trusts
Trust Medical Gas Pipeline Systems (MGPS)	Ensure availability of medical oxygen at a patient's bedside given increased demand challenging system design capacity
Conventional Procurement	Procure all available Mechanical Ventilation and allied Devices via NHS Supply Chain frameworks
ICU Consumables	Ensure all necessary ICU consumables were available to support patient care given global demand and supply disruptions
Supply Chain Management	Oversight and management of the supply chain and delivery pipeline from purchase order to delivery into NHS
Allocation Process	Institute a medically led demand management & allocation process to ensure appropriate distribution of scarce resources
Hard to Source Items	Procure products that conventional procurement routes struggled to access through direct DHSC contracts due to the extreme disruption of global supply chains

94. As regards conventional procurement, the following devices were purchased:

i. 9,000 Intermittent Positive Pressure Ventilation (IPPV);
ii. 11,000 Bilevel Positive Airway Pressure (BiPAP);
iii. 10,000 Continuous Positive Airway Pressure (CPAP);
iv. 5,000 Oxygen Concentrators; and
v. 15,000 Patient Monitors.

95. HM Treasury provided a total of £600 million to support conventional procurement, of which approximately £450 million was spent.

Phase 2

96. Phase 2 of the Programme spanned June 2020 to December 2020.With the end of the initial wave of COVID-19, renewed focus was placed on preparation for a potential winter 2020/2021 surge in COVID-19 cases.

97. The Programme workstreams continued to manage the deployment of ventilators and associated equipment across health and care, including ongoing logistics and handling requirements, appropriate storage, testing and asset management. The summer period afforded time to address the potential capacity requirements and demands associated with subsequent surges of COVID-19. Consideration was also given to the longer-term management of equipment assets and robustness of ventilator consumables availability.

98. The disrupted global supply chain made it challenging to plan the capacity and capability needed as there was significant divergence between expected and actual arrival dates of consumables and equipment that needed to be closely managed. To address these issues, the Programme focused on four themes during this phase:

i. Improving the quality and availability of devices – the Programme continued to deploy incoming devices to build capacity in the NHS. The

1,156 devices that had been borrowed from private sector organisations were returned by 30 June 2020. A long-term equipment reserve was established and used to provide additional capacity to NHS organisations and to swap out lower specification devices;

ii. Solidifying consumables system and building stockpiles – whilst the UK ended Phase 1 having secured the devices referred to in paragraph 94 (above) as well as, by 30 April 2020, 11,500 ventilators, the supply of consumables was more constrained by disruption in global supply chains. During Phase 2, the Programme established a continual shortage identification and response process. It was able to gradually increase consumable holdings;

iii. Establishing a new normal – a key focus of this phase was maintaining the connection and cooperation between the Department, NHSEI, Supply Chain Coordination Ltd (SCCL)[1] and NHS regional Emergency Preparedness, Resilience and Response and clinical leads in the allocation and management of consumables and equipment; and

iv. Reducing reliance on complex supply chain systems – this phase also focused on identifying opportunities to improve long-term resilience within the ICU consumable supply chain.

Phase 3

99. Phase 3 of the Programme spanned December 2020 to March 2021. This phase was initiated in response to the significant pressures over the winter of 2020/2021. The first challenge was to remobilise the Programme back to a seven-days per week operation and manage the highest demand experienced during the course of the pandemic.

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[1] **SCCL provides oversight and operational management for NHS Supply Chain and its service providers. SCCL is the legal entity through which NHS Supply Chain undertakes its procurement services and transacts with customers and suppliers. Its shares are owned by NHS England, but SCCL is a separate organisation.**

100. The major challenge was managing oxygen demand within hospitals. The technical position had improved since Phase 2 despite increased patient numbers due to ongoing oxygen infrastructure and management activities initiated during Phase 2.

101. As regards equipment operations, the objectives for Phase 3 were to manage the deployment of assets and to create a reserve for use as part of any future response. Key activities included:

i. Providing an equipment operations capability to handle ongoing allocation, asset management, and distribution issues;
ii. Operational management of and deep storage for devices as they were received, stored, distributed and returned;
iii. Managing the asset transfer process, primarily from the Department to NHS Trusts; and
iv. Ensuring use was made of device donations approved by Ministers;
v. Assessing opportunities for remedial action for devices that had not immediately passed all clinical appropriateness checks;
vi. Supporting other shortage response activities as appropriate; and
vii. Warehouse rationalisation – transitioning all warehouse contracts and operations to SCCL.

Phase 4

102. Phase 4 of the Programme spanned March 2021 to September 2021 during which the Department's MedTech Directorate was established to oversee key policy, stockpile issues, medical technology development, supply, and supply management issues.

103. The key activities during this phase included:

i. The completion of the transition of consumable and equipment stockpile warehousing, logistics and management to SCCL;

ii. The completion of right-sizing consumable stockpile and stock rotation processes;
iii. Data baselining and transition to core Department Management Information systems;
iv. Consolidation of oxygen policy, supplier management, consumption monitoring, contingent equipment and guidance; and
v. The extension of commercial arrangements to support ongoing resilience.

104. The O2VMD&CC Programme was closed down in September 2021, with responsibility for managing the legacy stockpile passed on to the Department's MedTech Directorate.

105. Although there is no evidence of substantial issues that were reported to the Department in relation to the availability of ventilators specifically, there was a National Audit Office report into both the CO and Department's ventilator programmes that looked at whether the urgent need for ventilators ever materialised, and if the Government, therefore, overspent on ventilators that were not needed. It concluded that the urgent need did not materialise and the overall costs of both programmes were higher than would be expected in normal times. However, it recognised that both departments maintained sufficient records of their programmes' rationale, the key spending decisions they took and the information they had to base those on. It also concluded that the departments had put in place effective programme management, controlled costs where they could and recovered some of their committed spending once it became apparent that fewer ventilators were needed than they had originally believed (**MS/JM/LC/47 - INQ000106555**).

Stock of ventilators

106. As described above, in March 2020 the NHS in England had approximately 7,400 mechanical ventilators. The Government adopted a formal UK-wide target to ensure that the UK had access to up to 30,000 mechanical ventilators, across the Ventilator Challenge and O2VMD&CC Programme,

by 30 June 2020. By 30 April 2020, the total number of mechanical ventilators available to the NHS had increased to 11,500 and by 30 June 2020, it stood at around 24,000, of which approximately 12,000 had been built via the Ventilator Challenge. The target of 30,000 was met in early August 2020.

107. During this period, the anticipated demand for ventilators in the NHS did not materialise and, although the 30,000 target was not met until August 2020, the Department is not aware of any UK patient being unable to access a ventilator when needed.

108. The numbers of ventilators physically on hand remained largely static between August 2020 and June 2022, with a slight downward trend as units were ordered piecemeal by trusts, or used for other purposes by Government, such as for overseas donation. Based on our records as at 30 May 2022, by the end of the period the stockpile still held over 30,000 ventilators of various types, with over half of these specifically being ventilator challenge machines (**MS/JM/LC/48 - INQ000339321**). The large-scale reduction to a more manageable and focused stockpile, based at around 3,000 ICU bays' worth of holdings, began in late 2022.

Other equipment to care for COVID-19 patients

109. I am asked about the availability of other equipment used to care for COVID-19 patients, including but not limited to continuous positive airway pressure (CPAP) and haemodialysis machines, and any steps taken by the Department to increase the availability of such equipment during the relevant period.

110. The O2VMD&CC Programme described above was not just focused on ventilators but on the whole system required to maintain intensive care ventilated beds to NHS clinical standards, such as oxygen systems, ventilation, medical devices and clinical consumables. The equipment and consumable stockpiles created by the Programme included a range of

patient support equipment, including patient monitors, feeding, infusion and suction pumps, humidifiers, syringe drivers and related consumables.

111. In addition to the 30,000 mechanical ventilators, the Department also built-up supplies of non-invasive ventilators (e.g. CPAPs) over this period. Although no individual targets were set for non-invasive ventilation, the National Audit Office (NAO) reported that by July 2020, the NHS had 27,700 non-invasive ventilators and CPAP machines, including up to 17,800 purchased by the Department since March 2020 (MS/JM/LC/45 - INQ000339270).

112. From mid-2021 through to early 2023, the reserve maintained core holdings capable of supporting 3,000 ICU beds for a period of up to six weeks – a level sufficient to meet the need similar to that seen in January 2021, when demand was at its peak. By March 2022, the reserve had allocated over 55,000 pieces of equipment to 194 NHS Trusts across England, with a further 10,000 devices going to the Devolved Administrations and Crown Dependencies. Around 4,000 pieces of equipment have been donated as international aid, including packages to Peru, India, Nepal, Zimbabwe and Ukraine.

Portable oxygen supplies and medical gas pipeline systems

113. I am asked for details of any major incidents relating to portable oxygen supplies or medical gas pipeline systems in acute hospital Trusts during the relevant period and any steps taken by the Department in response.

114. The Department was aware of an incident at Watford General Hospital on 4 April 2020 that highlighted the need to better understand trust oxygen infrastructure and to work more closely with the oxygen suppliers. The hospital had declared a critical incident as their oxygen system was suffering significant performance issues, including a pressure drop. The O2VMD&CC Programme worked with the relevant oxygen supplier and advised the hospital on adjusting their system settings and considering the appropriate

load which the system could carry – the trust's clinical teams will then have determined how best to provide safe and high-quality care to their patients within the resources available to them. Croydon Hospital faced a similar issue, and received advice of a similar nature. Both hospitals had engineers visit their facilities to tune their systems to get the best out of the infrastructure.

115. Consequently, an alert was issued through the MHRA Central Alerting System **(MS/JM/LC/48a – INQ000371235; MS/JM/LC/48b – INQ000269927; MS/JM/LC/48c – INQ000269928 MS/JM/LC/48d – INQ000269929** reminding trusts of guidance in relation to appropriate management of bulk oxygen systems. The aim was to make sure that trusts were more proactive in managing their systems.

116. Following an urgent upgrade of Watford General Hospital's bulk oxygen system, the National Oxygen Infrastructure Programme (NOIP), which was supported by NHSE, delivered further upgrades to NHS trust bulk oxygen systems. These occurred through 81 projects over five waves. Further information about NOIP can be obtained from NHSE.

117. The Department was not, however, responsible for recording major incidents declared by Trusts relating to oxygen supplies; NHSE may hold information relevant to this request.

118. The Department proactively worked with oxygen suppliers to better understand the oxygen supply position before NHS trusts got into difficulty. Suppliers provided data to the Department on oxygen supply to help understand pressures that might be building in the system. This included data on:

    i. Bulk oxygen that is piped through the hospital's medical gas pipeline system to wards, and
    ii. Cylinder oxygen in a range of physical cylinder sizes which are portable.

119. The supply data was a proxy measure to alert us to potential issues – it did not indicate that the trust had an oxygen incident. DHSC would then work with NHS England to understand the local position of individual trusts and deploy support as required.

120. The Department monitored various datasets, including oxygen supplier data, and took action accordingly, for example, contacting trusts that appeared to have a high flow rate versus their capability and deploying support in response, such as the provision of oxygen concentrators or oxygen regulators, additional deliveries of bulk or cylinder oxygen, or working through the steps required to improve the efficiency of the bulk oxygen system (**MS/JM/LC/48e – INQ000371238**).

121. Other ways that the Department worked closely with suppliers included:
    - Agreements for military drivers to conduct oxygen deliveries and maintain oxygen supply to hospitals in the event that oxygen suppliers had driver shortages due to sickness, and
    - Maintain a higher level of supply to Vacuum Insulated Evaporators (VIEs), the tanks that store liquid 'bulk' oxygen at hospital sites, which were typically at 35% of capacity during business-as-usual times. At the height of pandemic surges, the Department agreed with suppliers to fill them to 80%, then dropping to 50% as coming out of the peak and then back down to 35% after the surge ended to increase energy efficiency.

122. As set out in brief above, securing oxygen production and distribution was one of the key workstreams established during Phase 1 of the O2VMD&CC Programme. The objective was to ensure that sufficient medical oxygen was produced and distributed to NHS Trusts, ensuring the prioritisation of oxygen for medical use. This was achieved by the following key activity:

    i. Bulk oxygen supplier liaison enabled intelligence to be collected and risks to be identified and mitigated.

ii. Close working with the Ministry of Defence (MoD) ensured the readiness of a 24/7 operation, resulting in extra drivers undertaking training and tankers being converted for medical gas transportation.

iii. Control of cylinder allocation and distribution helped to manage and prioritise the demand alongside monitoring the flow of oxygen.

iv. Education and communication were provided on oxygen management and engagement across the health sector, including prisons, mental health, home oxygen and Nightingale COVID-19 units.

v. Contingency stocks were established, in excess of demand, and operational processes implemented to manage contingency plans within the oxygen supply chain.

vi. Forward planning ensured readiness for potential future surges, for example, closely working with gas providers to ensure that NHS Trust VIEs remained at increased levels.

vii. In response to specific local issues, several alerts and guidance materials were developed and issued.

Oximeters

123. A pulse oximeter is a small medical device that is put on the tip of the finger, to check oxygen levels. Pulse oximeters typically work by shining a light into the skin and measuring how this is absorbed by the blood to estimate how much oxygen is present. Pulse oximetry can help with the detection of low oxygen levels in the absence of other indicators such as the significant shortness of breath and help ensure more timely hospital treatment.

Accuracy of oximeters

124. I am asked whether the Department is aware of any evidence that the accuracy of oximeter readings may vary depending on the skin pigmentation of the patient and/or any assessment to ascertain whether patients with darker skin might be disproportionately affected by the provision of oximeters that did not provide accurate readings. I am also asked whether the

Department is aware of the effect of an inaccurate oximeter reading due to darker skin.

Concerns over pulse oximetry and racial bias

125. Questions have been raised about the accuracy of pulse oximeters in detecting oxygen saturation levels in people with darker pigmentation and skin tones. On 26 March 2021, MHRA published guidance entitled 'The use and regulation of pulse oximeters (information for healthcare professionals)' (**MS/JM/LC/49 -** **INQ000283587**. The guidance suggested that it is possible that patients with lighter skin may have small differences in the result reported when compared to those with darker skin. Skin colour was identified as just one of the factors that can alter the result produced, amongst other factors such as low perfusion, movement, and tattoos. The guidance noted that the relative change in a patient's reading may be of greater significance to clinical management than the absolute value and that the MHRA was not aware of any incidents where skin colour had had an adverse effect on the use of pulse oximeters when providing effective clinical care.

126. In March 2021, NHS Race and Health Observatory (RHO) published a rapid review entitled 'Pulse oximetry and racial bias: Recommendations for national healthcare, regulatory and research bodies' **(MS/JM/LC/50 -** **INQ000249826**.

127. The review identified that "*There is a growing body of evidence…that pulse oximetry is less accurate in darker skinned patients. Given the increased mortality amongst ethnic minority patients during the Covid-19 pandemic, it is possible that the differential accuracy of pulse oximetry is a contributing factor to this health inequality*". The review identified four recommendations:

i. An urgent review of pulse oximetry medical products used in the United Kingdom. The review suggested that this should be conducted by the MHRA to assess the accuracy of pulse oximeter readings in ethnic minority patient groups.

ii. Identification of suitable parameters to identify hypoxia (low oxygen levels in tissues). The review noted that it is possible for patients to present with severe hypoxaemia (low oxygen levels in blood) in the absence of dyspnoea (difficult or laboured breathing). It identified that the appropriateness of clinical signs for ethnic minority patients should be reviewed by critical care and respiratory academic groups and NHSEI. It identified that there may be a need to readjust thresholds for seeking care for ethnic minority groups.

iii. Review of all medical equipment and devices. The review recommended that all medical equipment and devices should be assessed for suitability of use with ethnic minority patients, as well as with the majority population. It was suggested that this should be sufficiently evidenced by manufacturers before devices receive market approval.

iv. Further research. The review recommended that further research in this area, with larger and more diverse populations, should be a priority for research bodies such as the NIHR to consider.

NIHR research

128. Given the concerns raised in the NHS RHO rapid review, NHSEI asked the NIHR to support further research. The NIHR's Health Technology Assessment (HTA) Programme commissioned research on the diagnostic accuracy of pulse oximeters. More specifically, the NIHR commissioned a study on the following question: "*What is the diagnostic accuracy of different pulse oximeters at oxygen saturation levels (Sp02) relevant to their use by patients at home and how does this vary in people with darker pigmentation and skin tones?*". The study is due to finish in September 2024 (**MS/JM/LC/50a – INQ000371239**).

Equity in medical devices independent review

129. Separately, in November 2021 the Department announced that it would be launching an independent review to consider and advise government on potential bias in items like oxygen measuring devices and the impact on

patients from different ethnic groups (**MS/JM/LC/51** - **INQ000339289**). The announcement noted that there were concerns that the way in which medical devices and technologies were designed could mean that a patient's diagnosis and treatment is affected by their gender or ethnic background, exacerbating existing inequalities in healthcare.

