

Witness Name: Sir Christopher Stephen Wormald

Statement No.: 1

Exhibits: CW/1-CW/455

Dated: 25 November 2022

UK COVID-19 INQUIRY

WITNESS STATEMENT OF SIR CHRISTOPHER STEPHEN WORMALD

1. I, Sir Christopher Stephen Wormald, of the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU, will say as follows:
2. I am employed by the Department of Health and Social Care (DHSC/the Department) as Permanent Secretary, a post I have held since May 2016.
3. Before joining DHSC, I was the Permanent Secretary of the Department for Education (DfE) between 2012 and 2016, and a Director General (DG) within the Cabinet Office (CO), between 2009 and 2012.
4. I make this statement in response to the request from the UK COVID-19 Public Inquiry (the Inquiry), dated 18 August 2022, under Rule 9 of The Inquiry Rules 2006 (SI 2006/1838), requiring the Department to provide the Inquiry with a witness statement in respect of specified matters relating to Module 1.
5. Save for where it is stated otherwise, the contents of this statement are within my own knowledge. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. Notwithstanding this, it is the case that the Department continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional material will be discovered. In this eventuality the additional material will of course be provided to the Inquiry and a supplementary statement will be made if need be.
6. For matters before 2016, my statement relies on Departmental records. For matters after 2016, I am relying on my own experience and recollection, and Departmental records. I have also consulted with colleagues in the Department, including previous

incumbents, in order to provide as robust an account as possible on behalf of the Department. Consultation with my predecessors was confined to their having the opportunity to read and comment on this statement in its near final form, offering any relevant observations drawing on professional memory.

7. I have also consulted with colleagues from the UK Health Security Agency (UKHSA), the Government Office for Science (GO-Science), the Department for Levelling Up, Housing and Communities (DLUHC) and the Department for Environment, Food and Rural Affairs (Defra) on matters of accuracy.

Structure of this statement

8. The matters referred to in this statement relate, for the most part, to the date range as specified by the Inquiry, namely between 11 June 2009 and 21 January 2020. I will make it clear where I refer to matters outside this range.
9. I have structured the statement around the outline scope of Module 1 as follows:-
 - The **first section** (paragraphs 11-55) covers the basic characteristics of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and Coronavirus disease (COVID-19). I also include information on other viruses and diseases that are relevant to this Module and to pandemic preparedness, for example Severe Acute Respiratory Syndrome (SARS). I have included background on other infectious diseases and pandemics to contextualise the work that was conducted between 2009 and 2020, as outlined in Section 3.
 - The **second section** (paragraphs 56-223) covers government structures and specialist bodies. This includes how DHSC was governed, but also how it worked with other government structures. It also includes information on emergency preparedness.
 - The **third section** (paragraphs 224-416) covers DHSC's role in preparing for a pandemic, including work up to 21 January 2020 and any lessons learned from live outbreaks and exercises. The Inquiry asked about the impact of European Union (EU) Exit on pandemic preparedness, and this is also covered in this section.
 - The **fourth section** (paragraphs 417-432) covers DHSC's relationship with public health services in preparing for a pandemic, including resourcing and funding. Issue 5 of Module 1 relates to "economic planning by relevant government bodies". DHSC did not have a primary role in economic planning; policy responsibility for that rested with other Departments. To the extent that I am able to speak to this, I do so within the fourth section.
 - The **fifth section** (paragraphs 433-439) includes some high-level reflections on the state of preparedness as of January 2020. I will provide more detail in a separate statement to the Inquiry.
10. In my statement, I use the names of organisations as they would have been referred to at the time. For example, I refer to Public Health England (PHE) for specific work conducted between 2013 and 2020. If something is non-specific, for example a statutory duty, then I refer to the organisation as it currently exists in October 2022 (e.g. UKHSA).

