Witness Name: Professor Sir Christopher Whitty

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UK COVID-19 INQUIRY

MODULE 3

FIFTH WITNESS STATEMENT OF PROFESSOR SIR CHRISTOPHER WHITTY

Contents

I, PROFESSOR SIR CHRISTOPHER JOHN MACRAE WHITTY, will say as follows:

Section 1: Introduction

1.1 I am the current Chief Medical Officer ("CMO") for England. I make this corporate statement on behalf of the Office of the Chief Medical Officer ("OCMO") and in response to a Rule 9 request received from the UK COVID-19 Inquiry ("the Inquiry") in draft on 9 May 2023 and in final version on 2 November 2023.

1.2 This is the third corporate statement submitted on behalf of the OCMO.

1.3 The first corporate statement, prepared for Module 2 of the Inquiry, explained the role of the OCMO, the part it played in the Governmental response to the COVID-19 pandemic and addressed the matters raised in a Rule 9 request dated 21 September 2022 insofar as they related to the activities of the OCMO ("the OCMO Module 2 corporate statement").

1.4 The second corporate statement, prepared for Module 1 of the Inquiry, explained the role of the OCMO in relation to the UK's resilience, pandemic preparedness and wider matters raised in a Rule 9 dated 24 November 2022.

1.5 Additional detailed personal statements have also been provided to the Inquiry for Module 1 and 2 and many of the issues addressed by those are relevant to the NHS and wider healthcare system. This statement should be read alongside the four witness statements I have previously provided, the two witness statements of Professor Sir Jonathan Van-Tam and the fourth witness statement of Professor Dame Jenny Harries.

1.6 The Inquiry's request comprises 34 main questions with multiple sub questions; this statement is an attempt to address these questions where OCMO are the right people to do so. It therefore addresses the areas the Inquiry has asked about rather than attempting to provide a wider narrative. Where others are better placed, or I have no direct knowledge of the event or issue I have tried to indicate that in the text. In addition to my previous four statements I also contributed to corporate statements on behalf of the Department of Health and Social Care ("DHSC") by Sir Christopher Wormald.

1.7 An important source for many of the technical aspects is the *Technical Report on the COVID-19 pandemic in the UK* ("the Technical Report") to our successors co-edited by me as lead editor, co-edited by the Government Chief Scientific Adviser ("GCSA"),

the other UK CMOs, the lead Deputy CMOs ("DCMOs"), the National Medical Director of NHS England ("NHSE") and the Chief Executive of the UK Health Security Agency ("UKHSA") along with many distinguished authors **(CJMW5/001 – INQ000203933)**. This includes chapters particularly relevant to this Module, especially chapters 1, 3 and 10.

1.8 I have only repeated things which are available in previous statements and the Technical Report where it is necessary for the flow of logic as all are available online. Where I think it would be useful to the Inquiry I have copied across sections of previous statements to respond to the questions in this Module of the Inquiry.

1.9 Before I start my answers to the questions posed I would like to reflect both on the suffering of many patients with severe COVID-19 and their families, and also the fortitude and skill of the response of NHS professionals. Watching the suffering of so many people with severe COVID-19 early in the pandemic when we had no vaccine and limited medical countermeasures was painful for all healthcare workers, and deeply traumatising for many. This of course pales in comparison to the trauma for the families of those who died or were permanently harmed by this new disease, including healthcare workers. Despite this, doctors, nurses and many other professionals in the NHS provided what I consider heroic levels of care, often whilst deeply concerned about the possibility that as a result of their profession they were putting themselves, or vulnerable family members they went home to, at increased risk. They could see the risks all around them. They still provided the care. I had, and have, great pride in their professional response, which was in the best traditions of the medical, nursing and allied health professions; it also extended to people in non-clinical roles. It is a central tenet of medicine that we should learn from all bad outcomes, and this Inquiry is part of that process. I would not however wish that to undermine the remarkable levels of courage, skill and dedication shown by staff throughout the NHS.

1.10 Medical, nursing and other staff learned rapidly during the pandemic. Survival rates improved significantly over the first year even in advance of vaccines as they learned how to manage this new disease better, partly through formal studies and trials, partly by learning from clinical experience. In the Technical Report, Chapter 10 reflects on this learning process within the NHS, drawing on the experience of doctors at various stages of their career and I hope it will be of assistance to the Inquiry.

1.11 Throughout the pandemic, and in particular in the early stages where knowledge of the virus and epidemiological information was sparse and there were limited medical

countermeasures without any immunity there were no good choices available either to clinicians, the NHS or the OCMO. The choices were often between bad outcomes or options, where one was probably worse. With the benefit of hindsight many decisions look more clearcut than they were at the time, for clinicians, public health experts and scientists from all disciplines. This included population-wide decisions, clinical decisions about best management of individual patients, the best ways to protect staff and the best way to deploy new medical countermeasures as they emerged. Medicine is usually about a balance between two or more risks and this was especially so of the response to the pandemic.

Section 2: My background

2.1 I have set out my qualifications in previous statements but for this Module in particular it is worth highlighting that I remain an NHS clinician and conducted clinical work during the pandemic according to my usual clinical rota, mainly on what were by this stage COVID-19 wards. I am an NHS Consultant Physician in infectious diseases and tropical medicine at University College London Hospitals NHS Trust (UCLH).

2.2 I hold a medical degree, a doctorate in science (DSc) in infectious diseases and a degree in physiological sciences all from the University of Oxford, a masters in epidemiology from the University of London, an MBA and an LLM in medical law, a diploma in economics and in tropical medicine and hygiene. Clinically I am a Fellow of the Royal College of Physicians, the Faculty of Public Health, and honorary Fellow of the Royal College of Paediatrics and Child Health, the Royal College of Pathologists, the Royal College of Physicians and Surgeons of Glasgow, the Faculty of Pharmaceutical Medicine, the Faculty of Occupational Medicine and other medical bodies. I am a Fellow of the Royal Society and the Academy of Medical Sciences.

Section 3: The role of the OCMO

Overview

3.1 Although I refer to the OCMO as a useful shorthand for all the work covered, it is important to make clear that it is not in the normal sense a corporate entity. The CMO, and the DCMOs past and present give their advice as senior public health and medical doctors, and therefore as health professionals, individually or occasionally collectively. We tried wherever time allowed however to form a collective view, based on scientific

advice from SAGE or other specialist groups where that was available. The development of scientific and clinical knowledge is a collaborative and iterative process, and this was no different. For many issues Private Secretaries may act for the CMO and/or for a DCMO, but this is based on their understanding of the professional views of the CMO/DCMO in post.

3.2 OCMO is a small advisory function. Collectively, the DCMOs and I are supported by a single private office (a small team that supports senior civil servants or Ministers). In addition to the traditional make up of a private office (private secretaries and diary managers) the team includes a small number of public health speciality registrars - trainees in public health - who edit the annual reports issued by the OCMO and provide additional clinical and public health input if appropriate. At its largest size during the height of the pandemic the OCMO was 19 people, including the CMO and DCMOs; its current more typical size is 12. There are a large number of eminent clinicians in NHSE and in UKHSA; also a very large number in the wider NHS; therefore, whilst OCMO was central to clinical and scientific advice informing many decisions by Ministers (covered mainly in Module 2), it was much less so for NHSE and the NHS decisions more widely for Module 3, many of which were more directly supported by advice from PHE/UKHSA. OCMO involvement was limited to some specific areas of clinical advice laid out below.

3.3 The CMO is a professionally independent position at Permanent Secretary level based in DHSC. The simplest way to understand the role of the CMO is as a doctor and public health leader who works in Government, giving medical, public health and scientific advice. In addition to clinical, public health and scientific advice within Government the CMO has always had a responsibility to communicate to the public on health matters in times of emergency, and to be part of the collective leadership of the medical and public health professions.

3.4 The advice given by a CMO should be where a senior clinical, public health or scientific opinion is needed. It often includes reflecting and summarising technical concepts in language accessible to lay people. If you do not need a clinical, public health or science qualification to give the advice it is usually better given by others - this includes for example economic, legal, diplomatic, operational or non-clinical policy advice.

3.5 The CMO role in England has evolved several times since its inception in 1855 but in its current incarnation, and throughout the period covered by this Module, it is principally a senior advisory role to Government at Permanent Secretary level. It is a

professionally independent role and that is demonstrated by the fact that the CMO can write reports and make public statements which do not accord with Government policy when relevant to public health. I sit on the Executive Committee and the Board of DHSC. The CMO currently reports to the DHSC Permanent Secretary.

3.6 Whilst the CMO provides independent advice to Ministers across Government on medical and public health issues, including on the NHS, this is not an exclusive responsibility. Public Health England ("PHE"), of which the health protection elements were subsequently incorporated into UKHSA, had considerable expertise in epidemics and other emergencies. NHS England and the wider NHS has many clinical experts including in infectious diseases, and for many of the issues of importance to this Module which concentrates on the NHS they were the central or only routes of clinical advice.

3.7 NHS and academic experts provided most of the specialist clinical advice directly to NHS clinicians and NHSE. PHE (and subsequently UKHSA) provided most of the public health advice to the NHS, including the provision of the technical evidence base on prevention of hospital-acquired infection and Personal Protective Equipment (PPE), and outbreak investigation.

3.8 Prior to 2012, the CMO had some of the responsibilities within the NHS now held by the National Medical Director, since January 2018 and currently Professor Sir Stephen Powis, and from 2013 to 2018 Sir Bruce Keogh. Before this Sir Bruce was Medical Director of the NHS from 2007-2013. Since 2012 the CMO and DCMOs have had no formal role in NHSE, NHS structures or PHE. Deputy Chief Medical Officer Professor Waite now attends the UKHSA Advisory Board.

3.9 The CMO for England covers all of England, but health being a devolved matter there are separate CMOs for Scotland, Wales and Northern Ireland. The CMOs for Scotland, Wales and Northern Ireland have some responsibilities for the NHS in those nations (or their equivalent) which are different to those of the CMO England.

3.10 I was appointed CMO on 1 October 2019 and therefore held the post throughout the period considered by Module 3. I remain in post. Three full-time DCMOs in post during the pandemic worked predominantly on COVID-19. Professor Sir Jonathan Van-Tam took on the role of DCMO for health protection in 2017 and relinquished it upon taking up a senior position in academia in March 2022. Professor Harries became DCMO for health improvement in 2019 and continued in that role until taking up the position of

CEO of UKHSA in April 2021. Professor Thomas Waite was appointed as an interim DCMO covering COVID-19 in July 2021. He subsequently succeeded Professor Van-Tam as DCMO for health protection and remains in post. In addition, Dr Aidan Fowler, whose main role is as the National Director for Patient Safety in NHS England, was also part-time a DCMO covering some relevant areas on COVID-19 for a part of the period being considered in Module 3; most of his responsibilities in the NHS derived from his NHSE role rather than his DCMO role.

Areas of responsibility within OCMO during the COVID-19 pandemic

3.11 The division of labour between me as CMO and the DCMOs changed over the course of the first 3 months of the COVID-19 pandemic but then became relatively stable. In the first 3 weeks of 2020 the majority of the day-to-day working on COVID-19 was undertaken by Professor Van-Tam as the DCMO for health protection (which includes emergencies and infections), although in close coordination with me. As the probability this was going to become a major international threat grew, increasingly I took the lead in communicating into the centre of Government. Two key inflection points were when I requested on 20 January 2020 that SAGE first meet on 22 January 2020, and on 4 February 2020 when I informed the Prime Minister that a major pandemic with 100-300 thousand deaths in the UK was now possible. From that point on SAGE advice became the principal official source of scientific advice to the Prime Minister, Cabinet and wider Government. This has been covered extensively in our witness statements to Module 2 of the Inquiry.

3.12 Between the CMO and the main two DCMOs we had a loose division of labour, but all of us were capable of cross-covering as needed and tried to keep one another briefed on developments. I had ultimate responsibility for all areas, and the DCMOs would check with me when there was a serious issue. Professor Van-Tam had an extensive history in vaccine development and respiratory infections, and he took the lead in the vaccine work including oversight of the Joint Committee on Vaccines and Immunisations (JCVI), and with the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) (which he had previously chaired).

3.13 Professor Van-Tam and I were involved in clinical research including vaccines and therapeutics most of which is likely to be covered more fully in Module 4 of the Inquiry. In part I did this in my role as Head of the National Institute for Health Research (NIHR) and DHSC Chief Scientific Adviser which I held concurrently with the CMO role until

August 2021. NIHR is the UK's leading Government research funder for applied medical research. My predecessor both as Chief Scientific Adviser (CSA) and then as CMO Professor Dame Sally Davies also held both roles concurrently for several years. NIHR plays an important research role in the NHS, although much of this work will be covered in Module 4. Much of the clinical research on COVID-19 in the NHS was undertaken using NIHR infrastructure or funded by NIHR.

3.14 Professor Harries, although officially the DCMO for health improvement (issues such as preventing heart disease and cancer) also had a long history of work in health emergencies and health protection, and in local authorities. She therefore took the lead in several technical areas such as shielding, schools and local authority work.

3.15 As I have set out above, Dr. Aidan Fowler was principally working in NHS England in a senior role in patient safety, but also had a DCMO role and took the lead in some of the testing work. As much of the work of Dr. Fowler in the pandemic was undertaken in his NHS capacity as National Director of Patient Safety in NHSE rather than as DCMO it is not covered in this statement. Professor Van-Tam and Professor Harries were however the main DCMOs for COVID-19 and did most of the work in commenting on the technical aspects of regulations and advice from across Government where possible and when this was presented to them. Given the speed of decision making, there was often a clash between important meetings happening in parallel; in these cases I usually covered meetings with the Prime Minister or Cabinet, or SAGE meetings, and the DCMOs covered other meetings. For some major meetings with the Prime Minister or Secretary of State for Health and Social Care I might be present with one, or both, DCMOs.

3.16 Once Professor Waite, who has a background in infectious disease epidemiology, started in July 2021 he took on some of the responsibilities of Professor Van-Tam.

The OCMO's role in relation to operational decision-making within NHS England between March 2020 and June 2022

3.17 As I have set out above, following the changes to the health system in 2012, the CMO in England does not have a direct role in the organisation or operation of the NHS. NHS England was and is the lead organisation on operational decision-making for the NHS in England. The clinical lead for medicine in the NHS is the National Medical Director of the NHS, Professor Sir Stephen Powis. NHSE has many other senior clinicians including the Chief Nursing Officer, Professor Dame Ruth May and several

National Clinical Directors in different areas of medicine. Therefore whilst OCMO took the lead role in most clinical advice in Government (covered in Module 2), and also took a leading role on clinical advice around development and deployment of vaccines and therapeutics (covered in Module 4) clinical advice to the NHS (principally relevant to Module 3) was largely led from within NHSE. There were a few exceptions which I cover below.

3.18 I did and do work closely with Professor Powis, as part of my broader contribution to the collective leadership of the medical profession in England. I and other clinicians in OCMO gave technical (as opposed to operational) advice which may be of use to operational decision-making by senior decision-makers in the NHS. I tried to ensure there was the opportunity to form a shared clinical view between NHSE, Government and PHE/UKHSA clinicians when that was relevant, for example via the Senior Clinicians discussion group. I and the other CMOs gave some technical or other messages directly to the medical profession via a variety of routes where that was appropriate. To assist the Inquiry I have outlined the most relevant technical advice provided to the medical profession by us in this statement.

3.19 I was in regular contact with the medical Royal Colleges through the Academy of Medical Royal Colleges (AoMRC). This was principally to provide a two-way dialogue between Government and the medical profession, mainly on technical matters including epidemiology and clinical advances, but also to discuss issues of concern to the profession including morale. I know from feedback that clinicians throughout the NHS listened to the Prime Ministerial and Ministerial led press briefings on COVID-19, in which I and the DCMOs played a major role (as did Professor Powis). Arguably one of our biggest direct contributions to the NHS frontline understanding was therefore those briefings.

3.20 For most issues of direct NHS decision making, however, OCMO played a supporting rather than a leading role.

Technical advice provided to the medical profession by OCMO

Case definition January 2020 to May 2020

3.21 The Central Alerting System (CAS) is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical

information and guidance to the NHS and others, including independent providers of health and social care.

3.22 On 23 January 2020 Professor Powis, Professor Sharon Peacock (PHE National Infection Service Director) and I sent a CAS alert to clinicians offering advice for clinical staff encountering patients with respiratory infections arrived from overseas. The alert stated:

"Advice for NHS organisations is as follows:

It is essential that an accurate travel history is obtained from all patients with acute respiratory infections to help identify potential cases.

Primary care practices are asked to identify possible cases, isolate them immediately, and seek specialist advice from a microbiologist, virologist or infectious disease physician at your local trust. They are not expected to under-take any clinical assessment or sampling. Guidance for primary care can be found here.

All acute trusts are expected to assess possible cases of Wuhan novel coronavirus using appropriate isolation facili-ties. They should review the Public Health England (PHE) guidance and ensure that they have considered how to operationalise this.

Acute trusts should be prepared to undertake sampling and transport samples to PHE for testing as well as making arrangements for such patients to be identified immediately and isolated according to the PHE guidance, or in dis-cussion with PHE, in home isolation if appropriate.

If the novel coronavirus is detected, the patient will be transferred to an Airborne High Consequences Infectious Diseases centre. PHE will undertake contact tracing and advise on management as more is known about this infec-tion. Guidance will be updated" **(CJMW5/002 – INQ000047537)**.

3.23 On 31 January Professor Powis, Professor Peacock and I sent another CAS alert updating the previous one. This advised an expansion of the geographical clinical case definition from Wuhan to all of mainland China, and included fever and removed sore throat from the clinical case definition **(CJMW5/003 – INQ000068530, CJMW5/004 – INQ000203867)**.

3.24 On 3 February Professor Powis, Professor Peacock and I sent another CAS alert to the health system. This was to healthcare professionals in primary care and community

settings, including pharmacy. It advised that members of the public who may have been exposed to COVID-19 should phone NHS 111 and not be referred to hospital emergency departments unless seriously ill. It also highlighted the public health advice, and guidance, which included:

"All travellers who develop relevant symptoms (fever or cough or shortness of breath), however mild, within 14 days of returning from mainland China, should self-isolate at home immediately and call NHS 111" **(CJMW5/005 – INQ000068531)**.

3.25 On 7 February Professor Powis, Professor Peacock and I sent an updated CAS alert. This changed the geographical part of the case definition to include Thailand, Japan, Republic of Korea, Hong Kong, Taiwan, Singapore, Malaysia and Macau **(CJMW5/006 – INQ000087249)**.

3.26 On 25 February Professor Powis, Professor Peacock and I sent an updated CAS alert. This made further edits to the geographical scope of the case definition.

"If you have returned from these specific areas since February 19th, you should call NHS111 and self-isolate even if you do not have symptoms:

- *Iran*
- *Specific lockdown areas in Northern Italy as designated by the Government of Italy*
- *Special care zones in South Korea as designated by the Government of the Republic of South Korea*
- *Hubei province (as previously noted)*
- *If you have returned from these areas since February 19th and develop symptoms, however mild, you should self-isolate at home immediately and call NHS111. You do not need to self-isolate if you have no symptoms.*
- *Northern Italy (defined by a line above, and not including, Pisa, Florence and Rimini),*
- *Vietnam*
- *Cambodia*

- *Laos*
- *Myanmar*

Those who have returned from previously identified geographic areas within the past 14 days and develop symptoms, however mild, should self-isolate at home immediately and call NHS111" **(CJMW5/007 – INQ000068537)**.

3.27 On 5 March Professor Powis, Professor Peacock and I sent an updated CAS alert further extending the geography of the case definition **(CJMW5/008 – INQ000068538)**.

3.28 On 10 March Professor Powis, Professor Peacock and I sent an updated CAS alert. The key changes were to expand the case definition to include those presenting in hospital with certain symptoms, regardless of travel history:

"Advice for NHS organisations is as follows:

Individuals presenting at hospital

To improve case detection in those with no geographic link, patients who require admission to hospital should be tested regardless of travel history if they present with

- *Clinical or radiological evidence of pneumonia or acute respiratory distress syndrome*

  OR

- *Influenza-like illness"* **(CJMW5/009 – INQ000068943).**

3.29 On 12 March Professor Powis, Professor Peacock and I sent an updated CAS alert which removed completely the geographical aspect of the case definition.

"Advice for NHS organisations is now as follows:

1. *From today the public are being advised to stay at home (self-isolate) without any testing for COVID-19, regardless of travel history or contact with confirmed cases, if they have:*

   a. *A new continuous cough*

   OR

b. *High temperature (of 37.8 degrees centigrade or higher)*

2. *The geographic element of the case definition has now been removed. Travel and contact history are no longer important for diagnosis, which is on the basis of symptoms alone. If people who have travelled do not have symptoms they do not need to stay at home, regardless of their travel history"* **(CJMW5/010 – INQ000048070)**.