130. In February 2022, it was announced that Professor Dame Margaret Whitehead would lead the review (**MS/JM/LC/52** - **INQ000339329**) which would be carried out by a panel of clinicians and academics with expertise in health inequalities and equity in diagnostic and artificial intelligence tools. The panel members were Dr Raghib Ali, Professor Enitan Carrol, Professor Chris Holmes and Professor Frank Kee (**MS/JM/LC/52** - **INQ000339329**).

131. Terms of Reference for the review were finalised in April 2022 (**MS/JM/LC/53 - INQ000339294**), which identified the purpose of the review as establishing the "*extent and impact of potential ethnic and other unfair biases in the design and use of medical devices and to make recommendations for more equitable solutions*". The Terms of Reference identified the following questions, which the panel would attempt to answer:

i. How far reaching is the problem?
ii. Where medical devices do not function equally well for all ethnic groups, is the scale of this difference of clinical significance, and could it cause adverse health outcomes for some ethnic groups?
iii. What could be done to mitigate such adverse outcomes?
iv. How effective are any such mitigations?
v. What further action should be taken to address these issues?

132. The Terms of Reference also identified that the review would make recommendations in relation to preventing potential ethnic and other inequalities related to the design and use of medical devices, including unintended or implicit bias. These recommendations would cover:

i. How to address potential ethnic and other unfair biases, including through a whole system approach – from design to use?
ii. What role could and should regulation play in removing identified bias?
iii. What systems need to be in place to ensure emerging technologies, including software, artificial intelligence and genomics-based tools as medical devices are developed without inbuilt ethnic and other unfair biases?
iv. How can the UK drive forward international standards to improve healthcare and promote equity in medical devices?

133. The review was completed by the independent panel and submitted to government in June 2023. It has been reviewed in detail and work is ongoing with system partners to finalise the government response to the review. Both the review and the government response are expected to be published in winter of 2023/24.

Oximetry at home

134. I am asked, in relation to the roll out of COVID Oximetry at home, to explain how and why the decision was taken to provide the service and to set out a brief summary of the service. I am further asked to set out any guidance given as to which patients should be eligible for the service and any analysis of the effectiveness and safety of this service, including the impact on the patient, the providers of primary and secondary care and any financial impact.

135. The Oximetry@home service was established by NHSEI as part of the NHS response to COVID-19. Its intention was to support people at home who had been diagnosed with COVID-19 and were at most risk of becoming seriously unwell (including those with symptoms who are aged 65 years or older, or under 65 years old and in a group identified as at higher risk from COVID-19 or whose clinicians considered their individual risk factors warranted support from the scheme). NHSE is best placed to respond to questions about the

operational implementation, including costs, of the scheme, but I have set out some information below.

Background

136. As stated above, home pulse oximetry uses a small device to monitor and record blood oxygen. Silent hypoxia is when a pulse oximetry check on a patient who does not appear short of breath results in an oximetry finding lower than a physician would expect. It was hoped that as treatment of COVID improved, earlier detection of silent hypoxia at home could help reduce mortality and hospital length of stay, potentially also freeing up critical care beds.

137. In November 2020, NHSEI recommended that all CCGs put in place the COVID at home model as quickly as possible as an important emerging part of the NHS response to the pandemic. The model was based on patient self-monitoring of oxygen levels.

138. Funding to establish the scheme and maintain it until the end of March 2022 was included in a ring-fenced General Practice Covid Capacity Expansion Fund of £150 million described in a letter that NHSEI sent to CCGs, GPs and general practice teams on 9 November 2020 (**MS/JM/LC/54 - INQ000058907**).

139. In a further letter to all CCG accountable officers (AOs), CCG Chairs and Community Provider CEOs NHSEI set out its recommendations on establishing an Oximetry@home model in more detail (**MS/JM/LC/55 - INQ000339278**).

140. The estimated implementation costs for full roll out of the Oximetry@home programme were £24.4 million to March 2021. Subsequent funding was provided through 2021/22 via primary care Covid Capacity Funding. Following this, the Oximetry@homeprogramme would have moved into

business as usual and the operational and financial process would have continued to be handled by NHSE.

The model and eligible patients

141. NHSEI's letter of 12 November 2020 recommended that as eligible patients presented at NHS services with COVID-19, they should be offered an NHS oximeter to monitor their own oxygen levels three times a day, for up to a fortnight.

142. Patients provided with oximeters were given the following advice:

    i. To go to hospital or call 999 if their oxygen level was 92% or lower; or
    ii. To call their GP surgery or 111 if the level is 94% or 93%.

143. Through a shared decision-making conversation, patients would also be given the option of receiving a regular prompt to check their oxygen levels with the oximeter at days 2, 5, 7, 10 and 12. They could choose to receive the prompt by text message, e-mail, or phone call.

144. At the end of the fortnight, a friend, family member or an NHS Volunteer Responder could collect and return the oximeter to the NHS for decontamination and reuse.

145. The letter made clear that there was evidence that those who would benefit most from Oximetry@home would be patients with:

    i. A diagnosis of COVID-19: either clinically or through a positive test result; and who are also
    ii. Symptomatic and were either:
    - Aged 65 years or older; or
    - Under 65 years and clinically extremely vulnerable to COVID-19.

Analysis of the effectiveness and safety of the service

146. NHSEI are best placed to comment on the effectiveness and safety of this service, including the impact on the patient, the providers of primary and secondary care and any financial impact.

147. Steps taken by the Department in launching an independent review to consider and advise government on potential bias in items like oxygen measuring devices and the impact on patients from different ethnic groups are set out in paragraphs 129 – 133.

C. NHS 111

Use of NHS 111

148. I am asked whether there was a specific policy to direct people with COVID-19 symptoms to contact 111 rather than attending at the Accident and Emergency department or their general practitioner, and if so, whether any patient safety concerns were raised regarding this shift in policy, and how successfully such concerns were mitigated.

149. NHS 111 is an established part of the NHS infrastructure and is a successor to NHS Direct. The service is intended to make it easier and quicker for patients to get the right advice or treatment they need and is available 24 hours a day, 7 days a week. The service is intended for urgent but not life-threatening issues and complements the 999 ambulance service.

150. There was a specific approach taken to direct the public to 111 for advice, either through 111 Online or the NHS 111 telephone service.

151. For example, on 1 March 2020 the Secretary of State made a statement about the government's approach **(MS/JM/LC/56 - INQ000339343)**. In this he encouraged people to *"follow clinical advice by calling NHS111 rather than going to A&E if you develop symptoms."* This was also set out through

the Central Alerting System (a web-based cascading system for issuing patient safety alerts, public health messaging, critical safety information and guidance) from the CMO and NHSE to NHS services.

152. NHSE has published a summary of the additional services that were established alongside NHS 111 as part of the response to the demand caused by COVID-19 (**MS/JM/LC/56 - INQ000339343**). This publication sets out the following information about NHS 111 COVID-19-related response services, which I have been asked to repeat here. NHSE is best placed to provide further information on additional services, such as the SCAC Clinical Safety Net and the CCAS:

- 582,240 calls were handled by the Public Health England Helpline between February and June 2020. The PHE Helpline was set up to provide information to patients relating to the coronavirus outbreak from February to June 2020;
- 1.53 million calls handled by Covid Response Centres during March to June 2020, October 2020 to March 2021 and in January 2022. Covid Response Centres (CRS) were set up to triage calls from patients who were experiencing symptoms relating to the coronavirus outbreak. Patients were transferred to these services after calling NHS 111. These were in operation from 5 March to 10 June 2020, from 5 October 2020 to 23 March 2021 and from 19 to 27 January 2022;
- 159,940 calls handled by the South Central Ambulance Service (SCAS) Clinical Safety Net between March 2020 and June 2020. Calls taken by a CRS from 5 March to 10 June 2020 that required further triage by a clinician were sent to the SCAS Clinical Safety Net;
- 559,850 calls handled by the Covid-19 Clinical Assessment Service (CCAS) during April 2020 to May 2021 and January to March 2022. CCAS was a further service set up to take calls requiring clinical input from the CRS. CCAS was operational from 1 April 2020 to 23 May 2021 and from 6 January 2022 to 31 March 2022; and
- 41,020 calls handled by the Repeat Prescription Service between February and March 2022. The Repeat Prescription Service was in

operation between 15 February and 31 March 2022 to alleviate pressure on NHS 111 services. Patients needing repeat prescriptions were transferred to this service after calling NHS 111.

153. On 2 March 2020 a new 111 Online service was put in place to help people experiencing COVID-19 symptoms.

154. While DHSC were involved in communicating the message asking people with Covid-19 symptoms to contact NHS111 rather than attend A&E or their general practitioner, the Department would not have been directly involved in commissioning these new services and their operation, which was the responsibility of NHS England.

155. Effective patient triage and the provision of effective clinical assessment are key elements of ensuring patient safety through NHS111 services. Non-clinical NHS111 call handlers are supported by the NHS Pathways clinical decision support system, which provides systematic and evidence-based triage of callers based on the symptoms they report when they call. Further, a range of NHS clinicians such as paramedics, nurses with specialist experience, mental health professionals, pharmacists, dental professionals, and senior doctors are available to speak to callers who need it via NHS 111's Clinical Assessment Service. For example, in September 2023 43.8% of triaged NHS111 calls were clinically assessed by this service.

156. In April 2020, a specialist COVID Clinical Assessment Service was established to support the COVID Response Service. This was commissioned nationally by NHSE and managed by South Central Ambulance Service NHS Foundation Trust. Prior to its establishment, callers who required further assessment were transferred to NHS111.

157. A Healthcare Safety Investigation Branch (HSIB) investigation published in September 2022 considered NHS111's response to callers with COVID-19 related symptoms during the pandemic (**MS/JM/LC/57 - INQ000320204**). This found evidence that the routing of all COVID-19 related calls to the

COVID Response Service did not function as intended, and shortcomings in the assessment and management of callers to the service with respect to referral for clinical assessment and the consideration of comorbidities. It included two safety recommendations for NHSE, one on contracts reflecting requirements for audio-recording calls, and another on reviewing the risks of increasing use of telephone triage for national healthcare emergencies. NHSE responded that future contracts will meet the minimum requirements for audio-recording calls and undertook to review risks with partners to improve the response to future emergencies.

D. Infection Prevention Control Guidance Formulation

158. I am asked whether infection prevention and control (IPC) in healthcare settings during the relevant period was primarily a matter for individual Trusts and primary care providers, or whether they were provided with national or regional guidance that they should follow. I am further asked about the involvement of the Department in the formulation of infection prevention and control measures within healthcare settings during the relevant period. I am further asked for details of any advice or guidance provided by the Department to prevent patients receiving treatment for non-COVID conditions in secondary care settings from contracting COVID-19, including the use of COVID-light surgical hubs, green pathways, Same Day Emergency Care clinics and community diagnostic hubs.

159. I am also asked about the extent of the involvement of the Department during the relevant period in the formulation of guidance regarding the use of PPE in the healthcare system, including which roles were designated as 'frontline' staff. I am asked for the details of any guidance issued by the Department that explained or mandated what forms and standards of PPE should be used by workers in both primary and secondary healthcare settings. I am asked how that guidance changed during the relevant period.

160. The guidance referred to below was not formulated by the Department. As set out in more detail below, the process by which it was formed was initially

with technical insight through PHE, who prepared initial guidance in consultation with clinicians and other professionals and based on available scientific evidence. Operational guidance would then be issued by NHSE for use in all healthcare settings under its governance. Each trust would then review the guidance and implement it according to local risk assessments. The Department does not itself provide advice or issue guidance to patients. However, to assist the Inquiry I have set out my understanding of the process by which guidance was created, providing examples where possible, as available to the Department. I have given key instances of published and revised guidance of particular relevance to the Department (for example for informing the supply of PPE) and for the NHS in making key organisational decisions.

161. IPC in healthcare settings seeks to minimise the potential for infectious disease spread.

162. The need to keep staff safe is an employer competency underpinned by the Health and Safety Act 1974 and regulated by the Health and Safety Executive (HSE). For CQC registered providers, providers are required to ensure that care and treatment is provided in a safe way, including in relation to IPC (see, regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) and must have due regard to the Code of Practice relating to healthcare associated infections (Health and Social Care Act 2008: code of practice on the prevention and control of infections) issued by the Secretary of State under section 21 of the Health and Social Care Act 2008. (**MS/JM/LC/58 - INQ000130549**; **MS/JM/LC/59 - INQ000339344**). Accordingly, the prevention of nosocomial infection, i.e., infection originating in the hospital or healthcare facility, to staff and patients is a core function of NHS.

163. Protection of staff and patients from nosocomial infections within the NHS is informed by local IPC policies. Individual providers base these policies on standardised best practice national guidance created by NHSE infection control specialists then use risk assessments to reflect the local potential for

infection transmission to provide targeted mitigations to control that specific risk. During the relevant period scientific expertise on infection risk was provided by PHE and later UKHSA to the IPC Cell which was overseen by NHSE (see below for detail) and which created guidance for the NHS and other healthcare settings.

164. IPC guidance and mitigations are based on the Health and Safety Executive's (HSE) 'Hierarchy of Controls'. In order to protect against risks, HSE guidance (**MS/JM/LC/60 - INQ000339330**) states that these controls should be considered in the following order, from the most effective, to the least effective:

i. Elimination – physically remove the hazard
ii. Substitution – replace the hazard
iii. Engineering controls – isolate people from the hazard
iv. Administrative controls – change the way people work
v. PPE – protect the worker with equipment

165. Following the emergence of COVID-19, PHE published national guidance on 16 January 2020 **(MS/JM/LC/14 - INQ000339104)** - classifying the virus as a High Consequence Infectious Disease (HCID), which meant that any suspected cases would be managed as inpatients in a small number of fully equipped specialist centres around the country. HCIDs are acute infectious diseases, typically with a high case fatality rate requiring an enhanced individual, population and system response to ensure they are managed effectively, efficiently and safely. This guidance was directed at NHS infection control specialists and NHS providers to allow them to make appropriate IPC and operational arrangements. Patients were initially expected to be managed in specialist infectious disease centres pending characterisation of the virus. Accordingly, patient care demanded a higher level of PPE to be worn by all personnel in the room, including: FFP3 respirator masks; fluid-repellent disposable gowns; gloves with long tight-fitting cuffs; disposable surgical caps; and eye protection. With minor

iterations, this secondary care guidance remained in place until the 6 March 2020

166. On 21 January 2020, IPC guidance for primary care **MS/JM/LC/19 - INQ000339106** was published by PHE. The focus was on safely managing infection control should a patient with suspected COVID-19 be identified in a primary care setting. On 25 February 2020, the guidance was updated to include PPE specific advice in the event of unavoidable patient contact; gloves, an apron and a fluid resistant surgical mask (Type IIR) were advised.

167. I am aware of a subsequent series of IPC publications collaboratively formulated by NHSE (including input from NHS bodies from Wales, Scotland and Northern Ireland and PHE), (UK IPC Cell) during the relevant period and published on behalf of the IPC Cell by Public Health England (and later UKHSA). The Department was not involved in the formulation of these publications. Department officials, on occasion, attended UK IPC Cell meetings, but did not participate in the making of guidance. The guidance set the relevant standards and the guidance was followed by the Department at all times, informing its related functions. For example, the level of PPE that the IPC Cell deemed necessary directly impacted the amount of PPE the health and care system required and, therefore, the Department's procurement and distribution efforts. The guidance also informed operational decision-making by the NHS to mitigate nosocomial risk, such as hospital reorganisation to separate COVID-19 from non-COVID-19 patients. Set out below are the most consequential updates.

168. On 28 January 2020, the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) first discussed COVID-19 PPE requirements and guidance. It concluded that the PPE recommendations previously formulated for pandemic influenza were acceptable for use.

169. On the 6 March 2020, IPC guidance for secondary care received a significant revision to the PPE required for clinical contacts which I have summarised in the table below (**MS/JM/LC/62 - INQ000339345**; **MS/JM/LC/63 -**

INQ000339346; **MS/JM/LC/64 - INQ000339347**; **MS/JM/LC/65 - INQ000339348**). The rationale for the change was that: "As we move from the containment phase, changes have been made to ensure that healthcare workers are protected and all hospitals remain safe, now and in the future. Therefore, different personal protective equipment (PPE) and mask and respirator combinations are being recommended now for different clinical scenarios and settings; this includes consideration of the infection status (confirmed versus possible cases) and the risk of exposure to aerosols containing the virus stated that the risk-based approach and recommendations had been reviewed and approved by experts including NHSEI, PHE and NERVTAG.

Patient type	Change in guidance
For symptomatic, unconfirmed in-patients meeting the COVID-19 case definition	PPE revised to include a change from FFP3 respirator mask to fluid resistant surgical mask, gloves, apron and eye protection if risk of splashing into the eyes.
For confirmed cases of COVID-19	Full PPE ensemble continues to use FFP3 respirator mask, disposable eye protection, preferably visor, long sleeved disposable gown and gloves.
For possible and confirmed cases of COVID-19 requiring an aerosol generating procedure	Full PPE ensemble as per previous guidance for confirmed cases: FFP3 respirator mask, disposable eye protection, preferably visor, long sleeved disposable gown and gloves.