SECTION 1: Nature of SARS-CoV-2 and Coronavirus Disease in the context of previous pandemics and epidemics in the UK

11. This part of my statement relies on the advice of the Chief Medical Officer (CMO) for England and other public health experts. I have also consulted him on other parts of the statement that are most relevant to his expertise, namely the sections on scientific groups (Section 2) and on outbreaks of specific diseases between 2009 and 2020 (Section 3).
12. Section 1 covers some background on pandemics and major epidemics in general (as they are relevant to the COVID-19 pandemic and its preparations), pandemic influenza specifically, as well as previous coronavirus epidemics/outbreaks, and high consequence infectious diseases (HCIDs).

Background

13. On 31 December 2019, the China Country Office of the World Health Organization (WHO) was informed of a cluster of cases of pneumonia of unknown cause detected in the city of Wuhan, Hubei Province, The People's Republic of China (China). On 9 January 2020, the WHO announced that a novel coronavirus had been identified in samples obtained from these cases and initial analysis of virus genetic sequences suggested that this was the cause of the outbreak. On 30 January 2020, the WHO Director-General Dr Tedros Ghebreyesus declared the novel coronavirus outbreak a public health emergency of international concern (PHEIC).
14. In February 2020, the International Committee on the Taxonomy of Viruses formally named this new virus severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2). The WHO named the disease caused by it COVID-19.
15. Coronaviruses are a large family of related RNA viruses that can cause diseases in animals. Six coronaviruses, in addition to SARS-CoV-2, are known to cause infection and be transmitted between humans. Most probably originated in bats, possibly via intermediate hosts.
16. Four human coronaviruses, 229E, NL63, OC43 and HKU1, usually cause less severe disease, such as some forms of the common cold or other generally mild respiratory illness, although more severe cases can occasionally occur in infants, the very elderly or immunocompromised people. Around 15% of cold-like illnesses are caused by these coronaviruses that circulate globally in children and adults with a seasonal spike in winter in the northern hemisphere.
17. Two coronaviruses which emerged recently can cause severe disease with significant mortality: Middle East respiratory syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). They are a different family of viruses from the influenza viruses that cause influenza.

18. SARS-CoV-2 is genetically related to the coronavirus responsible for the SARS outbreak of 2003 (SARS-CoV), although not closely, and to coronaviruses that have been isolated from bat populations. It is less closely related to the coronavirus responsible for MERS (MERS-CoV).
19. Module 1 is focused on the UK's preparedness for a whole system civil emergency. COVID-19 is not a disease that, as of 21 January 2020, the government could specifically prepare for, as the virus was first identified in December 2019. In order to give some context to the plans and preparations that the Department had made before January 2020, I therefore now set out some background, in conjunction with the CMO, on diseases that informed our preparedness plans up to 21 January 2020, both in the context of pandemic preparedness and work on emerging infectious diseases.

Relevant terms:

20. During the statement, I use various pieces of terminology regarding pandemics, disease outbreaks etc. I define the terms below, and also at the end of my statement is a glossary of terms and acronyms:
- a. Epidemic: The epidemiological definition of an epidemic is an increase in the frequency of occurrence of a disease in a population significantly above its baseline level for a specified period of time. Administrative definitions can be set for different diseases in which an arbitrary threshold is selected above which the term "epidemic" is applied. In the case of influenza, the Department of Health (DH) introduced in 1996 an administrative definition of an "epidemic" for a rate of consultation (with a sample of general practices) of 400 per 100,000 population in a week. An epidemic may cause substantial mortality but on a smaller geographical basis than a pandemic.
 - b. Pandemic: An epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people. It may be a new infection (e.g. COVID-19) or a known infection (e.g. influenza) of humans. The WHO usually declares a pandemic.
 - c. Emerging infectious disease: Infectious diseases that have newly appeared in a population (e.g. from animals) or have existed in humans but are rapidly increasing in incidence or geographic range.
 - d. HCID: In the UK, a HCID is a disease which requires very high-level isolation in specialist centres and is defined according to the following criteria:
 - i. acute infectious disease
 - ii. typically has a high case-fatality rate

- iii. may not have effective prophylaxis or treatment
 - iv. often difficult to recognise and detect rapidly
 - v. ability to spread in the community and within healthcare settings
 - vi. requires an enhanced individual, population and system response to ensure it is managed effectively, efficiently and safely
- e. Seasonal influenza occurs every year, with seasonal peaks usually during the winter in temperate countries. Deaths in the UK typically average about 9,000 a year but can be over 20,000 with wide variation.
- f. Pandemic influenza is a new strain of influenza sufficiently different from existing seasonal influenza to cause a pandemic, and usually when an expectation is that it will lead to considerably higher than usual mortality. Normally it will have emerged from an animal host.

