

Witness Name: Jenny Harries

Statement No. 5

Exhibits: JH3/01 – JH3/84

Dated: 31 January 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF PROFESSOR DAME JENNY HARRIES

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Introduction

1. I, Professor Dame Jenny Harries, of the UK Health Security Agency, 10 South Colonnade, London, E14 5EA, will say as follows:
2. I am employed by the UK Health Security Agency (UKHSA) as the Chief Executive, a post for which I have had full executive operational responsibility since the organisation's inception on 1 October 2021. Prior to this I was formally appointed as CEO of UKHSA on 1 April 2021 supporting the organisations formation. Additionally, I took over executive operational leadership of NHS Test & Trace (NHSTT) from 7 May 2021.
3. Before joining UKHSA, I was the Deputy Chief Medical Officer (DCMO) for England between 2019 and 2021 and the Regional Director of the South of England within Public Health England (PHE) between 2013 and 2019. Along with the Regional Director role I was interim Deputy National Medical Director for PHE between 2016 and 2017 providing specific support for strategic incident response. From April 2017 until July 2019 when I moved to the DCMO role, I held the strategic incident, Deputy Medical Director role in PHE on a formal basis alongside the Regional Director role.
4. I am a clinical doctor with specialist training in public health medicine, the latter undertaken in Wales. I hold a medical degree (MB ChB) and Fellowship of the Faculty of Public Health (FFPH) by examination. I hold other formal qualifications relevant to my current role including a BSc in Pharmacology, a Masters degree in Public Health (MPH), a Masters degree in Business Administration (MBA), a Postgraduate Diploma in Health Economics Evaluation, and a Postgraduate Certificate in Strategic Planning and Commissioning. I am a Fellow of the Chartered Management Institute, a visiting Professor of Public Health at the University of Chester and an Honorary Fellow of both the Faculty of Occupational Medicine (FFoM) and of the Royal College of Paediatrics and Child Health (FRCPCCH).
5. Prior to my roles with PHE and Department for Health and Social Care (DHSC) and since 2009 I worked as a Director of Public Health in Norfolk & Waveney, Swindon and

Monmouthshire and was additionally a chief officer in the two former Local Authorities. I have worked in clinical, operational, policy and health service economic and evaluation roles in the UK and globally since qualifying in medicine and have been a member of a number of national advisory groups including the Joint Committee on Vaccination and Immunisation, the National Advisory Committee on the NHS Constitution, the NHSE Clinical Priorities Advisory Group and the Women's Health Taskforce.

6. In my national work I have contributed to various significant health protection incidents including the Novichok poisonings (2018), the first cases of Monkeypox in the UK (2018), Zika (2016) and supported other global crises such as the Hurricane Irma response (2017). I was the National Programme Director for Ebola screening and the UK returning workers programme from 2014 to 2016 and the Senior Responsible Officer (SRO) for coordination of the subsequent development of the High Consequence Infectious Disease (HCID) programme. I have contributed knowledge to a number of relevant advisory groups as required during the current pandemic, chaired the SAGE Social Care Working Group from the end of the first wave of the pandemic in 2020 until leaving the DCMO post, led clinical work on the initial shielding programme and acted as SRO for coordination of the subsequent Enhanced Protection Programme (EPP) for those who may remain more clinically vulnerable to serious outcomes from COVID-19.
7. I make this statement in response to the request from the UK Covid-19 Inquiry dated 9 May 2023, under Rule 9 of the Inquiry Rules SI 2006/1838, requiring UKHSA to provide the Inquiry with a corporate witness statement in respect of specified matters relating to Module 3.
8. This statement is, to the best of my knowledge and belief, accurate and complete at the time of signing. Notwithstanding this, it is the case that UKHSA continues to prepare for its involvement in the Inquiry and it is possible that additional relevant information may come to light as the Inquiry progresses. In this eventuality the additional information or relevant material will be provided to the Inquiry and a supplementary statement will be made if requested by the Inquiry.

9. The matters in my statement rely on a mixture of my own experience, the records of UKHSA and its predecessor organisations, and the input from colleagues within UKHSA, who were employees of PHE and NHSTT, and those who have since left but hold relevant knowledge. These colleagues have been consulted as far as is practical, in order to provide as robust an account as possible on behalf of UKHSA.
10. While I have aimed for there to be a consistent level of factual detail provided in response to the questions posed by the Rule 9 request, as a result of the significant number of individuals that contributed to this statement, there may be some natural variation in that level of detail. I understand and expect that the Inquiry will request further detail on any matter if they require it.
11. Exhibits have been listed in this statement in response to the Inquiry's request and in order to provide context. I have not been able to review all the documents exhibited and a number of documents pre-date my own involvement or are derived outside the boundaries of my own operational sphere and in this case, I have relied upon subject matter experts to assist with the information presented.

Structure of the statement

12. In line with the Rule 9 Request to UKHSA, this statement focuses on the role of PHE and UKHSA, in relation to the policy and implementation of shielding measures for those at risk individuals referred to as clinically extremely vulnerable (CEV) and the policy and implementation of measures for those designated as clinically vulnerable (CV). In addition, the development of guidance in England for those referred to as CEV or CV. The remaining matters requested in the Rule 9 are being covered by the statement provided by Professor Susan Hopkins, Chief Medical Advisor to the UKHSA. The relevant period, as specified by the Inquiry, is 1 March 2020 to 28 June 2022. I have referred to matters outside of this date range where appropriate to provide a wider context.
13. In my statement I use the names of organisations as they would have been referred to at the time. For consistency, I refer to the Department of Health and Social care ("DHSC") throughout, rather than the Department of Health ("DH") as it was known prior to 2018. The

statement refers to a large number of organisations, institutions, frameworks and guidance. As a result, the statement sets out the full name once and then references the initials which will be used thereafter. A full set of the acronyms used with an explanation is at [Exhibit: JH3/01 – INQ000348123].

14. This statement where appropriate uses evidence including exhibits from previous statements provided by UKHSA.

15. This statement comprises one section with seven sub-sections:

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SECTION 1- Shielding, the Clinically Extremely Vulnerable and the Clinically Vulnerable

Overview - Clinical and Policy Development for ‘Vulnerable Groups’

16. The role of PHE, and subsequently UKHSA, was predominantly to provide public health advice. Neither PHE nor UKHSA led the development of policy for the Clinically Extremely Vulnerable (CEV) or Clinically Vulnerable (CV) groups. See paragraph 29 for the roles that were held by respective organisations during the Shielding Programme.

17. On 5 March 2020 SAGE discussed the concept of identifying particular groups who may be more clinically vulnerable to Covid by suggesting that ‘there is scientific data to support implementation of social isolation (cocooning) for those over 65 or with underlying medical conditions to delay spread, modify the epidemic peak and reduce mortality rates’. SAGE suggested that ‘cocooning of older and vulnerable patients can start later, and would have to continue longer, than other measures’ [Exhibit: JH3/02 – INQ000106152]
18. On 6 March 2020 the Cabinet Office chaired a meeting to discuss Non Pharma Interventions (NPIs). NPIs are public health and/or behavioural interventions that aim to prevent and/or control transmission of infectious pathogens, such as SARS-CoV-2, in the community and which are not solely dependent on medicines, antivirals and/or vaccines. On 6 March 2020 the Cabinet office commissioned NHSE and UK CMOs to scope the definition and size of a group who might be advised to ‘isolate to protect’, and to develop advice for this group [Exhibit: JH3/03 – INQ000348013 and JH3/03 A & B INQ000348014 and INQ000348015].
19. On 7 March and 8 March 2020, senior clinicians from DHSC, NHSE, NHSD and PHE had a telephone meeting [Exhibit: JH3/04 – INQ000348016] [Exhibit: JH3/05 – INQ000348020] 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. Those at the meetings, and in subsequent email correspondence, agreed a two-tiered approach:
- a. A wider group of approximately 17 million people who were eligible for annual NHS influenza vaccination on account of age or medical conditions who were thought likely to be similarly vulnerable to a novel respiratory coronavirus. Public health messaging and guidance would be created to alert them to their potential increased risk and advise they take extra precautions to avoid contracting Covid-19, but they would not be individually identified or contacted. This group would become the “clinically vulnerable” (CV) group.
 - b. A smaller group of 1-2 million people who may be immunosuppressed or have specific 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 [Exhibit: JH3/06 – INQ000348021] for those self-isolating, but for a period of at least 12 weeks. This group would become the “clinically extremely vulnerable (CEV) group.