170. On the 13 March 2020 IPC guidance received a further significant revision to the respiratory PPE required **(MS/JM/LC/66 - INQ000325350)**. It stated that NERVTAG recommended airborne precautions (wearing an FFP3) be

implemented at all times in clinical areas considered Aerosol Generating Procedure (AGP) hotspots such as ICU's. In other areas Type IIR surgical masks are recommended for all staff for close patient contact (within 1 metre), unless performing an AGP when an FFP3 respirator mask should be worn. A table of the recommendations was contained within the document:

Table 1: Transmission based precautions (TBPs): Personal protective equipment (PPE) for care of patients with pandemic COVID-19

	Entry to cohort area (only if necessary) no patient contact*	General ward *	High risk unit ICU/ITU/HDU	Aerosol generating procedures (any setting)
Disposable Gloves	No	Yes	Yes	Yes
Disposable Plastic Apron	No	Yes	Yes	No
Disposable Gown	No	No	No	Yes
Fluid-resistant (Type IIR) surgical mask (FRSM)	Yes	Yes	No	No
Filtering face piece (class 3) (FFP3) respirator	No	No	Yes	Yes
Disposable Eye protection	No	Risk assessment	Risk assessment (always if wearing an FFP3)	Yes

*Personal protective equipment (PPE) for close patient contact (within 1 metre) also applies to the collection of nasal or nasopharyngeal swabs.

171. On 19 March 2020, having assessed further evolving information, including fatality rates, the UK public health agencies declassified COVID-19 to no longer be an HCID (**MS/JM/LC/67 - INQ000106267**).

172. On the 2 April 2020, IPC guidance was updated to include tables describing recommended PPE use across different clinical scenarios and settings "in a period of sustained community spread of COVID-19". Close contact distance was increased from 1 metre to 2 metres. This update included a table, extending guidance on the wearing of PPE to "direct patient care/assessment within 2 metres of an individual not currently a possible or confirmed case" subject to a local risk assessment. (**MS/JM/LC/68 - INQ000339139[2]; MS/JM/LC/69 - INQ000339138[3]; MS/JM/LC/70 - INQ000339137[4]; MS/JM/LC/71 - INQ000339349[5]; MS/JM/LC/72 - INQ000325351[6]; MS/JM/LC/73 - INQ000117824 [7]; MS/JM/LC/74 - INQ000080939 [8]**)

173. The rationale for the IPC guidance being updated is given as: "This guidance has been updated to reflect pandemic evolution and the changing level of risk of healthcare exposure to SARS-CoV-2 in the UK. It is recognised that in contexts where SARS CoV-2 is circulating in the community at high rates, health and social care workers may be subject to repeated risk of contact and droplet transmission during their daily work. It is also understood that in routine work there may be challenges in establishing whether patients and individuals meet the case definition for COVID-19 prior to a face-to-face assessment or care episode."

174. On the 12 June 2020, IPC guidance was updated to include a requirement for face masks of at least Type I grade, (i.e. of clinical grade, as opposed to

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[2] MS/JM/LC/68 - INQ000339139 – gov.uk webpage – Guidance: Introduction and organisational preparedness
[3] MS/JM/LC/69 - INQ000339138 - gov.uk webpage – Guidance: Transmission characteristics and principles of infection prevention and control
[4] MS/JM/LC/70 - INQ000339137 – gov.uk webpage – Guidance: Personal Protective Equipment (PPE);
[5] MS/JM/LC/71 - INQ000339349 - Recommended PPE for healthcare workers by secondary care inpatient clinical setting, NHS and independent sector;
[6] MS/JM/LC/72 - INQ000325351 - Recommended PPE for primary, outpatient and community care by setting, NHS and independent sector;
[7] MS/JM/LC/73 - **INQ000117824** - Recommended PPE for ambulance staff, paramedics, first responders, other patient transport services and pharmacy staff;
[8] MS/JM/LC/74 - **INQ000080939** - Additional considerations, in addition to standard infection prevention and control precautions)

a homemade face covering,) to be worn by NHS staff, patients and visitors in secondary care. (**MS/JM/LC/75- INQ000339234)** On the 25 July this was expanded to primary and community settings. (**MS/JM/LC/76 - INQ000339265)**

175. On the 1 June 2021, the IPC Cell published a guidance update emphasising the hierarchy of controls and the potential need for enhanced respiratory protection informed by risk assessment where an unacceptable risk of transmission remains. (**MS/JM/LC/77 -** **INQ000271659**

176. On 14 April 2022, NHSE first published a national IPC manual (NIPCM) for England (**MS/JM/LC/78 - INQ000339296[9]).** Publication of the NICPM originates from a pre-pandemic commitment in the UK five-year national action plan on antimicrobial resistance published in January 2019 that the Scottish NICPM would be adopted in England as national standards. The NICPM was published to support and facilitate healthcare providers to demonstrate compliance with the code of practice on the prevention and control of infections and related guidance required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 **(MS/JM/LC/96 - INQ000339325)**.

177. I am aware that the Department facilitated an internal, independent review of the IPC Cell, identifying lessons to be learned. This was produced at the request of the IPC Cell after it was stood down and after the publication of the national IPC manual. The output of this review also contains the cell's Terms of Reference **(MS/JM/LC/97 - INQ000339322)**.

E. Personal Protective Equipment

[9] The Inquiry made a request for the Department to produce the IPC manual as a single document, rather than in sections that were initially provided as 18 separate exhibits. Therefore, the exhibit references from MS/JM/LC/79 to MS/JM/LC/95 are therefore no longer referred to in the statement, and it is correct that the next exhibit is MS/JM/LC/96.

178. Prior to the pandemic NHS and Social Care were responsible for their own procurement of PPE as with other supplies. SCCL, a Government owned company, trading as NHS Supply Chain, was one provider of PPE and other supplies and held circa 80% of the NHS PPE Market. Private sector wholesalers supplied Social Care and Primary Care. A stockpile of PPE (the PIPP stockpile) was held centrally to support the system in the event of a pandemic. It became clear early in the pandemic amidst a global scramble for PPE, that the existing system would not be able to meet the demand. Therefore, the Government set up a centralised buying and distribution system – the Parallel Supply Chain - to secure the necessary PPE and deliver it to the frontline. A joint PPE Cell was established drawing on DHSC, NHS, Cabinet Office, MOD and Armed Forces personnel to run the Parallel Supply Chain. Private Sector logistics experts were brought in to support this effort. Clipper Logistics, Royal Mail, eBay, Volo and Unipart were engaged to develop the necessary warehousing and distribution operation and the development of new approaches to supply of PPE to smaller providers through the PPE portal. These arrangements remained in place throughout the pandemic.

179. I am asked about the stock levels of PPE in the healthcare system as at 1 March 2020, and the nature of any guidance in existence at that time regarding the use of PPE by healthcare workers and those working in healthcare settings. I am further asked for an explanation of the process by which individual hospital and ambulance Trusts and primary care providers could access PPE and request additional PPE. I am also asked whether and how these processes changed during the relevant period. I am further asked whether the Department was made aware of any shortages of PPE in healthcare settings in England and any steps that the Department took to address the issue.

180. I am aware that the Department has received a further R9 request for a future module in relation to its approach to procurement and supply of PPE. In addition to the below, therefore, I expect this topic to be expanded upon at a later date.

PPE supply prior to the formation of the Parallel Supply Chain

181. There are a number of medical consumable items which are collectively termed "PPE" for use in health care settings. Within the NHS under standard IPC guidance, the only items of PPE used in significant volumes are gloves and aprons.

182. Medical masks can be either Type I, Type II or Type IIR. Collectively, these are known as surgical masks. The key difference between Type II and Type IIR masks is the addition of a fluid repellent barrier between the wearer and the environment.

183. Higher-grade respiratory protection will at times have been required to manage local or seasonal outbreak and infectious disease control requirements, in line with relevant IPC guidance. Globally, where it is appropriately recommended for Face Filtering Class respirators to be used, FFP2 respirator masks are most commonly advised. The filtration these provided is classed as 95% effective. In the UK a higher grade of respirator masks, an FFP3, has regularly been advised by HSE. This has a 99% filtration effectiveness.

184. Before the pandemic, NHS trusts procured their own PPE alongside other supplies. One of their options was NHS Supply Chain, trading as Supply Chain Coordination Limited (SCCL), at that time a Department-owned company. It held 56% of the NHS medical consumables market and circa 80% of the NHS PPE market by volume. Primary care and social care providers also procured their own PPE through private wholesalers or directly from suppliers. NHS Supply Chain did not supply to Adult Social Care (ASC) providers nor primary care. **MS/JM/LC/98 - INQ000339261)**

185. The NHS PPE market in England was estimated at circa £146 million in 2019 of which £61M was procured through NHS Supply Chain (**MS/JM/LC/99 - INQ000057714**).

186. PHE maintained Pandemic Influenza Preparedness Programme (PIPP) stockpiles, which included PPE in preparation for an influenza outbreak. It was designed to provide sufficient stock to protect UK health and care staff responding to a reasonable worst-case scenario influenza pandemic. PHE also held pre-existing contracts for delivery of PPE to be triggered if required to meet demand on the PIPP stockpile. A table of relevant PPE within the PIPP stock as at 18 February 2020 is given below.

Product type	**PIPP quantity available in hand**
Face Masks IIR	66,978,600
FFP3 Respirator masks	2,031,670
Aprons	119,059,000
Clinical Waste Bags	2,972,025
Eye Protection	25,679,430
Gloves	83,195,200
Surgical Gowns	0
Hand Hygiene (litres)	436,680

187. The Department had been advised by NERVTAG in 2019 to augment the PIPP stockpile with gowns for use as PPE for aerosol generating procedures in an influenza pandemic. The market analysis was being finalised prior to commencing the procurement exercise which was planned for early 2020. In light of the COVID-19 outbreak the focus shifted to procuring gowns for immediate distribution to the NHS and social care.

188. PHE used NHS Supply Chain to maintain the PIPP stockpile. NHS Supply Chain contracted with Movianto, a private sector warehousing contractor, to store the PIPP stockpile and provide logistics for distribution if required.

189. As mitigation against possible EU Exit supply chain issues on 31 January 2020, the Department had asked NHS Supply Chain to build a 6-week medical consumable buffer stock at normal usage rates, as set out at

paragraph 12 of the National Audit Office report dated 27 September 2019. (**MS/JM/LC/100 - INQ000339101**)

Initial Response

190. On 30 January 2020, NHSEI Incident response requested the convening of a Supply Chain Cell (the Cell) to manage product supply issues as part of the response to the emerging COVID-19 situation, and preparations in the UK. The Cell involved key stakeholders from the Department, NHSEI, PHE, NHS Supply Chain, MHRA and devolved government counterparts. (**MS/JM/LC/101 - INQ000339115**)

191. In relation to PPE supply, the Cell acted as the main decision-making forum in relation to new sourcing, inventory management and stock allocation, working under policy direction from the Department and established delegated authorities vested in PHE for the management of the pandemic influenza stockpiles Advice was provided by NHSEI on operational requirements and demand.

192. The Cell considered product already within the NHS Supply Chain network to support business-as-usual (i.e., typical use for pre-pandemic times) supply, stockpiles put in place for EU Exit and the stock held within the PIPP stockpiles.

193. The first official Cell meeting took place on 3 February 2020, with meetings held daily through to 12 March 2020 when they were replaced by the Department's governance structures working towards the rollout of the parallel supply chain. (**MS/JM/LC/102 - INQ000339268**)

194. During this period, NHS Supply Chain was reporting increased volumes of orders for PPE and other consumables as NHS Trusts sought to prepare themselves in line with the IPC guidance. As Trusts found their normal

wholesale suppliers less able to source the items they needed, they increasingly turned to the NHS Supply Chain. Similarly, PHE was receiving requests for support obtaining PPE from primary and social care providers.

195. At the first Cell meeting on 3 February 2020, PHE reported they had activated a pre-existing arrangement to purchase of 6.8 million FFP3 respirator masks for delivery from 28 February 2020 onwards to augment the PIPP stock. (**MS/JM/LC/102 – INQ000339268).** They also reported that the PIPP stock contained a quantity of masks which had passed their expiry date, however they were working with the manufacturer to explore if these could be safely deployed subject to appropriate testing.

196. At this meeting NHSE and PHE were also asked to produce realistic, worst-case 'escalation' scenarios to inform impact on demand for product and activation of the PIPP stockpile. A commentary on the development of COVID-19 demand modelling continues throughout the minutes of the Cell's meetings. (**MS/JM/LC/103 - INQ000339116)**

197. On 5 February 2020 permission was given from the Department for NHS Supply Chain to use the EU Exit stockpile to help meet the increased demand for medical consumables.

198. On 7 February 2020, NHS Supply Chain was asked by the Department to focus additional procurement on six specific areas of requirements: body bags; clinical waste bags; Type IIR face masks; FFP3 respirator masks; general purpose detergent; and gowns. (**MS/JM/LC/103 - INQ000339116**)

199. On 8 February 2020, NHS Supply Chain received delegated authority to place orders necessary for NHS supply without the need for the direct approval of an authorising officer from the Department (**MS/JM/LC/104 - INQ000339114**). This was extended to orders for primary and social care on 12 February 2020.

200. During the 17 February 2020 Cell meeting, NHS Supply Chain reported they had "significantly increased orders" on the six priority PPE category types: body bags; fluid resistant surgical masks; gowns; FFP3 respirator masks, general purpose detergent; and clinical waste bags. Lead times were, however, varied and they expressed concern over the ability of suppliers to fulfil orders. (**MS/JM/LC/102 - INQ000339268**)

201. At the same meeting, NHS Wales reported an inability to source FFP3 respirator masks from the manufacturer 3M. NHS Supply Chain reported they had placed an order for five million 3M masks across a range of sizes with expected delivery in four weeks to build the national contingency stock position. These were to be made available across the four nations.

202. At the 19 February 2020 Cell meeting, NHS Supply Chain placed an order limit on FFP3 respirator masks for secondary care based on business-as-usual ordering levels. **(MS/JM/LC/105 - INQ000339163)** During the preceding weeks, FFP3 demand was reported to have increased significantly (from 87k to 286k per week) as trusts made preparations. There was concern that if these orders were not managed, it would impact the ability to respond appropriately to any approaching increased demand due to COVID-19. Trusts were advised to raise supply issues through the NHS Emergency Preparedness Resilience and Response liaison. NHS Supply Chain placed similar order limits on Type IIR masks from 24 February 2020 and eye protection from the 26 February 2020. **(MS/JM/LC/102 - INQ000339268).**

203. On 20 February 2020 a four nations supply strategy meeting was held. This discussed the stock position of the four nations. The 17 February face mask order from 3M was discussed. 3M were unable to meet delivery of a portion of the order. The remaining 3.7 million masks were expected for delivery from the end of March over 8 weeks. **(MS/JM/LC/106 - INQ000339164)**

204. At the end of February 2020, the UK Embassy in Beijing was mobilised to support the identification of, and dialogue with, prospective new suppliers for PPE, as it became increasingly clear that demand could not be met solely

from established suppliers of PPE. Securing the requisite volumes, however, was impossible in a context where global demand was far outstripping global supply.

205. By 27 February 2020, the World Health Organisation (WHO) acknowledged the acute global shortage of PPE. On 3 March 2020, in response to the shortage of PPE endangering health workers worldwide, WHO issued a call for industry and governments to increase manufacturing by 40 per cent. However, acute global supply issues persisted. One effect of this was that countries banned exports of PPE, such as France and Germany who were two of the first to implement this policy. They banned exports of PPE on 3 March 2020. China announced additional restrictions on exports at the end of the month, effective from 1 April 2020.