Pandemics

21. Pandemics and major society-changing epidemics are rare. Much of what we understand on how to combat them in the initial phases, and hence how to plan for them, therefore comes from data over decades and centuries. Since the start of the 21st century, we have had a single, relatively minor (by historical standards) pandemic prior to COVID-19 that affected the UK. This was the influenza pandemic of 2009, covered below. There have however been several significant epidemics globally, and the HIV-AIDS pandemic (which was the last major pandemic) continues.
22. All pandemics in recent history have eventually been addressed by medical countermeasures based on scientific understanding of disease at the time, whether sanitation (cholera), vaccines (COVID-19, influenza) or drugs (HIV). Until these medical countermeasures are available, pandemics have to be addressed by societal measures to reduce transmission, also known as non-pharmaceutical interventions (NPIs).
23. The initial countermeasures which will be useful for an emerging infection depend on the route of transmission. The five main routes of transmission are: respiratory (influenza, COVID-19); sexual and intravenous (HIV, syphilis); oral from water or food (cholera, typhoid); vector transmitted from insects or arachnids (plague, malaria, dengue, typhus, Zika) and touch (Ebola, Lassa). Non-pharmaceutical countermeasures have to be based on the route of transmission, mortality rate, and the age structure of disease, among other factors.

24. The last major pandemic was HIV-AIDS (ongoing) which spread globally in the 1980s and has killed over 35 million people to date according to the WHO. When it emerged, mortality was 100% of those infected.
25. HIV-1 and HIV-2 are predominantly sexually transmitted, with additional blood-to-blood (intravenous) transmission, and morbidity and mortality are concentrated in young adults. NPIs therefore targeted sexual behaviours such as condom-wearing in this age group, and reducing needle sharing. Development of a vaccine for HIV has had substantial effort and resource but, 40 years later, we still do not have an effective vaccine against HIV, and drug treatments have underpinned medical countermeasures.
26. In the 20th century, three respiratory pandemics resulted from variants of influenza; 1918-19 ('Spanish flu'); 1957 ('Asian flu') and 1968 ('Hong Kong flu'). Mortality rates often vary by age. Age-specific mortality curves for 1957-58 and 1968-69 show a U-shaped pattern with increased case fatality ratio in the very young and then increasing case fatality ratio with increasing age. The 1918 pandemic also affected the very young and elderly, but additionally had relatively high mortality rates in young adults (**CW/1**). During the COVID-19 pandemic, children were fortunately much less affected. Influenza is discussed in more detail below.
27. There was also one major cholera pandemic in the 20th century starting in 1961, with multiple outbreaks. Cholera is a faeco-oral disease mainly spread via water and affecting all age groups. Although the UK was not affected by that cholera pandemic (the seventh) it was significantly affected by the previous six cholera pandemics in the 19th century, which led to the development of epidemiology and of the sewer network among other things. Faeco-oral epidemics are currently less likely in the UK due to clean water and good sewerage, although food-based oral outbreaks can be serious threats as evidenced by the spread of new variant Creutzfeldt-Jakob Disease (CJD) following the consumption of beef from Bovine Spongiform Encephalitis-infected cattle (BSE, 'mad cow disease').
28. Plague, a vector (flea) and respiratory transmitted pathogen and louse-borne typhus were historically significant epidemic threats in the UK. However, although some important vector-borne diseases occur in the UK, such as Lyme disease, vector-borne transmission is the least likely route for a major epidemic here. Vector-borne diseases remain a major threat globally.
29. It is however important to acknowledge that much of our current response to new pandemics and epidemics, until medical science develops disease-specific medical countermeasures such as drugs and vaccines, depends on measures which were developed in response to plague and other historic epidemics often over many

centuries. These measures include quarantine at borders, self-isolation of infected people, closure of venues where households mix indoors (such as theatres and hospitality) and restricting higher-risk close-contact professions such as barbers.