3.30 On 18 May 2020, the case definition was expanded to include anosmia **(CJMW5/011 – INQ000069318)**.

Classification as a High Consequence Infectious Disease

3.31 I was aware of and supported both the classification and de-classification of COVID-19 as a high-consequence infectious disease ("HCID"). On 13 January 2020, Professor Van-Tam suggested COVID-19 should provisionally be seen as an airborne HCID. This was in response to an email from PHE setting out that:

"the 4 Nations Public Health HCID List and Definition group who have considered the rationale for Wuhan novel coronavirus (WN-Cov)… made an interim recommendation that this should be considered as an airborne HCID". The email went on to say: "In material terms, this does not change our immediate public health response but will influence how the health services in the 4 nations manage patients" **(CJMW5/012 – INQ000151309)**.

3.32 Professor Van-Tam also suggested that PHE should seek the view of NERVTAG. NERVTAG met on 13 January 2020. The minute records the following:

"NERVTAG were briefed that the novel coronavirus has been reviewed by the 4 Nations Public Health Agencies who have recommended it is designated as an interim airborne HCID, although this now has to be considered by other bodies. The group had requested that this information was provided to the Chair of NERVTAG. NERVTAG have noted this and has not raised any specific problems around this precautionary measure." **(CJMW5/013 – INQ000023107)**.

3.33 As it became apparent that the mortality from COVID-19 at an individual level was low compared to most HCIDs (e.g. Ebola at up to 70%), and that widespread infection was occurring in early March the initial classification was re-assessed independently by NERVTAG and by the Advisory Committee on Dangerous Pathogens ("ACDP") on 13 March 2020. Their advice, which I consider was technically correct at that stage, was

to de-classify COVID-19 to be managed like other contagious disease **(CJMW5/014 – INQ000212195)**. In response to a direct theoretical question from the Inquiry, theoretically if COVID-19 had a mortality rate comparable to Ebola then the international and domestic response would have been substantially different on many levels. It would have been more pressing to maintain it as a HCID for as long as possible although ultimately most of the key practical measures would not be operationally sustainable if there was widespread community transmission on the scale of COVID-19. It is important to make clear however that this is a very theoretical point; if an infection with the transmissibility of COVID-19 and the mortality of Ebola had caused a pandemic, debates around HCID status would have been pretty marginal in the catastrophic population mortality that would have ensued.

3.34 Following his oral evidence given for Module 2, Professor Van-Tam asked the OCMO legal team to write to the Inquiry formally clarifying the chronological sequence of events leading up to the declassification of COVID-19 as an HCID. This was set out in a letter dated **(CJMW5/015 – INQ000398305)**.

3.35 In my Second Statement, I laid out some points about HCIDs, and repeat them below:

"A novel emerging infectious disease is likely to be treated as an HCID whilst the characteristics of the pathogen are still becoming known. Wuhan novel coronavirus was classified as an HCID on 16 January 2020 and declassified on 19 March 2020, following advice from ACDP. These decisions took into account the available information and uncertainty about this novel disease at the beginning of the outbreak and mortality rates among other factors.

There are significant disadvantages to a disease being classified as a HCID when it is not one. At the individual patient level it makes treatment more difficult and alarming as very strict barrier care will be in place, and ill patients may have to be transported around the country to specialist units with attendant risks. At an NHS-wide level each case of a HCID is highly resource-intensive, and the specialist provision of beds is limited. At a population level contacts will be very strictly isolated and monitored. There are therefore few advantages, and several risks, to having a HCID classification in place when it is not needed. De-classifying diseases down to a non-HCID wherever possible should therefore be seen as normal practice once initial risk assessments are in place".

Research

3.36 On 16 March 2020 Professor Powis and I wrote to all NHS Trusts asking for their full support in implementing the RECOVERY trial of drugs for patients with COVID-19 **(CJMW5/016 – INQ000048103)**.

3.37 On 1 April 2020 a UK CMOs and Professor Powis letter to clinicians supported the Urgent Public Health ("UPH") badging process for clinical studies by asking the NHS to prioritise recruitment to UPH trials, and to desist from prescribing off-licence drugs outside of trials **(CJMW5/017 – INQ000068589)**.

3.38 On 6 May 2020 the UK CMOs and Professor Powis wrote to clinicians to encourage enrolment by mobilising the NIHR and equivalent workforce in devolved nations **(CJMW5/018 – INQ000069095)**.

3.39 On 18 August 2020 the UK CMOs and Professor Powis wrote to clinicians to thank them and highlight the importance of research **(CJMW5/019 – INQ000070395**

3.40 Professor Van-Tam and I were throughout involved in setting up and approving the prioritisation of clinical trials and other clinical studies of COVID-19 in the NHS. I anticipate this being covered more fully in Module 4. In brief however this was to ensure that, by doing a more restricted group of studies but at greater scale, England and the UK more widely would reach clinically and statistically meaningful endpoints in the shortest period of time for the benefit of future patients. We were concerned that without this a very large number of studies would be launched which would not reach clinically or statistically meaningful endpoints due to 'competition' for trial participants, or at least not do so in a timely way. This did in fact happen in some nations outside the UK. The UK played a leading role globally in clinical studies.

Support for clinicians during an emergency

3.41 The UK CMOs, AoMRC, General Medical Council (GMC) and NHSE wrote to NHS doctors to support clinicians making decisions whilst working out of their usual scope of work on 11 March 2020, 11 November 2020 and on 12 January 2021 **(CJMW5/020 – INQ000049584, CJMW5/021 – INQ000071564, CJMW5/022 – INQ000072433)**. This was to ensure they were aware that it would be considered good medical practice to work outside their normal area of work during this emergency, and that they would not be held to 'specialist' expectation of levels of expertise when doing so. We also encouraged Trusts and others to support their clinical staff.

Other communication to clinicians

3.42 On 21 March 2020 Professor Powis and I sent a CAS alert to ask clinicians for help in the management and shielding of patients at highest risk of severe morbidity and mortality **(CJMW5/023 – INQ000068544)**.

OCMO's interaction with experts

3.43 OCMO worked closely with a wide array of clinical and other experts, both in Government, in the NHS, in academia and with international experts. Below I set out a summary of some of the work with expert advisory groups, with key expert colleagues and with the international expert community.

Expert advisory groups

3.44 OCMO worked closely with official expert advisory groups throughout the pandemic, examples include NERVTAG, SAGE, ACDP and JCVI. These groups brought experts together to discuss the data and to reach a consensus or central view. This was then fed into decision making.

<u>The New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG)</u>

3.45 NERVTAG is a DHSC committee advising the Government on the threat posed by new and emerging respiratory viruses. NERVTAG members are independent experts who volunteer to provide their expertise; they are competitively appointed. NERVTAG provide clinical and scientific advice. It was/is supported by a scientific secretariat from PHE/UKHSA. Members of the OCMO team attended NERVTAG as observers. NERVTAG minutes are published online.

3.46 NERVTAG was established in 2014, replacing the UK Scientific Pandemic Influenza Advisory Committee (SPI) and extending the role of the group to cover not only pandemic influenza but any new, emerging respiratory virus threat to the UK. With this expanded remit, NERVTAG has routinely considered a range of respiratory viral threats, including avian influenza viruses and MERS. On its establishment, it was agreed the group would draw on the expertise of scientists and healthcare professionals, including clinicians, virologists, microbiologists and public health practitioners, and colleagues in related disciplines and is scientifically independent.

3.47 Between 2014 and 2019 NERVTAG met 2 to 3 times per year. COVID-19 led to a substantial increase in such meetings.

3.48 Between January 2020 and June 2021 NERVTAG met around 75 times.

3.49 On 13 January 2020 NERVTAG met, at my request, to discuss the news of an outbreak in Wuhan, China. Professor Van-Tam attended that meeting **(CJMW5/013 – INQ000023107)**.

3.50 NERVTAG was chaired by Professor Sir Peter Horby for the period of relevance to Module 3. He remains chair.

3.51 Early in the pandemic, with limited data, NERVTAG provided initial advice including on clinical assumptions such as infection attack rate, duration of hospitalisation and case fatality rate. NERVTAG provided advice throughout the time period relevant to the Inquiry on a range of areas, including: clinical management of COVID-19 (including treatments), asymptomatic cases, asymptomatic transmission, contact tracing, symptoms and case definition, decontamination and environmental survival, immunity, epidemiology and travel. NERVTAG advice played a key role in the response to variants, for example NERVTAG advice from 18 December 2020 on the Alpha variant **(CJMW5/024 – INQ000120454) (CJMW5/025 – INQ000203959)**.

<u>The Scientific Advisory Group for Emergencies (SAGE)</u>

3.52 SAGE is the main conduit in the UK for scientific input to Cabinet or Cabinet Office Briefing Rooms ("COBR"), and Ministers more widely, in the event of a major emergency that needs such scientific input. SAGE is however set up to advise Ministers and Government rather than clinicians and the NHS. It has no standing membership other than the GCSA and is set up with relevant experts drawn from within and outside Government for any emergency that requires significant scientific advice on a cross-Government basis. SAGE exists to ensure Government can integrate science from multiple groups, and that a single version of the scientific advice, presented with appropriate levels of confidence and outlier opinion if relevant, is presented to policymakers rather than several slightly different versions of advice.

3.53 GO-Science and individual Government Departments maintain lists of experts who can be called on in an emergency, who tend to be the earlier members but later members were chosen for specific skill gaps. While SAGE main committee members generally have to have some generalist science skills to incorporate science from many

disciplines in addition to their own specialism, its specialist sub-groups have deep subject experts in particular fields. SAGE took advice both from the standing committees (already in existence) and ad hoc committees (set up for COVID-19) that considered issues such as care homes or schools. SAGE has been considered extensively in Modules 1 and 2 of this Inquiry.

3.54 During the pandemic the GCSA and I as CMO co-chaired SAGE. Once activated SAGE was the formal route for providing a central science view to COBR, Government and when appropriate the NHS. Although it was agreed that the GCSA would chair most meetings, the minutes for SAGE COVID-19 meetings were approved by both of us. The GCSA and I, both individually and together, represented the advice from SAGE within Government. Advice given in SAGE meetings was minuted and forms the official record of advice. All SAGE minutes are published and publicly available, along with background papers that inform that advice. The SAGE secretariat sits within GO-Science, which is best placed to set out how the processes and structures of SAGE work. The first pre-SAGE meeting of the pandemic was on 22 January 2020 **(CJMW5/026 – INQ000087535)**. Professor Powis as National Medical Director of the NHS sat on SAGE and was able to relay SAGE views directly to the NHS in so far as these were relevant to clinical practice or operations.

3.55 SAGE had a selection of sub-groups that fed advice into the main group. These have been laid out at length by GO-Science and OCMO previously but I will highlight some below to assist the Inquiry:

3.56 One was the Independent Scientific Pandemic Insights Group on Behaviours (SPI-B), comprised of behavioural scientists. They provided advice on the behavioural impacts of the pandemic and pandemic response. These were not specifically aimed at NHS workers.

3.57 Another sub-group of SAGE was the Scientific Pandemic Infections Group on Modelling, Operational subgroup (SPI-M-O). They provided the modelling input into SAGE. This modelling complemented modelling done by the NHS for operational reasons. It also relied for some of its work on NHS data, for example numbers of patients in ICU with COVID-19.

3.58 In non-emergency periods, the Scientific Pandemic Infections Group on Modelling (SPI-M) provides expert modelling and epidemiological advice to the DHSC and wider UK Government on scientific matters relating to the UK's response to a pandemic,

major epidemic or outbreak. The group may also provide advice on other emerging human infectious disease threats as required. DHSC has sponsorship of SPI-M and determines its programme of work.

3.59 During an emergency, SPI-M-O may be stood up as an operational subgroup of SAGE to support the Government's response. Participants may be partly or mostly drawn from SPI-M, but with additional contributors to reflect the specific emergency and expertise required. The secretariat for both groups is provided by DHSC.

3.60 Advice provided by SPI-M-O represents a consensus view of the group, with the co-chairs responsible for reporting the scientific advice to SAGE (SPI-M-O) and ensuring the scientific integrity of the group's discussion and outputs. SPI-M and SPI-M-O participants are typically from the academic community and public health agencies and contribute as experts in the field of epidemiological modelling and statistics.

3.61 The first meeting of SPI-M-O took place on 27 January 2020, with SAGE formally agreeing that "*SPI-M*[-O] *(Scientific Pandemic Influenza Group on Modelling) is now a formal sub-group of SAGE for the duration of this outbreak*" at the second SAGE meeting on COVID-19 on 28 January 2020.

3.62 SPI-M-O's consensus views brought together the modelling outputs and shaped the initial response. Given the sensitivity of modelling to assumptions made, and the wide panel of possible models, it was important to have SPI-M-O, who brought together different modelling groups and present a consensus view rather than relying on a single model. Modelling became increasingly sophisticated as the pandemic progressed and as much more detailed and accurate data became available.

<u>The Advisory Committee on Dangerous Pathogens (ACDP)</u>

3.63 The ACDP is an independent science advisory committee chaired by Professor Thomas Evans. I was its previous independent chair when not in government. Its role is to provide scientific advice on the risks of exposure to various pathogens on all aspects of hazards in particular the risks to workers. It is an expert committee of DHSC. Its work cuts across a number of organisations, including the Health and Safety Executive (HSE), UKHSA, and the Department for Environment, Food and Rural Affairs (Defra).

3.64 The ACDP is involved in classification and if appropriate declassification of a pathogen as a high consequence infectious disease among other responsibilities.

The Joint Committee on Vaccination and Immunisation (JCVI)

3.65 The JCVI provide advice on the use of vaccinations and immunisation, and as it provided advice directly to OCMO and DHSC rather than via SAGE for many of its decisions I give a fuller explanation here. The JCVI did not provide advice early in the pandemic response as there was no COVID-19 vaccine but was a key committee from summer 2020 as planning in anticipation of vaccines gained momentum. JCVI's advice on prioritisation of vaccination was relevant to the NHS which needed to consider the operationalisation of appropriate access. Unlike SAGE its advice had direct impact on how the NHS prioritised access to COVID-19 vaccines.

3.66 JCVI is an independent Departmental Expert Committee (DEC) and Scientific Advisory Committee (SAC) and, unlike most other DECs/SACs, has a statutory basis in England. It is formed of a main committee with subject specific sub committees. JCVI was originally an advisory board for polio immunisation that became the JCVI in 1963. It was put on a statutory footing when it became a SAC, established in England and Wales under the NHS Act 1977. The NHS (Standing Advisory Committees) Order 1981 (SI 1981/597) established the JCVI in its current form. That order specifies that it is constituted for the purpose of advising on *'The provision of vaccination and immunisation services being facilities for the prevention of illness.'*

3.67 JCVI provides advice and recommendations for all UK health Departments, based on its consideration of scientific and other evidence that is used by Government to inform, develop and make policy. All four nations have observers on the JCVI and while it has no statutory basis in Scotland or Northern Ireland, on most vaccine programmes JCVI advice is adopted.

3.68 JCVI when providing advice on COVID-19 was chaired by Professor Wei Shen Lim, standing in for JCVI Chair Professor Sir Andrew Pollard who had a perceived conflict of interest arising from his involvement with the Oxford/AstraZeneca vaccine.

3.69 The JCVI advice on COVID-19 is public and was widely publicised at the time with the Chair briefing the public, often alongside Professor Van-Tam. OCMO anticipates that further detail on the role of JCVI will be addressed in detail in Module 4.

Key experts

3.70 OCMO worked very closely with a wide range of expert colleagues in Government. Examples of this include the GCSA, experts in PHE (subsequently UKHSA) including

Professor Susan Hopkins and Professor Sharon Peacock, experts in the NHS, like Professor Sir Stephen Powis, and departmental Chief Scientific Advisers. The OCMO also had a number of regular meetings with expert colleagues. Key examples included the UK CMOs, Senior Clinicians Group, Academy of Medical Royal Colleges, Directors of Public Health, and Local Action Committee Bronze/Silver/Gold.

International

3.71 The DCMOs and I interacted with peers and experts internationally in informal groups, bilaterally and via the WHO or via regional groupings throughout the pandemic to learn and share expertise and experience. PHE (subsequently UKHSA) also had very good bilateral and multilateral relationships from which we learned. The GCSA and DCMOs also had international meetings on COVID-19 many of which I attended. WHO set up a structure for international peers to meet which especially early in the pandemic was very useful for getting a quick understanding of current epidemiology in advance of publications. They also provided bilateral meetings. As the pandemic progressed informal but regular meetings with peers facing similar challenges across Europe, North America and around the world were set up.

3.72 In the initial phases of the global pandemic when the majority of infection was in East Asia, scientists and clinicians from around the world, including the UK, learned from scientists and clinicians in China, South Korea, Singapore and Japan among others. When the UK had the first major outbreak of the Alpha variant scientists from other countries contacted UK scientists and clinicians to get an early understanding of this new threat and PHE provided group briefings. In turn, scientists from India provided important information on the Delta variant in advance of publications, and scientists and clinicians from South Africa gave us invaluable advice on Omicron on a bilateral basis as well as via international fora. The extent of international interaction between scientists and clinicians was considerable. They were often leading their own national response at the leading edge of the pandemic as well as advising their international peers who were further behind any given epidemic curve. This started with the clinical and scientific advice given bilaterally and multilaterally by scientists from China in the initial few weeks which was essential to the international and UK response.

3.73 Between January 2020 and July 2020, I had around 44 meetings on COVID-19 which were international in nature, this included individual meetings with representatives from the following countries: China, Singapore, Hong Kong, France, Canada, USA, Japan,

Italy, Netherlands, South Korea, Sweden, Germany, Switzerland and Spain. This included the international experts listed below:

- Dr Tedros Ghebreyesus (WHO)
- Sir Mark Lowcock (UN)
- Dr Hans Kluge (WHO, EURO)
- Dr David Nabarro (WHO)
- Dr Liang Wannian and Professor George Gao (China)
- Professor Chorh Chaun Tan (Singapore)
- Professor Gabriel Leung (Hong Kong)
- Professor Oh and Professor Choi Eun Hwa (South Korea)
- Professor Hitoshi Oshitani and Dr Takahiro Ueyama (Japan)
- Professor Silvio Brusaferro (Italy)
- Professor Christophe Denfert and Professor Bruno Hoen (France)
- Dr Fernando Simon (Spain)
- Dr Theresa Tam (Canada)
- Professor Jaap van Dissel (Netherlands)

3.74 As well as meetings with individual countries I also attended around 19 WHO meetings which were multi-country in nature. Other international meetings included meetings with the G7. Between August 2020 and June 2022, I had a further 118 international meetings, including with Dr Anthony Fauci (USA), Dr Rochelle Walensky (CDC USA), Prof Lothar Wieler (Germany), Søren Brostrøm (Denmark), Professor Tulio de Oliveira and others (South Africa), Professor Vijay Raghavan (India), Professor Paul Kelly (Australia), Dr Caroline McElnay (New Zealand), Dr Theresa Tam (Canada) and Admiral Rachel Levine (USA).

3.75 In giving advice relevant to the NHS, where possible I and the DCMOs relied on research evidence. In some cases this was only available in pre-print form. Normally it is best to use published evidence that has been through peer review, ideally synthesised through a systematic review, and when that was available that is what we used. Given the speed of the pandemic however we were frequently reliant on pre-

prints or even early descriptions of data for our initial view of its importance. Where I or the DCMOs considered such information to be sufficiently strong to present early to a wider audience (rather than wait for further peer review), then we did so, but this was taken on a case-by-case basis and was very rare. The main example was when the initial data from the RECOVERY trial were given to us showing a roughly one third decrease in mortality in those on ventilation and around one-fifth reduction in those on oxygen when given steroids. My risk-benefit judgement was that the trial was large and well done, the size of the mortality effect was sufficiently large it was very unlikely to be overturned in reanalysis, the drug (dexamethasone) was very well known, widely available and generally well tolerated in terms of side effects in short-term use, and the risks of delaying, with people untreated, were greater than the risks of proceeding. I therefore wrote out to the NHS on 16 June 2020 recommending it be used.

"Dexamethasone has been demonstrated to have a clear place in the management of hospitalised patients with COVID-19.

There were no excess harms identified in using this dose of dexamethasone in this patient population. Dexamethasone was not used in pregnant women.

Clinicians should therefore consider dexamethasone for the management of hospitalised patients with COVID-19 who require oxygen or ventilation.

Out of hospital treatment is not appropriate.

There is no current or anticipated constraint on supply of the medicine in the UK."

(CJMW5/027 – INQ000069714).

3.76 This was criticised by some as going against normal practice of waiting to peer review but in my judgement the risks of delay (many people not being treated) exceeded the risks of proceeding on provisional data given the high number of cases at the time. Peer review publication took many weeks.