206. During this period, the Cell discussed a series of PPE contract concerns by NHS Supply Chain and PHE. On 28 February 2020, Valmy, the manufacturer tasked with producing 6.8 million FFP3 respirator masks for the PIPP stock replenishment, reported an inability to fulfil the order as planned. They revised the order down to 130,000 per week from mid-March and at a higher price per unit. Similarly, the NHS Supply Chain and wholesalers were reporting increasing difficulty sourcing PPE. For example, on 19 February 2020, NHS Supply Chain reported they had confidence in the delivery of a total of 374,000 FFP3 respirator masks by 21 February 2020, from the company. (**MS/JM/LC/107 - INQ000339338)**. On 3 March 2020, NHS Supply Chain reported "no confidence in delivery" for an order from Valmy. On 17 March 2020, NHS Supply Chain was informed that the initial delivery of 130,000 Valmy FFP3 respirator masks for the PIPP stock could not be delivered due to export restrictions in France. **(MS/JM/LC/108 - INQ000339127)**

207. It is estimated that between 1 January 2020 and 24 February 2020, approximately 326 million items of PPE were distributed. **(MS/JM/LC/98 - INQ000339261)**

208. On 3 March 2020, the Secretary of State was made aware that NHS Supply Chain had introduced demand management measures to prevent over-ordering of stock and was planning to release PIPP stock to maintain continuity of supply. The submission contained a table showing the overall stock position on 3 March 2020 **(MS/JM/LC/109 - INQ000339119; MS/JM/LC/110 - INQ000339121; MS/JM/LC/111 - INQ000339120; MS/JM/LC/112 - INQ000339122)**, which also set these figures against the PIPP target. It highlighted areas of particular concern, such as the significant undersupply of gowns; then at 2% of the PIPP target. FFP3 stock was also a concern given the large volume of masks in the PIPP stock requiring testing, though these would be deployable subject to this. The figures also excluded stock held by individual NHS organisations as this information was not available to the Department. Another table set out that, at current rate of demand, there were 1.44 weeks of supply remaining for FFP3 respirator masks, 1.09 weeks for eye protection, 1.38 weeks for Type IIR masks and 12.09 weeks for gowns. This estimate excluded deploying the PIPP stock as support.

COVID-19 PPE STOCK DATA / PROJECTIONS, AND ADEQUACY RATINGS

Product Type	A. Available in UK and deployable [1]	B. Available in UK and deployable subject to clearance (PIPP quantity for testing) [1]	C. On order and confirmed delivery date [1]	D. On order but unconfirmed delivery date (at risk) [1]	E. Reasonable Worst Case Stock Position (RWCSP) [2] (A)	F. RWCSP + Orders with Confirmed Delivery Date (A + C)	G. Best Case Stock Position [3] (A+B+C+D)	H. PIPP target (EACH)	I. RWCSP % of PIPP target	J. RWCSP + Confirmed Orders % of PIPP target	K. Best Case % of PIPP target
Body Bags	23,257	0	10,250	18,655	23,257	33,507	52,162	NA	NA	NA	NA
Clinical Waste Containers	44,645	0	13,706	0	44,645	58,351	58,351	NA	NA	NA	NA
Face Masks FFP2	171,075	0	128,000	0	171,075	299,075	299,075	NA	NA	NA	NA
Fit Test (full kits)	231	0	311	0	231	542	542	NA	NA	NA	NA
Fit Test (solutions)	1,344	0	5,688	0	1,344	7,032	7,032	NA	NA	NA	NA
Pulse Oximetry	903	0	830	0	903	1,733	1,733	NA	NA	NA	NA
Swabs	103,075	0	90,425	0	103,075	193,500	193,500	NA	NA	NA	NA
Clinical Waste Bags (Yellow)	2,200,025	0	4,456,100	0	2,200,025	6,656,125	6,656,125	420,450	523%	1583%	1583%
Gloves	453,506,280	0	627,149,800	0	453,506,280	1,080,656,080	1,080,656,08	120,561,000	376%	896%	896%
Hand Hygiene- liquid hand soup and alcohol hand rub (litres)	892,852	0	121,164	0	892,852	1,014,016	1,014,016	398,319	224%	255%	255%
Eye Protector	25,723,146	0	8,352	93,600	25,723,146	25,731,498	25,825,098	25,969,800	99%	99%	99%
Apron	139,840,700	0	19,230,600	135,125	139,840,700	159,071,300	159,206,425	158,089,200	88%	101%	101%
Clinical Waste Bags (Orange)	7,125,550	0	4,855,400	0	7,125,550	11,980,950	11,980,950	9,144,775	78%	131%	131%
Face Masks IIR	67,864,825	87,001,200	7,538,300	0	67,864,825	75,403,125	162,404,325	197,886,000	34%	38%	82%
General Purpose Detergent / Environmental Cleaner (litres)	9,933,936	0	826,944	0	9,933,936	10,760,880	10,760,880	72,000,000	14%	15%	15%
Face Masks FFP3	2,415,950	26,266,260	3,935,270	829,710	2,415,950	6,351,220	33,447,190	22,777,800	11%	28%	147%
Gowns	377,680	0	425,835	0	377,680	803,515	803,515	19,340,700	2%	4%	4%

1. Data represents EACH unless otherwise stated
2. Reasonable Worst Case Stock Position is just the stock Available in UK and Deployable
3. Best Case Stock Position includes all in the reasonable worst case and also On Order but unconfirmed delivery date (at ris

Data shows that in comparison to the PIPP stock targets, there is **significant undersupply of Gowns and Face Masks (IIR and FFP3).**

RAG Key:
- Green = >95%
- Amber = 75% - 95%
- Red = <75%

DEMAND FOR PPE ITEMS HAD INCREASED RAPIDLY IN THE LAST FEW WEEKS (PPE CHANGE IN AVERAGE WEEKLY DEMAND)

Product Type	Weeks cover in NHSSC + EU Exit BAU Demand	Weeks cover in NHSSC + EU Exit Current Demand
Face Masks FFP2	19.83	8.68
Clinical Waste Bags (Orange)	6.27	6.21
Swabs	6.54	6.54
Apron	4.56	4.35
General Purpose Detergent	15.27	14.56
Gloves	10.20	9.72
Clinical Waste Containers	4.51	4.04
Body Bags	12.36	10.53
Gowns	14.83	12.09
Hand Hygiene	7.00	5.47
Pulse Oximetry	6.95	4.97
Clinical Waste Bags (Yellow)	4.58	4.16
Face Masks IIR	2.35	1.38
Eye Protector	4.93	1.07
Fit Test (full kits)	90.33	2.69
Face Masks FFP3	4.40	1.44
Fit Test (solutions)	14.93	2.49

RAG Key:
- Green = > 6 weeks
- Amber = 2 – 6 weeks
- Red = < 2 weeks

This data shows the increase in demand by comparing the weeks of cover at current demand levels with the average BAU demand over the historical pre-coronavirus period. This shows that stock is decreasing significantly more quickly for the majority of products with particular pressure on those towards the bottom of the table (Face Masks and Fit Test Solutions, as would be expected).**It is anticipated that demand will only increase in the coming weeks.** Therefore it is expected that BAU and Current demand both giving overestimates for the number of weeks cover for all products.

209. The Department did not hold any information on the stock held by NHS providers. Trusts had been encouraged by IPC guidance to make preparations by reviewing their PPE availability, but the impact of this was not known. The Department planning at this point assumed that Trusts would have built up a three-week buffer stock, as actual use would be negligible in the absence of sustained community spread of the virus.

210. IPC guidance published on 6 March 2020 required the use of gowns as well as FFP3 respirator masks when performing aerosol generating procedures. **(MS/JM/LC/113 - INQ000339123)** Evidence of medical care for COVID-19 emerging from China and Italy showed that the need for aerosol generating ventilatory support was considerable, including in ward-based settings as well as in intensive care and high dependency units. This was reflected in the 13 March IPC revision, a major change to IPC guidance which directly impacted on the model, and therefore purchase patterns, as it considerably increased the demand in acute settings. **(MS/JM/LC/66 - INQ000325350)**

211. The supply issues for gowns from this guidance change were compounded by the fact that the PIPP stock did not contain gowns, as well as the fact that gowns had previously been used in low volumes in the NHS. This meant that pre-existing supply chains were inelastic, consistently dealing in low volume, and local stockpiles were likely relatively low.

212. During March 2020, the Cell worked to support the NHS, wholesalers and community providers with releases from the PIPP stock. On the 8 March PHE authorised NHS Supply Chain via Movianto to distribute PPE from the PIPP stockpile on an ongoing basis via business-as-usual routes: that is moving it into NHS Supply Chain warehouses for distribution directly to NHS trusts and selling it to private wholesalers for distribution to ASC and primary care providers. **(MS/JM/LC/114 - INQ000339171)**

213. Direct distribution was also undertaken. On 3 March 2020 there was a push of 2.15 million Type IIR facemasks, 2.87 million aprons and 4.31 million gloves to 6,830 GPs from PIPP stockpiles, utilising DPD Logistics to assist

them to meet PPE guidance requirements. On 9 March 2020, there was a further push of 574,000 Type IIR facemasks, 2.29 million aprons and 2.29 million gloves to 11,480 community pharmacies and 7.57 million Type IIR Facemasks to 25,245 Care Homes, Home care providers and Hospices on 13 March 2020.

National Supply Distribution Response

214. On 16 March 2020, the Department, in response to supply chain distress, activated the National Supply Distribution Response (NSDR). This had been developed as part of our contingency planning for EU Exit. Providers with an immediate and urgent need for PPE – those at risk of running out of stock within 72 hours, which could not be remedied through other channels – could call the hotline to secure emergency supplies. On 21 March 2020, the NSDR hotline was expanded to a 24-hour service, providing around the clock emergency support. This helpline was available to support requests from all four nations and the Crown Dependencies. **(MS/JM/LC/115 - INQ000339335)**

215. NSDR had three core functions to support delivery of emergency PPE:

i. Operate a 24/7 helpline for providers who had an urgent requirement for medical products, including PPE. Call handlers would log details into a system that automatically prioritised cases in line with the information provided. The helpline's call volumes broken down by phases of the Department's response to the pandemic (based on waves and related restrictions) were (**MS/JM/LC/115a – INQ000371237**):
   - January 2020 to the end of July 2020 = 36,277 (The NSDR call centre was operational from 16th March 2020 and call volumes were not recorded until 23rd March 2020)
   - August 2020 to end of July 2021 = 7,690
   - August 2021 to 24 February 2022 = 355

ii. Provide a case management function. The case management team accessed the cases directly via the system and worked through them in

a prioritised process. This process involved triangulation of data including, for example, deliveries recently received by the organisation, the volumes requested and expected time of delivery.

iii. Co-ordinate an express freight desk solution. Once the case was reviewed and approved by the case management team, the freight desk was instructed to pick, pack and deliver an allocation of PPE to the provider. Once a delivery was received, the NSDR case was closed.

216. NSDR did not have access to the full lines of stock held at other large wholesalers or distributors but was used to mobilise small priority orders of critical PPE to fulfil an emergency need.

Parallel Supply Chain

217. The increase in requirement for PPE and the severe supply chain disruption made it clear that NHS Supply Chain's business-as-usual processes of PPE procurement and distribution was not able to meet demand and, therefore, any decentralised purchase of PPE should be discontinued; it was vital that domestic providers were not competing against one another for supply.

218. On 14 March 2020 the Department formally requested assistance from the Ministry of Defence.

219. My first involvement in PPE began on 18 March 2020 when I chaired a PPE policy meeting involving colleagues across DHSC, PHE and NHSEI.

220. On 19 March 2020 NHS Supply Chain moved to distributing PPE from the PIPP Stockpile to secondary care on a "push" basis. That is, initially all Trusts were "pushed" the same types of PPE at the same rate. There was a lack of information on local requirements but it was important that a steady supply of vital PPE continued to be delivered.

221. On 21 March 2020 CO staff were deployed to seek how best to augment PPE procurement and distribution. The initial leadership team was Emily

Lawson the NHSEI National Director for Transformation and Corporate Development who was acting as head of the newly formed PPE cell, Andrew Wood from the Complex Transactions Team of the CO and Brigadier Phillip Prosser from the Army's 101 Logistics Brigade who had been seconded to the PPE Cell to act as a technical advisor on the distribution of PPE. I was asked to join Emily Lawson as the Department lead for the PPE cell and Parallel Supply Chain.

222. On 1 April 2020, a 'Parallel Supply Chain' was established, bringing together staff from the Department, CO, NHSE&I, NHS Supply Chain, the Ministry of Defence and Unipart Logistics. **(MS/JM/LC/222 – INQ000339262)** A cell of over 400 staff, including Government procurement specialists, was established to create a centralised, Government-backed buying effort on the international market. As Module 5 is examining procurement decisions, including those for PPE, I will not focus on the procurement activities of the PPE Parallel Supply Chain in this statement except where relevant to the supply of PPE to the NHS. The impact of this effort was the procurement of 39.2 billion items of PPE for distribution to the health and care sector.

223. By creating a Parallel Supply Chain, the Government aimed to address not only the problem of securing supply, but also the challenge of distributing that supply to over 58,000 health and social care settings in the UK.

224. To ensure we had visibility across the programme, to allow informed decision making and to allow decisions to be easily cascaded we established a clear daily rhythm to manage the programme. Initially a daily priority call at 8.30am (I first attended on 2 April 2020) which was used to understand the supply and demand position and to set priorities and actions. This was later split into two meetings with a daily 18:00 "allocation meeting" being established in addition to the daily 8:30am update (I first attended the 18:00 meeting on 11 April 2020). The 18:00 allocation meeting looked at the very latest information on demand across the system, our inventory, and the expected incoming supply. The meeting was used to take daily decisions on the volume of PPE to be distributed to the NHS and other users. This daily review

of demand and supply also allowed us to agree a "Priority Buy List" to give guidance to the buying teams on which items we had the greatest need for. The following exhibits are daily PPE briefings spanning a date range of 17 April 2020 to 30 June 2020. (**MS/JM/LC/116 - INQ000339150; MS/JM/LC/117 - INQ000339155; MS/JM/LC/118 - INQ000339156; MS/JM/LC/119 - INQ000339158; MS/JM/LC/120 - INQ000339160; MS/JM/LC/121 - INQ000339162; MS/JM/LC/122 - INQ000339166; MS/JM/LC/123 - INQ000339167; MS/JM/LC/124 - INQ000339168; MS/JM/LC/125 - INQ000339172; MS/JM/LC/126 - INQ000339175; MS/JM/LC/127 - INQ000339177; MS/JM/LC/128 - INQ000339178; MS/JM/LC/129 - INQ000339180; MS/JM/LC/130 - INQ000339182; MS/JM/LC/131 - INQ000339184; MS/JM/LC/132 - INQ000339185; MS/JM/LC/133 - INQ000339186; MS/JM/LC/134 - INQ000339188; MS/JM/LC/135 - INQ000339191; MS/JM/LC/136 - INQ000339193; MS/JM/LC/137 - INQ000339194; MS/JM/LC/138 - INQ000339195; MS/JM/LC/139 - INQ000339197; MS/JM/LC/140 - INQ000339198; MS/JM/LC/141 - INQ000339201; MS/JM/LC/142 - INQ000339204; MS/JM/LC/143 - INQ000339203; MS/JM/LC/144 - INQ000339207; MS/JM/LC/145 - INQ000339209; MS/JM/LC/146 - INQ000339211; MS/JM/LC/147 - INQ000339212; MS/JM/LC/148 - INQ000339213; MS/JM/LC/149 - INQ000339216; MS/JM/LC/150 - INQ000339218; MS/JM/LC/151 - INQ000339223; MS/JM/LC/152 - INQ000339228; MS/JM/LC/153 - INQ000339230; MS/JM/LC/154 - INQ000339233; MS/JM/LC/155 - INQ000339237; MS/JM/LC/156 - INQ000339242; MS/JM/LC/157 - INQ000339243; MS/JM/LC/158 - INQ000339247; MS/JM/LC/159 - INQ000339250; MS/JM/LC/160 - INQ000339252; MS/JM/LC/161 - INQ000339256; MS/JM/LC/162 - INQ000339259; MS/JM/LC/163 - INQ000339141; MS/JM/LC/164 - INQ000339142; MS/JM/LC/165 - INQ000339143; MS/JM/LC/166 - INQ000339144; MS/JM/LC/167 - INQ000339146; MS/JM/LC/168 - INQ000339148; MS/JM/LC/169 - INQ000339149; MS/JM/LC/170 - INQ000339151; MS/JM/LC/171 - INQ000339157; MS/JM/LC/172 - INQ000339159; MS/JM/LC/173 - INQ000339161; MS/JM/LC/174 - INQ000339165; MS/JM/LC/175 - INQ000339169; MS/JM/LC/176 - INQ000339170;**

MS/JM/LC/177 - INQ000339173; MS/JM/LC/178 - INQ000339174; MS/JM/LC/179 - INQ000339176; MS/JM/LC/180 - INQ000339179; MS/JM/LC/181 - INQ000339181; MS/JM/LC/182 - INQ000339183; MS/JM/LC/183 - INQ000339187; MS/JM/LC/184 - INQ000339190; MS/JM/LC/185 - INQ000339192; MS/JM/LC/186 - INQ000339196; MS/JM/LC/187 - INQ000339202; MS/JM/LC/188 - INQ000339206; MS/JM/LC/189 - INQ000339208; MS/JM/LC/190 - INQ000339210; MS/JM/LC/191 - INQ000339214; MS/JM/LC/192 - INQ000339215; MS/JM/LC/193 - INQ000339217; MS/JM/LC/194 - INQ000339219; MS/JM/LC/195 - INQ000339220; MS/JM/LC/196 - INQ000339221; MS/JM/LC/197 - INQ000339222; MS/JM/LC/198 - INQ000339225; MS/JM/LC/199 - INQ000339224; MS/JM/LC/200 - INQ000339226; MS/JM/LC/201 - INQ000339227; MS/JM/LC/202 - INQ000339229; MS/JM/LC/203 - INQ000339231; MS/JM/LC/204 - INQ000339232; MS/JM/LC/205 - INQ000339235; MS/JM/LC/206 - INQ000339240; MS/JM/LC/207 - INQ000339239; MS/JM/LC/208 - INQ000339241; MS/JM/LC/209 - INQ000339244; MS/JM/LC/210 - INQ000339246; MS/JM/LC/211 - INQ000339245; MS/JM/LC/212 - INQ000339248; MS/JM/LC/213 - INQ000339249; MS/JM/LC/214 - INQ000339251; MS/JM/LC/215 - INQ000339253; MS/JM/LC/216 - INQ000339255; MS/JM/LC/217 - INQ000339254; MS/JM/LC/218 - INQ000339258; MS/JM/LC/219 - INQ000339257; MS/JM/LC/220 - INQ000339263; MS/JM/LC/221 - INQ000339262).