30. Whilst vector-borne, water-borne and food-borne pandemics are now less likely in the UK, respiratory infections retain their ability to travel rapidly around the world and therefore are the group most important to plan for. Sexually transmitted and touch-transmitted pandemics and epidemics also remain a risk to the UK but will usually expand more slowly. High mortality may come from a high case fatality rate in smaller numbers (e.g. HIV, Ebola) or moderate mortality in an infection with a very high attack rate, which is defined as proportion of the population infected (1918 H1N1 influenza). Mortality in pandemics ranges from 100% (HIV) to less than 0.1% (H1N1 2009). It is therefore unrealistic to have a plan for all possible pandemics given the range of threats, routes of transmission, mortality rates and age structures affected, amongst other variables.
31. Every year multiple outbreaks with fatalities, or of potentially fatal diseases, occur around the globe, some of unknown cause, reported to the WHO and national public health systems, and described on professional websites such as ProMED. For each one on emergence, the probability of it turning into a major epidemic is low, and a pandemic exceptionally low. For those that do emerge as major threats the evidence that it is going to become a national and then international threat accumulates slowly, and probabilities gradually change.
32. To give some sense of the frequency of these in September and October 2022 global outbreaks that are unlikely to, but could, cause major epidemics have included an ongoing monkeypox epidemic in Europe and elsewhere, declared as a PHEIC by the WHO in July 2022 but with low mortality; a respiratory outbreak in the Argentine Republic (Argentina) with high mortality which concerned the WHO but turned out to be Legionella; an Ebola Sudan type (for which we have no rapid vaccine) in the Republic of Uganda (Uganda); a hantavirus outbreak in Panama City (Panama); Marburg virus detected in the Republic of Ghana (Ghana); plague cases reported in the Democratic Republic of Congo (DRC); vaccine-derived polio detected in London and New York sewers and cholera in the Republic of Haiti (Haiti). In addition, there are various outbreaks of Avian influenza globally and multiple animal outbreaks such as chronic wasting disease in deer where the probability of it becoming a zoonotic infection is low but never zero.
33. When COVID-19 was first reported to the WHO on 31 December 2019, it was already an infection of significance in a localised part of China. Over the first 21 days of January 2020, which Module 1 covers, the evidence gradually suggested that this

could be a serious international threat rather than just a local one. This gradual change in probabilities with new data emerging is typical and is reflected by the fact that the WHO did not declare a PHEIC until 30 January 2020 and a pandemic until 11 March 2020. DHSC will cover this in more detail in witness statements for Module 2.

34. I turn now to some specific predominantly respiratory pandemics and epidemics of relevance to UK planning prior to COVID-19, which occurred after the turn of the 21st century; influenza and the two prior new severe coronaviruses affecting humans, SARS and MERS.

Pandemic influenza

35. Pandemic influenza has been at the top of national emergency planning since the UK's first National Risk Register (NRR) in 2008 (**CW/2**). This is because influenza has a proven ability to cause repeated pandemics with substantial mortality including in the UK.
36. Any new pathogen transmitted by the respiratory route is likely to share characteristics with influenza in that it can spread rapidly via close proximity, can travel rapidly and there are few easy immediate countermeasures. It has therefore been a planning assumption that a plan for pandemic influenza would have considerable overlap with a plan for other diseases easily transmitted by the respiratory route. This assumption was set out in the 2011 UK Influenza Pandemic Strategy (**CW/3**): "A pandemic is most likely to be caused by a new subtype of the Influenza A virus but the plans could be adapted and deployed for scenarios such as an outbreak of another infectious disease, e.g. Severe Acute Respiratory Syndrome (SARS) in health care settings, with an altogether different pattern of infectivity".
37. In particular the potentially rapid spread via the respiratory route, without physical contact and including to strangers who are in the same room or vicinity, leads to a very different pattern of transmission than other transmission routes, and potentially can lead to very high hospitalisation and mortality in short periods of time.
38. Pandemic influenza emerges as a result of a novel influenza virus which is markedly different from recently circulating strains (antigenic 'shift' rather than 'drift') and which affects humans. This usually emerges from birds or mammals.
39. The emergence of a new strain of the influenza virus and a lack of pre-existing immunity within the human population would mean that international spread is sometimes almost inevitable and rapid; population attack rates are high; and the illness itself may be (but is not always) more severe than is seen with seasonal influenza.