OCMO's interaction with healthcare providers and other bodies

The Secretary of State and/or Department of Health and Social Care

3.77 The OCMO provided advice to the Secretary of State for Health and Social Care, DHSC Ministers and DHSC officials on public health, science or clinical matters as required. This included advice that was collated by DHSC teams and passed to other

Departments or to central teams such as the Cabinet Office. Much of this has been covered in witness statements for Module 2 of the Inquiry.

3.78 DHSC is both the home Department for OCMO and the lead Department for much of the COVID-19 response and so there was a very large amount of interaction between DHSC and OCMO. For instance, my calendar indicates that I met formally with the Secretary of State for Health and Social Care around 245 times in the relevant time period, not including multiple Cabinet Office or No10 meetings where we were both present.

3.79 The OCMO worked to provide scientific and clinical advice within the process(es) and structures established by the DHSC. The DHSC is best placed to lay out the mechanism by which the Department, its senior policy officials and Ministers received advice.

3.80 As CMO I had, and have, a formal role in the DHSC structure, sitting on its executive committee (ExCo) and its Board, to provide clinical and scientific input.

3.81 From late January 2020, there was a Permanent Secretary (Sir Christopher Wormald) led series of meetings, and then from February 2020 onwards a Secretary of State for Health and Social Care led series of meetings. I or DCMOs (often both CMO and DCMOs) attended most of these meetings, which, along with written advice usually provided via emails, were the predominant route by which OCMO advice fed into the decision making in the Department.

NHS England

3.82 As laid out above, NHSE is operationally independent and the CMO has no formal role in its structures, or decision-making power. However, OCMO worked closely with clinical colleagues at NHSE on technical issues, particularly Professor Sir Stephen Powis. There were also discussions with the Chief Nursing Officer Professor Dame Ruth May, Professor Keith Willett Director for Acute Care and Lord Simon Stevens who was then the NHS England Chief Executive. Senior NHS England representatives were normally present at Permanent Secretary and Secretary of State for Health and Social Care meetings as well as the No10 dashboard meeting with the Prime Minister and COVID alert level meetings and fed information in both directions directly rather than mediated via OCMO. Early in the pandemic there were frequent tripartite meetings with OCMO, PHE and NHS England and communication to the health system as highlighted above.

The National Institute for Health Research

3.83 I was the CSA and Head (CEO) of the NIHR from January 2016 to August 2021, and line managed the CSA Professor Lucy Chappell thereafter. OCMO helped ready the research system to respond by ensuring that the existing infrastructure was pivoted to respond to COVID-19 **(CJMW5/028 – INQ000047546)**.

3.84 One way in which this was done was that NIHR set up a priority process and trials were designated 'Urgent Public Health (UPH) badged' by an independent expert panel **(CJMW5/029 – INQ000381243)**. This focused the research workforce on a smaller number of trials that resulted in larger recruitment across a narrower remit; therefore, trials were able to achieve statistically significant end points more rapidly. UPH badging also meant Health Research Authority (HRA) and Medicines and Healthcare Products Regulatory Agency (MHRA) regulatory approval was expedited.

3.85 About 1,600 applications in total were received, with 101 studies UPH approved. Targeted support from the NIHR research infrastructure was important for commercial trials as well as for publicly funded ones. The NIHR Clinical Research Network (CRN) supported recruitment of more than a million patients from across all four nations of the UK into UPH studies (Mar 20–Mar 21). Of necessity, the UPH process did mean that other studies got less support from NIHR sources. OCMO anticipate this part of NIHR work will be covered extensively in Module 4.

3.86 Following a review of the 2009 pandemic influenza outbreak, the NIHR commissioned a portfolio of projects, put on stand-by in a maintenance-only state and awaiting activation in the event of new influenza pandemic. The portfolio included studies covering surveillance, communications, triage, and clinical management. Some of those sleeping contracts were stood up and repurposed for COVID-19. This included:

- Evaluating and improving communication with the public during a pandemic, using rapid turnaround telephone surveys.
- Pandemic Respiratory Infection Emergency System Triage.
- Maternal and perinatal outcomes of pandemic influenza in pregnancy.
- Real time refinement and validation of criteria and tools used in primary care to aid hospital referral decisions for patients of all ages in the event of surge during an influenza pandemic.

- The ASAP trial (a double-blinded randomised controlled trial of early low dose steroids in patients admitted to hospital with influenza infection during a pandemic) was not activated but the study protocol was used to inform the dexamethasone arm of the RECOVERY trial.

3.87 Professor Van-Tam who had worked on FLU-CIN, a network of hospital surveillance for flu, set in train work to stand up CO-CIN, a network of hospital surveillance for COVID-19. Over the course of the pandemic before standing down it recruited over 300,000 patients. It provided the first open-access comprehensive clinical-epidemiological data at scale in the pandemic, reporting weekly to DHSC and SAGE. CO-CIN reports and papers fed into 80 SAGE meetings, 72 NERVTAG meetings, and many subgroups. CO-CIN provided insights into patients with severe disease helping with early reports of treatment outcomes, length of stay, pregnancy outcomes, clinical outcomes of variants of concerns and hospital case fatalities, all of which were important for the clinical and public health response. It also helped identify or confirm risk factors (such as obesity and several cancers), the role of nosocomial infection, and the interaction with other infectious such as influenza. CO-CIN data were used by NHS clinicians as well as academics and public health experts. All four UK nation's public health agencies were given direct access to the raw data. Aggregate data was shared with WHO, the US Centers for Disease Control and Prevention (CDC) and European Centre for Disease Prevention and Control (ECDC). If more information is needed about CO-CIN or the linked International Severe Acute Respiratory and Infection Consortium (ISARIC) Professor Calum Semple of the University of Liverpool is best placed to provide it.

3.88 In the March 2020 Budget Her Majesty's Treasury (HMT) 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'. This could be spent with joint agreement from me as CMO and the GCSA. The idea 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 the normal mechanisms, so this alternative funding was used. Work funded through this route included:

- £9.9m for clinical trials phase 1 and 2 of the Oxford Vaccine.

- £9.5m for CO-CIN to collect data for hospitalised COVID-19 patients.

- £8.5m for the COVID-19 Genomics UK Consortium (COG-UK) - to deliver large scale, rapid sequencing of the disease to monitor changes in the virus to see if new variants emerge.

3.89 The timeline for the research response is below for ease:

- 4 February 2020 - Rapid response research call went live. Deadline for first part 13 February. Deadline for second part 27 February.
- 2 March 2020 – Rapid response research call assessment panel met for first part of call. (vaccines and therapeutics).
- 17 March 2020 - Rapid response research call assessment panel met for second part of the call (wider research).
- 19 March 2020 - First patients recruited onto RECOVERY.
- 23 March 2020 – Rapid response research call: 6 first projects formally announced (note that researchers told before this and started research). Included £2.1m for RECOVERY and £2.6m for Oxford Vaccine **(CJMW5/030 – INQ000203986)**.
- 24 March 2020 - 10th patient recruited to RECOVERY.
- 27 March 2020 - 100th patient recruited to RECOVERY.
- 3 April 2020 - 1000th patient recruited to RECOVERY.
- 1 April 2020 – UK CMOs and Professor Powis send letter to clinicians asking for every effort to be made to enrol COVID-19 patients in clinical trials, not to use novel or off-label treatments outside of a trial **(CJMW5/017 – INQ000068589)**.
- 17 April 2020 - second wave of projects announced (note that researchers were told before this date and started the research).

3.90 The speed of action in setting up early research meant that results were delivered earlier than they otherwise would have been. Because the RECOVERY clinical trials platform was set up ahead of the first wave it was able to recruit at large scale by international standards and showed by June 2020 that dexamethasone reduced COVID-19 mortality, reducing deaths by about one-third in ventilated patients and by one fifth in other patients receiving oxygen only. This was the first drug shown to do so. The speed of that discovery saved substantial numbers of lives in the UK, and

internationally. Dexamethasone had the advantages of being well known to all clinicians, relatively safe, widely available and cheap, giving global applicability. RECOVERY as of December 2023 recruited just under 50,000 patients.

3.91 OCMO (Professor Van-Tam and I in the main) played a role on the research aspects of COVID-19 throughout the time period of Module 3. This includes at the start of the time period with RECOVERY, PRINCIPLE and REMAP-CAP[1], and in later stages key studies on vaccines including National Immunisation Schedule Evaluation Consortium (NISEC) studies such as COV-BOOST, COM-COV and COM-FLU-COV and further treatment trials such as PANORAMIC.

3.92 NIHR continued to fund important COVID-19 research throughout the later period of concern to this Module. Examples include an NIHR and UKRI jointly funded open call which was launched in the autumn of 2020, which focused on understanding Long COVID in the community. Four studies were commissioned at a cost of £18.5m. Successful projects were announced on 18 February 2021 **(CJMW5/031 – INQ000283412)**. A second open call, this time funded just by the NIHR and also on non-hospitalised patients, was launched in the spring of 2021, and focused on treatments and interventions, diagnostics and service delivery. This resulted in a further fifteen studies being funded, at a cost of £19.6m. These were announced on 18 July 2021 **(CJMW5/032 – INQ000283460)**.

3.93 The above summary gives some indication of the research activity driven and supported by the OCMO directly or indirectly. Further detail can be found in the Technical Report **(CJMW5/001 – INQ000203933)**.

Academy of Medical Royal Colleges

3.94 In order to provide collective leadership to the public health profession and contribute to the wider collective leadership of the medical profession, the OCMO had regular (up to weekly) meetings with the Presidents and Chairs of the Medical Royal Colleges through the Academy of Medical Royal Colleges and with other senior clinicians. These were information sharing and discussion meetings. I usually took the lead for OCMO in these meetings.

[1] PRINCIPLE was a UK-wide clinical study evaluating treatments for COVID-19 in the community. REMAP-CAP was originally conceived as a response to H1N1 influenza. It allowed for the simultaneous evaluation of treatment options on a national and global scale

3.95 The Presidents from the Royal Colleges set out in such meetings what they knew from their membership, asked questions and challenged Government thinking when they felt this was appropriate, whilst I laid out the emerging epidemiology and early Government thinking. This allowed a two-way confidential professional dialogue between the medical profession and the medical advisers in Government.

3.96 The first meeting with Royal Colleges was on 30 January 2020. I met with Royal Colleges around 65 times between January 2020 and June 2022.

UK Senior Clinicians Group

3.97 The UK Senior Clinicians Group was a group where senior clinical colleagues from across Government came together to discuss technical issues such as clinical epidemiology, death reporting, patients at risk of severe illness, letters of support for doctors, and research outcomes so there was an alignment in knowledge across the national system. It was not a decision-making group but designed as a place for rapid informal information sharing and discussion between clinical experts in different parts of the system **(CJMW5/033 – INQ000203910)**. It was conceptualised on 26 February 2020 **(CJMW5/034 – INQ000047880)**. Initially it brought together OCMO, PHE and the NHS, but it expanded to include further clinicians including the other UK CMOs. I generally chaired.

UK CMOs.

3.98 Each nation of the UK has a Chief Medical Officer and from early in the pandemic the four CMOs worked very closely together. The UK CMOs had regular meetings where we discussed technical issues, and where possible aligned the advice we were giving. I usually chaired the UK CMO groups other than the quarterly formal meetings which were chaired in rotation. Much of the advice of UK CMOs has been covered in our witness statements to Module 2.

3.99 The UK CMOs first met to discuss COVID-19 on 24 January 2020 **(CJMW5/035 – INQ000047552)**. In the period January 2020-June 2022 the UK CMOs met as a specific group more than 286 times, initially often at short notice when there were new developments. We also attended meetings together that were not specifically UK CMOs meetings, for example Silver meetings of the Local Action Committees (part of the COVID-19 surveillance structure set up by the DHSC) and the UK Senior Clinicians meetings.

3.100 The UK CMOs sometimes gave advice collectively. This was either to provide a basis for cross-UK decision-making, to give clarity across the four nations, to add strength of weight to the clinical advice or to make a clear public statement reflecting a collective clinical view. Some decisions that were seen to be almost entirely clinical were also taken by this group. These decisions and communications were made in committee generally chaired by me, and usually sent either as letters to the medical profession if clinical in nature, for example on medical regulation or clinical trials; to the general public, for example on education; or as a communication to Cabinet Office usually via email, for example on Alert levels.

3.101 Examples relevant to this Module include joint advice on:

- 30 January 2020 - Statement from the 4 UK Chief Medical Officers on novel coronavirus (CJMW5/039 – INQ000203938).
- 1 April 2020 - Clinical trials for treatments to NHS colleagues **(CJMW5/017 – INQ000068589)**.
- 23 August 2020 – Balancing risks and benefits in education: advice to the public, parents, teachers and other staff **(CJMW5/036 – INQ000070464)**.
- 4 December 2020 - Winter challenges **(CJMW5/037 – INQ000072041)**.
- 11 December 2020 - Self-isolation period **(CJMW5/038 – INQ000203967)**.
- 31 December 2020 - Dosing schedule for vaccination: advice to healthcare professionals **(CJMW5/040 – INQ000203963, CJMW5/041 – INQ000203969)**.
- 24 February 2021 - Alert levels **(CJMW5/042 – INQ000072901)**.
- 13 September 2021 - 12 to 15-year-old vaccination: advice to Ministers **(CJMW5/043 – INQ000203916, CJMW5/044 – INQ000203917, CJMW5/045 – INQ000203918, CJMW5/046 – INQ000203920, CJMW5/047 – INQ000066870, CJMW5/047a – INQ000070434)**.
- 14 December 2021 – 15 minute wait after mRNA vaccines **(CJMW5/048 – INQ000203961)**.

3.102 This is a sample of the advice that the UK CMOs gave together. We also aimed to give the same advice independently, within our own nations, having discussed, challenged where needed and come to a scientific conclusion.

3.103 It should be noted that with regards to the NHS and devolved equivalents, the CMOs for Scotland, Wales and Northern Ireland have different, and often more direct, responsibilities within the NHS structure than currently occurs in England. These are best laid out by them.

Section 4: Understanding of COVID-19

4.1 The Inquiry has asked several questions about our understanding of COVID-19. I give outline answers here but have given much more extensive answers including technical details in the Technical Report and in several witness statements to Modules 1 and 2 of this Inquiry. To avoid extensive repetition of information available elsewhere I concentrate below on issues most relevant directly to the NHS rather than wider policy.

Transmission

Routes of Transmission

4.2 The initial countermeasures which are useful for an emerging infection depend on the route of transmission and the known period of communicability. The five main routes of transmission capable of sustaining a pandemic or major epidemic are: respiratory (influenza, COVID-19); sexual and intravenous (HIV); oral from water or food (cholera, typhoid); vector transmitted from insects or arachnids (plague, malaria, dengue, typhus, Zika) and touch (Ebola, Lassa).

4.3 Some infections have a dominant route of transmission and secondary routes. For example plague has both a respiratory and a vector-borne route; Zika is a vector-borne disease which has a secondary sexual route.

4.4 In the case of COVID-19 it was established at an early stage that the dominant route was respiratory. It was assumed that touch (to mucus membranes) and possibly faeco-oral were potential secondary routes. In the case of respiratory transmission, this can involve the generation of particles from a few microns in diameter to several hundred microns in diameter. Particles of different sizes have different ballistic and other characteristics and the extent to which one size range dominates can be a very

important factor in transmission and therefore countermeasures. It is very rare that one size range dominates entirely and there will be inter-individual variation. Determining particle size emissions involves highly specialised aerobiological studies and is never known at the point when a novel respiratory virus emerges, indeed understanding for influenza remains incomplete despite decades of study and substantial research funding.

4.5 Non-pharmaceutical countermeasures have to be based on the known or assumed route of transmission, mortality rate, and the age structure of disease, among other factors. To take a practical example: the last major pandemic to affect humans with substantial mortality was HIV, a sexually and intravenously transmitted infection which infected predominantly young adults who remained infectious over many years. None of the societal measures that help control HIV such as condom use would have any impact on COVID-19, and the measures that were used for COVID-19 (home working, facemasks, reducing the numbers of people entering care homes etc.) would have almost no impact on an HIV epidemic.

4.6 One area of transmission where the central view in the UK and internationally (e.g. WHO) changed over the early pandemic was the relative contribution of droplet spread (usually at quite close quarters of a few metres) and aerosol spread (also mainly close range, but capable of infecting at a distance). Both are respiratory but this has implications for potential countermeasures. The relative contribution of aerosol was understood to be greater as time went on, but this was a gradual accumulation of evidence. This had implications for the NHS for example the relative importance of bed-spacing; where droplets are the principle transmission route spacing beds apart has a greater effect to reduce transmission than where aerosols are dominant. In practice both types of respiratory transmission were likely to be present but the expected reduction in nosocomial transmission in hospital or other healthcare settings by particular interventions will vary. Ventilation will have a greater impact on aerosol transmission, bed-spacing on droplet spread. Both should however be used.

Droplets, aerosols and surfaces (fomites)

4.7 For SARS-COV-2 it was clear from an early stage that it was predominantly an infection spread by the respiratory route. The early reporting out of China implied this and subsequent data confirmed it. There remained uncertainty about the relative split between droplet, aerosol and surface transmission from droplets as outlined above.

4.8 Respiratory viruses can be spread in a number of ways. When COVID-19 emerged one of the important questions to answer was which routes of transmission were important. As the WHO explained:

"- Current evidence suggests that the virus spreads mainly between people who are in close contact with each other, for example at a conversational distance. The virus can spread from an infected person's mouth or nose in small liquid particles when they cough, sneeze, speak, sing or breathe. Another person can then contract the virus when infectious particles that pass through the air are inhaled at short range (this is often called short-range aerosol or short-range airborne transmission) or if infectious particles come into direct contact with the eyes, nose, or mouth (droplet transmission)

- *The virus can also spread in poorly ventilated and/or crowded indoor settings, where people tend to spend longer periods of time. This is because aerosols can remain suspended in the air or travel farther than conversational distance (this is often called long-range aerosol or long-range airborne transmission).*

- *People may also become infected when touching their eyes, nose or mouth after touching surfaces or objects that have been contaminated by the virus* **(23 December 2021 – CJMW5/049 – INQ000203978)**.

4.9 Several routes were recognised early on as possible routes of transmission **(14 February 2020 – CJMW5/050 – INQ000047770, 14 February 2020 – CJMW5/051 – INQ000047771)**. This can be seen in the measures introduced to limit transmission. There was scientific debate about the relative importance of each, with particular focus on suspended aerosol transmission. The exact proportion of each still remains uncertain, but as more evidence emerged the scientific central view has shifted to consider suspended aerosol as being of more importance (a greater proportion) than was originally thought. In turn this led to a progressively greater emphasis on the role of ventilation. This can be seen in the Environmental Modelling Group papers (a SAGE sub-group who provide advice on the role environmental modelling, data analysis and environmental sampling can play in understanding COVID-19 transmission) **(30 September 2020 – CJMW5/052 – INQ000203993, CJMW5/053 – INQ000203979)** and in the campaigns launched on ventilation **(18 November 2020 - CJMW5/054 – INQ000203922)**.

4.10 Fuller details are found in Chapter 1 of the Technical Report of the CMOs and GCSA **(CJMW5/001 – INQ000203933)**.

Pre-symptomatic and asymptomatic transmission

4.11 I was aware of the possibility of asymptomatic spread of COVID-19 (as opposed to there being just asymptomatic cases, without the potential for those cases in turn to then generate further infections) from early January 2020. As an example, I discussed this possibility with Sir Jeremy Farrar (Director of Wellcome) on 19 January 2020 **(CJMW5/055 – INQ000183355)**.

4.12 There is however a significant difference between the possibility that asymptomatic infection might occasionally occur (likely), and the idea that asymptomatic transmission would be a major part of the force of transmission. Evidence that asymptomatic transmission was a sufficiently important part of the epidemiology that it had a significant impact on the pandemic overall accumulated slowly. There was no single point where I and others in the international scientific community moved from thinking it was improbable to thinking it was a major issue; rather it was a gradual process of the accumulation of evidence. The UK was not an outlier in this and WHO also gradually changed its position as the evidence accumulated. Even as late as 9 July 2020, the WHO's position was that the scale of asymptomatic transmission was unknown (**CJMW5/056 – INQ000203997)**.

4.13 The exact proportion of asymptomatic transmission has still not been established beyond doubt and has likely changed over time. The current central view is that COVID-19 has a greater proportion of asymptomatic transmission than previously seen with other novel coronaviruses. The proportion is likely to have changed throughout the pandemic as new variants with different infectiousness, and the roll-out of vaccination, meant people benefitted from immunity which tends to make symptoms less severe, or less apparent.

4.14 The midpoint of the scientific view, and therefore our advice to Ministers and other core decision-makers, including in the NHS, about the reliability of testing asymptomatic people changed over the first few months of the pandemic. The initial advice in SAGE given by Dr Maria Zambon, who had originally developed the test and is an acknowledged international expert in this area, was that testing for asymptomatic disease was likely to be less sensitive than that for symptomatic disease **(28 January 2020 – CJMW5/061 INQ000057492**. Accordingly, with very limited testing capacity available in the UK for many months, it was initially appropriate not to test asymptomatic patients if this would cause shortages that would leave us unable to test symptomatic patients. Subsequently, studies showed that it was possible to identify

asymptomatic people by means of testing, and so the advice changed, as did testing capacity.