225. The management effort of the PPE Cell was focused on those items in most short supply. Papers from the 18:00 allocations meeting show the attention paid to gowns, FFP3 and IIR masks in this early period and the priority that was placed on securing further supply of these products, while building our stock position across the range of PPE required.

226. Further major changes to IPC guidance on 2 April 2020 advised a risk assessment on the use of PPE for all episodes of care. This change in guidance created the most significant increase in demand and placed additional pressure on PPE supplies, as it included the potential requirement

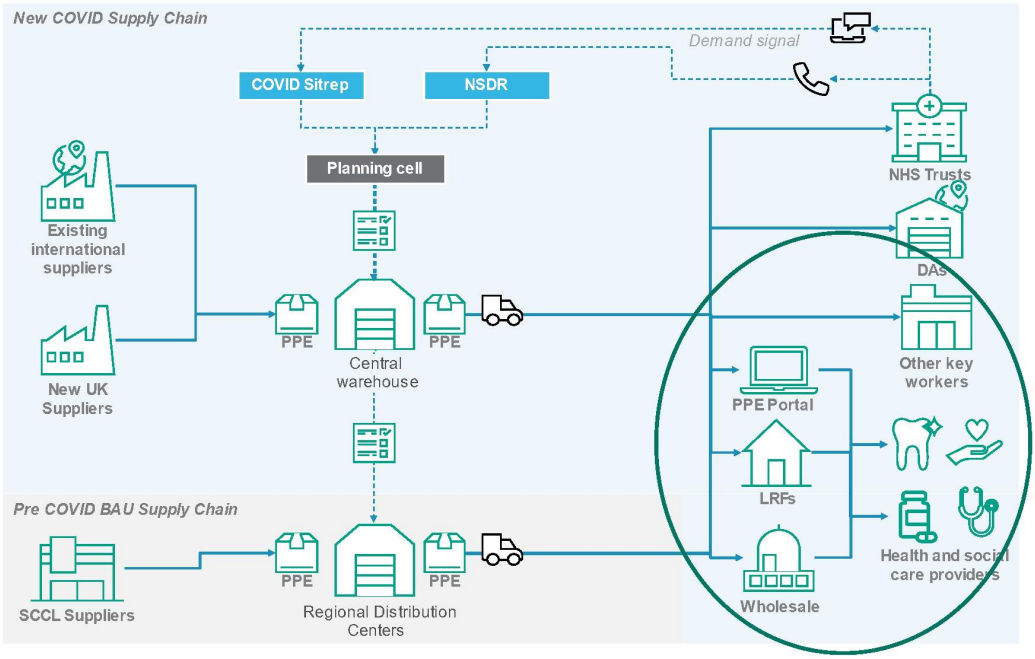
to wear Type IIR masks, gloves and aprons at all times for all episodes of care. There was a caveat in the guidance that PPE could be used on a sessional basis, in some circumstances, rather than changing it between each patient.

227. On 10 April 2020, the Department published a PPE Plan setting out procurement and supply activities – focusing on "guidance, distribution and future supply." (**MS/JM/LC/222 - INQ000050008)**. The document set out the IPC guidance as updated on 2 April 2020 and the activities of the PPE parallel supply chain.

228. Over the course of April 2020, our most acute concerns were over the supply of gowns, FFP3 and IIR masks. The priority buy list also included gloves and aprons in this period. FFP2 masks were considered as a viable alternative to FFP3 masks on the basis of the WHO guidance which already advised the use of FFP2 masks in parallel settings to where we would advise the use of FFP3s (e.g. whilst performing AGPs), as well as on the basis of published guidance on 2 April 2020 from Public Health England ("COVID-19 personal protective equipment (PPE)") which also confirmed that FFP2s could be used as substitutes for FFP3s where they are not available: "The HSE have stated that FFP2 and N95 respirators (filtering at least 94% and 95% of airborne particles respectively) offer protection against COVID-19 and may be used if FFP3 respirators are not available."

Parallel Supply Chain: PPE Distribution

PPE Distribution: System



229. NHS trusts had existing supply chain links and so received direct distribution from NHS Supply Chain warehouses and/or Parallel Supply Chain warehouses, as set out in the above diagram **(MS/JM/LC/223 - INQ000339189)**

230. Continuing the approach begun on 19 March, NHS providers were initially allocated and "pushed" national stock based on predicted demand. Early modelling was based on reasonable worst-case scenarios (RWCS) for the virus, from SAGE, and our understanding of how much PPE would be required in those scenarios.

231. We were concerned about the ability for smaller providers to access PPE. We had already supported wholesalers and provided direct deliveries of PPE. In addition, for primary care, social care, and NHS community-based

services (such as dentistry and community pharmacy), the Department worked with the Ministry of Housing, Communities and Local Government (MHCLG) to engage the network of 37 Local Resilience Forums (LRFs) to create a further temporary emergency channel for supply and to coordinate response to local supply issues. This was beneficial as it would have been inefficient to attempt to supply small providers such as GPs in the same ways as organisations. The LRFs acted as hubs for onward distribution of stock with large volumes pushed to the LRF for onward distribution. The first push through LRFs began on 6 April and at the peak of demand in April 2020, when over 35 million items of PPE were delivered to LRFs in a single week.

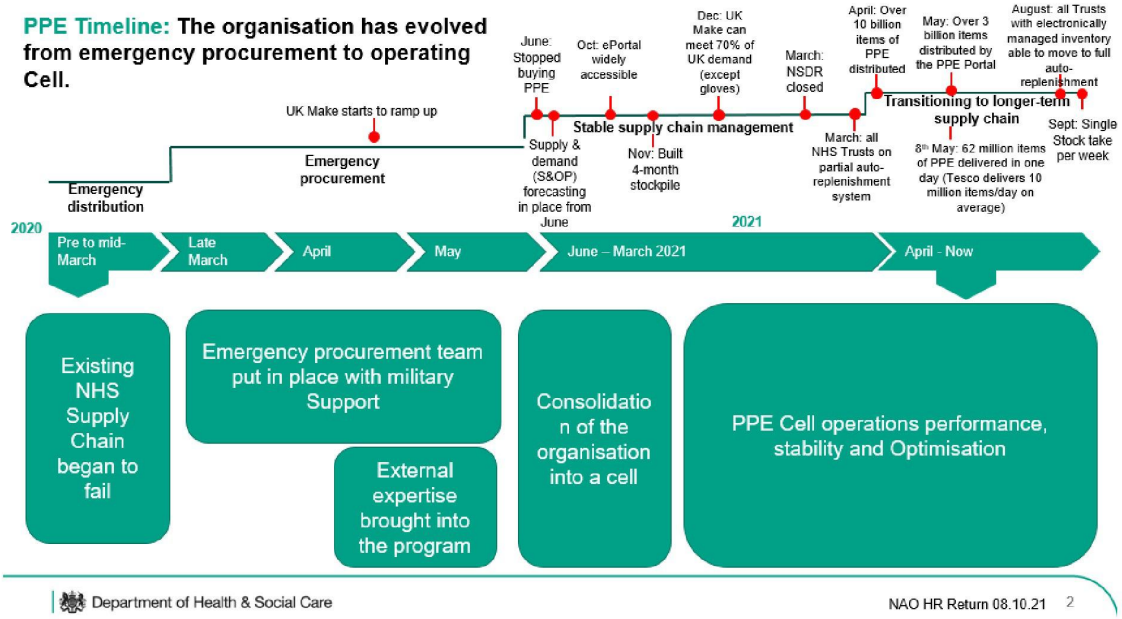
232. On 9 April 2020, the Department started the pilot phase of a PPE Supply Portal (the Portal). The Portal was established as an online platform, developed and delivered through the Department partnering with eBay, Clipper Logistics, Royal Mail, the NHS, Volo, and Unipart to be an 'emergency top-up system' of PPE for providers, specifically for COVID-19 needs. It took over from LRFs as the route of distribution for primary care, community providers and ASC.

Stabilising PPE supply

233. From mid-May 2020 onwards, the Department began to receive information on stock positions from NHS Trusts, initially from the London area. This information enabled distribution to be tailored to Trusts' existing stock position rather than being pushed stock irrespective of their actual stock levels.

234. Stabilising PPE supply and delivery was one of the five key tests set by the Government in consideration of relaxing the first lockdown. At the 21 May 2020 meeting with the PM, Lord Deighton reported that he was confident that supply over the next 90 days would meet newly modelled demand. He confirmed that, overall the PPE test was being met, in that operational challenges were now in hand with supply able to meet future demand.**(MS/JM/LC/224 - INQ000339205)**

235. In Early June 2020 a supply and demand planning process was established, adopting industry Sales and Operational Planning (S&OP) principles. This covered the entire process from forecasting of demand to distribution of the products, and ensured the building and maintenance of a stockpile which could confidently meet PPE needs across a range of scenarios. The process also provided much better visibility of inventory and spend, driving efficiencies and ensuring the right amount of PPE was delivered to end providers at the right time.



236. Once we were confident we had sufficient PPE supplies on order to create a 4 four-month supply stockpile in mid-June 2020, the purchase of most categories of PPE was halted. The dates buying was halted for each type of PPE were:

PPE ITEM	INSTRUCTION TO STOP BUYING
All Critical PPE	
Eye Protection	16 June 2020
Hand Hygiene	18 June 2020
Type IIR facemasks	24 June 2020
Clinical Waste Bags	26 June 2020
Aprons	26 June 2020
Gloves	26 June 2020
Gowns	29 June 2020
FFP3 Respirator masks	30 June 2020

237. By the end of June 2020, most eligible GPs and smaller ASC providers were able to register with the Portal with all community and care settings being granted access by September 2020. As additional need for PPE was identified, providers were registered with the Portal. For example, in September 2021 vaccination centres were able to source their PPE via the Portal.

238. On the 14 September 2020, with PPE supply stabilised and the rollout of the portal, ongoing LRFs were stood down in some areas and their function replaced by Local Authorities. A total of 637 million items were distributed via LRFs and Local Authorities by 31 March 2023. **MS/JM/LC/225 - INQ000339145; MS/JM/LC/226 - INQ000339353**

239. On 28 September 2020, the PPE Strategy was published, reiterating the offer of free PPE until the end of March 2021. **MS/JM/LC/227 - INQ000339271**The Strategy set out how the Government was moving beyond the emergency COVID-19 response and towards building stability and resilience. This would be achieved through having a clearer view of demand, developing a more resilient and diverse supply chain, and building up stockpiles. Amongst other

things, the strategy outlined the steps already taken to establish a strong domestic supply base through 'UK Make' and the creation of a four-month stockpile to cope with any future surge from December 2020.

240. In the PPE Parallel supply chain's first year to 24 February 2021, 8.49 billion items of PPE were distributed predominantly for use by health and social care services in England, compared with approximately 2.04 billion items distributed in 2019.

241. On 12 February 2021, it was reported to Minister Jo Churchill that 50,686 providers were registered to obtain their PPE through the Portal. **(MS/JM/LC/228 - INQ000339281).**

242. From 25 February 2020 to 2023, the Department distributed 27.1 billion items of PPE, predominantly for use by health and social care services in England. 10.6 billion items were distributed via the Portal.

243. I acknowledge that individual staff reported shortages of PPE and that in the early stages of the pandemic there were points where stock in certain areas was extremely low. However, in their report, "The Supply of PPE During the COVID-19 Pandemic" (**MS/JM/LC/99 - INQ000057714)**, the National Audit Office reported that all of the NHS providers consulted were always able to get what they needed in time. I think it important to note in relation to these individual reports, that there would always have been further localised logistical complications on a micro level within trusts and health and care settings themselves, that were beyond the reach of the Department or the supply chains set out in this statement.

244. The management of supply was returned to NHS Supply Chain fully from 31 March 2023. The Department will continue to supply free PPE to health and care providers, including via the Portal, until March 2024 or until stocks are depleted. **(MS/JM/LC/229 - INQ000339355).**

Parallel Supply Chain Governance

245. During the relevant period governance of the PPE Cell and Parallel Supply Chain evolved. I have already set out the tempo of twice daily decision-making meetings which served as an initial senior leadership forum.

246. On the 27 March 2020 there was the first meeting of a PPE oversight board with membership drawn from DHSC, PHE and NHSE. The board reported to the DHSC Reasonable Worst Case Scenario Oversight Board.

247. On 29 March 2020, a PPE Supply and Demand Report was presented to the Prime Minister. This set out the current understanding of supply and demand, measures taken to mitigate supply issues and the current status of the PIPP stockpile. **(MS/JM/LC/230 - INQ000339131)**

248. On 1 April 2020 PPE Other Government Department (OGD) Forum was established including membership from MoJ, FCO, DfE, MHCLG, HO, MOD, CO, DA's, DHSC, NHSE and PHE.

249. Initial cross-departmental ministerial governance was via Health Ministerial Intergovernmental Group (HMIG) meetings. PPE was discussed at the 2 April 2020 HMIG with activity since the creation of the parallel supply chain discussed and expected impact on supply. **(MS/JM/LC/231 - INQ000106321; MS/JM/LC/232 - INQ000083632).**

250. On 19 April 2020, Lord Deighton was appointed by the Prime Minister to lead the national effort to increase the domestic production of PPE. Then, in May 2020, this role was expanded to include leading the taskforce with responsibility for buying PPE from abroad, and for ensuring an efficient and effective PPE distribution system to all relevant settings across the UK. The governance structure and core components of the Parallel Supply Chain as at 29 April 2020 are set out in this discussion pack for Lord Deighton. **(MS/JM/LC/233 - INQ000339331)**

251. On 21 April 2020, 27 April 2020, 13 May 2020 and 21 May 2020 the Department reported in a series on meetings on PPE to No. 10 chaired by the Prime Minster (PM). These focused on work to secure the necessary supply of PPE and distribute it to the front line.

252. On 12 June 2020 there was the first meeting of a PPE Programme Delivery Board. **(MS/JM/LC/234 - INQ000339236)** This became the main review and decision-making body for delivery performance, financial and contractual matters in connection with the sourcing, procurement and distribution of PPE from this point as the programme stabilised and moved to consolidate its governance structures.

Supply intelligence, Modelling and Shortages

Modelling

253. Modelling the demand requirement for PPE during the pandemic was challenging. There was no previous experience to draw on and so a modelled approach was taken. The modelling was based on assumptions for the numbers of covid cases, the health and care they would require and the use PPE in accordance with the IPC guidance. The models continued to be refined in line with our changes in our understanding. For example, modelling a much wider use of PPE for interactions with covid and non-covid patients following the 2 April IPC guidance update. The model covered both Health and Social care and very significant efforts were taken to ensure the model gave a credible view of care home demand for PPE.

254. Initial COVID-19 modelling became available on the 20 March 2020. An iteration with quality assured figures became available on 26 March 2020. This modelling assumed a 32 week long infective wave with 81% of the population infected. There would be 32 million total bed days and 10% of those admitted to the NHS would need ICU care.

255. As at 26 March 2020, the demand estimate for PPE across the NHS and ASC showed a 32-week demand of 481 million Type IIR masks, 63 million FFP3 respirator masks and 26 million gowns. This compared with pandemic flu estimates of 197 million, 72 million and 19.4 million respectively. On this date it was reported that there were 69.8 million Type IIR, 21.3 million FFP3 respirator masks and 68,445 gowns centrally available for deployment.

256. From 23 March 2020, with consultancy support from McKinsey & Company, the Department produced a full estimate of the PPE that would be required to manage COVID-19 over a 90-day period, based on adherence to government guidance on PPE. A first iteration of this was used at the end of March 2020 and informed a briefing provided to No. 10 on 29 March 2020. **(MS/JM/LC 299 – INQ000339355)**

257. At this meeting it was reported that this initial modelling showed there was 10 weeks supply of FFP3 respirator masks, greater than 12 weeks supply of Type IIR, 12 weeks' supply of eye protection, greater than 13 weeks' supply of gloves and aprons, but less than 2 weeks' supply of gowns.