20. From 8 March, senior clinicians from DHSC, the DAs, NHS England and NHS Digital, and PHE worked to draw up a list of conditions which would form the basis of the highest risk group, with the intention of identifying them digitally wherever possible using coded primary and secondary care data. This work was undertaken at high speed, and involved emails, phone calls and formal discussions at the CMO-led Senior Clinicians Group (SCG).
21. On 10 March 2020, the Civil Contingencies Secretariat circulated papers for the COBR(O) meeting the same afternoon to attendees across government including several representatives from PHE [Exhibit: JH3/07 – INQ000381214] [Exhibit: JH3/08 – INQ000348023 and JH3/08 A & B; INQ000052411 and INQ000106173]. Included was a presentation on NPIs which included consideration of the stay at home measures for the over 70s and the most vulnerable cohort. The presentation confirmed that the modelling for this proposed policy was to be validated at the SAGE meeting on the same day.
22. On 10 March 2020, SAGE agreed that ‘social distancing measures for the elderly should apply to those aged 70+’. They also advised that ‘social distancing interventions should consider 2 distinct groups: a) those aged 70+ who are generally well and b) vulnerable groups of all ages (including those aged 70+). They provided advice about tiering of the stringency of social distancing advice to these groups as well as some modelling around the trigger points for the introduction of particular measures. They also noted that setting the boundary for this policy to 70 years rather than 65 years of age would not significantly increase deaths, and that GPs should have the discretion to identify patients who did not automatically fall into the highest risk category and add them to the cohort, based on their individual risk. [Exhibit: JH3/09 – INQ000109125]

23. On 13 March 2020 SAGE noted that 'there are no strong scientific grounds to hasten or delay implementation of either household isolation or social distancing of the elderly or the vulnerable in order to manage the epidemiological curve compared to previous advice'. It also noted that there were social and health disbenefits of 'cocooning (shielding) of the elderly as well as coronavirus related benefits' [Exhibit JH3/10 – INQ000109142].

24. The term 'cocooning' which was initially used by SAGE was subsequently refined to 'shielding' by SAGE. The concept of 'cocooning' as initially envisaged by SAGE on 5 March related to measures which they had originally opined would shift the epidemiological curve. By 13 March SAGE advice had developed further to that, as set out in paragraph 23. This formed the basis of the subsequent 'shielding' policy, which was advisory and always intended to protect the group who were advised to shield from Covid-related morbidity and mortality.

25. In parallel, the group which had been identified by senior clinicians on 7 and 8 March as clinically vulnerable but not at highest risk, were identified in the Staying at Home Guidance which was published on 16 March 2020 [Exhibit: JH3/11 – INQ000348029]. This guidance advised 'Clinically vulnerable people' to 'take particular care to minimise contact with others outside your household' and identified the group as those who are:

- a. Aged 70 or older (regardless of medical conditions)
- b. Under 70 with an underlying health condition listed below (that is, anyone instructed to get a flu jab as an adult every year on medical grounds):
 - Chronic (long-term) mild to moderate respiratory disease, such as asthma, chronic obstructive pulmonary disease (COPD), emphysema or bronchitis
 - Chronic heart disease, such as heart failure
 - Chronic kidney disease
 - Chronic liver disease, such as hepatitis
 - Chronic neurological conditions such as Parkinson's disease, motor neurone disease, multiple sclerosis (MS) or cerebral palsy

- Diabetes
- A weakened immune system as the result of conditions such as HIV and AIDS, or medicines such as steroid tablets
- Being seriously overweight (a BMI of 40 or above)
- Pregnant women

26. On 18 March 2020 CMO, with the agreement of the DA CMOs, agreed the list of diseases to be included in the list of the most vulnerable [**Exhibit: JH3/12 – INQ000348030**] [**Exhibit: JH3/13 – INQ000348031**] and shared it with a distribution list including PHE, DHSC, NHSE, and the Cabinet Office. The final agreed list included:

- “1. Solid organ transplant recipients
2. People with specific cancers
 - People with cancer who are undergoing active chemotherapy or radical radiotherapy for lung cancer*
 - People with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
 - People having immunotherapy or other continuing antibody treatments for cancer
 - People having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
 - People who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs
3. People with severe respiratory conditions including all cystic fibrosis, severe asthma and severe COPD
4. People with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as SCID, homozygous sickle cell)
5. People on immunosuppression therapies sufficient to significantly increase risk of infection
6. People who are pregnant with significant heart disease, congenital [“or acquired” subsequently added by DCMO Jenny Harries]”

27. By 18 March 2020 a programme of work to identify, contact, and provide public health advice and support to the highest clinical risk group was simultaneously being established. This programme, which came to be known as the shielding programme, was announced on 21 March 2020. [Exhibit: JH3/14 – INQ000086747]. On this date, PHE published the first piece of guidance for the highest risk group, which introduced the terms “clinically extremely vulnerable” (CEV) to refer to the most clinically vulnerable group, and “clinically vulnerable” (CV) to refer to those at clinically increased risk of severe outcomes.

28. Shielding advice was voluntary from the outset and remained so. Individuals did not have to comply with the recommendations to shield and this was made clear throughout the programme in the guidance published and through direct communications from the Government to this group.

Programme structure

29. The role of PHE, and subsequently UKHSA, was predominantly to provide public health and clinical advice. Neither PHE nor UKHSA led the development of policy for the CEV or CV groups. The table below sets out this role in more detail and provides the responsibilities of different bodies involved in the CEV/CV programme.

<p>Ministry of Housing, Communities and Local Government (MHCLG)</p>	<p>Had overall responsibility for overseeing and delivering the shielding programme.</p> <p>Led on coordination of support to enable people to follow shielding advice.</p> <p>Commissioned local authorities to provide basic support and secured funding from HMT to deliver this.</p>
<p>Office of the Chief Medical Officer (OCMO)</p>	<p>Led on the development of clinical inclusion criteria for both the CV and CEV groups.</p> <p>Strategic clinical oversight of the process for identifying all CEV patients.</p> <p>Clinical lead for updating shielding guidance to CEV group.</p> <p>Commissioner and clinical lead for work on a data-driven risk stratification prediction model and tool (QCOVID).</p>

DHSC	<p>Responsible for delivering the clinical elements of the cross-government Shielding Programme including:</p> <p>Commissioning NHSE and NHSD to identify and contact CEV patients;</p> <p>Leading on the development of shielding and QCovid risk stratification policy;</p> <p>Communication to CEV, the wider health system including professional representation bodies, and patient groups and charities;</p> <p>Evaluation of the shielding programme and liaising with other government departments as needed, such as the Department for Work and Pensions, MHCLG, and the Health and Safety Executive.</p>
NHS Digital	<p>Produced and maintained the Shielded Patient list (SPL).</p> <p>Developed a central platform to run QCOVID on national patient records, drawn from multiple datasets, used to identify 1.5 million highest risk patients with multiple risk factors and add them to the SPL.</p>
NHSE/I	<p>Developed the first letters sent to the CEV cohort on publication of the guidance in March 2020.</p> <p>Communicated with the NHS (primary and secondary care) about the role of the wider system in creating and maintaining the SPL.</p> <p>Ran the service to get medicines to people using local pharmacies on behalf of DHSC and enhanced support to CEV people through the NHS Volunteer Responder service.</p>
PHE	<p>Contributed to early clinical discussions led by CMO about the definition and identification of the CV and CEV groups.</p> <p>Drafted the initial shielding guidance in March 2020 with input from DHSC, NHSE and the OCMO prior to publishing the guidance on gov.uk.</p> <p>Commissioned and published translations and easy read versions of guidance.</p> <p>Provided clinical and public health input to update shielding guidance throughout the programme in 2020 and 2021.</p>
UKHSA	<p>Jenny Harries as Chief Executive of UKHSA was SRO for coordination of the Enhanced Protection Programme (EPP). This was established in January 2022 to ensure people with weakened immune systems who remained at</p>

	higher risk of serious illness from COVID-19 following vaccination were identified and received appropriate interventions, support and communication. Dame Jenny Harries chaired the Clinical Oversight Group of senior clinicians from NHSE/NHSD/DHSC/the DAs and UKHSA that ran in parallel to an implementation and coordination group chaired by DHSC.
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30. Information on my personal role in this area, as a former DCMO, is provided in Section 8.4, paragraph references 8.54 to 8.91 of my individual witness statement for Module 2 (**INQ000273807**), which I have copied below for ease.