4.15 I would like to make clear the difference between pre-symptomatic and asymptomatic spread. First, it is sensible to repeat a point made in witness statements in Modules 1 and 2; asymptomatic infection (a person is infected without having symptoms) is different from asymptomatic transmission (a person with no symptoms but who can transmit to others). Pre-symptomatic transmission is where a person becomes infectious, and becomes symptomatic, but they are infectious for a period (hours or days) before the symptoms appear. In asymptomatic transmission, the individual can transmit the virus despite having no symptoms at any point.

4.16 There are important differences between pre-symptomatic transmission and asymptomatic transmission from a perspective of disease control. The most important is that in pre-symptomatic transmission the case will be identified and counted, and their contacts can be identified and isolated, relatively easily (albeit later than in symptomatic infection). In asymptomatic transmission, it is much less likely the index case will be identified early enough to institute contact tracing unless they are by chance tested whilst infectious. This makes contact tracing as a method of control less effective, and if a large proportion of the infection is from asymptomatic transmission much less effective.

4.17 Whether, and to what extent, there was asymptomatic infection and asymptomatic or pre-symptomatic transmission was debated from the beginning of the epidemic, with robust data accumulating slowly in the global literature. This gradual accumulation is laid out in the Technical Report to future CMOs and GCSAs (**CJMW5/001 – INQ000203933)**. This was a global view - for example on 9 June 2020 Dr Maria Van Kerkhove, the WHO's technical lead on the COVID-19 pandemic, made it clear that the actual rates of asymptomatic transmission were not yet known.

4.18 For SARS and MERS, two other coronaviruses which emerged recently, asymptomatic and pre-symptomatic transmission is thought to be very rare although asymptomatic infection without transmission may occur. This influenced initial thinking. Diseases where a small proportion of infected people are infected from an asymptomatic source, even when it occasionally occurs, can be controlled by removing only those who are symptomatic as this would be likely to pull R below 1 and so end an epidemic, or an epidemic wave.

4.19 Asymptomatic infection and asymptomatic transmission are different and care is needed not to conflate them. Asymptomatic infection is where a person has acquired the virus but does not have symptoms; it occurs in many diseases. Asymptomatic viral transmission occurs when the infected but asymptomatic person passes the virus on to someone else. Asymptomatic infection does not necessarily lead to asymptomatic transmission (though it is a prerequisite). In principle it is possible to have extensive asymptomatic infection with almost no asymptomatic transmission. Asymptomatic transmission or not is also not a binary division - for some diseases (but not for all) there is a correlation between severity of symptoms and infectiousness with a mildly symptomatic person being less infectious than a severely symptomatic one. Many symptoms, such as coughing and sneezing, are themselves part of the transmission mechanism expelling virus with greater ballistic force (fewer symptoms leads to lower transmission). People tend to avoid those obviously symptomatic and symptomatic people tend to try to protect others by avoiding close contact with them (so more symptoms lead to lower transmission). Someone who is infected and infectious may start as asymptomatic and then become symptomatic (pre-symptomatic) or they may have symptoms that are very mild and so will not alter their behaviour or necessarily be seen by the individual as symptoms (pauci-symptomatic). Whether to classify the pre-symptomatic and pauci-symptomatic as asymptomatic or not adds to the difficulty of knowing the degree of asymptomatic transmission. There are important practical differences between pre-symptomatic and asymptomatic spread.

4.20 Asymptomatic and pre-symptomatic transmission are for these and other technical reasons not easy to study. In the absence of a reliable test that detects infection in an individual without symptoms, determining who is asymptomatically infected is not possible.

4.21 Another important factor in transmission is viral load, put simply the extent to which the virus multiplies in the infected host. It is possible to have two patients infected with COVID-19 with broadly similar symptoms. However the viral loads and therefore the propensity for transmission (the most amount of virus available in respiratory particles from that patient able to be passed on) will also vary between patients and over time. Viral load is generally unknown with an individual patient unless they are being studied by repeat sampling over time. However it is known to rise and then fall with a typical COVID-19 patient and may persist for up to 14 days and occasionally longer, although 7-10 days is more standard. Peak infectiousness is however for a shorter period. Viral

load is generally a good predictor of infectiousness but is of little practical value unless the patient can be tested repeatedly, usually daily.

4.22 Asymptomatic transmission (or not) is one important part of the response to a pandemic, as is isolating those who have the virus. Before a rapid test is widely available this can be done by asking anyone with a specific set of symptoms to isolate. The higher the level of asymptomatic and pre-symptomatic transmission and the greater the range of non-specific symptoms that are possible, the less well this will work.

4.23 It was recognised at an early stage of the initial outbreak that asymptomatic transmission could be a possibility **(25 January 2020 – CJMW5/058 – INQ000047556)**. As with many aspects of COVID-19 knowledge about the degree of asymptomatic transmission accumulated over time, with a consequent shift in the emphasis given to the role of asymptomatic infection. There was no single instance or study where it suddenly became clear that asymptomatic transmission was happening in x% of cases. It is possible to see the evolving evidence by looking at the minutes of NERVTAG and of SAGE from January 2020 to June 2020 which refer to both asymptomatic infection and asymptomatic transmission:

NERVTAG 21 January:

there are currently no data on infectiousness in relation to symptom onset and whether asymptomatic or subclinical patients are infectious **(CJMW5/059 – INQ000023119)**.

NERVTAG 28 January:

members were not unanimous but the predominant view was that the force of infection from asymptomatic individuals, if present at all, is likely to be lower than symptomatic individuals **(CJMW5/060– INQ000047820)**.

SAGE 28 January:

There is limited evidence of asymptomatic transmission, but early indications imply some is occurring **(CJMW5/061 – INQ000057492)**.

SAGE 4 February:

asymptomatic transmission cannot be ruled out and transmission from mildly symptomatic individuals is likely **(CJMW5/062 – INQ000051925)**.

NERVTAG on 21 February one member brought up some evidence that:

suggests that 40% of virologically confirmed cases are asymptomatic. Another noted the data on asymptomatic and symptomatic proportions in China are not well documented **(CJMW5/063 – INQ000119469)**.

SAGE 13 March asked PHE:

to contact Italian counterparts to request serology samples. If available, PHE to test these samples to ascertain symptomatic vs asymptomatic case ratio **(CJMW5/064 – INQ000109142)**.

SAGE 16 March:

antibody testing is particularly vital to address the central unknown question of the ratio of asymptomatic to symptomatic cases **(CJMW5/065 – INQ000075664**

NERVTAG 3 April:

there is information available on the detection of infection in asymptomatic individuals but little information on the transmission risk from asymptomatic individuals…. the importance of clarifying between pre-symptomatic transmission and asymptomatic transmission and using the correct terminology. It was agreed that there is data of pre-symptomatic transmission (both direct and indirect, based on the models) both pre-symptomatic and asymptomatic transmission are assumed in the SPI-M models. In their model, ~40% of cases don't seem to display symptoms and these cases are given an arbitrary assumption of 50% infectiousness compared with symptomatic cases. Imperial have a similar model and use similar assumptions… They concluded that the level of 50% for asymptomatic infectiousness was realistic and recognised that more data is required **(CJMW5/066 – INQ000220209)**.

NERVTAG 24 April PHE reported that:

swabs were taken in six care homes in London over the Easter weekend. All residents and staff were sampled and a total of approximately 500 swabs were collected. The six care homes were at different stages of outbreak. One of the homes had only identified two cases and had very few symptomatics. It was found that 75% of the residents carried the virus and only 25-33% were symptomatic. Approximately 45% of the healthcare workers were also carrying the virus, with 25-33% symptomatic **(CJMW5/067 – INQ000120161)**.

1 May NERVTAG:

SPI-M and Imperial use an estimated figure of 50% infectiousness for asymptomatic compared with symptomatic infections. The proportion of asymptomatic infections is age-dependent in the SPI-M model, from approximately 75% in children to <20% in the over 70s. Snap shot data may be misleading as some individuals may be pre-symptomatic not asymptomatic. Members discussed the strength of the evidence of infectiousness of asymptomatic individuals. The assumption used for modelling is asymptomatics are 50% as infectious as symptomatics. JE referenced work from Vietnam and Germany which appears to show asymptomatic transmission but acknowledged the difficulty in distinguishing asymptomatic from pre-symptomatic infection **(CJMW5/068 – INQ000220211)**.

13 May NERVTAG:

noted that NERVTAG had been asked to comment on the proportion of individuals who were truly asymptomatic and the relative infectiousness of those individuals. AH's team have produced a systematic review, using papers with complete follow-up. The pooled estimate is 11% (CI of 4-18%), with a wide range of values in the studies. Members discussed other reviews and suggested that this value was low compared with other estimates, which average around 30% **(CJMW5/069 – INQ000203994)**.

14 May SAGE:

NERVTAG has reviewed various studies on asymptomatic infection. Many do not differentiate between asymptomatic/pauci-symptomatic individuals and pre-symptomatic individuals. SAGE noted that longitudinal sampling in the ONS study will assist in clarifying this difference going forward but needs to include more than "asymptomatic on the day of infection". Taking all evidence into account, between 10% and 35% of individuals may be truly asymptomatic (low confidence), and many more may have few symptoms. Review of ONS data will help refine the estimate. It is possible that asymptomatic individuals are less infectious, but this cannot currently be quantified. There is a key knowledge gap concerning how positive testing correlates with the presence of live, recoverable virus (i.e. infectiousness), although PHE is currently investigating this **(CJMW5/070 – INQ000120519)**.

11 June SAGE said:

the percentage of people who are asymptomatic remains uncertain and could be between 30-80%; it may vary by age and other characteristics **(CJMW5/071 – INQ000120527)**.

18 June SAGE said:

individuals likely to facilitate the seeding of super-spreading events may be asymptomatic or paucisymptomatic. Understanding asymptomatic infection is key to understanding super-spreading events **(CJMW5/072 – INQ000120531**

4.24 On 9 July 2020 WHO published a report acknowledging asymptomatic transmission **(CJMW5/056 – INQ000203997)**. It still concluded that the scale of asymptomatic transmission remained unknown.

4.25 NERVTAG looked at 22 studies prior to 25 August 2020 and found a pooled estimate for the asymptomatic proportion of SARS-CoV-2 infections to be 28% (95% Confidence Intervals (CI) 20%-35%) **(CJMW5/073 – INQ000203996)**. Note that this is for infection, not transmission; asymptomatic transmission by definition has to be from asymptomatic people, but not all people with asymptomatic infection will transmit on (and indeed in some infections only a very small proportion will, or none at all).

4.26 The exact proportion of asymptomatic transmission has still not been established beyond doubt and has likely changed over time. The current central view is that SARS-COV-2 has a greater proportion of asymptomatic transmission than previously seen with other major coronaviruses (MERS, SARS). The proportion is likely to have changed throughout the pandemic with new variants with different infectiousness, and with the roll-out of vaccination meaning people have immunity which tends to make symptoms less severe, or less apparent.

Infectiousness

4.27 COVID-19 was, from the outset, a highly infectious disease. Over the course of the pandemic it evolved to become more infectious, and indeed is still evolving. Some of that evolution was gradual with slightly more infectious or (later in the pandemic) immune-escaping variants displacing one another with relatively limited impact on the epidemic, but there were three significant points where its infectiousness increased markedly in the UK; the evolution of Alpha, Delta and Omicron, each successively more infectious than the last. Each of these gave rise to a wave of infection.

4.28 The best, although not only, shorthand for the infectiousness of the infection was R, the force of transmission. When R is above 1 an epidemic or pandemic is expanding (doubling), when it is below 1 it is contracting (halving). The natural R_0 for the original (Wuhan) variant was between 2 and 3, meaning on average one person gave it to two to three others, in the absence of immunity and any countermeasures. The natural R_0 for Omicron was significantly higher than this, but it emerged into a population with significant prior immunity due to vaccination and prior infection which dampened (but did not remove) its effective force of transmission R (also sometimes known as R_t).

4.29 R was calculated by several groups internationally, and in the UK brought together to SAGE following work by the SPI-M-O modelling and epidemiology group. The advice I and the DCMOs gave both to the public and the NHS on transmissibility was based on their calculations, which can be tracked through the minutes of SAGE.

4.30 Alongside this there was a significant international effort to understand biological mechanisms of transmission. There was a major shift in the evolution from Delta to Omicron in the effectiveness of the transmission of COVID-19. This is covered in the Technical Report, Chapter 1: understanding the pathogen **(CJMW5/001 – INQ000203933)**.

Hospitalisation and deaths

4.31 Identification of those who were at highest risk from serious illness, hospitalisation and death from COVID-19 was clearly an important fact to ascertain. There is a technical difference between infection fatality rate IFR (the proportion of those infected who die) and case fatality rate CFR (generally the proportion of those with symptoms and an infection who die). In diseases where a lot of people are infected asymptomatically IFR will be lower than CFR. IFR is not possible to calculate accurately without a test that picks up asymptomatic cases. Chapter 1 section 5 of the Technical Report covers the technical area of calculating these figures over time and the steady improvements of methodology that occurred over the first 6 months of the pandemic. **(CJMW5/001 – INQ000203933)**.

4.32 The IFR for COVID-19 was and is low compared to the previous novel coronaviruses SARS or MERS, but high compared to prior human coronaviruses 229E, NL63, OC43 and HKU1 that cause cold-like symptoms, so extrapolating from any of them would have been hazardous.

4.33 For clinical practice the more important figure is the CFR as this starts with a symptomatic person, which is the norm for people presenting for NHS care.

4.34 On 28 January 2020, SAGE observed that the CFR was *"currently estimated to be lower than SARS, but many uncertainties remain"* **CJMW5/061 - INQ000057492**.

4.35 On 11 February 2020 and then 27 February 2020, SAGE maintained an estimation of a 2-3% CFR for planning assumptions, albeit that this had wide confidence intervals **(CJMW5/074 – INQ000075784, CJMW5/075 – INQ000074896)**.

4.36 On 5 March 2020, SAGE agreed with the following assumptions in a paper **(CJMW5/076 – INQ000074987)**:

Infection fatality rate:

Age	Proportion of infected that die
0-9	0.01%
10-19	0.01%
20-29	0.04%
30-39	0.09%
40-49	0.15%
50-59	0.69%
60-69	2.21%
70-79	5.92%
80+	8.76%

Proportion of infected people hospitalised (threshold for hospitalisation assumed to be needing oxygen):

Age	Proportion of infected people hospitalised
0-9	0.24%
10-19	0.34%
20-29	1.05%
30-39	2.34%
40-49	3.95%
50-59	9.81%
60-69	22.50%
70-79	36.20%
80+	43.79%

Fatality rate for hospitalised people:

Age	Fatality rate for hospitalised people
0-9	3.64%
10-19	3.64%
20-29	3.64%
30-39	3.64%
40-49	3.77%
50-59	7.07%
60-69	9.83%
70-79	16.36%
80+	20.00%

4.37 IFR is more important for population control of infectious diseases. On 27 February 2020 SAGE agreed with the estimation of a 1% IFR for the initial (Wuhan) variant with a wide variation depending on age and with a fair degree of uncertainty **(CJMW5/077 – INQ000203874)**. Both the IFR and the CFR changed later in the pandemic, with new variants and the roll-out of vaccine altering the relationship between infection and death. CFR fell over the two years of the pandemic due to improved medical management and prior immunity in patients who were infected due to vaccination and prior infection. An age gradient remained however.

Risk Factors

4.38 Mortality rates varied considerably across the population, with the strongest risk factor by some way being older age; this was identified early. The Inquiry has asked whether older age alone was a risk factor; it was, as it is for many infectious diseases. Inevitably however some other risk factors accumulate with age, so this is compounded for many older people by one or more other risk factors, with the effect being cumulative. Other risk factors for mortality include pre-existing health conditions including obesity. The understanding of who was at risk changed through the pandemic, but older age was established early and remained the most common risk factor. Children and young people were at very low risk of severe outcomes relative to adults, but severe cases and deaths still occurred in this age group **(CJMW5/078 – INQ000066784)**.

4.39 People from ethnic minorities were at higher risk of mortality from COVID-19 overall. There was a complex interaction between COVID-19 and ethnicity that became clearer with time. The increased representation of people from ethnic minority groups was in large part due to increased risk of being infected, for example due to occupation (e.g. in close contact occupations) or living in higher risk areas, but there were additional factors including higher pre-existing rates of chronic diseases. I commissioned a report on this from PHE Regional Director for London Professor Kevin Fenton which was published by PHE in June 2020 **(CJMW5/079 – INQ000176354)**. Subsequent studies built on this work. The risk by ethnicity changed over the course of the pandemic.

4.40 The report entitled "Beyond the data: Understanding the impact of COVID-19 on BAME groups" report consisted of a rapid literature review and stakeholder engagement. The literature review found evidence that Black, Asian and Minority Ethnic (BAME) groups were more likely to test positive for, and die from, COVID-19 than White British groups. These increased risks were exacerbated by social and structural determinants of health such as housing, income, occupation and poorer experiences of healthcare. Themes from stakeholder engagement included a view that the pandemic exposed and exacerbated longstanding inequalities, rather than creating them; a higher incidence of chronic diseases in BAME groups, increasing the risk of complications and death from COVID-19; and potentially racism, discrimination, stigma, fear and lack of trust in healthcare services as root causes affecting health.

4.41 Following the release of the report into disparities in the risks and outcomes of COVID-19, the Government's Equality Hub led by Equalities Minister, Kemi Badenoch MP took forward work to tackle these disparities **(CJMW5/079a – INQ000089741)**.

4.42 Addressing the increased risk of some ethnic minority groups acquiring COVID-19, including within the NHS estate and workforce was principally an issue for public health interventions. By contrast addressing the increased risk of those from ethnic minority groups with COVID-19 dying or having severe disease is principally a clinical management question within the NHS.

4.43 As with most epidemic infections those in areas of deprivation suffered most from higher infection and mortality.

4.44 Mortality rates from COVID-19 in the most deprived areas of the country were more than double that found in the least deprived areas, with differences remaining after adjustment for age, sex, region and ethnicity. As a single group, ethnic minorities experienced higher all-cause death rates and death rates from COVID-19 compared to those of white British ethnicity, with relative differences varying throughout the pandemic and across different ethnic groups **(CJMW5/080 – INQ000101218**.

4.45 In the working-age population, COVID-19 death rates were consistently and markedly higher for men than women throughout much of the pandemic, but this varied by occupational group **(CJMW5/081 – INQ000148395)**.

4.46 Another group at particularly high risk for severe disease and premature mortality were those with a disability. In the first wave, 6 out of 10 deaths in England were among people who reported having a disability **(CJMW5/082 – INQ000089756)**. Research based on the learning disability register found a persistent, unadjusted, marked increased risk in COVID-19 hospitalisation and mortality for people with a learning disability – though it is important to note that there are major limitations with the learning disability register as a robust assessment tool, with wider coding for learning disability, difficulties in risk attribution to particular learning disability conditions and that not all analyses adjusted for underlying health conditions **(CJMW5/083 – INQ000381220)**.

4.47 Co-morbidities such as diabetes, severe asthma and obesity were identified as risk factors for poor outcomes and were more prevalent in more deprived and in some ethnic minority groups. Linked primary care records of over 17 million adults with over 10,000 deaths between February and December 2020 found that while comorbidity did explain some of the different death rates by ethnicity, people from black and South Asian ethnic groups were both more likely to test positive and more likely to die from COVID-19 during the first wave compared with people from white ethnic groups after

adjustment for deprivation, age, sex and comorbidity **(CJMW5/084 – INQ000381221)**. Analysis of the second wave found that while differences in testing positive and higher death rates among South Asian ethnic groups remained, they were far less stark for black ethnic groups.

4.48 Disentangling the principal drivers was often complex because of the overlapping nature of many of the risk factors. For example, some British South Asian populations might have a higher probability of being in contact professions such as taxi driving or care work, higher rates of diabetes, more multigenerational households and be in an area of enduring transmission such as in the north-west of England.

4.49 Identifying which was a risk factor and which was a confounding factor was inevitably complex and some residual confounding was likely.

4.50 The risks of severe infection for pregnant women were significantly higher than for non-pregnant women of the same age, and there were increased rates of mortality in pregnant women. These findings were not apparent very early on in the pandemic and only became clearer as more data emerged. The risks were higher for pregnant women in the later stages of pregnancy (28 weeks or beyond). Those aged over 30, living with obesity or with gestational diabetes were at particularly high risk **(CJMW5/085 – INQ000381222)**. This was compounded later in the pandemic by the fact that uptake of vaccine was lower in pregnant women than other groups. This low uptake was driven in large part by disinformation, some deliberate, about risks of the vaccine in pregnancy.