258. Refinement of this model continued through March and April with a stable version available from 12 April 2020, though development continued. The model anticipated an enormous increase for some types of PPE compared with the calculations for pandemic influenza, with large increases in demand for aprons (820%), gloves (388%) and face masks (125%). The estimate covered critical care, acute care, primary care, community care and social care.

259. These figures emphasised the need for rapid procurement, but also the need to effectively manage stock as it was received and redistributed. They also emphasised the need to manage demand where it was possible and safe to do so.

Supply Intelligence

260. The information available centrally on the supply of PPE across the Health and Care system developed over the course of the response to the pandemic.

261. In the initial months stock held by NHS Supply Chain and in the PIPP and EU Exit stockpiles was available centrally, alongside expected deliveries of new orders of PPE. NHS supply chain had information on NHS orders for PPE, but not underlying usage or local stocks.

262. NHSE Regional Teams worked with individual NHS Trusts to better understand their requirements and were able to alter the quantities of PPE delivered through the Parallel Supply Chain "push" deliveries. From mid-May 2020 real time information on local PPE stocks in NHS Trusts began becoming available centrally giving much better intelligence on overall supply.

263. For Social Care, no central information was held prior to the pandemic. The roll out of a Capacity Tracker allowed Care Homes to report concerns in relation to PPE Supply.

264. The NSDR hotline allowed all Health and Care providers a route to secure immediate supplies if in acute need. On 14 April 2020 the NSDR handled circa 600 active cases a day from social care falling to 50 by 21 May 2020. **(MS/JM/LC/235 - INQ000339199)**

265. The supply of PPE to Health and Social Care was carefully managed against supplies available nationally and the expected arrival dates of new stocks of PPE. This included reducing the volumes delivered in order to ensure an ongoing supply across the system and that supplies went to those most in need. For gowns supplies were initially restricted to those for immediate use only and managed by NSDR for a short period in April 2020.

266. Concern over potential shortages of PPE led to the release of an PPE Acute Shortages Protocol on 17 April 2020. This document was produced by PHE. Where acute shortages occurred, and where it was safe to do so, it approved the sessional and reuse of specific pieces of PPE as well as guidance on substitutes. Release of the guidance was recommended by CMO, cleared by the Secretary of State and agreed by HSE **(MS/JM/LC/236 - INQ000339152**; **MS/JM/LC/237 - INQ000339153**; **MS/JM/LC/238 - INQ000339154).** This guidance was withdrawn on 16 September 2020 when it was judged supply was sufficiently stabilised.

267. The Department also worked closely with the Devolved Governments to obtain a unified picture of UK supply and demand. This built on existing relationships through the NHS supply cell at which, Scotland, Wales and Northern Ireland had been represented, and the 4 Nation approach to the management of the PIPP stock. During the first months of the pandemic this approach involved "mutual aid" with transfer of PPE between the 4 nations to meet emergency shortages informed by regular four nation supply calls **(MS/JM/LC/239 - INQ000339332).** Over time, and as supply and demand planning matured, the relationship formalised as a Devolved Administration Board for PPE with stock comparisons and discussions of shared issues. This met 10 times between 11 November 2020 **(MS/JM/LC/240 - INQ000339337)** and 8 August 2022 **(MS/JM/LC/241 - INQ000339277)** when ownership of ongoing DA engagement on PPE moved to SCCL.

PPE and Technical Assurance

268. PPE for use within the UK must meet technical requirements as set by the relevant competent authority which, depending on the product, is either the MHRA or the Office for Product Safety Standards (OPSS). The Department was not involved in setting these existing technical standards. The relevant market surveillance authority for England is the HSE.

269. However, in one instance where a need was identified for a new transparent mask standard, the Department asked a working group to provide a technical

specification, published in July 2021, for transparent masks as an alternative to Type IIR medical masks. Patients, service users and healthcare workers had requested a transparent version of a face mask. A transparent face mask can support communication between those who have hearing difficulties or are deaf and may rely on lip-reading, patients and service users with cognitive problems such as dementia, and those with learning disabilities.

270. I am aware there were regulatory adjustments made by MHRA and OPSS relating to CE marking (the EU's mandatory conformity marking) for PPE. They introduced two fast-track procedures allowing certain types of PPE to be sold without the CE mark. Guidance for how to secure fast-track approval was first published on 25 March 2020 (**MS/JM/LC/242 - INQ000339130).**

271. With the many new manufacturers and suppliers for PPE in mind, the Department published documents on 30 March 2020 setting out the Regulatory and Technical standards required for PPE **(MS/JM/LC/243 - INQ000339132[10]; MS/JM/LC/244 - INQ000339323[11]; MS/JM/LC/245 - INQ000339324[12]).**

PPE Quality Assurance and Quality Control

272. I am asked how the adequacy of the PPE provided to the healthcare system was assessed, including whether it was possible to test the adequacy of PPE before providing to healthcare providers, where and when any tests were conducted and upon whom the PPE was tested. I am further asked whether the Department's approach to the above matters developed during the relevant period.

[10] MS/JM/LC/243 - INQ000339132 - gov.uk webpage containing links to published documents defining the technical and regulatory standards for Personal Protective Equipment titled 'Specification for Examination Gloves' and 'Specification for Personal Protective Clothing (PPE) to include: Gowns, Surgical Face mask, Respirator masks, Eye Protection, Protective Coveralls' ;
[11] MS/JM/LC/244 - INQ000339323 – published document titled 'Specification for Examination Gloves';
[12] MS/JM/LC/245 - INQ000339324 – published document titled 'Specification for Personal Protective Clothing (PPE) to include: Gowns, Surgical Face mask, Respirator masks, Eye Protection, Protective Coveralls').

273. For existing suppliers and manufacturers as well as buying teams within the NHS and NHS Supply Chain, technical specifications were well established. There were also additional requirements by the NHS for preferred product.

274. Products purchased went through a technical assurance process to assure that they met the specification needed. This involved a review of technical documentation prior to purchase and a check on delivery that the product received was as ordered. This developed as the Parallel Supply Chain matured. Checks in the first weeks were performed by a team comprising MHRA/HSE working alongside the British Army to determine the suitability of product before distribution.

275. Upon receipt, technical certificates were reviewed and, where there was concern over compliance a sample of each product was reviewed by the Department's Technical and Regulatory Assurance team. The product was held from supply until this review was completed.

276. Where a product had been through the standard process described and was deemed not suitable for release it was categorised as 'Do Not Supply' (DNS) and subject to further investigation. From June 2020 onwards the Department undertook a comprehensive review of stock and put processes in place to assure the quality PPE the Government purchased as it arrived within the UK. This process determined whether products were suitable to be released to the frontline. On 7 November 2023 we reported to the Public Accounts Committee that by 30 June 2023 99.8% of stock had been quality assured. Of all the items received, 3.8 billion items (9.8% of all items received) were classified as DNS and of this 1.38 billion (3.5% of all items received) were classed as not fit for any purpose. **(MS/JM/LC/246 - INQ000371236).**

277. Technical quality was not expected to be an issue with items distributed from the PIPP stock, though there were some issues with a small minority of products. For example, in May 2020, 16 million Tiger Eye goggles were

recalled, having been found not to meet the clinical standards specific to COVID-19 for splash protection.

278. The vast majority of stock was suitable to be used for its original intended purpose. Where this was not possible, efforts were made to repurpose or donate stock.

Ensuring appropriate PPE for all staff

279. The Department was mindful in its efforts to supply the NHS of the diversity of the workforce. For items of PPE that came in a variety of sizes, such as gloves and gowns, distribution planning made sure that an appropriate range of sizes were dispatched during the "push" phase of the response and during the "pull" phase providers could directly request what they required, including by size.

280. Higher grade respiratory protection using FFP3 (or an FFP2) grade mask requires an individual assessment that the respirator is correctly fitting (a "fit-check"). This ensures that adequate protection is being provided and is an HSE requirement. Where an individual fails a fit check, the employer should redeploy that staff member and not expect them to participate in the activity containing the risk unless alternative protection or mitigation can be identified.

281. In order to be able to successfully meet the requirements of the diverse workforce a range of shapes and sizes of FFP3 are required so that the best chance of a fit test pass is achieved. Accordingly, the PIPP stock contained a range of different masks and sizes. Our procurement of FFP3 masks during the pandemic also sought to expand the range of masks available to suit the widest possible range of staff needs.

282. Prior to the pandemic, FFP3 respirator mask use was limited within the NHS. As part of NHS preparations from January 2020 onwards NHS Supply Chain reported to the Department that NHS organisations were increasing their fit

testing to support the expected use of FFP3 respirator masks by relevant staff. **MS/JM/LC/102 – INQ000339268).**

283. There was recognition that deployment of the PIPP stock may create additional need for fit testing, accordingly in March 2020 PHE engaged the services of RPA (an independent Respiratory Protective Equipment (RPE) fit testing company), to offer free immediate support to trusts who are being asked to use FFP3 respirators that may not be their Business as Usual (BAU) respirator of choice. **(MS/JM/LC/ 247 - INQ000339128).**

284. In June 2020, a FFP3 respirator mask fit testing project was launched across 47 NHS Trusts which collected data from over 5,500 participants from a range of diverse backgrounds. NHSEI worked with manufacturers to build this feedback in to their products. Since this project was initiated, the Department made a further eight types of mask to the four already available, so from late 2020, 12 different models were available, providing a portfolio of different shapes and sizes of mask to cater to a diverse range of users of PPE.

285. Recognising this larger portfolio would increase the need for additional fit testing, from November 2020, the Department recruited and trained over 220 fit testers to HSE standards and completing over 325,000 tests (16 Nov 2020 to 18 Nov 2022). Data from December 2022 confirmed there was a good fit-test performance achieved across protected characteristics, including ethnicity, age and gender. **(MS/JM/LC/249 - INQ000339333).**

286. In June 2022 the Department worked together with the NHS Electronic Staff Record team to build in recording of FFP3 respirator mask fit testing and outcomes for NHS staff allowing that information to be centrally collected. This information can be used to inform procurement and supply decisions as well as following staff members should they move between NHS organisations. **(MS/JM/LC/250 - INQ000339295**; **MS/JM/LC/251 - INQ000339334).**

Staff engagement

287. The Department took steps to identify and respond to the diverse needs of the health and social care workforce in the supply and distribution of PPE. This included understanding and addressing issues of inequalities experienced by frontline staff with different protected characteristics during the pandemic.

288. In order to effectively understand the different needs of frontline users, the Department established customer engagement panels through which staff groups with protected characteristics, including those from different ethnic backgrounds, took part in panel discussions to ensure that their experiences were heard. This forum ensured that user feedback from the frontline was incorporated into PPE provision.

289. Reflecting this feedback, Chapter 6 of the PPE Strategy published in September 2020 **(MS/JM/LC/252 - INQ000234522)** set out the Department's approach to improve the user experience.

290. Further to the engagement panels, in March 2021, the Department commissioned the CO COVID-19 Taskforce Field Team to consult directly with health and social care frontline workers. This focused particularly on those from different ethnic minority backgrounds, to better understand their experiences of PPE. This engagement highlighted the following key themes:

    i. Some staff felt that they had been given lower priority than others in PPE provision. Examples of staff that felt this were: those working in social care; those working in more deprived areas where rates of COVID-19 and mortality tended to be higher; and those working where the proportion of frontline workers from ethnic minority backgrounds was higher.
    ii. A lack of confidence in some to raise concerns or a feeling that they would not be listened to.

iii. Reports that that the fit of PPE should have been better, the range more varied, and a request for approved clear masks.
Clearer national PPE guidance that is consistently communicated to frontline staff;
iv. Requests for greater agility in future emergencies, recognising that there were many positive lessons learned from the pandemic experience.

291. The outcomes of this informal engagement broadly confirmed that the steps being taken by the Department to address the PPE needs of frontline workers from different ethnic backgrounds were correct. This was particularly true in relation to access to correctly fitting PPE and ensuring a resilient supply of PPE to be more responsive in future emergencies. This engagement work highlighted that fit testing masks was crucial to ensuring the safety of individuals working on the frontline.

292. Lessons learned by the Department in relation to the supply of PPE to the healthcare sector during the pandemic and how such lessons will inform the response to a future pandemic will be addressed in a further Corporate Witness Statement in respect of Module 3 that will be provided by the Department.

F. Protecting the vulnerable from COVID-19 infection through shielding

293. We are asked about the extent to which the Department developed the shielding policy and guidance for the clinically vulnerable and the Clinically Extremely Vulnerable (CEV) groups in England. We are further asked about:

i. The process by which certain medical conditions were identified as giving rise to clinical vulnerability;
ii. A chronological overview of the shielding guidance;
iii. The dissemination of the shielding guidance;
iv. Any assessment of the impact of shielding on the clinically vulnerable and clinically extremely vulnerable; and

v. Any support for the clinically and extremely clinically vulnerable provided by or on behalf of the Department during the relevant period.

294. MHCLG was the overall lead for overseeing and delivering the shielding programme within Government, but a number of organisations were involved in different aspects of the programme:

i. MHCLG led on coordination of support to enable people to follow shielding advice. They commissioned local authorities to provide basic support and secured funding from HMT to do this;
ii. The CMO, working with other clinical experts, was responsible for clinical advice including to determine who should shield. The DCMO provided clinical leadership on the initial shielding programme and acted as Senior Responsible Officer (SRO) for the coordination of the subsequent Enhanced Protection Programme;
iii. The Department wrote letters to clinically extremely vulnerable people advising them about who should shield, and any changes to these groups (co-signed with MHCLG) and was responsible for evaluating the impact of shielding.
iv. DEFRA led on providing food to people who were shielding;
v. NHSEI ran the service to get medicines to people on behalf of DHSC, using local pharmacies, and for providing enhanced support to clinically extremely vulnerable people through its NHS Volunteer responder service;
vi. NHS Digital managed the Shielded Patient List (SPL);
vii. The Government Digital Service (GDS) developed the digital services that CEV people could use to request support;
viii. The Department for Work and Pensions provided a national shielding contact centre and also ensured that people who were shielding were entitled to Statutory Sick Pay, Employment Support Allowance or Universal Credit, depending on their circumstances.

295. By way of context, the Department's Opening Statement for Module 2, dated 26 September 2023, sets out that "*The aim of the Department was to*

minimise the spread of the virus overall and by doing that, protect the vulnerable. The understanding of which groups or pre-existing underlying drivers of ill health would have the greatest impact also evolved as the pandemic developed. For example, the early assumption that old age would be a significant vulnerability was borne out in the growing evidence, while it was not until later that it was understood that living with obesity was a vulnerability. The changes in the Department's understanding of vulnerabilities throughout the pandemic is illustrated to an extent by the changes to the Shielded Patient List.'

The initial development of the shielding guidance

296. The concept of shielding to identify, protect and support those most at risk of serious adverse outcomes from COVID-19 was discussed at SAGE on 5 March 2020 (**MS/JM/LC/253 - INQ000106152**). Shielding was always advisory, and never mandatory. On 6 March CO chaired a meeting and commissioned NHSE and UK CMOs to define the clinically vulnerable cohort and develop advice for this group.

297. On 7 March and 8 March 2020, senior clinicians from the Department, NHSE, NHSD and PHE had a telephone meeting in which options for clinical inclusion criteria for and identification of people thought most likely to be at highest risk from Covid-19 were discussed **(MS/JM/LC/254 - INQ000339124; MS/JM/LC/255 - INQ000339125).** Those at the meetings, and in subsequent email correspondence, agreed a two-tiered approach:

i. A wider group of approximately 17 million people who were eligible for annual NHS influenza vaccination on account of age or medical conditions. Public health messaging and guidance would be created to alert them to their increased risk and to suggest they take extra precautions to avoid contracting Covid-19, but they would not be individually identified or contacted.
ii. A smaller group within the 'flu' group of 1-2 million people who may be immunosuppressed or have specialist conditions likely to confer very high

risk from a novel respiratory coronavirus. This group would be proactively identified using existing NHS datasets, and contacted and advised and supported to follow something close to the current PHE guidance for those self-isolating, but for a period of up to 13 weeks.

298. At SAGE meetings of 10 and 13 March 2020 SAGE agreed that "cocooning" a group of vulnerable people should be implemented immediately in order to shield them from the wave of virus which was approaching. SAGE recognised that there were trade-offs to this policy, noting "long periods of social isolation may have significant risks for vulnerable people."

299. There followed a series of discussions led by OCMO between senior clinicians at the Department, NHSE, NHSD, PHE and the Devolved Administrations. This led to the identification of a group who were immunosuppressed or had specialist conditions which meant that they were likely to be at very high risk from a novel respiratory coronavirus. An agreed list of conditions was circulated on 18 March 2020. This led to the development of the SPL, which was a list of those considered CEV.