Module 2 Statement Excerpt

31. On 5 March 2020, SAGE discussed an initial concept of what was termed 'cocooning' of the most vulnerable. This included the elderly and those with significant underlying health conditions and aimed to protect the most clinically vulnerable from routine societal interactions during the peak waves of the pandemic so as to reduce the likelihood of them being infected. The formal shielding/CEV policy adopted had similar aims but varied in its application for practical reasons from that originally considered at SAGE [**Exhibit: JH4/054 — INQ000061521**].

32. On 7 March 2020, I set out an agenda for a call with a group of senior clinicians across PHE, DHSC, NHSE and NHSD (including the DCMOs) to discuss the potential approaches that could be adopted to protect those understood at the time to be the most clinically vulnerable [**Exhibit: JH4/056 — INQ000151540**]. I outlined these efforts at paragraph 7.36 to 7.37 above. I later emailed the CMO to ensure he was content with the approach being proposed [**Exhibit: JH4/058 — INQ000151543**]:

"...just wanting to check with you that you are content with the position we have arrived at.

- 1. This is effectively quite a liberal social distancing position for the majority of older people and those with underlying chronic conditions — which would*

- include going to work if necessary and appropriately manageable (ie work environments etc) since this is actually the data with which the modellers worked. This group is largely the 'flu vaccination' group. They could exceptionally go to the shops, but advice would be to wash hands ++, limit trips to times when not busy etc etc. There are a few cohorts within this for whom we would need to take further more detailed consideration (eg healthcare workers).*
2. *A much tighter group where we think a true 'cocooning' policy should apply is for exceptional high risk groups eg immunocompromised. We think we could identify these through clinical sources and advise directly. These individuals should self isolate almost as if a confirmed case.*
33. The CMO replied stating that he agreed the approach in principle but that it would need to be put to the other UK CMO's and SAGE to ensure it aligned with their thinking [**Exhibit: JH4/058 — INQ000151543**]. All work subsequent to this, including the agreement of those considered to be at clinical risk and any further policy changes, were considered across all four UK nations. Although identification of those at risk, implementation dates of policies or their practical utilisation varied from time to time to align to local data systems and health services, the underlying principles were agreed on a four nations basis throughout the shielding programme.
34. On 13 March 2020, SAGE stated [**Exhibit: JH4/073 — INQ000109142**]:
- "The science suggests that household isolation and social distancing of the elderly and vulnerable should be implemented soon, provided they can be done well and equitably. Individuals who may want to distance themselves should be advised how to do so."*
35. I updated the CMO on 14 March 2020 [**Exhibit: JH4/167 — INQ000151591**]:
- "the objectives are listed but key ones are (1) to identify the clinically vulnerable groups (2) to understand the process for them to move safely into isolation and equally for them to receive appropriate clinical and social care (inc Covid and non-Covid] whilst*

isolated and (3) describe the links with local communities eg through LAs or LRFs so that the latter are fully aware of their local clinical and socially vulnerable populations"

36. An important practical consideration in the implementation of the shielding policy was how to robustly agree and then identify those who would need to be contacted and included. Given this particular policy was clinically risk based this was firstly a medical question, i.e. which conditions were likely to confer particular individual vulnerability to COVID-19, and advice was sought rapidly through a number of clinical expert conversations; and then one of how those individuals could be identified, contacted and appropriately supported.
37. On 17 March 2020, a final draft list of the proposed CEV cohort was circulated to the SCG. On 18 March 2020, OCMO wrote to the NHS Digital lead to ask them to digitally identify patients that fell into the agreed cohorts, so that they could be contacted with a recommendation to follow stringent social distancing measures initially for 12 weeks **[Exhibit: JH4/168 — INQ000048118]**. Equally important was the need to ensure that an appropriate package of social support was in place for those who were being advised to isolate themselves to a degree not previously implemented at this level of population inclusion.
38. On 15 March 2020 I, with input from various stakeholders, produced a briefing note on the shielding policy which was sent to the CMO **[Exhibit: JH4/077 — INQ000151604]** and practical policy inclusion was worked through with Cabinet Office leads. The policy was announced on 16 March 2020 **[Exhibit: JH4/079 — INQ000203947]**.
39. On 19 March 2020, I provided comments on the detailed "Guidance on shielding and protecting extremely vulnerable persons from COVID-19" **[Exhibit: JH4/086 — INQ000151611]**.

40. Distinct from this protective advice for the clinically extremely vulnerable, the Government published separate advice on 16 March 2020 advising a wider group with other clinical conditions which it was thought at the time may place an individual at higher risk from COVID-19, albeit not with the same predictability or to the same extent as the clinically extremely vulnerable cohort.
41. This group was referred to as the clinically vulnerable group (or "CV" group) and was distinct to the clinically extremely vulnerable (or "CEV") group who were able to be supported by the shielding programme. The advice for the CV group in effect encouraged them to be particularly careful in their adherence to the social distancing guidance published for the population in general.
42. Nomenclature which included the word "vulnerable" was very active in many other government departments for recognised different elements of vulnerability e.g. socio-economic, transport, education etc. Therefore, the need for somewhat cumbersome but important lengthy clinical definitions to ensure reach to those at predictable risk was important as was the need to continue to reinforce the advisory nature of shielding guidance. At no time was shielding compulsory or legally prescribed. At all times it was a patient choice.
43. On 21 March 2020, Professor Stephen Powis, National Medical Director of NHS England, and the CMO sent a CAS alert to clinicians asking for help in the management and shielding of patients considered at that point likely to be at the highest risk of severe morbidity and mortality [**Exhibit: JH4/169 — INQ000068544**]. The alert described the complex process needed to enable maximum inclusion of potentially affected patients, many of whom could not be identified by centralised electronic systems e.g. those on particular immunosuppression therapies. Identification and subsequent communications, on an ongoing basis, therefore included complex work with NHSE, subspecialty clinical leads in secondary care services, the Academy of Medical Royal Colleges ("AoMRC"), the Royal College of General Practitioners ("RCGP") and numerous patient advocacy groups for all of whom I contributed to meetings and/or chaired frequent webinars.