4.51 Infection with COVID-19 during pregnancy, in common with many other infections, increased the risk of premature birth **(CJMW5/086 – INQ000381223)**.

4.52 The Royal College of Obstetrics and Gynaecology produced useful advice for pregnant women about COVID-19, some of which included work with OCMO, the Royal College of Midwives and the Faculty of Occupational Medicine **(CJMW5/087 – INQ000381249)**.

Disparities

Identifying disparities

4.53 Once an epidemic or pandemic begins, it is likely to lead to some groups living in disparity or discrimination being affected disproportionately. This has been true for

almost all infections through history, although the mechanism by which this occurs, and the groups it affects, vary depending on the infection. I explained this phenomenon in greater detail in my Second Statement at paragraphs 5.55 to 5.58.

4.54 As I have stated above, the earliest disparity that became apparent in respect of COVID-19 was age, and specifically older age: this was first indicated by data from Chinese scientists and clinicians and was subsequently repeated in Italy, the UK and globally. Various subsequent risk factors appeared early in the data and included gender (this varied over the pandemic's first years), obesity, diabetes, immunosuppression, neurodisability, several other medical comorbidities, disabilities and ethnicity. Deprivation remained a risk factor of its own even when other factors were controlled for. Older age remained however the greatest risk factor at a population level.

4.55 The aim of identifying these disparities was not merely to observe, but to act to try to minimise preventable harm. I was involved in putting in place at a relatively early stage of the pandemic studies to try and identify medical conditions associated with poor outcomes, and to examine the causes of, and potential solutions to, the observed differences by ethnicity, outlined below.

4.56 In considering the various groups at risk, it is important to differentiate between an increased risk of acquiring COVID-19, and an increased risk of having severe disease or dying from COVID-19 once it was acquired. These have very different practical implications. For example, obesity or older age do not increase the risk of infection (in fact in the case of age it is probably the reverse due to relatively fewer different social contacts compared to younger adults on average) but they do increase the risk of severe outcomes once infection has occurred.

4.57 On the other hand, living in a multigenerational household, being employed in a high contact role such as social care or taxi driving, or living in densely populated areas do not in themselves increase the risk of severe outcomes. They do however significantly increase the risk of a vulnerable individual acquiring the infection. In practice, deprivation often simultaneously increased the risk both of infection, including through housing and employment, and the risk of severe disease, for example through higher pre-existing rates of diabetes, obesity or multi-morbidity. Deprivation also often served to reduce the speed with which individuals sought care and their level of engagement with health services in addition to having worse pre-existing health and greater risk of acquiring disease.

4.58 Exacerbating this, many of the key social measures taken to combat COVID-19 had greater negative impacts in areas of deprivation than in more affluent areas. Greater proportions of the population in these areas depended on work paid only for the time spent working, meaning that time off for self-isolation was more financially damaging than for salaried work; families were often less equipped to be able to support home schooling for children; outdoor spaces were less available for relatively safe social mixing; and so forth.

4.59 This led to an extremely difficult combination whereby the probability of someone in an area of deprivation acquiring, having severe disease from, and being harmed by, the countermeasures to COVID-19 were all greater compared to more affluent areas. Many of these households were also least able to home-school as parents were not able to work from home. Later in the pandemic, disparity also manifested itself in differential uptake of vaccination, with inevitable consequences.

4.60 It was in my view predictable that there would be significant structural inequalities in the health outcomes for COVID-19. It was not in my view entirely predictable which groups would be most affected other than that broadly people living in deprivation tend to have less good outcomes from most infections and indeed most public health problems. To give an example of this, the last major pandemic with substantial mortality was HIV/AIDS. There was in the UK very heavy inequality in HIV centred around gay men (then highly discriminated against), people of both genders with a heritage from southern Africa, intravenous drug users and commercial sex workers - all groups who suffered from discrimination and often deprivation. This is a completely different group from those affected disproportionately by COVID-19, although the issues of segregated risk into marginalised and vulnerable communities were equally severe.

Response to the disparity in outcomes

4.61 Given this, we felt it was important to undertake the collection of data and research studies to identify the key vulnerable groups, and in turn identify any possible countermeasures. It is important here to recognise the difficulties involved in confounding and bias in epidemiological studies of this kind. In the first wave of COVID-19, people of African and Afro-Caribbean heritage were sadly very highly overrepresented in those who acquired and died from the disease. Identifying the proportion of that excess risk which was as a direct result of ethnicity, and that which was due to the fact that a higher than average proportion of people living in densely

populated areas or in high contact professions (and who therefore could not work from home) came from these communities, was not straightforward. It did however have important practical implications. In the second wave, UK citizens of South Asian heritage had a much higher risk than in the first wave. This reflected the fact that the first wave had a particularly big impact in London, which has a very high proportion of UK citizens of African and Afro-Caribbean heritage, and the second wave initially had a particularly high impact in the Midlands, where there is a very high proportion of the UK's population with South Asian heritage.

4.62 Accordingly, OCMO was involved in the commissioning of several relevant studies. This included setting up CO-CIN (discussed above), commissioning NERVTAG and Professor Hippisley-Cox to do detailed work on the risk for different groups (QCOVID) **(CJMW5/088 – INQ000236458)** and directing the NIHR to do a themed call on ethnicity. The latter funded 10 studies including:

- UK-REACH: United Kingdom Research Study into Ethnicity And COVID-19 outcomes in healthcare workers; **(CJMW5/089 – INQ000236443)** This is an ongoing programme of work with follow up expected until 2025. Further funding has been obtained to also study Long-COVID in healthcare workers. Some 30 publications have been released through UK-REACH with more expected. Key findings from these UK-REACH publications so far include:
    - Vaccine hesitancy – Healthcare workers (HCWs) from Black Caribbean, Mixed White and Black Caribbean, Black African, Chinese, Pakistani and White Other ethnic groups were significantly more likely to report vaccine hesitancy when compared with White British HCWs.
    - Infection risk – HCWs were shown to be at higher risk of infection with SARS-CoV-2 than the general population, with black HCWs shown to be at higher risk than white HCWs. However, after adjustment for all covariates, this association was diminished.
- Ensuring that COVID-19 trials consider ethnicity: the INCLUDE Ethnicity Framework for randomised trials; **(CJMW5/090 – INQ000236444)**. The INCLUDE Ethnicity Framework aimed to increase engagement of individuals of Black, Asian and Minority Ethnic (BAME) backgrounds in research. Specifically, the target was to complete the INCLUDE ethnicity framework (originally initiated in 2018 by NIHR) and apply this to several trials to produce an example set for other trials to use

when planning COVID-19 activities. The framework was launched in October 2020 and is available open access.

- Quantifying the association between COVID-19, ethnicity, and mortality: A cohort study across three UK national databases **(CJMW5/091 – INQ000236445)**. This cohort study has finished. Its key findings were:

    - People with South Asian ethnicity in the UK had significantly elevated risks of severe COVID-19 compared with the general population, even when adjusted for age, deprivation and comorbidities. Only about 40%-60 of excess risks were explained by variation in clinical and demographic factors in certain groups.

    - Children from non-white ethnic groups were less likely to have a COVID-19 test and more likely to be admitted to ICU than white children.

    - Sickle cell disease was associated with an increased risk of COVID-19 hospitalisation and an increased risk of dying due to COVID-19, adjusting for age, ethnicity and sex.

4.63 Further examples are the report on the impact of COVID-19 on BAME communities discussed above **(CJMW5/079 – INQ000176354)**, the NERVTAG sub-group work on stratifying by risk **(CJMW5/092 – INQ000236454)**, an evidence call for research on ethnicity by NIHR in April 2020 **(CJMW5/093 – INQ000236455)** and the CO-CIN study, which reviewed a range of risk factors including ethnicity **(CJMW5/094 – INQ000425563)**. Research studies have various audiences including clinicians, academia and Government. OCMO used the knowledge gained from such research in discussions and advice.

4.64 I was also involved in discussions with healthcare colleagues from multiple ethnic minority and other cultural groups to get their insights into the experience of the communities they had closest links with, and to identify possible countermeasures to COVID-19 in those communities. Later in the pandemic, this included supporting those groups to maximise vaccine uptake. The importance of healthcare worker volunteers from different communities engaging with their communities whilst continuing to maintain their very hard main jobs was both very inspiring, and based on external evidence, very important **(CJMW5/095 – INQ000236421, CJMW5/096 – INQ000236420)**.

4.65 Notwithstanding the efforts described above, whilst I did my best to reflect the importance of disparities and inequalities in the advice I gave to key decision-makers, and I am also confident this was true for the DCMOs, nobody looking back at COVID-19 can claim this was sufficient. The scale of the difference by deprivation and ethnicity is clear; what would have been effective countermeasures is less so. The biggest difference numerically was, and remained throughout the pandemic, older age.

Limitations of our response

4.66 One weakness in data capture is that ethnicity is often poorly or confusingly captured, or not captured at all. Ethnicity was for example not a part of death certification. NHS data on ethnicity is often patchy and does not always rely on self-identified ethnicity, although this is arguably improving. In fairness to those who try to do this, it is not a straightforward endeavour. Many people, entirely reasonably, have multiple simultaneous cultural identities, combinations of ethnicities by biological heritage and cultural choice. Even in research studies, classification by ethnicity is often crude and lumps together groups of individuals who are culturally or genetically very distinct.

4.67 It is essential that in any pandemic or epidemic there is an assumption and recognition that some particular groups will be particularly badly affected. It should also be assumed that there is a very high chance these will be in deprived groups or those living with social stigma or other forms of inequality. Identifying these in advance is however often difficult. It was in COVID-19; many of the disparities identified were obvious in retrospect but were not clear before they became apparent. Looking for disparities in outcomes with the expectation they will be found in marginalised groups but without preconceptions as to which, and then responding to these differences where that is practical, is key.

4.68 Even more important than identifying that there are disparities in risk is identifying differences in response to countermeasures. In the case of COVID-19, these included a differential ability to take time off work, to isolate within homes, varying levels of trust in health services and public health messaging, and the response to the vaccine being available including vaccine uptake. Identifying and addressing these was of great importance.

Reinfection

4.69 It was uncertain at the start of the pandemic how protective having had a previous infection was. Over time it became clear that a previous infection was partly protective against future infection. There were very few reinfections identified early in the pandemic. However, as the virus mutated, and the time between infection and present got longer, we started to see more reinfections.

4.70 Risk of reinfection has varied widely in epidemic-potential infections, ranging from lifelong infections where people remain infectious from infection to death such as untreated HIV, infections where a single short-lived infection generally confers lifelong protection such as measles, and infections where prior infection provides partial, temporary, or minimal protection from subsequent infection such as influenza and malaria. Cross-protection between different variants of a disease is also highly variable.

4.71 Extrapolation from biologically similar or evolutionarily related pathogens provided the earliest clues to whether reinfection was likely, and after what interval. Immunity to SARS-CoV-1 and MERS-CoV was thought to wane over time based on best available evidence, and there was evidence of confirmed reinfections with seasonal human coronaviruses. This meant that from an early stage there was an assumption that reinfections with SARS-CoV-2 were possible. There was also a reasonable assumption that the virus would mutate over time which in turn could impact reinfection risk through immune escape.

4.72 Early data on the proportion of individuals who mount an antibody response to SARS-CoV-2 infection, and the timescale of this antibody response, became available in the first few months of the pandemic. Antibodies did not inevitably mean protection from infection (nor did lack of antibodies preclude it) but they were thought to be broadly correlated (subsequently confirmed).

4.73 The first published case reports of SARS-CoV-2 reinfection confirmed by whole genome sequencing emerged in mid-2020. Several other reports of reinfection emerged at this time, though many did not have sufficient data to distinguish between persistent primary infection and reinfection.

4.74 In late 2020 and early 2021, large scale longitudinal studies such as SIREN and VIVALDI confirmed the possibility of reinfection but demonstrated the protective effect of prior infection as measured by antibodies.

4.75 For example, SIREN study analysis published in early 2021 showed that SARS- CoV-2 reinfection was possible and could occur, but that there was an over 80% reduction in infection among people who had previously contracted COVID-19 compared to those who had not.

4.76 As new variants emerged, there was a need for further data on risk of reinfection and how it was impacted by the changed antigenic makeup of the new variant. Throughout 2020, national surveillance data was used to monitor reinfections, including with newly emerging variants, and showed evidence of increased reinfections with the emergence of the Delta and Omicron variants. In all cases confirmed positive on a daily basis on average until mid-November 2021 around 1.4% were in those who had previously been infected (and therefore counted as reinfections), increasing to 10% in January 2022 following the emergence of Omicron.

Risks to workers in healthcare settings

4.77 Throughout the pandemic, healthcare staff went to extraordinary efforts in highly pressured environments to deliver care and protect patients and colleagues, even when this presented potential risk to their physical and mental health, and the impact on morale was considerable. I and the DCMOs would like to pay tribute to their extraordinary commitment and skill. For many doctors, nurses and other health and care workers concern that they would as a result of their work take infection back to vulnerable family members at home exacerbated the concerns they had about their own health. Despite that, healthcare workers across the NHS came to work to care for others. The public appreciation that was shown at the time for their work and courage was entirely justified.

4.78 Healthcare workers were at an increased risk of catching COVID-19 as a result of their proximity to infected people as well as the frequency in which they will have come into contact with the virus. They had all the day-to-day risks of the communities from which they came, but additionally had the risks of having to take public transport and meet co-workers when others did not, and occupational exposure from sick patients. Effective infection prevention and control measures including detection and isolation of infected patients and the use of PPE reduced the risk of occupational exposure from infected patients specifically, but not the other risks.

4.79 Whether healthcare workers would become more severely ill as a result would be connected to the individual and the risk factors highlighted above. In my view, the key

to improving the safety of higher risk individuals was principally to optimise safety for all rather than to trying to differentiate by every at risk group in the work place. This is outside those groups who were advised to shield, and pregnant women who were already identified as at-risk.

Other issues related to this topic are covered in other paragraphs in this statement:

- Morale and mental health:
    - Paragraph 12.1 - I tried to keep abreast of morale in the medical profession for example through close contact with the medical Royal Colleges. We also had discussions with individuals who were closely involved in this for example Dr Kevin Fong **(CJMW5/194 – INQ000072310, CJMW5/195 – INQ000074691, CJMW5/196 – INQ000381208)**.
- Working outside of normal practice:
    - Paragraph 3.41 - The UK CMOs, AoMRC, GMC and NHSE wrote to NHS doctors to support clinicians making decisions whilst working out of their usual scope of work on 11 March 2020, 11 November 2020 and on 12 January 2021 **(CJMW5/020 – INQ000049584 (CJMW5/021 – INQ000071564) (CJMW5/022 – INQ000072433)**. This was to ensure they were aware that it would be considered good medical practice to work outside their normal area of work during this emergency, and that they would not be held to 'specialist' expectation of levels of expertise when doing so. We also encouraged Trusts and others to support their clinical staff.
- Beyond the data: Understanding the impact of COVID-19 on BAME groups:
    - Paragraph 4.39 - People from ethnic minorities were at higher risk of mortality from COVID-19 overall. There was a complex interaction between COVID-19 and ethnicity that became clearer with time. The increased representation of people from ethnic minority groups was in large part due to increased risk of being infected due to occupation (e.g. in close contact occupations) or living in higher risk areas, but there were additional factors including higher pre-existing rates of chronic diseases. As I have discussed above I commissioned a report on this from Professor Kevin Fenton which was published by PHE in June 2020.

Variants of Concern

4.80 A significant number of new variants emerged during the period of this Module. This was to be expected for a coronavirus and most did not cause any significant concern once characteristics and vaccine effectiveness were able to be fully assessed. Each variant which was expanding needed investigating and it can take weeks fully to understand any differences in infectiousness or severity compared to prior variants, although if significant we would expect to start to see signals in the epidemiological evidence relatively early.

4.81 When public health officials assess that a mutation might have significant characteristics such as increased transmissibility, severity or ability to infect a person this is designated a Variant of Concern (VOC). The key VOCs during the time period were;

- Alpha (B.1.1.7) designated a VOC by the WHO on 18 December 2020. Alpha first emerged in the South-East of England, was significantly more transmissible than the original Covid-19 variant and had UK and global impact.

- Beta (B.1.351) designated a VOC by the WHO on 18 December 2020. Beta emerged in Southern Africa. It had a relatively modest impact in the UK.

- Gamma (P.1) designated a VOC by the WHO on 11 January 2021. Gamma emerged in Brazil. It had a relatively modest impact in the UK.

- Delta (B.1.617.2) designated a VOC by the WHO on 11 May 2021. Delta emerged in India, and dominated in the UK and globally in 2021. Delta was intrinsically more transmissible that previous variants and showed some immune escape.

- Omicron (B.1.1.529) designated a VOC by the WHO on 26 November 2021. Omicron emerged in Southern Africa. It had a large number of mutations and from early data a potential more sizeable immune escape. Omicron dominated in the UK and globally from then to the end of the time period covered by this Module.

4.82 The most relevant ones for this Module are Alpha, Delta and Omicron. The basic R_0 number for subsequent variants increased, with Alpha, Delta and Omicron all having a higher natural R number than the original Wuhan variant. The higher the R number, the more action is required to bring it below 1 and so change the epidemic from one that is doubling to one that is halving. The SPI-M-O estimates of the R number are

available online and I have provided a copy with this statement **(15 May 2020 – CJMW5/097 – INQ000203987)**.

4.83 As new variants emerged, there was a need for further data on risk of reinfection and how it was impacted by the changed antigenic makeup of the new variant. Throughout 2020, national surveillance data was used to monitor reinfection rates, including from newly emerging variants, and showed evidence of increased reinfections with the emergence of the Delta and Omicron variants. In all cases confirmed positive on a daily basis on average until mid-November 2021 around 1.4% were in those who had previously been infected (and therefore counted as reinfections), increasing to 10% in January 2022 following the emergence of Omicron.

Alpha

4.84 Alpha emerged in the second half of the second wave (November 2020) and became a very serious threat both in the UK and internationally. The second wave from September 2020 to March 2021 should in reality be seen as two separate waves; a Wuhan second wave and then a subsequent Alpha first wave which overlap with one another. Alpha was significantly more transmissible than the original COVID-19 strain.

4.85 Towards late 2020 rising case rates in the south-east of the UK were investigated and found to correlate with a negative result for the S gene target. This variant was later labelled the 'Alpha' variant by the WHO and was relatively easy and fast to track using S gene target failure in qPCR testing **(CJMW5/098 – INQ000103186)**.

4.86 It was found through phenotypic testing to have increased transmissibility conferred by changes in receptor binding and also changes in innate immune control **(CJMW5/099 – INQ000381237, CJMW5/100 – INQ000381225)**.

Delta

4.87 The next period was the Delta wave from February 2021. First described in India this even more transmissible variant travelled globally and was imported into the UK.

4.88 Delta began to exhibit a more rapid growth rate and went on to dominate globally in 2021. This was occurring at the same time as the UK was rapidly vaccinating its population and gradually lifting Non-Pharmaceutical Interventions (NPIs). Laboratory studies showed that Delta was intrinsically more transmissible than previous variants **(CJMW5/101 – INQ000381226)**. It also showed some modest immune escape properties, potentially allowing it to break through immunity granted by vaccination or

prior infection from wild type SARS-CoV-2 with greater efficiency than Alpha **(CJMW5/102 – INQ000273318)**.

Omicron

4.89 By November 2021 many countries worldwide, including the UK, were reaching their highest rates of sequencing. Sequencing from Southern Africa and travel-related sequencing from Hong Kong allowed the rapid identification of a novel variant of concern, Omicron, as soon as the first 4 sequences had been uploaded by Southern African researchers to the online sequence database GISAID **(CJMW5/103 – INQ000381239)**.

4.90 The characteristics of Omicron meant that in people whose antibody resistance to the virus was diminishing were at increased risk. To give a fuller, more technical explanation: Omicron was characterised by a very large number of mutations, including 35 across the spike gene (a structural protein in coronaviruses), many at known antigenic epitopes (places which may have a material effect on whether the immune system recognises the protein). The large antigenic distance between Omicron and the wild type spike protein, meaning how different the protein of the new variant is compared to the older variant, combined with antibody waning (antibody levels falling over time since last vaccination or infection), resulted in some relatively poor neutralisation of Omicron by sera from vaccines. This necessitated rapid implementation of vaccine booster programmes by the NHS to counter immunological waning associated with the establishment of this variant **(CJMW5/104 – INQ000381240)**.

4.91 At the start of the first UK Omicron wave, we had confidence in only two things based on the data; that Omicron was substantially more transmissible even than Delta (clear epidemiological evidence), and that there were multiple genetic variations which might have been associated either with vaccine escape or other features which could be beneficial to the virus (based on genetic data).

4.92 Although there were media reports of the virus being less severe in South Africa, which were strongly pushed by some South African commentators, the technical advice we were getting from the highly competent South African authorities was considerably more cautious than this. They had also just had a major Beta wave (inducing Beta immunity widely in their population) which made interpreting the epidemiology from South Africa in the UK context, where we had not had such a Beta wave, more difficult.