300. The following conditions were agreed by UK CMOs as being relevant to determining which patients might be CEV, and form the first iteration of the SPL. (**MS/JM/LC/256 - INQ000106311**):

i. Solid organ transplant recipients.
ii. People:
    - with cancer who are undergoing active chemotherapy or radical radiotherapy for lung cancer
    - with cancers of the blood or bone marrow such as leukemia, lymphoma or myeloma who are at any stage of treatment
    - having immunotherapy or other continuing antibody treatments for cancer
    - having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors

- who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs.

iii. People with severe respiratory conditions including cystic fibrosis, severe asthma and severe chronic obstructive pulmonary disease (COPD).

iv. People with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as severe combined immunodeficiency (SCID), homozygous sickle cell).

v. People on immunosuppression therapies sufficient to significantly increase risk of infection.

vi. Women who are pregnant and who also have significant heart disease, congenital or acquired.

301. The first step in building the SPL was to use national NHS datasets to identify anyone who was recorded as having one or more of the conditions identified by the UK CMOs as criteria for shielding. SPL1 was built in 2 days, and it used hospital data, maternity data and prescribed medicines data, but not GP data as it was not yet available. The first iteration of the SPL was completed on 20 March 2020 **(MS/JM/LC/257 - INQ000106464; MS/JM/LC/256 - INQ000106311)**, and consisted of c. 868k patients.

302. The second iteration, 12 April 2020 added a further c.418k patients. The increase was primarily due to the use of GP datasets and GPs using these datasets to add patients not yet identified who either had one or more of these conditions, or who GPs felt, using their clinical judgement, should be added to, or removed from, the SPL. Consultants in secondary care were also able to add or remove people from the list over time.

303. On 21 March 2020 the Department and PHE jointly published guidance entitled 'Guidance on shielding and protecting people defined on medical grounds as extremely vulnerable from COVID-19' (**MS/JM/LC/258 - INQ000106266)**. The guidance recommended shielding for those who were CEV and set out the list of conditions which put people in the CEV group.

The guidance made clear that the NHS in England would be directly contacting people with these conditions to provide further advice.

304. Letters were the main form of communication with those on the SPL, and the timeline of those most important shielding letters is set out below:

i. 21 March - Initial shielding letter (SPL1) - 0.9m people
ii. 30 March - Updated shielding letter to first shielding cohort (SPL1) - 0.9m people
iii. 07 April - Addition of SPL2 cohort - 0.4m additional people received letter for first time
iv. Those added through GP/clinical review in SPL3, SPL4 and beyond were contacted locally, so no major national letter run until update on shielding policy in June
v. 22 June - Letter to all CEV updating them of policy change after announcement that shielding would be extended to end of July, but then it would be paused. - 2.24m on shielding list at that time, which remained stable for rest of 2020

305. Text messages were also sent when shielding was extended in late June 2020, but only as an additional measure. Following a consultation of users, this form of communication was felt to be less trusted than letters. Letters started to be distributed via email in November 2020, but as only c. 800k email addresses of patients were initially held, letters remained our primary means of communication. I am asked whether there have been any steps taken since then to increase the number of email addresses held. NHSE is best placed to provide details of NHS Digital's ongoing work and the plans to further improve patient contact data, including email addresses.

306. On 22 March 2020, the Secretary of State for MHCLG announced that CEV people were advised to stay at home, at which point the shielding programme started (**MS/JM/LC/259 - INQ000106278)**. The criteria for which conditions made people CEV was publicly available on Gov.uk, as was the relevant guidance. If the situation arose where an individual knew they had a

condition, but had not received a letter, they could still find and follow the guidance.

307. In addition to this, individuals who thought they were CEV but had not received a letter, could register for support through the register created by GDS for MHCLG, in recognition of the fact that some people would know they were in the shielding cohort before they received their letter. The majority of the group were subsequently added to the SPL.

308. As data accrued, it became apparent that there were conditions which conferred particularly high risk from Covid-19, which had not been included on the original list of CEV conditions. OCMO frequently received representations from patient advocacy groups and specialist clinicians to request consideration of particular conditions for inclusion in the definition of CEV. As a result, the UK CMOs established the UK Clinical Panel for Shielded Patients, consisting of at least one senior clinician nominated by each of the UK CMOs. The remit of the panel was to consider any evidence which may be relevant to the maintenance of the SPL (including operational and definitional issues), as well as updating and revision of the CEV conditions (**MS/JM/LC/260** - INQ000298952). The office of the UK CMOs also provided the secretariat function for the Clinical Panel for Shielded Patients. The Panel met weekly and at times commissioned evidence reviews from NHS England to inform its deliberations. The panel made evidence-based recommendations to the UK CMOs about changes to the inclusion criteria for the CEV cohort.

309. The following conditions were added at later dates:

i. Dialysis (recommended entire population addition on 22 April 2020);
ii. CKD Stage 5 (recommended case by case addition at the panel on 28 April 2020, recommended entire population addition on 25 September 2020);
iii. Motor Neurone Disease (recommended case by case addition by the panel on 28 April 2020);

iv. Laryngectomy and tracheostomy (recommended case by case addition by the panel on 28 April 2020);

v. Rare diseases (recommended case by case addition by the panel on 28 April 2020);

vi. Decompensated liver disease (recommended case by case addition on 8 July 2020 after reviewing paper commissioned from NHSEI); and

vii. Down's Syndrome (recommended case by case addition on 8 July 2020 after reviewing paper commissioned from NHSEI, recommended entire population addition 25 September 2020).

310. The following table provides an indication of the gradual increase in the size of the CEV. It should be noted that the following are headline figures. NHSE, which holds more granular information on this issue is best placed to provide a more detailed breakdown of the changes in numbers of patients on the SPL, should this be required:

20 March 2020	867,789 CEV identified
12 April 2020	Cumulative 1.3 million people identified as CEV (additional 417,639 added since 20 March 2020)
18 April 2020	Cumulative 1.8 million people identified as CEV (additional 561,845 added since 12 April 2020 – single biggest increase, driven by GP and clinician review of SPL.
1 May 2020	Cumulative 2.16 million identified as CEV (addition of 316,033 since 18 April 2020, again primarily driven by GP and clinician additions)
7 May 2020	SPL stabilized at 2.2 million CEV people (net increase of 49,320 since 1 May 2020 – from here on there is little significant change to the size of the

	SPL until the QCOVID tool added 1.5m on 15 February 2021as the GP and clinician review completed)

Further guidance on shielding

311. On 15 May 2020, a submission was sent to the Secretary of State regarding the review of shielding policy (**MS/JM/LC/261 - INQ000106430**; **MS/JM/LC/262 - INQ000106431**). This followed a commitment by the government to review shielding policy drawing on the latest clinical evidence from the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) and SAGE about those at heightened risk from COVID-19. The submission provided the Secretary of State with background on the shielding categories and noted the anticipated NERVTAG/SAGE advice that was due within the next week, and upon which a decision would likely be recommended. The Secretary of State noted the submission on 21 May 2020 (**MS/JM/LC/263 - INQ000106443)**.

312. On 9 June 2020, a submission recommending pausing the shielding advice was sent to and agreed by the Parliamentary Under Secretary of State and Secretary of State (**MS/JM/LC/264 - INQ000050887; MS/JM/LC/265 - INQ000234388; MS/JM/LC/266 - INQ000234385; MS/JM/LC/267 - INQ000050876**). The basis for this submission was clinical advice from DCMO based on the incidence rate in the community being sufficiently low to mean that advice for those in the CEV group could be paused. On 12 June 2020, a further submission was sent which outlined the MHCLG's intention (**MS/JM/LC/268 - INQ000234389**). The Department's Ministers agreed with this extension (**MS/JM/LC/269 - INQ000234391**; **MS/JM/LC/270 - INQ000233842**; **MS/JM/ LC271 - INQ000234390)**.

313. On 22 June 2020, the Secretary of State announced the relaxation of shielding guidance for the CEV individuals across England from 6 July 2020 due to the continued reduction of infection rates, and that from 31 July people

would no longer be advised to shield. (**MS/JM/LC/272 - INQ000106491; MS/JM/LC/273 - INQ000106520; MS/JM/LC/274 - INQ000106521**). However, the guidance remained unchanged for a small number of local areas where the infection rate remained high, and this position was regularly reviewed.

314. On 8 July 2020, the CMO and NHS Medical Director wrote to all GP practices and trusts with instructions that clinicians should review and, where appropriate, remove children and young people from the SPL in line with new guidance from The Royal College of Paediatrics and Child Health (RCPCH) (**MS/JM/LC/275** - **INQ000339264**).

315. On 23 July 2020, the Secretary of State was sent a submission (**MS/JM/LC/276 - INQ000106547; MS/JM/LC/277 - INQ000106548**) in which the Department recommended that decision making authority on introducing and pausing shielding, at both a local and national level, be retained as a Ministerial decision. The Secretary of State responded to the submission and agreed that decisions on resumption of shielding (whether at a local or national level) should be made at a national level.

316. On 30 July 2020 COVID-O met (**MS/JM/LC/278 - INQ000106550**[13]**; MS/JM/LC/279 - INQ000106552**[14]**; MS/JM/LC/280 - INQ000106553**[15]). It was reconfirmed that shielding guidance would be paused as planned from 1 August 2020 for most of England, and that shielding could be reintroduced if infection rates of COVID-19 increased.

317. On 1 August 2020, the advice to shield was paused nationally except for local lockdown areas. In these instances, the DCMO (Professor Dame Jenny Harries) representative would advise Gold meetings that the prevalence/infection rate was high enough to trigger shielding. This decision would be taken for each area that moved into local lockdown/Tier 4. For

[13] MS/JM/LC/**278** INQ000106550 – meeting agenda;
[14] MS/JM/LC/**279** INQ000106552 – meeting actions in email format
[15] MS/JM/LC/**280** INQ000106553 – meeting actions as attachment to covering email).

instance, shielding advice continued until 5 October 2020 in Leicester and other parts of Leicestershire and Blackburn with Darwen. Letters were sent to individuals from the CEV cohort based in these areas every three to four weeks, updating them and extending their shielding notification period so that they would be eligible for support (e.g. by way of Statutory Sick Pay (SSP)).

318. On 24 September 2020, a submission was sent to the Department's Parliamentary Under Secretary of State and the Secretary of State on options for linking shielding advice to tiers (**MS/JM/LC/281 - INQ000109775**). The submission recommended that:

i. There should be tiered advice for the CEV cohort;
ii. The advice to shield should not automatically be triggered at Tier 3 but only introduced in the very highest risk areas on the recommendation of DCMO; and
iii. A recommendation should be put to COVID-O that shielding should not be introduced nationally.

319. The Secretary of State replied on 25 September 2020 that he agreed shielding should not be introduced nationally. He also agreed that the advice to shield should not be automatically triggered at Tier 3 but only introduced in the very highest risk areas on the recommendation of DCMO. (**MS/JM/LC/282** - **INQ000339269**)

320. On 13 October 2020, new guidance was introduced for members of the CEV cohort based on the concept of tiers (**MS/JM/LC/283 - INQ000339274**).

321. On 4 November 2020, a patient letter from the Department and MHCLG was sent to the full CEV cohort which outlined new guidance and informed them of the new national restrictions that would run from 5 November 2020 to 2 December 2020. It stated: "the Government has taken the following action requiring people to stay at home, except for specific purposes, preventing gathering with people you do not live with, expect for specific purposes and

closing certain businesses and venues, like hospitality and non-essential retail (**MS/JM/LC/284 – INQ000234602; MS/JM/LC/285 -** INQ000137034 **).**

322. On 27 November 2020, a letter from the Department was sent to the CEV cohort (**MS/JM/LC/286 – INQ000059087**). The letter informed them that their guidance was changing on 2 December 2020, and that the Government was no longer advising them to stay away from work or school. Instead, they should continue to minimise social interactions and reduce the amount of time spent in settings where they would be unable to maintain social distancing.

323. On 20 December 2020, letters from the Department and MHCLG were sent to individuals from the CEV cohort based in areas placed into new Tier 4 restrictions, advising them to follow extra precautionary shielding measures similar to those advised in November's national lockdown (**MS/JM/LC/287 - INQ000059347**). Areas under Tier 4 restrictions were extended on 29 December 2020 and the individuals from the CEV cohort in those areas were sent another letter from the Department and MHCLG on 30 December 2020 advising them to continue shielding (**MS/JM/LC/288 – INQ000059396**).

324. Following the Prime Minister's announcement on 4 January 2021 that a further national lockdown would be put in place, letters from the Department and MHCLG were sent to the full CEV cohort on 7 January 2021 (**MS/JM/LC/289 -** INQ000059496). These letters outlined the new lockdown measures, stating that "the Government is also advising all clinically extremely vulnerable people to take extra shielding measures to protect themselves". This advice applied until 21 February 2021.

325. On 15 February 2021, letters from the Department and MHCLG and guidance were sent to the full CEV cohort extending shielding advice until 31 March 2021 **MS/JM/LC/290 - INQ000059953**)

326. On 3 February 2021, COVID-O agreed to use a predictive risk tool, QCOVID to prioritise people for vaccination and add them to the SPL. QCOVID is a

predictive risk model, commissioned by the CMO in May 2020 and developed by a NERVTAG subgroup. QCOVID used a data driven approach to combine clinical and demographic risk factors to predict the absolute and relative risk of death of an individual based on weighted, cumulative risk. These risk factors included age, ethnicity, gender and deprivation as well as a number of clinical conditions. QCOVID was peer reviewed, published and independently validated and found to be performing in the 'excellent' range. A central technological platform was built by NHS Digital to run QCOVID nationally on patient records to identify those at highest risk of death. This resulted in around 1.5 million people being added to the SPL. NHSE is best placed to answer questions about how NHS Digital used QCOVID to develop the COVID-19 Population Risk Assessment to estimate the risk of a person catching coronavirus and becoming seriously unwell.

327. On 17 February 2021, letters from the Department and the NHS were sent to these individuals, informing them that they were newly qualified as CEV and that they were advised to shield until 31 March 2021 (**MS/JM/LC/291 - INQ000110718**).

328. On 17 March 2021, letters from the Department and MHCLG were sent to the full CEV cohort informing them that the advice to shield would end on 1 April 2021 **(MS/JM/LC/292 - INQ000060339)**. Shielding was paused on 1 April 2021 and guidance updated **(MS/JM/LC/293 - INQ000060345)**.

329. On 17 May 2021, guidance for the full CEV cohort was updated to provide advice on meeting friends and family inside and outside homes **(MS/JM/LC/294 - INQ000234906)**.

330. On 18 May 2021, COVID-O met regarding the future of shielding. It was decided that shielding would be maintained as a contingency option until the end of March 2022, subject to further review.

The end of shielding

331. On 16 July 2021, Department officials put forward options to the DCMO on the future of the SPL. The options presented were to either discontinue the SPL or to rationalise it and rename it the Highest Clinical Risk list **(MS/JM/LC/295 - INQ000112536).**

332. On 19 July 2021, guidance for the full CEV cohort was updated to advise them to follow the same guidance as the rest of the population **(MS/JM/LC/296 - INQ000234996).**

333. On 20 July 2021 a meeting took place between the DCMO, Professor Jonathan Van-Tam, and Mary Ramsey Head of Immunisation at the UKHSA at which it was agreed that the SPL, as it then stood, was not the right list for targeting vaccines, therapeutics or antivirals. There was agreement that closing down the SPL and bringing to an end the CEV terminology would be helpful (**MS/JM/LC/297 - INQ000061420**).

334. On 23 July 2021, a submission was sent to the Department's Parliamentary Under Secretary of State and the Secretary of State (**MS/JM/LC/298 - INQ000061458**), which provided the following recommendations on the future of shielding policy and the maintenance requirements for the SPL:

    i. "That you agree to formally end the shielding programme and move away from a model of centralised shielding / precautionary advice for the CEV cohort as a whole, back to the pre-pandemic model whereby those susceptible to infectious disease receive risk advice from their NHS clinician.
    ii. That you consider whether you would want to write out to 3.8 million CEV people informing them of the end of the shielding programme.
    iii. That you agree to maintain the SPL only until the JCVI published its final advice on booster vaccinations in August, after which, a decision should be taken about the SPL's ongoing usefulness to the vaccines programme".

335. The submission noted that the full CEV cohort (3.8 million people) were included in JCVI's initial priority groups for vaccination in early 2021, and that 91% had received one dose and 88% had received two doses. A study by PHE suggested that for the majority of individuals who were CEV, there was little reduction in vaccine effectiveness compared to those not identified as high-risk. As a result, senior clinicians including the DCMO and the Chief Executive of UKHSA advised that it was highly unlikely that the Government would need to advise the full CEV cohort to shield again.

336. It was recognised that some with conditions making them specifically immunocompromised or immunosuppressed may not respond as well to COVID-19 vaccines as the rest of the population. In such cases, these patients were advised to consult with their clinician, similar to pre-pandemic approaches. This approach best allowed for nuances in vaccine effectiveness, including the permanency of any immunosuppression, and individual risk to be properly addressed to ensure individuals received the most appropriate and tailored advice.

337. On 28 July 2021, the Private Office to the Parliamentary Under Secretary of State informed the Secretary of State that she was content to stop the Shielding Programme. The Minister commented that it was important to have a communications plan in place and suggested two options on when and how to announce the decision.