44. It was recognised at the start that whilst the majority of individuals could be identified relatively quickly, for others there would be a time lag and therefore a phased inclusion into the CEV cohort. For obvious protective reasons, we did not delay alerting the majority whom we could reach digitally and immediately. As a result, there was a planned expansion of the cohort over several weeks as different clinicians in different specialties identified individual patients and conversations with those patients took place, and a recognised continuous change in numbers as patients moved into and out of the 'at risk' cohort and/or the evidence changed. The final initial cohort size was an everchanging but approximate 2.2 million people.
45. The programme of shielding was initially envisaged as one of approximately twelve weeks duration. Alongside the clinical elements of shielding, a support programme ("the Shielding Programme") was led by MHCLG which covered all relevant support packages with the exception of the medicines delivery service which was overseen by DHSC. I tried to explain in simple terms the likely forward approach for shielding advice from an epidemiological perspective to policy colleagues in DHSC on 15 April **[Exhibit: JH4/170- INQ000151753]**.
46. On the same day, I also provided feedback on rapidly constructed proposals from DHSC to measure the effectiveness of the shielding programme following a request from No 10 **[Exhibit: JH4/171 — INQ000151754]**, in particular its effectiveness in improving mortality and/or morbidity. I expressed my concerns that the proposed evaluation framework was not adequate or robust for the task in hand. This was in large part due to the heterogeneity of the group identified and the uncertainty about the virus and therefore the difficulty in identifying an expected versus observed mortality outcome. The note also highlights an early request to the ONS on potential evaluation of many of the behavioural aspects of the CEV group, although in practice the reports which were later produced did not actually capture the formally identified CEV cohort.

47. Given the potential serious risk to this group of patients based on clinical plausibility, it would have been unethical not to commence the programme as early as possible or, alternatively, to try to have any process which would lead to more robust methods of evaluation, such as a non-interventionalist study arm. Nor do I think this was possible. It was recognised that the shielding programme would have an impact on daily living and independent ethics advice was obtained on the appropriateness of making changes to the programme. There was also considerable post hoc resource expended in trying to understand for future benefit what the impact of the programme had been and how any future similar programmes, if appropriate, could be improved.
48. In April 2020, the UK Clinical Panel for Shielded Patients (which I chaired along with senior clinical representation from all UK CMOs offices) was established to review the evidence on which groups were considered most vulnerable at that time and make recommendations to the UK CMOs as to who should be added to the Shielded Patients List ("SPL"). Changes to that list were made only with the support of all UK CMOs.
49. In the context of the future of the shielding programme and possible growth of the group asked to shield, I provided advice to DHSC on 26 April [**Exhibit: JH4/172 — INQ000151804**] and 29 April 2020 [**Exhibit: JH4/173 — INQ000151814**]. These documents both highlight the difficulties of maintaining clarity of the purpose and delineation of shielding for the CEV group across policy makers as well as the voluntary nature, and personal benefit, of its design and objective.
50. As the relaxation of NPI's began to be considered, there then needed to be consideration of the advice to be given to those shielding. I gave my view to DHSC on the matter on 4 May 2020 [**Exhibit: JH4/174 — INQ000151824**]:

"My own proposal is that we should keep the original clinical vulnerable group (ie generally clinically vulnerable including the shielded group) within the group which SAGE identified and separate from the rest of the population. If the rate of

implementation had stayed as originally envisaged the different groupings would be well understood by the public — it was because of growing evidence from Italy that we then responded rapidly to new data and moved the general population into a lockdown position almost as soon as the generally clinically vulnerable group were identified. In short we should put everyone back in their original risk groupings for this weekend. There may be new advice for the public at large but there is existing advice for the clinically identified groups, the criteria for inclusion for this group being under active review"

51. This process continued over the course of the month. On 24 May 2020, I advised DHSC on the need for caution when considering loosening the requirement for the clinically extremely vulnerable and those of 70 or over to shield. I noted for example the risks of someone having to isolate for a long period and "bubbling" **[Exhibit: JH4/175 - INQ000152001]**.

52. From 6 July 2020, with the changing epidemiology, advice to the CEV group was made less restrictive. I provided written clinical advice on more than ten occasions to inform and clarify the policy discussion with this decision summarised in a final recommendation **[Exhibit: JH4/176 — INQ000203905]**:

"We have now received initial clinical advice from the DCMO that the incidence rate in the community is sufficiently low that advice for those in the CEV group to shield could be paused. The DCMO has advised that the CEV group could be advised to follow the same guidance as the clinically vulnerable (CV) group from the end of June, noting that it will be important to maintain the CEV cohort, even if advice is stepped down, to allow us to rapidly step up support again should this be needed in the future. There are likely to be significant associated psychological as well as physical impacts of a change in policy. It is therefore recommended to be managed gradually and with detailed clinical professional as well as patient and public communications."

53. Accordingly, the formal advice that they should pursue extensive restrictions on their daily lives was revisited **[Exhibit: JH4/175 — INQ000152001]**. In circumstances however where local prevalence of the disease remained high, a different approach needed to be taken. This was for instance the case in Leicester in the summer of 2020 **[Exhibit: JH4/177 — INQ000152493]** **[Exhibit: JH4/178 — INQ000152563]**.

54. On 29 July 2020, I responded to a request from DHSC regarding whether I supported maintaining the 'at risk' and 'clinically extremely vulnerable' categories in care home guidance despite the pausing of the shielding programme. I replied **[Exhibit: JH4/337 — INQ000152614]**:

"I am fully supportive of the policy team position for two reasons:

- Whilst the shielding advice will end most in England on 31st July, this a paused process. Therefore we should continue to recognise this group of vulnerable individuals in consideration for safe policy and operational developments*
- In some areas eg Leicester, Luton etc where local lockdowns are in force this will remain relevant*
- It is very likely that there will be ongoing surges in community transmission across the country and potentially nationally again at a single point in time in the autumn/winter*
- This group remain highly vulnerable to Covid-19, particularly the very elderly, within a setting where we are still looking to fully explore and mitigate risks of transmission and therefore it is important that all appropriate steps in care should continue".*

55. In the context of rising case rates in autumn 2020 and the prospect of a new national lockdown, consideration needed to be given to the approach of advising the CV and CEV groups. On 31 October 2020, I advised DHSC **[Exhibit: JH4/179 — INQ000153080]**:

- "We should not return people to fully restrictive shielding ie never leaving the house, given the known negative mental health impact, particularly given the*

extended periods of relative isolation we have reached through the pandemic to date

- *We should however move to the Tier 3+ advice already drafted - which is effectively the 'modern' form of shielding - and already signalled in existing advice and will in large part be being followed by the general public in any national intervention*
- *This includes the following provision:*
 - *Those on the SPL [the Shielded Patients List] should stay at home at all times except for exercise or critical exit requirements (eg essential healthcare)*
 - *Medicines delivery should be turned on to support staying at home for those who need it*
 - *Food access arrangements should be supported through local community engagement delivery prioritisation volunteers*
 - *Those unable to work from home (current estimate c 62k should) should have access to SSP — this should be accessible through the digital portal already developed. The intervention is for a specified period and the assumption will be this ceases at the end of the 4 week period*
 - *School children who are due to remain on the SPL indefinitely should NOT attend school (but there will be some detailed messaging required to ensure children due to leave the SPL are encouraged to stay in school)*
 - *We should continue to rapidly include those additional groups already identified by the Clinical Panel at increased risk and not yet included in the SPL - CKD5 and Downs. This work has been paused by CO but there is clinical agreement with NHSE that work should proceed apace on Monday unless other factors preclude this.*
- *in addition advice should be that those on the SPL do NOT provide childcare or other caring arrangements even though these are permitted more generally*

Generally clinically vulnerable

- *There is broad advice in the public domain for individuals to take extra care if they are elderly or have underlying health conditions — this covers large numbers of the population and all will be supported by the fact all will be required to work from home where they can*
- *SPI-M modelling was based on 70 + age groups as a key inflection point in risk rise and current advice reflects this. In reality age risk starts to rise in mid-life and varies by gender therefore the point at which advice is commenced cannot easily be isolated to a fixed period to encompass all increased risk*
- *For simplicity and consistency in adherence in messaging / suggest we continue to use the 70+ age cut off in existing guidance but ensure that it sits within a wider comms message that as one gets older risks increase, **this is particularly true for those in older age groups from 70+**"*

56. On 20 November 2020, I provided advice to the Cabinet Office on shielding including during the Christmas period and the maintenance of consistent messaging between the four nations, which was strongly supported by all UK CMOs and their representatives on the Clinical Panel **[Exhibit: JH4/180 — INQ000153288]**.
57. When the vaccine rollout began in December 2020, the CEV group was deemed a highest priority group by JCVI and hence included in Phase 1 of the roll-out.
58. On 19 December 2020, I advised MHCLG, DHSC, HMT and the Cabinet Office on shielding in tier 4 areas **[Exhibit: JH4/181 — INQ000153507]**.
59. The CEV group was again advised to shield from 5 January 2021 due to significantly rising case numbers.
60. On 10 February 2021, I provided advice regarding the extension of the shielding advice until 31 March 2021 **[Exhibit: JH4/182 — IN0000153711]**:

"I am content to recommend that our current shielding advice time period be extended to 31st March.