40. Influenza pandemics are highly unpredictable in terms of when they will occur, how many waves there will be, and the precise timing, duration and severity including case fatality of each wave. Past influenza pandemics have varied in scale, severity and consequence, ranging from the 1918 outbreak of Spanish flu which killed many tens of millions globally, through to the 2009 swine flu pandemic which had a lesser impact on society than some normal flu seasons. More information on the 2009 swine flu pandemic can be found in Section 3. Mortality in influenza pandemics is usually seen in young children as well as the elderly.

High Consequence Infectious Diseases

41. The definition of HCIDs can be found in paragraph 20 above.
42. MERS and SARS are classified as HCIDs in the UK, alongside a number of other acute infectious diseases, typically with very high case fatality rates. They can be either contact (e.g. Ebola virus disease and Lassa Fever) or airborne (e.g. avian influenza H5N1 and pneumonic plague), although other routes including sexual or via breastmilk are possible, usually as a secondary route of transmission. Classification of HCIDs is made by the UK public health agencies, the Advisory Committee on Dangerous Pathogens (ACDP) and the National Health Service (NHS) and are kept under review; a current list is exhibited at **(CW/4)**.
43. HCIDs are rare in the UK and when cases do occur they are typically associated with recent travel to an area where the disease is endemic or where there is an outbreak. They are typically treated in NHS specialist isolation units. No HCIDs are currently endemic in the UK, and the known animal reservoirs are not found in the UK.
44. The UK has had some experience of planning, exercising and incident management for HCIDs, as detailed in Section 4. An emerging infectious disease, likely to be an HCID, was included on the government's NRR from 2010. The NRR 2010 edition is exhibited at **(CW/5)**.
45. 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. These details will be covered in Module 2 but I have set out the definition of HCIDs here for background information.

SARS-CoV

46. Prior to 2002, only four human coronaviruses were circulating despite many animal coronaviruses. SARS, caused by SARS-CoV, was a coronavirus with significant

mortality that emerged in China, probably in 2002, and which was reported to the WHO in 2003. It caused a widespread epidemic affecting east Asia and Canada among others with some spill-over cases including in the UK. It disappeared for reasons that are not entirely clear (although control measures contributed significantly) in 2004 and to date has not re-emerged in humans.

47. SARS is caused by the SARS coronavirus, known as SARS-CoV. The SARS virus was spread mainly in small droplets of saliva coughed or sneezed into the air and probably by aerosols. SARS can also be spread by fomites (infected objects), surface contamination and possibly faecally. This occurs when an uninfected person touches infected surfaces, and then touches their mouth, for example through eating, or their eyes. SARS has flu-like symptoms that usually begin two to seven days after infection. Sometimes, the time between coming into contact with the virus and the start of symptoms (incubation period) can be up to 10 days. There is currently no vaccine. Asymptomatic transmission of SARS is thought to be very rare although asymptomatic infection without transmission may occur. Information on SARS is exhibited at **(CW/6)**.
48. In 2004 there was another smaller SARS outbreak linked to a medical laboratory in China.
49. During the main period of these outbreaks there were 8,098 reported cases of SARS and 774 deaths. The disease has a case fatality rate of between 3-10% depending on the method it is calculated, including younger adults.
50. There are some similarities between SARS-CoV and SARS-CoV-2, including that both are coronaviruses that are spread in large part via small droplets and respiratory secretions. However, SARS-CoV has a higher case fatality rate than SARS-CoV-2, and was much less transmissible, generally requiring close contact with symptomatic people. It was therefore a particular hazard for healthcare workers who as part of their work have to come close to, and handle, sick people.