They were also initially less certain that it was less severe, and if so by how much. The South African population is also significantly younger than that in the UK.

4.93 A significantly more transmissible virus, which is slightly less likely to cause severe disease, can still lead to very high numbers of severe cases, and especially if there was some degree of immune escape to vaccination (in other words the immune system, even with vaccination, struggles to respond to an infection agent).

4.94 A strong narrative developed among some that Omicron was just a trivial infection and nothing to worry about. This struck me and the DCMOs as being based more on expediency and hope rather than hard data. The subsequent surge of hospitalisations into the NHS as the Omicron wave pushed through the UK, despite widespread vaccination of the at risk population, backs up that interpretation.

4.95 Had Omicron been only slightly more severe, or the vaccine slightly less effective against the significantly genetically diverse new variant, the situation would have been potentially quite serious. Neither of these were known with certainty in late 2021. Even with significant restraint by the general public in terms of social mixing, 16,537 people were in hospital with COVID-19 on 14 January 2022, most of which were Omicron cases. It was not a trivial infection for many people, especially for the elderly **(CJMW5/105 – INQ000236456, CJMW5/106 – INQ000236457)**.

4.96 The UKHSA's Variant Technical Group publish variant risk assessments which may be of interest to the Inquiry.

Long COVID

4.97 OCMO's role in relation to the group of syndromes that came to be known as Long COVID was primarily supporting research rather than identification and characterisation of Long COVID, developing guidance or putting in place clinical systems and clinics to manage it. There is much that we still do not know about this group of chronic debilitating syndromes. To assist the Inquiry, I will outline some information on Long COVID and the research response.

Research response to Long COVID syndromes

4.98 Once the group of syndromes that make up Long COVID was recognised, a major international research effort developed to delineate the syndromes, determine their incidence, prevalence and outcomes, and most importantly identify potential

treatments for trials. The UK remains one of the major contributors to this research effort, and the NIHR which I headed for the early part of the pandemic was a major part of this. Some of the early work is outlined below, but research continues and is likely to do so for some time.

4.99 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 **(CJMW5/107 – INQ000069876)**. This was published in October 2020 **(CJMW5/108 – INQ000236442)**.

4.100 In July 2020, NIHR and UKRI funded the Post-HOSPitalisation COVID-19 study – a national consortium to understand and improve long-term health outcomes (PHOSP-COVID). This made available £8.4 million to assess the impact of COVID-19 on hospitalised patients' health and recovery. The study established working groups across multiple clinical areas including renal, cardiac and metabolic, pulmonary, lung fibrosis, mental health and neurology, intensive care, immunology, airways disease, and rehabilitation and inflammation.

4.101 In November 2020, NIHR and UKRI launched a Long COVID research call focused on understanding Long COVID in the community. This funded four studies at a cost of £18.5m and included:

- REACT: this study aimed to better understand the genetic, biological, social and environmental signatures and pathways of Long COVID;
- TLC: this aims to identify treatments for Long COVID;
- CloCk: a study intended to characterise symptoms typical of Long COVID in non-hospitalised children and young people. It also aims to assess risk factors, prevalence and how long the disease may last; and
- CONVALESCENCE: this study aims to best define long COVID, its risk factors and mechanistic pathways, consequences for physical and mental health and to enhance diagnosis and management.

4.102 On 25 March 2021, NIHR launched a second call for research into Long COVID. This funded a further fifteen studies at a cost of £19.6m, including:

- STIMULATE-ICP (Symptoms, Trajectory, Inequalities and Management: Understanding Long COVID to Address and Transform Existing Integrated Care Pathways): the study aims to assess the efficacy of drugs to treat Long COVID;

- LOCOMOTION (Long COVID multidisciplinary consortium: optimising treatments and services across the NHS): intended to identify and promote the most effective care for Long COVID patients, ranging from accurate assessments in specialist clinics, best practice in surgeries, and home monitoring methods to show flare-ups of symptoms; and

- CICERO (Cognitive Impairment in Long COVID: PhEnotyping and RehabilitatiOn): a project to determine which elements of brain function are most affected in people with Long COVID.

4.103 In addition, the Long COVID Research Group was formed by researchers leading Long COVID studies in the UK to share key findings and promote rapid knowledge exchange. The PHOSP-COVID consortium was formed by the researchers who came together to run the Post-hospitalisation COVID-19 ("PHOSP") study.

4.104 In total, over £50m of Government funding has been invested in Long COVID research projects, much of which was undertaken under the auspices of the NIHR.

4.105 By the summer of 2021, it was becoming apparent that many patients had ongoing symptoms after recovery which persisted for longer than 3 months. One prospective study of 431 individuals testing positive for COVID-19 in Switzerland, published in July 2021, found that 6 to 8 months after infection 55% of the cohort reported ongoing fatigue, 25% had some degree of breathlessness, and 26% fulfilled criteria for depression **(CJMW5/109 – INQ000381217)**. Since that time, the range of chronic symptoms recorded for cases of COVID-19 has expanded greatly **(CJMW5/108 – INQ000236442)**. A diagnostic definition of the condition has been made as post-COVID-19 syndrome by the National Institute for Health and Care Excellence (NICE), more commonly referred to as 'Long COVID' by sufferers and clinicians, although in reality it is likely to represent several overlapping syndromes **(CJMW5/110 – INQ000238545)**. The exact number who have experienced longer-term symptoms after COVID-19 is likely substantial but remains unclear, as does the aetiology of the syndromes, including whether it was one or (more likely) a number of different overlapping syndromes. In July 2022 the ONS Covid Infection Survey (CIS) estimated that 1.4 million people in the UK were experiencing Long COVID symptoms that

adversely affected their day-to-day activities in the 4 weeks ending 4 June 2022 **(CJMW5/111 – INQ000381236)**.

4.106 The initial planning for COVID-19 took no account of the group of chronic (prolonged) syndromes which have subsequently become known as Long COVID. It was not that the possibility of some chronic sequalae was not accepted (it was), but rather that the nature and scale of it was not foreseeable. Post infectious chronic fatigue is well recognised for a number of infections, and several infections are particularly liable to lead to post-infectious syndromes specific to them. Examples include Subacute sclerosing panencephalitis (SSPE) after measles, Guillain-Barré syndrome (GBS) after several infections including recently Zika, post infectious reactive arthritis after several infections including Chikungunya, post-infectious irritable bowel after gut infections and post-malaria neurological syndromes. None of these are however easy to predict in advance of their first description by observant clinicians.

4.107 The fact that post viral syndromes occur, and indeed postinfectious syndromes more widely, does not however mean that Long COVID as it manifested was predictable. Different infections and different situations leading to different syndromes are common. Some very severe diseases rarely have post infection syndromes whilst other relatively trivial infections can have quite common and prolonged ones. It is therefore both true, but also largely unhelpful, to say 'there might be a postinfectious syndrome'. In itself this would not obviously have helped us respond in the initial period, unless it was severe enough significantly to interfere with the lives of many people (as Long COVID did and does).

4.108 Within what we currently call Long COVID, there are several syndromes, and they have not yet been fully elucidated. In those who were admitted to intensive care these include an overlap with the well documented post-ICU syndromes. For example, a group of symptoms is associated with chronic scarring of the lung visible on CT scan, something frequently observed in other patients treated by mechanical ventilation.

4.109 Separately, there is in some patients an overlap with the post-infectious chronic fatigue syndromes, for example that which may occur after Epstein-Barr virus or dengue fever among other infections. There is certainly another group of symptoms which occur after COVID-19 which seem relatively specific to this infection and have some similarity to PoTS syndrome (Postural orthostatic tachycardia syndrome), caused by autonomic dysfunction amongst other factors. Within all these there is a range in the severity and longevity of symptoms. There may also be overlap between them. I make these points

because lumping all the syndromes covered by the term Long COVID together as a single entity may do a disservice to those affected who will have a very wide range of outcomes both functionally and over time. It also makes identifying treatments more difficult.

4.110 Although rarer, there are also chronic post COVID-19 syndromes in children. These overlap with, but are not always the same as, adult Long COVID - for example the syndrome PIMS-Ts (Paediatric Inflammatory Multisystem Syndrome) is a post-COVID-19 immune syndrome largely confined to children.

4.111 It follows that it is very unlikely that the same interventions will treat all of the syndromes currently referred to as Long COVID.

Non-research measures for Long COVID

4.112 Separate to the research commissioned into Long COVID, the Government and NHS responded broadly to its emergence in three ways. The first was to move even more sharply away from the concept that it was possible to identify those at risk from COVID-19, protect them and then allow everyone else to be infected as recommended by adherents of the Great Barrington Declaration and similar schools of thought. Shielding those identifiably most at risk would have done very little to reduce the risk of Long COVID syndromes as most were younger than most shielded patients; reducing community transmission did reduce the risk. The second was the establishment by the NHS of specialist Long COVID clinics to concentrate expertise, mainly for the benefits of the patients affected, but also to learn as much as possible in a clinical setting. Finally, we discussed the phenomenon with other nations, in particular the USA where significant research was also, and is also, being undertaken.

4.113 Various structures were involved in this effort, although I and the DCMOs were much less involved directly in these. These included the Long COVID Oversight Board- an official-led meeting, which provided a forum for a whole-system overview of activity to address the challenges posed by Long COVID. This was attended by DHSC, NHS England and Improvement, relevant arm's length bodies and other Government departments such as the Department for Education and Department for Work and Pensions.

4.114 I was involved in trying to assess whether data coming from studies implied that countermeasures, and in particular vaccines, reduced the incidence or severity of Long COVID. If so, it was also necessary to identify what proportion of this was due to

reduced infection incidence, and what proportion was a result of disease modification. This is still not a fully settled question. The evidence currently available is that vaccines do reduce both the incidence and severity of Long COVID, although not to zero **(CJMW5/112 – INQ000236459)**. This is, if it is needed, a further argument in favour of vaccination, but given that we were already giving liberal vaccination advice it did not in practical terms change our approach.

Section 5: Healthcare provision and treatment for COVID-19

5.1 Rightly, the great majority of decisions on the therapeutic approach to COVID-19 were taken within the medical, nursing or allied health professions. Some of these were specific to particular disciplines; for example techniques such as proning were debated within the ICU specialities as they were not used much outside these. Other examples of these professionally directed specialist areas were invasive and non-invasive ventilation of patients, use of continuous positive airways pressure (CPAP), renal replacement therapy for COVID-19 patients with acute kidney injury, and identification of relevant types of clinical staff to provide treatment for severely or critically ill patients. For the occasions that I was working on the wards I took the advice and followed the guidelines of the relevant specialist area. It was not the view of the OCMO that we had any particular role in these decisions given the range of experts within the NHS.

5.2 In a limited number of situations where clinical research was the basis of advice and I had access to early data which I was able to assess in advance of publication we gave national advice. Probably the most important of these was advice to use dexamethasone in patients requiring oxygen **(CJMW5/027 – INQ000069714)**.

5.3 When it came to research studies, including clinical trials I was however involved in decisions about which therapeutic options for both older repurposed drugs and new drugs should continue through to clinical testing given the limited capacity to test multiple drugs in parallel. This prioritisation was led by the Clinical Trials Accelerator Platform (CTAP) on behalf of NIHR (of which I was head) and MRC but I reviewed their advice and gave final sign off. Professor Van-Tam was also involved in this process of prioritising clinical research. I anticipate this process will be a major theme in Module 4 of the Inquiry so do not expand on it here.

5.4 When we give advice for clinicians this is sent out as a general letter to the medical profession. Signing off on UPH designation prioritisation of trials for research was

undertaken following review by an expert clinical research committee chaired by Professor Nick Lemoine.

5.5 OCMO was not involved except peripherally when estimates and numbers of critical care beds, ventilators, or other medical resources such as oxygen supplies were given to Ministers and policymakers. This was led out of NHSE, with some modelling from SPI-M-O relevant to their projections. I was not involved in projections, although occasionally I was in meetings when projections were being discussed with political leaders (covered in Module 2). Operational issues around supply of medical equipment and consumables such as oxygen were within NHSE and other operational parts of the system.

5.6 I was aware of the use of pulse oximeters both as CMO and used them as a clinician. Later in the pandemic I was aware of the concerns about accuracy of readings relating to skin pigmentation and in particular the efforts of the then Secretary of State the Rt Hon Sajid Javid MP to address them but OCMO were not central to these.

Clinical trials

5.7 Professor Van-Tam and I were involved in some of the decisions around setting up major observational studies including SIREN, VIVALDI and CO-CIN, but the studies were led by others. Professor Van-Tam was also involved in a number of these and led on several for OCMO, in particular CO-CIN. We used the outputs of these studies in policy advice. Those leading these studies are best placed to answer specific questions about them: for example Professor Susan Hopkins (UKHSA) for SIREN, Dr. Laura Shallcross (UCL) for VIVALDI and Professor Calum Semple (Liverpool University) for CO-CIN.

5.8 I was, with many others, also involved in decisions around setting up of therapeutic trials including RECOVERY (partially funded by NIHR of which I was Head/CEO), and encouraging clinicians to take part in them. I, and NIHR were involved in the practical arrangements for setting up vaccine trials, and Professor Van-Tam was closely involved in vaccines and their development (which will be the focus of Module 4) **(CJMW5/113 – INQ000381241, CJMW5/114 – INQ000047636, CJMW5/115 – INQ000047637, CJMW5/116 – INQ000047587, CJMW5/117 – INQ000047670, CJMW5/118 – INQ000047676, CJMW5/119 – INQ000047681, CJMW5/120 – INQ00047784, CJMW5/030 – INQ000203986, CJMW5/028 – INQ000047546, CJMW5/121 – INQ000069096, CJMW5/018 – INQ000069095)**.

5.9 There was strong pressure both in the public domain and from some political leaders internationally to use any therapeutic which had any theoretical basis given the severity of the pandemic. It was my strong view, supported by clinical and scientific colleagues, that getting the right risk-benefit analysis for therapeutic interventions depends on good clinical trials. Many drugs which are reputed to work for particular conditions do not, and almost all drugs have side effects, some significant. With other senior clinicians I therefore wrote out to fellow NHS clinicians on 1 April 2020 strongly encouraging them to avoid off label prescription of drugs outside clinical trials which could give a clear indication of risk-benefit **(CJMW5/017 – INQ000068589)**. This decision was not popular with all but my view at the time and subsequently was that this was important to the UK's ability to undertake several definitive trials of therapeutics, both of repurposed drugs and of new therapeutic drugs. In my view at the time, most clinicians in the UK who are very heavily trained in evidence-based medicine would have been naturally supportive of that approach but they needed senior support and encouragement. In the event most of the interventions which received enthusiastic support from some commentators including chloroquine, ivermectin and Vitamin D did not work in clinical trials and it would have been an error to allow them to become established medical practice. To note as an infectious disease physician specialising in tropical medicine I had significantly greater clinical experience of both chloroquine and ivermectin in infectious diseases than most clinicians in the UK.

Section 6: Infection prevention and control ("IPC")

6.1 At paragraph 7.83 of my Fourth Witness Statement I explained as follows, *"Largely, guidance to healthcare providers was given either by the NHS, or by PHE as it was, on matters such as infection prevention and control."* Infection prevention and control in hospitals and other healthcare settings is an important but specialist area and there is considerable expertise within the NHS as well as PHE in this area. Considerable work on operational guidance was done by the NHSE chaired 4 nations IPC cell; the OCMO was not involved in this. Much of the practical expertise in the NHS in IPC is in the nursing profession and the Chief Nursing Officer Dame Ruth May and her Scottish, Welsh and Northern Ireland equivalent were much more closely involved than OCMO.

6.2 The OCMO's involvement in the development of operational IPC guidance for healthcare settings was only ever at a high-level. As such, most of the questions posed by the Inquiry on this subject are more appropriately directed to NHSE or the UK public

health bodies. PHE/UKHSA and UK nations equivalents provided technical IPC evidence. However, I set out below a summary of the relatively limited input that the OCMO did have into the development of IPC guidance. In addition to the below, I would also direct the Inquiry to Chapter 10 of the Technical Report, which includes detail on how IPC guidance evolved during the pandemic **(CJMW5/001 – INQ000203933)**.

Initial PHE guidance

6.3 On 15 January 2020, PHE published on its website the Wuhan novel coronavirus (WN-CoV) infection prevention and control guidance, which stated that it was *"based on knowledge gained from experience in responding to coronaviruses with significant epidemic potential such as Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV)"* **(CJMW5/122 – INQ000184034).** The OCMO did not provide any advice on that initial guidance.

6.4 On 5 March 2020, Professor Van-Tam advised on a revised version of that guidance. Specifically, he provided input on the discrete issue of categorising nebulisation as an infectious aerosol generating procedure, which would have had consequences for IPC and PPE considerations when such treatment was being administered **(CJMW5/123 – INQ000381163, CJMW5/124 –** INQ000119470

Adapted influenza IPC guidance

6.5 At its meeting on 17 December 2019, NERVTAG approved revised IPC guidance for pandemic influenza in healthcare settings **(CJMW5/125 – INQ000381161)**. That document updated and replaced previous guidance from 2009. In early January 2020, that updated 'flu guidance was still being considered by Professor Van-Tam (amongst others) when the news of the Wuhan novel coronavirus was emerging. He provided comments on the guidance to Dr Lisa Ritchie of Health Protection Scotland on 6 and 7 January 2020 **(CJMW5/126 – INQ000381162)**[2]. At this stage the guidance was still being considered for 'flu.

[2] I understand that this updated flu guidance was never published but was ultimately incorporated into subsequent guidance published by UKHSA.

6.6 On 28 January 2020, SAGE agreed that *"Pandemic Influenza infection control guidance should be used as a base case and adapted"* **CJMW5/061** – **INQ000057492**

6.7 On 10 March 2020, Dr Ritchie sent an email to Professor Peter Horby (copying Professor Van-Tam) asking as follows:

"Is NERVTAG able to advise whether the final draft of the Pandemic Influenza IPC Guidance I sent back a couple of weeks ago, post comments received from NERVTAG members (after the NERVTAG meeting in December 2019) has been signed-off? What is the status of this document currently, as HPS IPCT would like to consider a move to this guidance in response to the escalating COVID-19 situation?" **(CJMW5/127 – INQ000381165)**.

6.8 On 11 March 2020, Professor Van-Tam responded asking for *"a fully tweaked version (call it the Adapted for Covid-19) version. That I can pass on to PHE and NHSE today"* **(CJMW5/128 – INQ000381168)**. Dr Ritchie responded the following day with an updated version of the guidance, adapted for Covid-19 **(CJMW5/129 – INQ000381171, CJMW5/130 –** **INQ000381172**

6.9 Late in the evening of 12 March 2020, Professor Keith Willett emailed Professor Van-Tam to ask that he *"approve/secure sign off of"* the revised guidance. He explained that *"We need to secure that ASAP so NHSE/I IPC team can update the guidance on gov.uk and hence make it consistent with what we are now saying tonight in a CAS Alert to the NHS system that moves us to the 'influenza' level of isolation, PPE, decontamination etc"*. Professor Van-Tam responded that it was not his role to do so, but he had nevertheless been through the document line by line and corrected residual errors. He explained that the guidance should still go to NERVTAG, but he was happy to provide DCMO sign off in the interim **(CJMW5/131 – INQ000381174)**.

6.10 The guidance was then considered by NERVTAG at its meeting on 13 March 2020. The actions arising from that meeting included the following, *"JVT* (Professor Van-Tam) *& LR* (Dr Ritchie) *to update IPC guidance document"* and *"NERVTAG to review and approve IPC guidance via correspondence if required"* **(CJMW5/014 – INQ000212195)**.

6.11 Later on 13 March 2020, Professor Van-Tam was involved in further email correspondence that sought to finalise the guidance **(CJMW5/132 – INQ000381176)**. The guidance was published online on 13 March 2020 **(CJMW5/133 –**

INQ000381178). As at mid-March 2020 it was logical to use the influenza IPC guidance as a starting point rather than starting from no base at all given that this was a respiratory virus that appeared to share broadly similar routes of transmission with pandemic influenza. WHO's first interim guidance was published on 19 March 2020. It is important to consider WHO guidance when developing domestic guidance. It is one of the WHO's core functions. In COVID-19 they had the significant difficulty of having to provide advice relevant to all countries simultaneously, with different epidemiology, population structure, healthcare system and purchasing power. Their advice therefore had to allow for local adaptation. PHE/UKHSA, working with NHS England are the key organisations giving advice in this area, with PHE/UKHSA reviewing the scientific and technical advice. NHSE's responsibility was to derive and implement the operational guidance for the NHS services. We have outlined details to assist the Inquiry but the OCMO did not have a primary role in IPC guidance.