This reflects:

- 1. The reducing but continued high background community transmission rates of Covid-19*
- 2. Our current very rudimentary understanding of vaccine effectiveness, particularly in some of the CEV groups*
- 3. The ongoing pressures on NHS capacity, both from Covid-19 and additionally in recent days from support required due to winter pressures*

As previously we do not want to extend this too far into the future without good reason given the important consideration of the impact on mental as well as physical health and infection risk."

61. This advice continued until 1 April 2021, when the shielding programme was paused and the CEV group were advised to follow the national restrictions alongside the rest of the population whilst taking certain extra precautions. From 19 July 2021, the CEV group were advised to follow the same guidance as everyone else. On 15 September 2021, the shielding programme was formally stood down; this was largely due to the success of the vaccine program. I and Sir Jonathan provided advice on this on 23 July 2021 [**Exhibit: JH4/183 — INQ000203914**].
62. At this point, the final total identified cohort was 3.8 million, a rise from the c2.2 million originally identified through clinical routes, to incorporate utilisation of the intersectional risk scoring of the Q-Covid Risk Tool, a product described later in this document and developed with Oxford University early in the pandemic to support individual patient risk discussions with work overseen by myself and colleagues in OCMO.

Shielding and children

63. Although this issue will likely fall for detailed consideration in a later module, it is important to recognise that a cohort of children were considered on a precautionary basis to potentially fall within the clinically extremely vulnerable group which formed part of the original CEV cohort. It became clear after early review that the risk of serious disease or death in most children from COVID-19 infection at that time was very low.
64. In turn, the CEV child cohort was reviewed with RCPCH, the NHSE clinical director for children and other specialists, including from the four nations, and it was agreed by the UK CMOs that only those with significant neuro developmental and other specific conditions needed to be advised to shield. These changes were communicated through both clinical and direct patient/carer routes and guidance for children to return to school for the autumn term 2020 clearly included all those previously identified on the SPL except where individual clinical advice had been received to continue shielding.

Involvement of UKHSA with the Shielding Programme

65. Around the same time as the establishment of UKHSA and through 2021, new evidence on individual clinical condition risks began to strengthen as well as evidence of effectiveness of vaccines for many of those on the SPL, including those with significant immunosuppression. There was recognition within government that: (a) patient groups remained concerned about their own individual condition risk factors; (b) vaccine effectiveness and new treatment information would be critical both over time and with new product approval; and (c) that as had been evidenced in the original set up of the programme, complex communications across policy, NHS delivery, vaccine and therapeutics recommendations, priority testing access and epidemiological changes all benefitted from a mechanism of coordination.
66. In January 2022, the Government therefore established a new coordination programme, called the Enhanced Protection Programme (EPP), for which I was

asked to resume a coordinating lead in my role as UKHSA CEO [**Exhibit: JH4/184 - INQ000287603**]. The purpose of the EPP was to ensure that cohorts of individuals at higher risk of serious illness from coronavirus (due to immunosuppression or a specific other medical condition), largely identified through the shielding programme, continued to be easily identified and received appropriate interventions, support and communication. To ensure oversight of the programme, a Clinical Coordination Oversight Group was established and ran across all relevant contributing organisations, with myself as chair, from 11 January 2022 to 19 April 2023. This work was broadly very similar to that which I had led on previously from April 2020 to September 2021 in my DCMO role.

67. As before, the various organisations' combined work was to ensure that cohorts of high risk individuals were identified for current and future clinical advice and, if appropriate, treatments and interventions. There was a process for reviewing inclusion criteria through NHSE specialist clinical reference groups and for ensuring wherever possible all communications were coordinated and a process for reviewing public health advice was agreed. A complimentary Coordination and Delivery Group was established with DHSC oversight but with contributions from those working in all the main contributory organisations.

68. The EPP was brought to a close in April 2023 with those with specific clinical conditions being managed through their own specialists and test and treatment systems in place for them to rapidly access antivirals. However, there was recognition that meetings for the CEV group representatives will be arranged for any significant changes in policy, with UKHSA oversight. The Oversight Group can be convened by any contributing organisation at any point where there is a need for wider action and/or policy agreement to support those in the CEV group, both for COVID-19 but importantly for novel pathogens or significant relevant future health protection incidents.

(Statement excerpt ends)

Refining the CEV and CV Cohort and identifying CEV and CV Individuals

69. See above for an overview of the background and early clinical and policy development for these cohorts.
70. The initial CV/CEV distinction reflected advice SAGE gave to stratify protective support to individuals by the risk attributable at that time to their age and/or underlying medical conditions at its thirteenth Covid-19 meeting on 5 March 2020, minutes of which are exhibited here **[Exhibit: JH3/02 – INQ000348012]** and at paragraph 17.
71. Following this meeting the OCMO coordinated a senior clinicians call to refine the approach into 2 distinct groups: a wider CV group and a group CEV group. PHE was part of these discussions.
72. The clinical conditions that defined the CEV cohort were agreed by the UKCMOs throughout the shielding programme. As new knowledge emerged about the virus and its potential to cause severe disease in certain populations, the UKCMOs revised the list of medical conditions understood to equate to those identified as CEV. OCMO is best placed to provide information on the governance and processes for identifying clinical inclusion criteria for and identifying individuals as CEV.
73. NHSD led on the technical process for identifying the initial digital cohort of individuals categorised as CEV and on maintaining a dynamic list of patients who met the clinical criteria, known as the Shielded Patient List (SPL). On 20 March 2020, NHSD produced the first iteration of the SPL. **[Exhibit: JH3/15 – INQ000298956]**
74. OCMO coordinated initial clinical engagement across the health system where a digital approach to identification of people meeting the clinical criteria for inclusion on the SPL was not possible. This resulted in manual additions to the SPL by GPs and hospital teams in parallel.

75. NHSE took forward communication with healthcare settings to identify those with conditions and/or risks of clinically extreme vulnerability [**Exhibit: JH3/16 – INQ000348035**] [**Exhibit: JH3/17 – INQ000237534**]
76. NHSD's digital identification capability was developed at the outset of the pandemic in response to the need to rapidly identify individuals at higher risk of serious illness from Covid-19. The clinical codes representing the conditions which defined the CEV cohort and which underpinned the SPL were regularly updated as the clinical conditions defining the CEV cohort changed in line with emerging evidence. The SPL was also run nationally every week, to ensure newly diagnosed patients were included on the list.
77. This stepped approach to identification of the CEV (digitally/centrally run using codes and with a manual 'safety net' of GP and hospital consultant additions) meant those who could be identified rapidly were included and contacted as quickly as possible to maximise risk mitigation.
78. As data from the first wave of the pandemic in England accrued, the CMO commissioned NERVTAG in May 2020 to produce a data-driven, predictive risk model for Covid-19 death to better understand the cumulative effect of weighted risk factors (demographic and clinical). This was published in the BMJ on 20 October 2020. [**Exhibit: JH3/18 – INQ000348038**]. The model (QCovid) combined a number of characteristics to estimate the risk of catching and then being hospitalised or dying from Covid-19. The risk factors in QCovid included age, ethnicity, gender and deprivation, reflecting an inequalities focus. Clinical conditions and treatments were also included.
79. NHS Digital built a platform to apply QCovid at scale to centrally held medical records to identify highest risk patients who had not previously been identified using the conditions based approach to CEV definition at the start of the pandemic in the absence of data.
80. NHSD added 1.7 million patients to the SPL and to the CEV cohort in February 2021 as a result of the application of QCOVID to national patient records and the subsequent

identification of a group of people who exceeded agreed relative and absolute risk thresholds, recommended by the UKCMOs and agreed by ministers. The QCovid risk stratification of England's population resulted in an additional group of more than 800,000 adults being prioritised for vaccination as a result of inclusion in the Joint Committee for Vaccination and Immunisation vaccination cohorts (which recognised the CEV cohort as requiring prioritisation). [Exhibit: JH3/19 – INQ000348039].