MERS-CoV

51. MERS is a viral respiratory disease caused by a coronavirus that was first identified in the Kingdom of Saudi Arabia (Saudi Arabia) in 2012.
52. MERS has been reported in 27 countries since 2012, with approximately 80% of human cases reported by Saudi Arabia. There have been three cases of MERS imported into the UK since 2012, with 1,500 possible imported cases tested in UK labs in the same timeframe **(CW/7)**. There was transmission of two cases in 2013 and one subsequent death, with a total of five MERS cases in the UK. The most recent case was identified in August 2018, with previous cases diagnosed in 2012-13 **(CW/8)**. The WHO report that up to September 2019, a total of 2,468 laboratory-

confirmed cases of MERS have been reported globally, including 851 associated deaths.

53. Although most cases have been directly or indirectly linked to camel exposure in the Arabian Peninsula, there was a significant outbreak of MERS in the Republic of Korea (South Korea) in 2015, which involved 186 cases, including 36 fatalities, 44% of which were nosocomial (transmitted within a healthcare setting). All, or the great majority, of human-to-human transmission was from symptomatic people. Asymptomatic transmission of MERS human-to-human is thought to be very rare, although asymptomatic infection without transmission may occur.
54. The mortality rate for people with MERS reported to the WHO is approximately 35%.
55. Unlike SARS-CoV-2, MERS-CoV does not currently pass easily from human-to-human and the risk to residents in the UK from imported cases remains very low. Identifying MERS and SARS patients by their symptoms and isolating them contained the spread of those outbreaks because a high proportion of patients displayed symptoms in the early stages of infectiousness whilst transmissibility only peaked later on.

SECTION 2: DHSC structures

56. This section of my statement will cover the committees and decision makers within DHSC, both in relation to senior decision making and to specific pandemic preparedness activity. It will also cover how DHSC worked with departmental agencies (such as UKHSA and the Medicines and Healthcare products Regulatory Agency (MHRA)), NHS England (NHSE), Other government Departments (OGDs), Local Government, the Devolved Governments, and international partners.
57. Decision-making in DHSC (as in OGDs) is largely carried out through submissions to the Secretary of State and other DHSC ministers which set out an issue and recommendation and give information to note. The relevant ministers take decisions based on this advice, and sometimes will call meetings to discuss this advice before making a decision. Urgent decisions are sometimes taken in meetings or in other discussions. All government decisions should be recorded by the minister's private office. Decisions that require cross-government input or alignment are made through the well-established approaches to collective agreement. These are led by the CO and agreement is sought and received either meeting in person or in writing, through Cabinet Committees, or Cabinet itself.
58. Financial allocations, including for public health and the NHS, are agreed in regular Spending Review processes between the Department and His Majesty's Treasury (HMT). Depending on the level of spend and its features, areas are either within departmental delegation or require further agreement with HMT or CO. The Department implements the policy and financial decisions accordingly. In the time period covered by Module 1, there were Spending Reviews in 2010, 2013, 2015 and 2019.
59. These processes apply to pandemic preparedness policy and spending as they do for any other area of government responsibility.

Role of DHSC

60. The Secretary of State has a statutory duty to continue the promotion in England of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis and treatment of physical illness: 2006 (NHS Act 2006), s.1.
61. DHSC is supported by two executive agencies, UKHSA (and its predecessor bodies) and MHRA, and partner organisations, for example NHSE. Their involvement in pandemic preparedness is discussed later in Section 3.
62. Generally, DHSC does not directly fund or deliver adult social care and much of the funding for adult social care is raised locally. The Care Act 2014 places the duty to plan and secure adult social care services on 152 Local Authorities (LAs) in England,

who commission services through a predominantly outsourced market of approximately 14,000 provider organisations. DHSC is responsible for setting national policy and the legal framework, while DLUHC oversees Local Government funding and the financial framework.

63. The Secretary of State also has a duty to take such steps she considers appropriate to protect the public in England from disease or other dangers to health: s. 2A NHS Act 2006. I set out more information on public health services in Section 4.

Executive decision makers and advisers

64. Key decision makers in respect of the Provisional Outline of Scope of Module 1 including names, roles and dates in roles are exhibited at **(CW/9)**. The data provided is to the best of the Department's knowledge based on records the Department has been able to access. More information on senior roles and responsibilities are set out below.