Additional OCMO advice on IPC guidance for healthcare settings

6.12 As explained in the Technical Report, *"Continual evidence reviews were undertaken by the UK public health bodies to identify changes in the evidence base for IPC interventions and reflected in updated guidance…"* **(CJMW5/001 – INQ000203933)**. The OCMO was occasionally asked to review updated guidance and provide advice, particularly in relation to nosocomial transmission and the concomitant IPC considerations. I set out below a summary of the key advice that OCMO provided in this area.

6.13 On 20 and 21 February 2020, Professor Harries advised PHE on IPC considerations for paramedic staff who were involved in the transfer of individuals that had been repatriated from Japan **(CJMW5/134 – INQ000151499, CJMW5/135 – INQ000151503)**.

6.14 On 30 March 2020, in advance of a meeting of the Senior Clinicians Group, Professor Van-Tam advised in relation to a paper on nosocomial transmission that had been prepared by NHSE and PHE for SAGE **(CJMW5/136 – INQ000068750**. Professor Van-Tam suggested that although incorrect wearing of PPE or lapses in IPC practices might be contributing to nosocomial transmission, a further issue was the extent to which healthcare workers were being exposed to infection because COVID-19 patients were presenting with atypical symptoms and therefore *"staff exposure is occurring*

before the diagnosis of Covid-19 is very high up on the differential diagnosis or at all" **(CJMW5/137 – INQ000068584)**.

6.15 On 18 April 2020, Professor Willett sent me, Professor Van-Tam and others within PHE and NHSE, a report from a Professor of Orthopaedic Surgery at Tsinghua University, Beijing, addressing the measures that Beijing hospitals had taken to keep patients infected with COVID-19 segregated from non-infected patients **(CJMW5/138 – INQ000151757, CJMW5/139 – INQ000151758)**. Thereafter, Professor Van-Tam attended a call with NHSE colleagues to discuss reaching out to international counterparts for information on their approaches to managing COVID-19 segregation in hospitals **(CJMW5/140 – INQ000236489)**. Professor Van-Tam agreed the questions that would be posed and then engaged in email correspondence with public health officials in Germany, Sweden, Norway and Singapore. He passed responses to NHSE colleagues and, in mid-June 2020, requested an update on the status of the work **(CJMW5/141 – INQ000236504)**. The responsibility for developing and implementing any guidance in response to information gleaned from abroad lay with NHSE.

6.16 On 21 April 2020, the Deputy Chief Nursing Officer (DCNO), Sue Tranka, emailed DCMO Dr Aidan Fowler attaching '*a paper on the IPC principles, segregation and cohorting'*. Dr Fowler responded with further questions for the DCNO to consider **(CJMW5/142 – INQ000068895)**.

6.17 On 25 June 2020, Professor Van-Tam attended a meeting with Dame Ruth May and Professors Wilcox, Hopkins and Powis, to discuss the issue of nosocomial transmission and IPC. A contemporaneous note of that discussion is exhibited at **(CJMW5/143 – INQ000069844)**.

6.18 On 5 November 2020, following a discussion with some of my European counterparts, I emailed Professor Powis to advise that Europe was experiencing increased nosocomial transmission in the current wave. I suggested to Professor Powis that *"this reinforces the view we both share that we really need to get on with asymptomatic testing of patient-facing staff, in all tiers. This should be asap"* **(CJMW5/144 – INQ000071482)**. On 9 November 2020 NHSE confirmed that asymptomatic testing of all patient facing staff would start that week.

6.19 On 30 November and 1/2 December 2020, Professor Harries reviewed and commented on IPC guidance for providers of maternity services that had been prepared by NHSE **(CJMW5/145 – INQ000071972, CJMW5/146 – INQ000071973)**.

Section 7: Personal Protective Equipment (PPE)

7.1 As with the IPC guidance generally, the OCMO played only a high-level role in respect of advising on PPE use within healthcare settings. This work was led by NHSE, with PHE providing technical advice and the HSE also playing a significant role in respect of issues such as the adequacy or standard of PPE. DHSC was responsible for stockpiles and procurement of PPE. NHSE, PHE and HSE would be better placed to respond to the questions which the Inquiry has asked about PPE within healthcare settings.

7.2 The OCMO's advice in respect of PPE within healthcare settings was limited to reviewing draft guidance produced by others and providing advice in relation to specific issues as they arose.

OCMO contributing to guidance

7.3 On 25 March 2020 I asked to be sighted on PHE's draft guidance on PPE in healthcare settings prior to its publication **(CJMW5/147 – INQ000381183)**. Subsequently, on 1 April 2020 I provided the following quote in support of the guidance which demonstrates the OCMO's peripheral role in the formulation of PHE's guidance:

"Professor Chris Whitty, Chief Medical Officer for England said: "It is absolutely right that frontline staff have the appropriate PPE so they are safe and can have the confidence they need to do their jobs. "Public Health England has updated their advice to provide additional clarity for staff. This was done with the support of a wide range of professional groups and it has my full support. NHS England and the Government are working hard to secure the supply lines in this challenging period so staff have the appropriate equipment." **(CJMW5/148 – INQ000068614)**

OCMO advice regarding forms and standards of respirators and supply issues

7.4 On 4 February 2020, Professor Van-Tam advised the Department for International Development on standards of respirators, he raised potential supply issues the UK may face and how they may impact procurement plans **(CJMW5/149 – INQ000047673)**.

7.5 On 25 March 2020, recognising HSE's lead role in relation to the standard of PPE, Professor Van-Tam emailed regarding potential purchases of FFP2, FFP3 and N95 respirators stating:

"I fully recognise that HSE has not yet completed its deliberations on the technical comparability between N95 and FFP2. At a clinical level, we understand these to be highly similar specs and to note USA and WHO both recommend and use N95 for Covid-19, TB and multiple other pathogens.

I have to be frank, whilst I do support going first for FFP2 stock, I do not support (and formally in my DCMO role advise against) any delays in procuring N95 if it becomes clear or is already clear that we have either exhausted FFP2 ordering or that what we can order of FFP2 is too volume constrained for our full term pandemic needs. Bear in mind that FFP3 will be incredibly difficult to source at volume for at least 12 months." **(CJMW5/150 – INQ000151644)**.

Professor Van-Tam's advice resulted in PHE being requested to prioritise the procurement of FFP2/N95 respirators **(CJMW5/151 – INQ000381182)**.

7.6 On 26 March 2020 Professor Van-Tam contributed to an email discussion regarding whether FFP2 and FFP3 masks had to be fit tested within healthcare settings, highlighting the potential impact of supply issues **(CJMW5/152 – INQ000381186)**. The OCMO did not provide any advice in respect of poorly fitting PPE.

7.7 On 29 May 2020, in response to draft PPE guidance for hospital visitors, Professor Harries highlighted that PPE supply chains for healthcare workers were still fragile, the impact of which needed to be factored into the content of the guidance **(CJMW5/153 – INQ000069471)**.

OCMO proposals for work to be undertaken by others

7.8 The OCMO made various requests or proposals for work to be undertaken. On 20 March 2020 Professor Van-Tam copied the NERVTAG Chair (Professor Sir Peter Horby) and Secretariat into correspondence regarding creating *"a proportional plan for sensible, prioritised use of what PPE we have and can get"* suggesting that PHE, HSE and others could meet with NERVTAG **(CJMW5/154 – INQ000381179)**. On 23 March Peter Horby confirmed his agreement **(CJMW5/155 – INQ000381180)**.

7.9 On 22 March 2020 I advised that NERVTAG should reconsider concerns which had been raised by the British Society of Gastroenterology, highlighting the risks of losing the confidence of *"specialist societies and other generally sensible people think we are not taking their safety seriously"* **(CJMW5/156 – INQ000048173)**. The issue was whether, and what, invasive procedures were aerosol-generating. If a procedure generates no aerosol it can generally be managed by standard respiratory PPE. If it does generate an aerosol, the next question is whether it has the virus in high enough concentrations to be significantly infectious. This depends on the viral load in the part of the body and tissues involved. If a procedure is both aerosol-generating and significantly infectious a much higher grade of respiratory protection is recommended, and often specifically FFP3 respirators. Given limitations in the more high-specification PPE, and specifically respirators, early in the pandemic it was important to prioritise the procedures which where both aerosol-generating and infectious. Bronchoscopy (scopes put into the lungs) was an obvious example; the lungs clearly had a relatively high viral load in this respiratory infection. There was a more legitimate debate however about a scope put into the lower gut (colonoscopy) with a scope put into the upper gut (endoscopy) being between those two. This (whether an aerosol is generated, and if so how infectious it is) is a technical area in which the OCMO had no particular expertise, and we acted here to communicate a reasonable challenge from clinical specialist societies to the relevant expert group (NERVTAG). We differentiated between emergency procedures which cannot be postponed without significant risk to the patient and routine procedures where some delay is unlikely to lead to major deterioration. As with all decisions taken early in the pandemic there were no perfect technical options- all the options were bad with some being worse than others. It would however have caused net harm to clinical colleagues if, given the reality of constrained global and UK supply of PPE, much of the stock of the high-specification FFP3 respirators were used for what were in fact relatively low-risk procedures, meaning that stocks ran down so fast that at some point those undertaking actually high-risk procedures would not have access to them. The clinical question posed to NERVTAG was therefore not an easy one.

7.10 On 24 March I agreed that Professor Harries should offer to chair a group aimed at encouraging cooperation across all sectors to help resolve the governance and supply issues being experienced at the time **(CJMW5/157 – INQ000381181)**.

7.11 Professor Harries was subsequently co-Chair of three groups (alongside Jonathan Marron, Director General of Prevention, Community and Social Care at DHSC) that

were established at the end of March: the PPE Oversight Board, the PPE Four Nations Oversight Board, and the PPE Other Government Department (OGD) Board (also referred to as the PPE OGD Forum). These temporary Boards were created to help coordination and establish more sustainable governance. They only ran for a couple of months until more fixed governance was put in place by DHSC and NHSE and Professor Harries stepped back from her chairing roles by early May 2020. Copies of the Terms of Reference are exhibited at **(CJMW5/158 – INQ000381190, CJMW5/159 – INQ000106342 CJMW5/160 – INQ000381202)**.

7.12 On 3 April 2020 Professor Van-Tam requested that HSE urgently provided its view *"and maybe experiment"* on a proposal for using Ultraviolet Germicidal Irradiation to treat FFP3 masks so that they could be decontaminated and reused **(CJMW5/161 – INQ000381195)**.

7.13 And on 15 April 2020 my Private Secretary, acting on my behalf, asked that HSE be commissioned to complete work which Susan Hopkins at PHE had led on regarding the safety of reusing PPE **(CJMW5/162 – INQ000068814)**.

Section 8: Testing for healthcare workers

8.1 OCMO was not involved in the development of the COVID antigen test. UKHSA is best placed to advise on its development, trials and sensitivity and specificity over time. OCMO was aware of and very supportive of the SIREN study, including in communications to healthcare workers but this was led from PHE/UKHSA. There is information in Chapter 6 of the Technical Report which the Inquiry may find helpful **(CJMW5/001 – INQ000203933)**.

8.2 OCMO was involved in establishing a testing prioritisation list for when more testing became available, it was not significantly involved or responsible for the testing guidance for NHS Trusts or workers. However to assist the Inquiry, I have highlighted some of the key dates when groups were added to testing eligibility, as testing capacity expanded:

- 27 March 2020 – Antigen testing of NHS staff with symptoms and their symptomatic families.
- 12 April 2020 – Antigen testing of symptomatic NHS non-frontline staff and their symptomatic household.

- 27 April 2020 – Antigen testing of all emergency admissions to hospital.
- 30 May 2020 – Antibody testing launched for health and social care staff in England.

8.3 On 18 August 2020, I wrote to the Rt Hon Jeremy Hunt MP, then the Chair of the House of Commons Health and Social Care Select Committee outlining my views on asymptomatic testing of NHS staff:

"Reducing infection in high risk settings is very important to managing the impact of the pandemic and testing of asymptomatic health and care staff can have an important role as part of that. There is still uncertainty as to the proportion of cases who are asymptomatic, although the ONS survey is giving better data on this, and a wide range of estimates on how infectious they are to others.

There is no doubt about the central importance of testing healthcare and social care workers who are symptomatic, and this has been a priority as soon as we had the testing capacity to do so. This also allows for contact tracing and isolation. The role, and optimal frequency of antigen testing of asymptomatic health and social care workers in low incidence settings without an outbreak is not yet settled, and the relative importance of using testing for this indication compared to others has changed over time. There is broad agreement that wide testing of asymptomatic healthcare workers and social care workers in places with outbreaks is a key part of the response.

The ONS infection survey currently indicates that 67% of UK infections are asymptomatic. The New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) conducted a meta-analysis of methodologically-appropriate evidence and found that 4% to 43% individuals may be truly asymptomatic. The closest exact figure given was 17%. On June 11th SAGE considered the percentage of people who are infected asymptomatic remains uncertain and is between 30-80%. This is therefore not a settled question. The infectiousness of those who are asymptomatic is also unclear with a wide range of estimates, although it is clear pre-symptomatic people can be infectious in the 2-3 days before their symptoms start and much of the NHS test and trace work is to identify people who are contacts of cases and isolate them before they become pre-symptomatic.

In the absence of good data on optimal frequency of testing of asymptomatic healthcare or social care workers (although many opinions) my main advice is that at the current stage of the epidemic with low incidence in most parts of the country, in

settings without outbreaks, the best way to deploy regular antigen testing in asymptomatic healthcare workers and social care workers is as part of a study such as SIREN (NHS) and VIVALDI (social care), or systematic point prevalence surveys or local studies. Doing this through studies allows for systematic data capture, which tells us more than a large amount of unconnected data would. It also means antigen testing and antibody testing can be done on the same cohort, which provides more information than using the tests alone, including quantifying the relevance, if any, of antibody testing in those who are seropositive and whether they have a different incidence of subsequent infection. I would be very happy to send you details of these studies if it would be useful to the Committee.

Currently our advice is that systematic asymptomatic antigen testing of healthcare workers or social care workers should be used widely during incidents, outbreaks and settings where it has been shown that there is currently high incidence. It is likely our advice on the best approach to testing asymptomatic health care workers and social care workers in settings without outbreaks will change with three things: changing national and local epidemiology; more data which will allow a better fix on optimal asymptomatic testing frequency in different settings; changing testing capacity. It may also change if we get new tests such as saliva-based lateral flow devices which would be easier for NHS staff to use and provide near-instantaneous results, but we do not yet have robust data that these tests are reliable." ***(CJMW5/163 – INQ000070408)***.

8.4 On 1 September 2020, I wrote to Professor Powis and Professor Sue Hill:

"Although at the moment we are, through SIREN, getting more data on the likely place and yield of testing NHS staff, I am concerned that this should not be seen to be a reason to delay increasing substantially the capacity to test NHS staff. If, as seems likely, we get to an autumn or winter surge we almost certainly will need to be testing all patient-facing staff on a regular basis (weekly for the sake of argument). The exact frequency and staff groups are to be determined, but we will definitely need substantially more. This will be for a combination of transmission reduction, staff case identification and public confidence reasons.

I do not want to get to a situation where, predictably, we need to be able to do this fairly soon and are then told that the capacity is not there.

What is your current pathway to being able to do this kind of regular testing of NHS staff? Can we discuss at senior clinicians next week as I suspect there will be learning across the 4 nations.

And on a separate point just to reemphasise the need to be able to test people with respiratory symptoms in general practice that Patrick highlighted over the weekend. Again we need to be in a position where lack of laboratory capacity is not the reason we cannot do it. There are several ways we could operationalise it but the ability to test within the NHS is critical here." **(CJMW5/164 – INQ000070545)**.

8.5 On 3 November 2020, Professor Powis and I wrote to the Rt Hon Jeremy Hunt MP:

We agree with the general principle that regular testing of asymptomatic staff who may have patient contact can be a valuable tool. The value of regular asymptomatic testing to reduce nosocomial transmission is likely to increase as incidence increases, as previously laid out to the Committee. As such, advice has for some time been that asymptomatic testing of healthcare staff should be used during hospital outbreaks and in high incidence settings. In addition, NHS staff have been recruited into the SIREN study and SIREN-associated studies, which we anticipate will provide further evidence on the impact of seropositivity and the optimum frequency of testing.

Testing capacity has of course practically limited what is achievable at any point in time. There are a number of different demands on testing capacity and prioritisation amongst these given capacity at any one time has been complex. These include clinical management (the top priority), testing of symptomatic people, asymptomatic testing in social care settings, asymptomatic testing of elective patients and other uses. DHSC's published testing prioritisation hierarchy, dated 21st September, can be accessed at: www.gov.uk/government/publications/allocation-of-covid-19-swab-tests-in-england/allocation-of-covid-19-swab-tests-in-england

Nevertheless, as testing capacity increases it is becoming possible to extend regular NHS staff testing. On 12 October we announced the commencement of regular staff testing in geographical areas designated by the government as very high risk (tier 3) and this programme has now begun. Testing capacity has been initially provided by the NHS ('pillar 1') and by the government Test & Trace laboratories ('pillar 2').

Furthermore, with the arrival of new testing technologies we are now in a position to expand asymptomatic staff testing further. We have successfully piloted the use of saliva-based testing using Loop Mediated Isothermal Amplification (LAMP). Our aim is

to use this technology, which is less intrusive than swab testing, to become the main form of testing for NHS staff. This technology has already been introduced in several laboratories and our aim is to establish sufficient hubs through NHS Labs and the 'Test and Trace' programme around the country by December 2020 for routine weekly testing of all patient facing clinical staff in the NHS." **(CJMW5/165 – INQ000071446, CJMW5/166 – INQ000381227)**.

8.6 On 9 November 2020, Professor Powis wrote again to the Rt Hon. Jeremy Hunt MP confirming that asymptomatic testing of all patient-facing NHS staff would begin that week **(CJMW5/167 – INQ000071546)**.

Section 9: Shielding

Overview – Clinical and Policy Development for 'Vulnerable Groups' across the four nations

9.1 SAGE recommended shielding of the most at-risk patients in early 2020. Ministers agreed the policy, and other parts of Government were involved in practical issues such as the provision of food and medicines to those shielding. In considering shielding it is important to be clear there was a balance of risk involved. Shielding conceptually was likely to reduce the incidence of infection and therefore reduce the risk of severe disease in the most vulnerable. On the other hand it led to significant distress, loneliness, risk of increased fear and practical limitations on the lives of those shielded even in addition to the effects of lockdown. It made provision of medical and other care for people with non-COVID related conditions practically more challenging. Clinicians, including in OCMO, recognised these risks from before the start of the programme. Adding people to the shielding list if they were not actually at risk was not in their interests, and balancing the potential benefits and dis-benefits of shielding for the individuals concerned was central to the decision-making.

9.2 The role of OCMO was to lead the development of the definition for both the Clinically Vulnerable (CV) and Clinically Extremely Vulnerable (CEV) groups. This was undertaken in close consultation with the UK CMOs and senior clinicians from the Devolved Administrations (DAs), NHS England, NHS Digital and PHE. OCMO had strategic clinical oversight of the process for identifying CEV patients. It was the clinical lead for public health advice to the CEV group. OCMO was also the commissioner and clinical lead for work on a data-driven risk prediction model and tool (QCOVID) which

calculated individual weighted, cumulative risk of catching and dying from COVID-19. I discuss the development of QCOVID in more detail at paragraph 9.21 of this statement. OCMO also clinically led the programme of work to carry out a data-driven population risk stratification of England using QCOVID. Professor Harries led on all of these workstreams for OCMO except where indicated otherwise. Key dates relating to advisory guidance that was issued to the CEV cohort are contained in Table 1 below.

9.3 There was always consensus amongst the UK CMOs about the clinical principles behind the policy for vulnerable groups. The other nations may be able to help the Inquiry establish whether the resulting CV/CEV policy and guidance was uniform across the UK. It was clear that at times there were differences (eg in data and technical architecture) which meant that the clinical principles had to be operationalised in different ways. For example, Wales, Scotland and Northern Ireland were unable to use QCOVID to risk stratify the population but they were able to use QCOVID data to update the conditions included in the definition of CEV (the appropriate bodies within the other nations are likely better placed to give further information on how they used QCovid).

9.4 Shielding advice across the UK 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.

Shielding Programme in England – Timeline / Overview

9.5 To provide context to this section of this statement, a timeline of key events relating primarily to the clinical elements of the shielding programme is provided below:

5 March 2020	SAGE discussed need for vulnerable groups to be identified and protected
9 March 2020	Government commissioned the development of an offer of support for CEV people who may need to shield at home.
18 March 2020	UK Chief Medical Officers agreed criteria for who was to be advised to shield.