Communication with CEV patients

81. DHSC held overall responsibility for communication with CEV and CV individuals and is better placed to address this. PHE and subsequently UKHSA were mainly involved in the production of guidance.

82. The Government communicated advice to the CEV cohort via multiple channels coordinated by DHSC including:

- a. National guidance, which PHE and then UKHSA helped to develop
- b. Letters coordinated by the NHS and MHCLG
- c. Patient advocacy groups with which OCMO engaged
- d. Via their clinicians, to whom the NHS and OCMO provided guidance and information about CEV and shielding advice.

83. The CV group was not contacted individually, but advice to the CV group was incorporated in the guidance issued to the general public throughout the pandemic. The national guidance published by PHE on 16 March 2020 identified the clinical inclusion criteria for the cohort and provided public health advice to them.

Development of guidance for the CV and CEV cohorts

84. Although various individual guidance documents for CV and CEV groups have previously been mentioned, this section provides a narrative of the publication sequence for clarity, finishing with a table setting out key versions of the guidance. By 12 March 2020, following a

commission from DHSC, PHE had begun developing guidance for those at higher risk for severe disease from COVID-19 (which would become known as the CEV group). [Exhibit JH3/20 – INQ000348040] [Exhibit JH3/21 – INQ000348041].

85. On 16 March 2020, PHE issued guidance for a wider group with other clinical conditions which were thought at the time to potentially place an individual at higher risk from COVID (which would become known as the CV group), as a separate section within the wider public social distancing guidance, exhibited here [Exhibit JH3/20 – INQ000348040] and above at paragraph 84. This advised the group to be ‘particularly stringent in following social distancing measures’ published for the population in general. No standalone guidance was issued. The CV guidance was voluntary and there was no requirement for those considered CV individuals to comply.
86. The guidance for the CV contained within the wider social distancing guidance was updated 3 times between 16 March 2020 and 30 March 2020 before Cabinet Office took ownership of this guidance on 1 May 2020 [Exhibit: JH3/22 – INQ000348043].
87. On 21 March 2020, PHE published the first iteration of the guidance on shielding and protecting people defined at that time on medical grounds as extremely vulnerable from COVID-19 [Exhibit: JH3/23 – INQ000348044], now referred to as the CEV. The guidance was cleared through a delegated senior clinician in PHE, the DCMO, the Secretary of State for Health and Social Care and subsequently the Prime Minister’s Office. This advised that people in the CEV group who had one of the listed highest outcome risk, underlying health conditions, would be contacted separately by letter and were advised to stay at home for at least 12 weeks from the day they received the letter.
88. In the days leading up to the publication of this guidance PHE and the NHS (who led on the practical digital and administrative identification of high-risk individuals) provided clinical content for the letters to the CEV group covering topics such as mental wellbeing and consistency with guidance around exercising outside. [Exhibit JH3/23a - INQ000408908 and [JH3/23a(i)] NQ000408909], [Exhibit: JH3/23b - INQ000408910 and [JH3/23b(i)] INQ000408911], [Exhibit: JH3/24 – INQ000348045 and [JH3/24A] INQ000348046]. The

NHS incorporated this clinical information into these letters and sent them out to the CEV group in tandem with guidance being published.

89. The role of PHE, and subsequently UKHSA, was predominantly to provide public health advice. Neither PHE nor UKHSA led the development of the policy reflected in the guidance for the CEV or CV groups. Both DHSC and PHE could initiate changes to the guidance. DHSC typically instigated updates to the guidance in line with policy changes and PHE typically instigated changes when there were cross-cutting changes to make, for example, regarding terminology, and around stay at home or testing policy. If DHSC made changes regarding policy, PHE would provide comments, quality assuring the text to ensure that it was still well written, was consistent with other published guidance, and would also contribute public health advice.
90. As an example of the correspondence between PHE and DHSC regarding updates to the guidance, on 30 May 2020 DHSC shared suggested amendments to the existing guidance for the CEV to reflect the relaxation of Government guidance to the general population. **[Exhibit: JH3/24a – INQ000408912]** **[Exhibit: JH3/24b - INQ000408913]** **[Exhibit: JH3/24c – INQ000408914]** **[Exhibit: JH3/24d – INQ000408915]**. Key changes to the guidance are set out in the table later in this section.
91. Guidance for the CEV was updated as the epidemiology changed through the course of the pandemic and to make each version of the guidance accessible through easy read versions and translations of the guidance.
92. On 25 June 2020 PHE and DHSC discussed whether DHSC should take on sole ownership of the guidance for the CEV at this point, given PHE's limited role in advising on the guidance or leading on the updates. DHSC's view was that this was 'public health guidance' so should continue to be published by PHE. **[Exhibit: JH3/25 – INQ000348048]**. Guidance as a result continued to be published under PHE until October 2020.
93. From October 2020, the CEV guidance was published on gov.uk jointly by DHSC and PHE.

94. On 20 September 2021, the shielding programme officially closed and the guidance pointed readers to the main guidance for the public on staying safe and preventing the spread of COVID-19. More detail is provided in the table below.

95. The table below sets out PHE and UKHSA input to the guidance for the CEV and the CV and lists some of the notable changes to the guidance. It does not include updates of the easy read and translated versions of the guidance which took place after every major update of the main guidance; these are discussed in more detail at paragraphs 96 to 102.

Date	Guidance	Who published	Update	Link
16 March 2020	CV Guidance	PHE	Publication of “guidance on social distancing for everyone in the UK and protecting older people and vulnerable adults”.	[Exhibit: JH3/11 – INQ000348029]
21 March 2020	CEV Guidance	PHE	Publication of “COVID-19: guidance on shielding and protecting people defined on medical grounds as extremely vulnerable.”	[Exhibit: JH3/23 – INQ000348044]
30 March 2020	CEV Guidance	PHE	Guidance updated. List of CEV conditions amended	[Exhibit: JH3/28 – INQ000348049]
1 May 2020	CV Guidance	Cabinet Office	Publication of “Staying at home and away from others (social distancing).”	[Exhibit: JH3/22 – INQ000348043]
5 May 2020	CEV Guidance	PHE	Publication of “Guidance for young people on shielding and protecting people most likely to	[Exhibit: JH3/30 – INQ000348050]

			become unwell if they catch coronavirus”.	
18 May 2020	CEV Guidance	PHE	Guidance update to include updated information on symptoms.	[Exhibit: JH3/31 – INQ000348051]
31 May 2020	CEV Guidance	PHE	Guidance updated in line with upcoming changes to the regulations from 1 June 2020.	[Exhibit: JH3/32 – INQ000348052] [Exhibit: JH3/33 – INQ000348053]
5 June 2020	CEV Guidance	PHE	Guidance for young people updated in line with changes to the regulations from 1 June 2020.	[Exhibit: JH3/34 – INQ000348054]
23 June 2020	CEV Guidance	PHE	Guidance updated to reflect Government advice from 6 July relaxing social distancing guidelines and allowing people who were shielding to meet in groups of up to six people outside their homes.	[Exhibit: JH3/35 – INQ000348055]
7 July 2020	CEV Guidance	PHE	Updated guidance to include clinical risk to children and young people.	[Exhibit: JH3/36 – INQ000348056]
8 July 2020	CEV Guidance	PHE	Guidance updated to include a link to local lockdown guidance.	[Exhibit: JH3/37 – INQ000348057]
31 July 2020	CEV guidance	PHE	Guidance update to reflect the pause of the shielding policy from 1 August 2020.	[Exhibit: JH3/38 – INQ000348058]