Ministers and Special Advisers

65. Ministers in role from 11 June 2009 to 21 January 2020 including names and dates in roles are exhibited at **(CW/10)**.
66. Special Advisers in role from 11 June 2009 to 21 January 2020 including names and dates in roles are exhibited at **(CW/11)**. Responsibilities have not been included for Special Advisers due to the changing nature of their roles and shared ownership of portfolios.

Permanent Secretary

67. As Permanent Secretary, I am responsible for:
- a. Ensuring ministers receive advice on strategy and objectives for the health and social care system;
 - b. Acting as the Department's chief executive, setting standards and managing risk and assurance; and
 - c. Acting as the Department's accounting officer, reporting to Parliament.
68. The Permanent Secretary is the most senior civil servant in a department. Each supports the government minister who is the head of the department, who is accountable to the Prime Minister, Cabinet, Parliament and the public for the department's performance.
69. The people who held the post of Permanent Secretary between 2009 and my appointment in 2016 are Sir Hugh Taylor (until 2010), Richard Douglas (Acting Permanent Secretary from June-September 2010 inclusive), and Dame Una O'Brien (October 2010- April 2016).

Chief Medical Officer for England

70. The CMO acts as the UK Government's principal medical adviser, and the professional head of all directors of public health (DPH) in Local Government and the medical profession in government. The CMO provides public health and clinical advice to ministers in DHSC and across government on both communicable and non-communicable diseases. The CMO is an independent position at permanent secretary level. The current post holder is Professor Sir Chris Whitty who took office in October 2019. Professor Sir Liam Donaldson was in post from 1998 to 2010 and Professor Dame Sally Davies was in post from 2010 to 2019.

71. The CMO is assisted by Deputy Chief Medical Officers (DCMOs), one of whom is specifically responsible for health protection, which includes infectious threats. The DCMO for health protection was Professor Sir Jonathan Van Tam from 2017 to 2021. His predecessor was Professor John Watson, from 2013 to 2017. The second main DCMO normally covers health improvement (non-communicable diseases), but is in an emergency expected also to cover health protection issues. Professor Dame Jenny Harries was the DCMO for health improvement from July 2019 to May 2021, but due to the pandemic spent much of her time on health protection issues related to COVID-19.

72. Scotland, Wales and Northern Ireland also have CMOs and DCMOs for devolved health issues. The UK CMOs meet regularly.

Second Permanent Secretary

73. The role of the Second Permanent Secretary in DHSC was created in response to the COVID-19 pandemic. Initially the role was held by David Williams who led on Finance (including COVID-19 Finance), Group Operations and business as usual. Increasingly, as COVID-19 became the majority of the Department's work, David acted as my deputy across the board.

74. Shona Dunn became Second Permanent Secretary in April 2021. She is an additional accounting officer on all departmental matters and acts as deputy to the Permanent Secretary across the board. She has direct responsibility for all matters relating to Finance and Group Operations.

DHSC Chief Scientific Adviser

75. DHSC also has a Chief Scientific Adviser (CSA), who acts also as the head/CEO of the National Institute for Health Research (NIHR) and advises on scientific aspects of health. In the period 2016 to 2021 this was held by Professor Sir Chris Whitty. Prior to that it was held by Professor Dame Sally Davies. Professor Lucy Chappell is the current CSA, taking over from Professor Sir Chris Whitty in August 2021.

Chief Nursing Officer

76. The Chief Nursing Officer (CNO) for England provides clinical and professional leadership for all nurses and midwives in England (with the exception of public health and adult social care nurses) including the 350,000 nurses and midwives who work for the NHS and who make up the largest group of the total NHS workforce. Prior to 2020, leadership was provided by PHE's Director of Nursing and the Chief Nurse for Adult Social Care for public health and adult social care nurses respectively.
77. Prior to the pandemic (and the merger between NHSE and NHS Improvement (NHSI) in 2022), The CNO was accountable for providing expert clinical and workforce advice to the NHS, and the Boards of NHSE and NHSI.
78. The CNO was a member of the joint NHSE / NHSI national leadership team, and participated fully in the wider work of NHSE and NHSI Boards as a voting member of each Board.
79. Prior to the establishment of NHSE in 2013, the CNO was an employee of DHSC. Previous CNOs were Dame Christine Beasley from 2004 to 2012 and Professor Jane Cummings between 2012 to 2019. The current post holder is Dame Ruth May.