20 March 2020	First iteration of Shielded Patients List produced by NHS Digital using a centralised digital approach on coded patient records. (867,789 CEV identified in SPL 1). Digital search is re-run and the SPL updated weekly.
21 March 2020	NHS begins advising people meeting the CMO's clinical criteria to follow shielding guidance.
22 March 2020	Secretary of State for Housing, Communities & Local Government announced CEV people should stay at home - at which point shielding started.
27 March 2020	First food boxes delivered.
9 April 2020	Medicines delivery service began.
9 April 2020	NHSE asks GPs to identify and add CEV people to the Shielded Patient List (10th April for clinicians in NHS Trusts).
12 April 2020	Cumulative 1.3 million people identified as CEV (additional 417,639 added since 20 March).
18 April 2020	Cumulative 1.8 million people identified as CEV (additional 561,845 added since 12 April – single biggest increase, driven by GP and clinician review of SPL).
22 April 2020	UK CMOs recommend the addition of all patients on dialysis to the CEV group.
1 May 2020	SPL 3 – cumulative 2.16m identified as CEV (addition of 316,033 since 18 April, again primarily driven by GP and clinician additions).
1 May 2020	CMO commissions NERVTAG to combine all available evidence and develop a new predictive risk model, which incorporates emerging relevant risk factors such as age, sex, BMI, deprivation and ethnicity, alongside detailed clinical conditions and specific treatments.
29 June 2020	QCOVID underlying research methodology published (preprint) ahead of peer reviewed publication in BMJ and subsequent validation by ONS (published in Lancet Digital Health).
7 May 2020	Shielded Patients List stabilised at 2.2 million CEV people. (net increase of 49,320 since 1 May – from here on there is little significant change to size of SPL as GP and clinician review completed).
6 July 2020	The advice for CEV people was reviewed to include advice on meeting up to 6 people outdoors and forming a support bubble.

8 July 2020	CMO and NHS Medical Director wrote to all GP practices and trusts with advice that clinicians should review and, where appropriate, remove children and young people from the SPL in line with new guidance from the RCPCH (93k at the time).
1 August 2020	National shielding programme paused (although shielding did continue in Leicester and Blackburn with Darwen until 5 October because of persistent high rates of virus in these areas).
1 August – 5 October 2020	Shielding was continued until 5 October in: Leicester and parts of Leicestershire Blackburn with Darwen Letters were issued to CEV in these areas every 3-4 weeks updating them and extending their shielding notification period so that they would be eligible for support (e.g. SSP).
25 August 2020	COVID-O agrees principles and priorities for developing QCOVID to (a) be used by HMG to understand population risk and better target interventions and (b) be used by clinicians to discuss ways to mitigate risk with their patients
30 September 2020	Based on interim findings from QCOVID, UKCMOs agree that patients aged over 18 with Down's Syndrome and Chronic Kidney Disease (Stage 5) should be added to the SPL.
20 October 2020	COVID-O updated on options to apply QCOVID to patient records nationally to identify a new highest risk group for addition to the SPL. COVID-O agrees that QCOVID should be used to set a new highest risk threshold (of 2% absolute and 2% relative risk of death from COVID-19) for this purpose.
5 November 2020	November National Restrictions – CEV advised not to go to work or school. Letter announcing CEV people should take extra precautions during period of national restrictions in November.
27 November 2020	Issued letter to announce end of lockdown and return to tiers.
2 December 2020	JCVI published its final advice on priority groups for vaccination (Phase 1). This prioritised the highest risk clinical risk group, including all those considered by the Government to be CEV.

10 December 2020	COVID-O was updated on plans to use QCOVID to support vaccine prioritisation, clinical risk calculator/tool, development and potentially a public facing risk calculator/tool.
21 December 2020	Tier 4 created in SE, London and parts of East England – CEV advised to shield in Tier 4 areas.
30 December 2020	Tier 4 extended further.
6 January 2021	Start of National lockdown – all CEV advised to shield until 21 Feb.
25 January 2021	ONS independently validates QCOVID and shows that it performs in the 'excellent' range, and accurately identifies patients at highest risk from COVID-19. This means that the model is robust and meets the highest standards of evidence.
3 February 2021	Ministerial agreement to use QCOVID to add previously unidentified highest risk people to the SPL and prioritise them for vaccination.
16 February 2021	Announcement of the adoption of the QCOVID risk model in the NHS, adding up to 1.7m adults to the SPL and prioritising c820,000 for priority access to vaccination.
1 April 2021	On the basis that the enhanced risks posed to the CEV by COVID-19 had been sufficiently mitigated following the introduction of vaccination and then therapeutics for this group, the shielding programme was paused. This was outlined in the exhibited letter from MHCLG and DHSC to those on the shielding list (published by PHE on 18 March 2021).
15 September 2021	The shielding programme closed. The CEV were advised to follow the current Cabinet Office guidance to the general public on staying safe and preventing the spread of COVID-19 and to consider advice from individual health professionals regarding additional precautions. General advice on additional precautions to take was also given.

Process for the initial identification of conditions giving rise to CV or CEV Status

9.6 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"* **(CJMW5/168 – INQ000106152)**.

9.7 On 6 March 2020 the Cabinet Office chaired a meeting to discuss NPIs and 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 **(CJMW5/169 – INQ000052373)**.

9.8 On 7 and 8 March 2020, senior clinicians from DHSC, NHSE, NHS Digital and PHE had a telephone meeting at which options for clinical inclusion criteria for and identification of people thought most likely to be at highest risk from COVID-19 were discussed **(CJMW5/170 – INQ000381245, CJMW5/171 – INQ000381246)**. 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 for those self-isolating, but for a period of at least 12 weeks **(CJMW5/172 – INQ000220123)**. This group would become the "clinically extremely vulnerable" (CEV) group.

9.9 From 8 March 2020, 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 rapidly identifying them digitally wherever possible using coded primary and secondary care data.

9.10 On 10 March 2020, the Civil Contingencies Secretariat circulated papers for the COBR(O) meeting the same afternoon to attendees across Government **(CJMW5/173**

– INQ000106173 **CJMW5/174 –** INQ000106171 **CJMW5/175 – INQ000381214).** 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.

9.11 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 additional patients who did not automatically fall into the highest risk category and add them to the cohort, based on their individual risk **(CJMW5/176 –** INQ000109125 **.**

9.12 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"* **(CJMW5/064 – INQ000109142).**

9.13 The term 'cocooning' which was initially used by SAGE was subsequently refined to 'shielding' by SAGE. By 13 March 2020 SAGE advice had developed further to that, as set out above. 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.

9.14 In parallel, the group which had been identified by senior clinicians on 7 and 8 March 2020 as clinically vulnerable but not at highest risk, were identified in the Staying at Home Guidance which was published on 16 March 2020 **(CJMW5/177 –** INQ000348029 This guidance advised 'Clinically vulnerable people' to *"take particular care to minimise contact with others outside your household"*. For this reason the CV group were not individually contacted (in contrast to the CEV), but were identified in national guidance 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 neuron 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

9.15 On 18 March 2020 OCMO, with the agreement of the other UK CMOs, finalised the initial list of diseases to be included in the list of the most vulnerable from clinical first principles about infection, and what was then known about risk factors for COVID-19. It was assumed this would be updated as new data came in. The list was shared through 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 Professor Harries] **(CJMW5/178 – INQ000381244, CJMW5/179 – INQ000381242)**.

9.16 By 18 March 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 **(CJMW5/180 – 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.

Creation of the Shielded Patients List (SPL)

9.17 In order to identify individual patients classified as CEV, OCMO, principally Professor Harries except where indicated otherwise, oversaw the coordination of several parallel workstreams:

- NHS Digital centrally identified an initial cohort of individuals categorised as CEV by translating the UK CMOs agreed list of conditions into clinical codes. These were then run against NHS electronic patient records to identify the first iteration

of the Shielded Patients List (SPL 1) on 20 March 2020 **(CJMW5/181 – INQ000298956)**.

- In parallel, OCMO led rapid clinical engagement with the medical Royal Colleges, specialist groups and the NHS to ensure that individual patients could be identified by their own clinicians where central datasets were not sufficiently granular to capture particular conditions or treatments (for example patients on immunosuppressant therapies). On 21 March Professor Powis and I wrote to the NHS to ask them for help with management and shielding of patients who were at highest risk of severe morbidity and mortality from COVID-19 **(CJMW5/023 – INQ000068544)**. Medical Royal Colleges and clinical specialist groups produced their own communications for their members **(CJMW5/182 – INQ000381230, CJMW5/183 – INQ000381231, CJMW5/184 – INQ000381232, CJMW5/185 – INQ000381233)**.

- An important additional principle of the CEV inclusion criteria was that hospital specialists and GPs were provided with guidance asking them to add patients who they felt were at very high risk from COVID-19 but who did not meet the conditions-based criteria for inclusion on the SPL, for example the frail elderly with multimorbidity who were well known to primary care.

9.18 The SPL was centrally updated weekly as new people were identified. By early May 2020 the list stabilised at around 2.2m people, which is when the GP and hospital specialist additions to the list had largely been completed. The SPL remained roughly this size until 16 February 2021 when approximately 1.7m people were added to the SPL as a result of the QCOVID driven risk stratification of England's population based on information about risk factors that emerged over the early months of the pandemic. (see table at paragraph 9.5).

Process for revising and updating the definition of CEV

9.19 As the first wave progressed, evidence began to accrue about specific conditions which conferred higher risk of death or serious illness from COVID-19.

9.20 As a result, a process was developed for revising and updating the definition of CEV in line with new evidence: Professor Harries chaired a 4 nations UK Clinical Review Panel, whose membership included senior clinicians from the 4 nations, nominated by the UKCMOs. The panel usually met weekly and considered clinical matters relating

to the CEV group, including the evolving evidence base relating to clinical risk from COVID-19. The Clinical Review Panel considered evidence from a wide range of sources including patient groups, clinical specialist societies, medical Royal Colleges and academic groups. Where further evidence was needed, the Panel commissioned evidence reviews from NHS England to assist with their deliberations. It then made recommendations based on evidence about changes to the CEV inclusion criteria to the UK CMOs. In making these recommendations the panel weighed up the mental and physical health risks of stringently following shielding advice with the strength of the available evidence about the level of risk for the condition in question. The UK CMOs considered the recommendation and made the final decision about any resulting changes to the CEV inclusion criteria. Changes that were made to the criteria are detailed in Table 1, above. In England these were operationalised by NHS Digital and/or NHS England who may be able to provide further information about the numbers of patients added or removed to the CEV cohort as a result.

Development of QCOVID and Population Risk Assessment (PRA)

9.21 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 deaths to better understand the cumulative effect of weighted risk factors (demographic and clinical) **(CJMW5/186 – INQ000221970, CJMW5/187 – INQ000221965)**[3]. The model (QCOVID) combined a number of characteristics to estimate the risk of catching and then being hospitalised or dying from COVID-19. A key aim was to use data to address health inequalities which had been exacerbated by COVID-19. Variables in QCOVID included age, ethnicity, deprivation, homelessness and gender as well as clinical conditions and treatments. QCOVID was published in the BMJ in October 2020 and externally validated by ONS (published in Lancet Digital Health) and was shown to perform in the 'excellent' range which meant it would be safe to use accurately to identify those at highest risk in the wider population **(CJMW5/188 – INQ000315529, CJMW5/189 – INQ000328640)**.

9.22 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. A precautionary approach was taken to records with missing data, in which the highest risk category for ethnicity (Black African) and a

[3] These meetings were attended by Dr Nisha Mehta, a clinical advisor in OCMO. She was accidently redacted from the minutes despite being SCS1.

higher than average BMI (31) were used as default values to ensure that patients with missing demographic data were not inadvertently disadvantaged by the use of average values. This identified 1.7m patients who exceeded agreed relative and absolute risk thresholds (2% for each), recommended by the UK CMOs **(CJMW5/190 – INQ000385575**. These patients were added to the SPL and became part of the CEV cohort. This stratification of the population by risk (Population Risk Assessment) resulted in an additional group of around 820,000 adults being prioritised for vaccination as a result of their inclusion in JCVI cohort 4.

9.23 Of the 1.7 million 'QCOVID' cohort, 86% had an ethnicity recorded, of whom 36% were non-white, compared to 17% non-white ethnicity recorded in the adult population. The local authorities which saw the largest additions to the SPL are areas with high rates of disparities (eg Birmingham, Newham, Tower Hamlets).

9.24 QCOVID and the Population Risk Assessment was commissioned and clinically led by OCMO. The UK CMOs reviewed early QCOVID data in October 2020 and agreed in principle that QCOVID should be used to risk stratify the population **(CJMW5/190 – INQ000385575**. The decision to proceed with the risk stratification in England was agreed by Ministers. DHSC led on policy development and data analytics, NHS Digital led on the technical workstreams, NHS England coordinated the involvement of and impact on the NHS, and the University of Oxford led on development and refinement of the model with regular input from the NERVTAG Epidemiology subgroup. The research was funded by the NIHR.

9.25 The Population Risk Assessment and underlying research won a number of awards and was particularly commended for its focus on addressing inequalities **(CJMW5/191 – INQ000381247)**.

Whether the effectiveness of the shielding advice was assessed by reference to the numbers of CEV people hospitalised with COVID-19

9.26 OCMO did not directly undertake evaluation of the effectiveness of shielding advice. It is not possible to assess the effectiveness of shielding by reference to the numbers of people hospitalised with COVID-19 (or by reference to mortality rates). This is because disentangling the impact of shielding from other factors such as lockdown and individual behaviours has not been possible. It is also because there was no control group of similarly at-risk individuals who were not asked to shield.

9.27 NHS Digital published data between March and September 2020 about emergency admission rates, all cause mortality and test positivity rates for individuals on the SPL.

9.28 The Shielding Behavioural Survey ran in 6 waves between April and July 2020 and surveyed CEV individuals about their behaviours and physical and mental wellbeing. These were self-reported data and likely included both those formally advised to shield and others outside the programme who had decided for personal reasons to follow similar recommendations. Interviews were first delivered by the Department for Work and Pensions and later by ONS (with ONS analysis throughout). Results of the latter 4 surveys were published by ONS **(CJMW5/192 – INQ000339267**

9.29 The COVID High Risk Group Insights Study ran in 7 waves and was delivered and analysed by ONS between January and October 2021. There was one ONS survey in April 2022 of those who were previously CEV (the programme having formally closed in September 2021). These were regarded as Experimental Statistics and the results have been published by ONS **(CJMW5/193 – INQ000381229)**.

Section 10: Other matters within the scope of Module 3

10.1 The Inquiry has asked me about the involvement of the OCMO in multiple aspects of operational NHS care. These include clinical criteria for escalation of care, establishment of Nightingale hospitals, the use of private hospitals, staffing levels, allocation of staff in the healthcare system, elective surgery, clinical criteria for discharge, remote patient consultations, risk-based clinical pathways. Whilst I and other members of OCMO had some peripheral involvement or awareness of these issues it was slight and we neither initiated nor made or advised on the final decisions about them.

Screening services

10.2 The OCMO had some greater influence over the suspension of screening services, and the subsequent re-establishment of those services although we were not central to this decision. The reason for the suspension was twofold. The most important was to minimise the risk that individuals coming forward for screening, or the staff to screening them, were unnecessarily exposed to contact during the height of the pandemic. This was to minimise transmission risk. By definition people coming forward for screening do not (or should not) have symptoms implying they have serious disease

so exposing them to increased risk of infection at a point when vaccination was not available was likely to increase their overall risks to health rather than decrease it. The second reason was to allow some screening staff to be redeployed to other areas of the health system which were under considerable strain. Once vaccination was established the benefits of screening were proportionately greater.

Palliative and end-of-life care

10.3 I had some limited involvement in palliative and end-of-life care discussions to the extent that the Moral and Ethical Advisory Group (MEAG) reported in part to me. MEAG at the early stages of the pandemic had important discussions around how to support clinicians rationally to make difficult end-of-life decisions. There was some discussion about whether national guidance should be issued by the Government but in the end the decision, with which I agreed, was that it should not. It was rather incorporated into thinking and guidance by the relevant specialist groups within the medical profession, which seemed to me to be a much better way of making these decisions.

Stay-at-home messaging

10.4 In common with other clinicians I had a constant concern about the best balance between stay-at-home messages to discourage unnecessary social contact, and discouraging people with acute medical problems, unrelated to COVID-19 from attending the NHS when needed. Professor Powis and I in particular tried to make clear during live press briefings that the NHS remained open for emergencies throughout the pandemic. There is little doubt in my mind that there was a decrease in people attending for emergency presentations which would have benefited from medical care, for example acute cardiac syndromes. The extent of this is debatable but the fact of it is reasonably clear. How best to get the balance of advice right between encouraging people to come forward for essential emergency medical care, and discouraging people from coming forward to often crowded emergency departments where there were often large numbers of patients with COVID-19 was a judgement call.

Section 11: Regulatory issues

11.1 I was involved in giving advice to support the granting of professional temporary registration to recently retired and trainee doctors. I was not involved in decisions around nurses. This was part of a wider necessity for the medical profession to expand its normal scope of practice during the emergency. I and the other UK CMOs made clear during the pandemic in several letters and other communications that the expectation of regulators and others was that doctors would be judged by the reasonable standards expected during an emergency rather than outside it given the critical need for sufficient medical staff and therefore for people to work outside their usual scope of practice **(CJMW5/020 – INQ000049584 CJMW5/021 – INQ000071564, CJMW5/022 – INQ000072433)**. I had conversations with the GMC about this to ensure we are all aligned and they kindly signed up to the letters, which provided reassurance to clinicians that their regulator recognised the very different situation on scope of practice that occurred during the first 2 years of COVID-19.

11.2 I was not involved in a meaningful way in decisions around suspending Care Quality Commission (CQC) inspections during the height of the pandemic but I agreed with them.

Section 12: Impact and equalities

12.1 I was concerned about the mental health and well-being of medical practitioners throughout the pandemic. Within the significant limitations of travel restrictions and necessity to minimise contact I tried to keep abreast of morale in the medical profession for example through close contact with the medical Royal Colleges. We also had discussions with individuals who were closely involved in this for example Dr. Kevin Fong **(CJMW5/194 – INQ000072310, CJMW5/195 – INQ000074691, CJMW5/196 – INQ000381208)**. To the best of my ability I relayed concerns to others, and also joined with the other CMOs and Professor Powis to write out to the system to express our profound admiration of what they were doing, and reflect that we were aware of the pressures they were under **(CJMW5/197 – INQ000048595 CJMW5/037 – INQ000072041, CJMW5/198 – INQ000381210)**. I do not know to what extent this was useful and it was unclear what realistic alternatives there were to try and address very genuine stress and mental health concerns by colleagues on the back of a prolonged severe emergency.

12.2 As set out in sections 4 and 9 of this statement, OCMO took a role in trying to identify the risks to vulnerable groups including ethnic minorities and different risk groups eligible for shielding. Referenced in sections 4 and 9 of this statement.

Section 13: Reports and lessons learned exercises

13.1 The principal lesson learning exercise of relevance to this module on the NHS is the Technical Report on the COVID-19 Pandemic in the UK to our successors **(CJMW5/001 – INQ000203933)**. This distils the views of a wide variety of clinicians and scientists involved on the COVID-19 response. Chapter 10 'Improvements in the care of COVID-19', Chapter 9 on 'therapeutics and vaccines' and Chapter 1 'understanding the pathogen' are particularly relevant to Module 3.

13.2 I do not wish to repeat lessons learned laid out in that Report, or in previous witness statements by me or on behalf of OCMO. However some very major lessons are worth highlighting.

13.3 The first, and most important, is that the remarkable professionalism and fortitude of the medical, other clinical and non-clinical staff of the NHS and wider health and public health system were on full display. The pressure on individual clinicians was immense, combining exceptionally long hours, fear for themselves or, more commonly, their families, and the psychological distress of treating so many very sick patients. Despite that the professions responded, day after day. Whenever the medical and other professions have been asked to respond to major emergencies they have done so and will continue to do so.

13.4 The heavy emphasis OCMO, and the UK clinical system more widely, put on research is one of the positive lessons of the pandemic. Despite some scepticism at the time, it was justified. Observational studies and clinical trials were essential to the reduction of mortality seen over time even in advance of the first vaccines.

13.5 It is however not just from formal studies, but also learning by doing that medicine advances. Many of the key lessons of COVID-19 clinical management including ventilation, proning, structured use of oxygen therapy, the central role of anticoagulation and others were discerned by astute clinicians learning well in advance of formal clinical trials or studies confirming them. Clinicians learn, and communicate their learning to others, via multiple paths.

13.6 The best approach to PPE was the one area, in my view, where some of the medical profession did not always have confidence in some of the guidance they were given by fellow professionals for a period. The advice was developed and promulgated by experts in infection control in good faith, using what was available and current knowledge, and some of the concerns were not science-based. The importance of getting this right, and then communicating it, in an infectious emergency is however clear.

13.7 Constant two-way communication between the leaders of the medical profession was essential. The Presidents of the Royal Colleges as the senior clinicians for their professional groups, the NHSE National Medical Director and the OCMO among others hugely benefitted from regular contact.

Statement of Truth

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

Signed: PD

Dated: 01.02.2024