4 August 2020	CEV guidance	PHE	Out-of-date guidance for young people removed.	[Exhibit: JH3/39 – INQ000348059]
18 August 2020	CEV guidance	PHE	Updated section on young people who are clinically extremely vulnerable and who have been shielding.	[Exhibit: JH3/40 – INQ000348060]
4 September 2020	CEV guidance	PHE	Update added new guidance for young people who are clinically extremely vulnerable and have been shielding.	[Exhibit: JH3/41 – INQ000348061]
29 September 2020	CEV guidance	PHE	Updated to remove references to rates of transmission of coronavirus falling, in response to user feedback.	[Exhibit: JH3/42 – INQ000348062]
13 October 2020	CEV guidance	PHE/DHSC	Guidance now co-badged with DHSC. New guidance for children, young people, and adults, who are CEV linked to the introduction of Local Covid Alert Levels replaced previous guidance.	[Exhibit: JH3/43 – INQ000348063]
4 November 2020	CEV guidance	PHE/DHSC	Updated guidance in line with national restrictions that were due to commence on 5 November 2020 requiring people to stay at home. The update included letters from the	[Exhibit: JH3/44 – INQ000348064]

			Secretaries of State for Health and Social Care and for Housing, communities and Local Government to the CEV cohort and parents of children who were CEV.	
2 December 2020	CEV guidance	PHE/DHSC	Updated guidance to reflect policy changes relating to tiering and include information on local tiering.	[Exhibit: JH3/45 – INQ000348065]
20 December 2020	CEV guidance	PHE/DHSC	Added new shielding advice for the clinically extremely vulnerable in Tier 4.	[Exhibit: JH3/46 – INQ000348066]
7 January 2021	CEV guidance	PHE/DHSC	Guidance was updated to reflect the introduction of national lockdown. The guidance also included reference to the vaccination programme and the CEV cohort.	[Exhibit: JH3/47 – INQ000348067]
16 February 2021	CEV guidance	PHE/DHSC	Updated definition of clinically extremely vulnerable groups.	[Exhibit: JH3/48 – INQ000348068]
25 February 2021	CEV guidance	PHE/DHSC	Updated to reflect new shielding end date, and updated shopping and support sections.	[Exhibit: JH3/49 – INQ000348069]

18 March 2021	CEV guidance	PHE/DHSC	Added link to new letter to all people on the SPL that took effect from 1 April 2021.	[Exhibit: JH3/50 – INQ000348070]
1 April 2021	CEV guidance	PHE/DHSC	Guidance updated to reflect pausing of the shielding programme.	[Exhibit: JH3/51 – INQ000348071]
17 May 2021	CEV guidance	PHE/DHSC	Guidance on meeting family and friends was updated to state this was a personal choice but encouraging caution to be exercised.	[Exhibit: JH3/52 – INQ000348072]
21 June 2021	CEV guidance	PHE/DHSC	Updated to reflect national restrictions had changed.	[Exhibit: JH3/53 – INQ000348073]
12 July 2021	CEV guidance	PHE/DHSC	Guidance updated as per government's advice for clinically extremely vulnerable people to, as a minimum, follow the same guidance as the general population.	[Exhibit: JH3/54 – INQ000348074]
21 July 2021	CEV guidance	PHE/DHSC	Updated to reflect move to Stage 4 of the Roadmap, including section on socialising inside and outside the home. Added information about vaccinations for eligible children and young people.	[Exhibit: JH3/55 – INQ000348075]

3 September 2021	CEV guidance	PHE/DHSC	Updated to reflect the removal of the majority of children and young people from the Shielded Patient List.	[Exhibit: JH3/56 – INQ000348076]
14 September 2021	CEV guidance	PHE/DHSC	Updated to reflect the end of the shielding programme from 15 September, and to advise that guidance will be updated shortly.	[Exhibit: JH3/57 – INQ000348077]
20 September 2021	CEV guidance	PHE/DHSC	Given the successful rollout of the vaccination programme (with vaccines now having been offered to all of the adult population in England) and the availability of other treatments and care pathways, the shielding programme officially closed. The guidance became a very short document advising people that they should follow the main guidance for the public on staying safe and preventing the spread of COVID-19.	[Exhibit: JH3/58 – INQ000348078] [Exhibit: JH3/59 – INQ000348079]

Measures taken to ensure accessibility of advice

96. Members of the CEV group were alerted to the guidance through the letters coordinated by the NHS and the other channels coordinated by DHSC, set out above.
97. PHE published guidance on social distancing and for the CV group and the main guidance for the CEV group in an HTML format, to ensure compatibility with screen readers for those that use them. All PDF documents were available as accessible formats through clicking a link on the gov.uk website.
98. There was also an option to request an accessible alternative of the guidance, with the webpage stating, “if you use assistive technology (such as a screen reader) and need a version of this document in a more accessible format, please email publications@phe.gov.uk. Please tell us what format you need. It will help us if you say what assistive technology you use.”
99. PHE produced translations and easy read formats of the CV guidance it published on 16 March 2020 and for each version it published of the CEV guidance:
- a. On 20 March 2020, PHE published translations of the guidance on social distancing and for the CV group into Arabic, Chinese – Traditional, Chinese – Simplified, French, Polish and Welsh. The Arabic translation is exhibited here as an example: **[Exhibit: JH3/60 – INQ000348080]**
 - b. On 23 March 2020 PHE published further translations of the guidance on social distancing and for the CV group into Bengali, Gujarati, Portuguese, Punjabi and Urdu. The Bengali translation is exhibited here as an example: **[Exhibit: JH3/61 – INQ000348081]**
 - c. On 24 March 2020, PHE first published an easy read version of the guidance for the CEV **[Exhibit: JH3/62 – INQ000348082]**, three days after the main guidance. Easy read versions of the guidance continued to be published as it was updated until 25 February 2022.

- d. On 30 March 2020 PHE commissioned and published translations of the guidance for the CEV into Arabic, Bengali, Chinese – Traditional, Chinese – Simplified, French, Gujarati, Polish, Portuguese, Punjabi, Urdu and Welsh. The Arabic translation is exhibited here as an example: **[Exhibit: JH3/63 – INQ000348083]**. Translations of this guidance continued to be published as it was updated until 25 February 2022
 - e. On 30 March 2020, PHE published easy read versions of the guidance on social distancing and for the CV group. **[Exhibit: JH3/64 – INQ000348084] [Exhibit: JH3/65 – INQ000348085]**.
100. On 30 April 2020 PHE’s Behavioural Science Team and Imperial College London (ICL) conducted a review of the shielding guidance with focus groups comprised of members of the public, the majority of whom were either themselves in one of the “at-risk” or “vulnerable” groups, or were a carer and/or a family member, of those known to be CV or CEV and who were being asked to take extra measures to protect themselves against COVID-19. The groups focused on reviewing the guidance to provide feedback on clarity, to identify any information that individuals felt was missing, and to suggest any other potential improvements. ICL produced a report and provided an executive summary of the insights gained from comments and perspectives to PHE on 7 May 2020 **[Exhibit: JH3/66 – INQ000224000] [Exhibit: JH3/67 – INQ000348087] [Exhibit: JH3/68 - INQ000348088]**.
101. On 11 November 2020 PHE also published on gov.uk easy read and translated versions of the letters sent to the CEV, following a commission from DHSC **[Exhibit: JH3/69 – INQ000348089] [Exhibit: JH3/70 – INQ000348090]**.
102. DHSC also coordinated large print, audio and British Sign Language video formats of the guidance produced. On 9 December 2020 British Sign Language videos, large print and audio versions of the CEV guidance were first added to gov.uk. These continued to be published until 25 February 2022.