338. On 2 August 2021, given the size of and considerable public interest in the decision, the Secretary of State requested a meeting to discuss the submission.

339. A meeting was subsequently scheduled on 11 August 2021 and was attended by the Secretary of State, the DCMOs, Chief Executive of UKHSA, Jenny Harries, and Department officials. The meeting concluded with the Secretary of State confirming that he would recommend to COVID-O that the Shielding Programme and SPL should be stood down and that the announcement should be clinically led.

340. Following an evidence review that concluded that children and young people were, in general, not considered to be at high risk of serious illness from COVID-19, they were formally removed from the SPL on 23 August 2021.

341. On 31 August 2021, CEV guidance for children and young people was published (**MS/JM/LC/299 - INQ000066720**).

342. On 6 September 2021, it was agreed at a COVID-O meeting that the term CEV and any associated bespoke policy for them, particularly regarding shielding, should formally end. The committee agreed that the SPL and associated Shielding Programme and contingency support offer should be stood down. The committee recognised this may need to change in the future if there was a vaccine-escaping variant of concern or similar change in clinical risk.

343. On 15 September 2021, there was an announcement by the Department of the decision to end the shielding programme due to the success of the vaccine roll out, improvements in treatment and clinical care, and a growing understanding of the virus (**MS/JM/LC/300 -** **INQ000237463**).

344. On 17 September 2021, letters from the Department and NHS were sent to the full CEV cohort informing them of this decision. (**MS/JM/LC/301 - INQ000066933)**

Responding to the Omicron variant

345. In response to the Omicron variant, consideration was given to the contingency plans that may be required for people at higher risk of serious illness from COVID-19, depending on the variant's prevalence and severity, particularly those who were severely immunosuppressed. On 3 December 2021 a submission was sent to the Minister for Vaccines and Public Health asking them to note this contingency planning work, whilst confirming that

shielding was not currently being considered as an intervention due to the limited understanding of the new variant at the time, and its impact. Contingency planning discussions commenced with CO and the Department for Levelling Up, Housing and Communities (DLUHC) to consider what plans could be put in place should they be required by those at higher risk.

346. On 10 December 2021, Departmental officials sent a paper requesting clinical advice from the DCMO, Dr Thomas Waite, and the Chief Executive of UKHSA, Professor Dame Jenny Harries on those who were deemed to be at higher risk (**MS/JM/LC/302 - INQ000067634).**

347. On 12 December 2021, the Secretary of State received clinical advice from the DCMO and UKHSA CEO to not reintroduce shielding.

348. In the context of rapidly rising cases of the Omicron variant and in response to meetings with Ministers, officials, NHSEI and the Antiviral and Vaccine Taskforces, the UKHSA Chief Executive convened two clinical roundtables on 14 and 16 December 2021. It was agreed that while shielding should not be reintroduced, a single 'higher risk' group of immunosuppressed people should be confirmed to include those already identified and any other clinically relevant groups, and that this 'higher risk' group should be provided with advice on public health measures they may wish to consider to support them during the current Omicron wave. This was confirmed in a submission to the Secretary of State on 20 December 2021 (**MS/JM/LC/303 - INQ000067731**). Consideration was given to other forms of support such as access to SSP, if working from home was not feasible, the delivery of medicines, priority access to PCR testing and access to antiviral treatments and monoclonal antibody treatment if they caught COVID-19.

349. On 24 December 2021, the Government issued updated public health advice to two separate groups. The first group, previously considered to be CEV, were advised to follow the same guidance as the general public. The second group (of approximately 1.8m) were people aged 12 and over, who were immunosuppressed or had a specific other medical condition. The advice to

this group was to follow a range of precautions to reduce their risk of catching COVID-19 (**MS/JM/LC/304 - INQ000328154**).

350. On 7 February 2022, the Secretary of State agreed a submission received on 4 February 2022 (**MS/JM/LC/305** - **INQ000339291**) regarding the establishment of the Enhanced Protected Programme (EPP). (**MS/JM/LC/306 - INQ000339292**)

351. The EPP was a coordination, time limited, programme, overseen by a Clinical Oversight Group chaired by the Chief Executive of UKHSA. The secretariat for the programme was provided by the Department and it aimed to ensure that cohorts at higher risk of serious illness from COVID-19 (due to immunosuppression or a specific other medical condition) were identified and received appropriate intervention, support, and communication (including booster vaccinations for example). The EPP served to establish and improve the coordination between various advisory, clinical and delivery groups and advice they might give to at risk cohorts.

352. The Department and UKHSA officials worked with the Chief Executive of UKHSA to coordinate and bring further coherence to a number of interrelated programmes across the health system, including NHSE. Accountability for constituent programmes and policy (across vaccines, antivirals and therapeutics) remained within each organisation.

353. On 25 February 2022, the Department and the UKHSA published updated guidance for people previously identified as clinically extremely vulnerable from COVID-19 (**MS/JM/LC/307 - INQ000339293**). This guidance recommended that these people should get vaccinated if they hadn't done so already (including booster vaccinations when offered) and follow the same advice as the rest of the general public. There was a further update to this guidance on 1 April 2022 (**MS/JM/LC/308 - INQ000339129**), which reiterated the advice of 25 February 2022, stated that there was no longer separate guidance for people previously identified as clinically extremely vulnerable. The need for the EPP was kept under review.

354. Ministers received advice to close the EPP on 22 February 2023 and agreed the recommendation to close the EPP on 7 March 2023. The EPP was formally closed on 19 April 2023.

Assessing the impact of shielding

355. I am asked whether the impact of shielding on the clinically vulnerable and clinically extremely vulnerable was assessed, and whether and when any changes were made to the shielding guidance as a result. The early impact of shielding can be assessed through the results of the below Office for National Statistics (ONS) survey series commissioned by the Department.

Office for National Statistics surveys

356. In the early stages of the pandemic, the Department commissioned a series of surveys on COVID-19 and the shielding of the clinically extremely vulnerable in England. The survey was produced, run and analysed in collaboration between the Department, the Department for Work and Pensions (DWP), the GDS, MHCLG and delivered by the ONS.

357. The survey was compiled rapidly to answer questions about the shielding population. It examined the shielding population's behaviour in terms of compliance with shielding guidance and reasons for leaving home, as well as health and mental and physical wellbeing and employment circumstances of those shielding. The findings from the survey contributed to policy considerations on relaxation of shielding guidance, and what appropriate support should be offered, alongside the clinical advice. For example,the survey findings informed the 24 September 2020 advice on options for linking shielding advice to tiers that is set out in paragraph 317.

358. The ONS published a total of 4 reports on 15 June 2020 (**MS/JM/LC/309 - INQ000339238**), 29 June 2020 (**MS/JM/LC/310 - INQ000339260**), 23 July 2020 (**MS/JM/LC/311 - INQ000339266**) and 5 August 2020 (**MS/JM/LC/312 - INQ000339267**).

359. Each report identified a series of key observations. By way of example, the central points arising out of the report published on 5 August 2020 were as follows:

i. Approximately two-thirds (68%) of CEV people who normally worked (prior to receiving shielding advice) were comfortable going back to work outside the home if protective measures were in place.
ii. 6% of CEV people who normally worked are planning not to return to work in the next four months.
iii. Between 9 and 16 July, 65% of CEV people reported receiving no visitors except for support with personal care; this was a statistically significant decrease from 77% between 24 June and 30 June, reflecting the guidance which advised CEV people that they can form a support bubble with another household.
iv. An estimated 328,000 CEV people (15%) lived in a household with children aged under 16 years; 3% (68,000 CEV people) reported that living in this type of household had an impact on their ability to shield.

360. The survey was discontinued following the report which was published on 5 August 2020.

National Audit Office report

361. Aside from the ONS Survey, there were also other attempts to examine the impact of shielding guidance on CEV.

362. On 10 February 2021, the NAO published a report on protecting and supporting the clinically vulnerable during lockdown (**MS/JM/LC/313 - INQ000059879**). The purpose of the report was to look at how effectively

government identified and met the needs of CEV people to 1 August 2020. In summary, the report identified the following:

i. The government acted quickly in the absence of detailed contingency plans for identifying and supporting a large population advised to shield;
ii. Government decided to use a centrally directed model of support for CEV people;
iii. CEV people were identified based on clinical judgment of the risk of severe illness or mortality from COVID-19;
iv. At the start of the pandemic, there was no mechanism to allow a fast 'sweep' across all patients to identify, in real time, those who fell within a defined clinical category;
v. By 12 April 2020, three weeks after shielding was announced, some 1.3 million people were identified as CEV, advised to shield and formally eligible for central support;
vi. A further 900,000 people were added to the CEV list between 18 April 2020 and 7 May 2020;
vii. Government's communications with CEV people were not always clear;
viii. Government worked rapidly to create a range of ways that CEV people could register for the support they may need while shielding;
ix. The contact centre was unable to register 815,000 CEV people;
x. The Department for Environment, Food & Rural Affairs (Defra) quickly designed a food support service and identified suppliers who could deliver it;
xi. Defra used emergency procurement procedures and secured some reductions on initial prices;
xii. Local authorities have criticised the quality of emergency bulk food supplies;
xiii. Most CEV people were satisfied with the food boxes they received;
xiv. Despite indications that the medicines delivery service worked well, NHSE&I had limited assurance that CEV people got their medicines as and when needed;
xv. MHCLG could not track the delivery of basic care to CEV people as it wanted so took assurance in other ways;

xvi. MHCLG's engagement with local authorities was initially poor but did improve;

xvii. Most CEV people followed guidance on shielding;

xviii. The Department is unable to say whether shielding led to fewer deaths and less serious illness in CEV people than would otherwise have been the case, although it is likely to have helped;

xix. The total expenditure on the programme up to 1 August 2020 was £308 million;

xx. The departments involved in the shielding programme have applied the lessons learned to the second lockdown.

363. The NAO set out a number of recommendations to improve support to CEV people when advised to shield in the future. Those recommendations that involved the Department were as follows:

i. The Department should ensure that healthcare data systems allow easy, but secure, access to healthcare data;

ii. The Department should set out the core data requirements it is likely to need in a future pandemic or civil emergency and how it can access these data in a timely manner;

iii. The Department should establish a robust plan on how to communicate clearly, quickly and consistently with CEV people to ensure that people are clear if they need to shield, why they need to shield, how to shield and the support available to them.

364. Steps taken by the Department on implementing the recommendations will be outlined in a further Corporate Witness Statement in respect of Module 3 that will be provided by the Department.

BMC Public Health study

365. On 22 November 2022, an article was published in BMC Public Health – a peer-reviewed journal focused on the epidemiology of disease and the understanding of all aspects of public health – entitled 'Exploring the impact

of shielding advice on the wellbeing of individuals identified as clinically extremely vulnerable amid the COVID-19 pandemic: a mixed-methods evaluation' (**MS/JM/LC/314 - INQ000408813).**

366. The study was supported by the NIHR HPRU in Behavioural Science and Evaluation at the University of Bristol, in partnership with UKHSA, UKRI and the Department. It involved a mixed methods study, including a structured survey and semi-structured telephone interviews with a sample of individuals who had been identified as needing to shield by the Bristol, North Somerset and South Gloucestershire CCG.

367. The survey, which was completed by 203 participants, found that official shielding advice offered to CEV individuals during the first lockdown in England was deemed to be sufficient by 80% of survey responders, although some interviewees criticised the delayed timing of this advice and frequently sought supplementary information to inform shielding behaviours. The individual focus of shielding advice was considered impractical and restrictive by some participants, with 66% of survey responders considering it necessary to shield with all household members. Organisational support (e.g., NHS, council, government, charity) was requested and received by 92.1% of survey responders, although the type and amount of support varied between individuals, and was frequently supplemented with help from family, friends, or neighbours. 90% were worried about COVID, with 35% agreeing that shielding was making their physical health worse and 43% reporting a negative impact on their mental health, 11% of survey respondents reported that shielding had a negative impact on their physical health.

Support for CEV people provided by or on behalf of the Department

368. We are asked about the details of any support for the clinically and extremely clinically vulnerable by or on behalf of the Department during the relevant period.

369. DLUHC had responsibility for delivering the majority of the support package offered to the CEV which included delivery of food boxes and securing supermarket delivery slots. DWP amended regulations so those who were in work could claim SSP while shielding. The Department, together with NHSE, however, had responsibility for:

i. the medicine delivery service; and
ii. the NHS Volunteer Responders (NHSVR) programme

370. The medicine delivery service started on 10 April 2020 and was stood up whenever shielding advice was in place. The service enabled vulnerable and shielding patients to have medicine delivered to their home. Under the service, all pharmacies and dispensing doctors were obliged to ensure delivery of medicines to the clinically vulnerable. Individuals were advised to first seek the help of a family member, friend, carer or volunteer to collect medicine on their behalf. Where this was not possible, pharmacies or dispensing doctors arranged delivery to the individual, free of charge, for which they were reimbursed. The rate of the reimbursement depended on whether they opted to deliver the medicines to the patients themselves or arrange delivery free of charge. By the end of July 2020, 2,436,289 deliveries had been carried out at a total cost of £32.4 million.

371. The NHSVR programme, commissioned by NHSE, was launched in March 2020 (**MS/JM/LC/315 - INQ000106294 ; MS/JM/LC/316 - INQ000106308**) to support the NHS and people who were shielding or self-isolating. Volunteers provided help with fetching prescriptions, shopping, welfare calls, plus delivery of equipment for the NHS and patient transport. Referrals for volunteer support could be made by the following health and care professionals (**MS/JM/LC/317 - INQ000339133**):

i. GPs / social prescribing link workers / practice nurses concerned about an at risk or vulnerable individual they have advised to self-isolate;
ii. Hospital discharge teams;
iii. Community pharmacists;

iv. NHS 111 and ambulance trusts;

v. Community health trusts that need volunteer support for patients leaving hospital; and

vi. Local authorities.

372. Between April 2020 and July 2021, 750,000 people signed up as volunteers to provide help and support through the NHSVR programme, though only half made themselves actively available to receive tasks. The programme re-launched and expanded into adult social care in 2023 (**MS/JM/LC/318 - INQ000339318**) and there are currently over 30,000 volunteers available to complete tasks nationally.

Non-shielding vulnerable groups

373. Aside from the cohort of those advised to shield, evidence suggested that there were other groups who faced increased risks during the pandemic – either as a direct result of the virus itself, or indirectly as a result of the lockdown and accompanying restrictions on public life and health services. This included those with clinical vulnerabilities who did not meet the threshold for the shielding support programme as well as a range of groups with specific support needs such as victims of abuse, those on low incomes, people with disabilities, people with mental health conditions and marginalised groups, such as those experiencing homelessness.

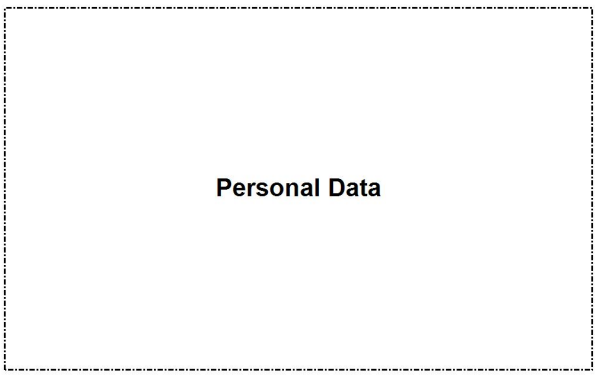
374. At the start of the pandemic, Defra led across government on the response to the needs of 'non-shielded vulnerable groups' (NSVs), in recognition of the most pressing requirement at the time – namely, being able to access food and supermarket delivery slots. Increasingly, MHCLG also began to play a part in this work, as local government was called on to provide additional support to those who were not in the shielding programme.

Lessons learned

375. Lessons learned by the Department in relation to its involvement in the shielding programme, and how such lessons will inform the Department's response to a future pandemic will be addressed in a further Corporate Witness Statement in respect of Module 3 that will be provided by the Department.

Statement of Truth

We believe that the facts stated in this witness statement are true. We 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: 

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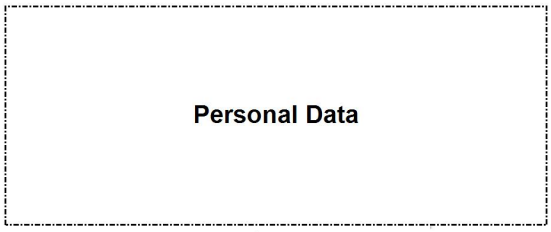
Signed: 

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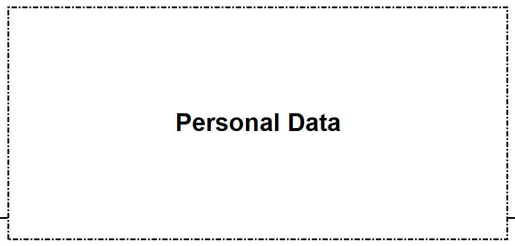
Signed: 

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