Risks Relating to CEV and CV Not Accessing healthcare

103. The guidance for the CV group published on 16 March 2020 strongly advised this cohort to use remote access to NHS and essential services (for example telephone appointments or online access) and to talk to GPs and clinicians regarding scheduled face to face medical appointments to ensure that patients still received the care they needed. This guidance is exhibited here [**Exhibit: JH3/11 – INQ000348029**] and at paragraph 25.
104. The guidance for the CEV group exhibited here [**Exhibit: JH3/23 – INQ000348044**] and above at paragraph 87) was published on 21 March 2020. Although in general, health services were advised to be carried out remotely, where appropriate the guidance specifically advised any in this cohort with scheduled hospital or other medical appointments to speak with their GP or treating clinicians to ensure they continued to receive the care they needed.
105. NHSE undertook further work to ensure it continued to deliver appropriate healthcare access for CEV patients and it will be able to provide further information on this.
106. On 30 March 2020 PHE published guidance for the public on the mental health and wellbeing aspects of COVID-19. The guidance acknowledged the potential worry and anxiety that might be experienced by those staying at home and social distancing. It encouraged those who were being treated or taking medication for existing conditions to continue accessing treatment and support where possible and to let relevant services know that they were staying at home and of their foreseeable ongoing needs.
- [Exhibit: JH3/71 – INQ000348091]**. PHE regularly updated the guidance until it was superseded by the NHS's "Every Mind Matters" tool on 19 July 2021.
107. On 31 May 2020 PHE supported the rapid development of updated COVID-19 guidance on shielding and protecting people defined on medical grounds as extremely vulnerable. The criticality of ensuring those in the CEV group continued to attend for health interventions in both the immediate future and longer term was recognised and was supported by suggested changes to wording in iterative drafting between DHSC, the Cabinet Office, and PHE. For example, in email exchanges a PHE employee noted that under Hospital and GP

appointments, 'we have removed the word "absolutely", asking people who are shielding to discuss with their GP or specialist which appointments are "essential". This paragraph going forward will need further review, as this group of people will need to be accessing medical services.' **[Exhibit: JH3/72 – INQ000348092] [Exhibit: JH3/73 – INQ000348094].**

October 2021 Onwards – Enhanced Protection Programme and Reversion to Business as Usual

108. The original shielding programme closed on 15 September 2021 although underlying structures to advise those at risk remained in place including at the point of subsequent emergence of the Omicron variant. On 24 December 2021 UKHSA and DHSC issued updated public health advice to two separate groups outlined below with DHSC leading on the drafting of the guidance and UKHSA providing technical comments as required.
109. The first group was the CEV group. The success of the COVID-19 vaccination programme meant that most people who were part of this CEV patient cohort were no longer at substantially greater risk than the general population and were advised to follow the same guidance as the general population on staying safe and preventing the spread of COVID-19 and other respiratory infections, as well as any further advice received from their healthcare professional. **[Exhibit: JH3/74 – INQ000348095].**
110. The second group was a cohort of approximately 1.8 million people, whose weakened immune system meant they were at higher risk of serious illness from COVID-19, despite vaccination and were offered enhanced protections such as treatments, booster vaccines, free lateral flow tests and public health advice. The second group included those over 12 who were immunosuppressed or had a specific other medical condition. Whilst there was some overlap with the former CEV group, this later cohort consisted of those eligible for the additional primary dose of the vaccine and those identified as potentially eligible for antiviral and therapeutic treatments. These individuals had a reduced ability to fight infections and other diseases, including COVID-19. **[Exhibit: JH3/75 – INQ000348096].**
111. It became clear that there was clinical complexity about differing vaccination schedules and therapeutics required for various clinical conditions. In order to address this in a

clinically consistent and coherent way, a new programme, the Enhanced Protection Programme (EPP), was established. Its aim was to coordinate work across the health system to ensure people at higher risk of serious illness from COVID-19 were easily identified and received appropriate interventions, support and communication **[Exhibit: JH3/79 - INQ000348112]**. The programme sat between DHSC and UKHSA and as the CEO of UKHSA, I acted as SRO for the coordination of the programme. DHSC sent a submission with my input updating ministers on the EPP on 4 February 2022 **[Exhibit: JH3/76 – INQ000348097]** **[Exhibit: JH3/77 – INQ000348098]**.

112. The EPP provided the secretariat for a Clinical Oversight Group, chaired by me (Professor Dame Jenny Harries) and was attended by clinicians from DHSC, UKHSA, NHSE/I, NHSD and the Devolved Administrations. An agenda for a meeting and a Chair's brief of the Clinical Oversight Group are provided here **[Exhibit: JH3/78 – INQ000348100]** **[Exhibit: JH3/79 – INQ000348112]** as examples. The group's purpose was to make clinical decisions to ensure a coordinated, evidence-based and operationally achievable approach to all groups requiring enhanced protection, as outlined in the chair's brief for the group's first meeting which is exhibited above. The group's remit specifically included:

- a. ensuring that each organisation in the health system retained responsibility for their respective programmes,
- b. confirming which clinical cohorts were in scope of this work and determining whether a single cohort could or should be identified for current and future interventions and advice,
- c. ensuring a process for identifying cohorts eligible for specific interventions to be practically implemented and understood by clinicians and patients, and
- d. agreeing a process for reviewing public health advice to the cohort(s)
- e. centrally coordinating all communications to the cohort(s). **[Exhibit: JH3/80 – INQ000348113]**.

113. During the EPP, a fortnightly communications working group consisting of representatives from UKHSA, DHSC, NHSE and NHSD and chaired by DHSC also convened to ensure key messages to patients and their support organisations were aligned (slide 7 of the EPP legacy playbook exhibited here **[Exhibit: JH3/80 – INQ000287603]**)

114. The Clinical Oversight Group (COG) commented on an independent report which had been commissioned by DCMO Professor Sir Jonathan van Tam before the EPP was set up **[Exhibit JH3/81 – INQ000348103]** **[Exhibit JH3/82 – INQ000067910]**. The academic group which produced the report had done some initial work to understand which conditions led to the highest risk of an adverse COVID-19 outcome in vaccinated patients particularly referencing any new condition specific evidence. The intention of this work had been to inform eligibility criteria for specific therapeutics (primarily oral antivirals and monoclonal antibodies) should individuals with those conditions become infected with COVID-19. The report was updated after some clinical input from the COG, and it was published on 30 May 2022. The final report evaluated the risk of poor outcomes for those with clinically proven COVID19 using QCOVID3 and International Severe Acute Respiratory and emerging Infection Consortium data, since these large population studies gave indicative risk groups based on community data. The report also examined literature of studies that examined the effectiveness of vaccines in the context of cohorts of patients with particular conditions or receiving particular immunosuppressive medications. Using expert opinion where necessary, those patient cohorts with the greatest capacity to benefit from a given therapeutic agent were considered and identified. **[Exhibit: JH3/83 – INQ000348121]**.
115. Guidance for people previously identified as CEV was withdrawn with closure of the programme and replaced on 30 January 2023 with guidance for people whose immune system means they are at higher risk in keeping with the EPP. This guidance, drafted by DHSC, remained available on gov.uk.
116. On 31 March 2023, given that enhanced protections for the CEV group were now well embedded in the health system, under specialist clinical oversight for individual patients, and in line with the broader transition to the Living with Covid approach, the EPP closed, as agreed by Ministers. **[Exhibit: JH3/84 – INQ000348122]** (see also the EPP legacy playbook exhibited here **[Exhibit: JH3/80 – INQ000348113]**). The Clinical Oversight Group can be convened by any contributing organisation at any point where there is a need for wider action and/or policy agreement to support those in the CEV group as set out in the EPP Legacy Playbook exhibited above.

I believe that the facts stated in this witness statement are true. I understand that proceedings for contempt of court 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 in its truth.

Signed:

Personal Data

Dated: 31 January 2024