Department of Health and Social Care Executive Structures

80. The bodies that are most relevant to departmental governance are the following:

Departmental Board

81. The Departmental Board is chaired by the Secretary of State. The Departmental Board is an advisory board made up of members of the DHSC leadership team, ministers and independent non-executive board members (NEDs). It meets quarterly to discuss how the Department is performing against its objectives; identify potential threats, emerging issues and opportunities that could have an impact on policy; and provide oversight of delivery partners (namely, the Department's Arm's Length Bodies (ALBs)). The Board's work is at the discretion of the Secretary of State, with whom powers and responsibilities ultimately lie.
82. The Audit and Risk Committee (ARC), a sub-committee of the board, advises the Departmental Board and the Department's accounting officer on risk management, corporate governance and assurance arrangements for the Department and its subsidiary bodies and reviews the comprehensiveness of assurances and integrity of financial statements.

Executive Committee

83. I chair the Executive Committee (ExCo) which oversees the management of the Department. Issues it considers include strategy, finance, performance and core departmental business including Secretary of State and other ministers' priorities; system-wide finance; matching resources to priorities; and departmental pay policy

decisions. ExCo meets monthly, except in August, and ad hoc when the Department's business needs require. Its current membership includes the Second Permanent Secretary, CMO, CSA, Directors General (DGs) and Directors of Human Resources (HR), Information Risk Management & Assurance (IRMA) and Ministers, Accountability and Strategy.

84. ExCo does not create departmental policy. Its role is to set standards and procedures in the Department.
85. From June 2009 to 2013, Executive Committee was known as the "Executive Board" which comprised the Permanent Secretary, CMO and DGs. From 2013 to 26 March 2015, it was known as the "Leadership Team", before becoming the ExCo. Membership of ExCo from 11 June 2009 to 21 January 2020 are exhibited at (CW/12), including names, roles, dates in roles and reporting lines. The data provided is, to the best of the Department's knowledge based on records the Department has been able to access.

Emergency preparedness

86. The Secretary of State is designated as a Category 1 responder under the Civil Contingencies Act 2004 (CCA).
87. The Secretary of State's responsibilities as a Category 1 responder apply to emergencies that have potential impacts on the public's health and the health and social care sectors. The CCA's definition of an emergency, that holds most relevance for the Secretary of State's Category 1 responder role, is 'an event or situation which threatens serious damage to human welfare in a place in the United Kingdom': CCA s.1(1)(a).
88. These civil protection duties conferred on the Secretary of State by the CCA include: assessing the risk of emergencies occurring and using this to inform contingency planning; putting in place emergency plans and business continuity arrangements; putting in place arrangements to make information available to the public about civil protection matters and maintain arrangements to warn, inform and advise the public in the event of an emergency; and sharing information and cooperating with local responders to enhance emergency response coordination and efficiency.
89. The Secretary of State discharges these duties through policy and emergency preparedness teams throughout the Department.
90. Since before 2009, the Department has maintained a dedicated, Director led, Emergency Preparedness, Resilience and Response (EPRR) function within the Department. This EPRR function leads on the planning for and response to all incidents where there is a potential risk to the public's health. The threats or incidents that this includes are operational incidents such as fuel shortages and medicine

supply disruption, environmental threats such as adverse weather, deliberate threats such as terrorism, infectious disease outbreaks such as Monkeypox and Ebola, and the potential impact of a pandemic.

91. Response plans include, but are not limited to, standard operating procedures for emergency incidents, the roles of teams across the Department and across the wider government and ALBs, decision-making procedures, alert systems, and training manuals. NHSE, ambulance services, NHS Hospital Trusts and UKHSA are also defined as Category 1 responders under the CCA.
92. Response capabilities across the health and social care system have been enhanced following the lessons learned from responding to incidents and exercises and as a result of preparedness for a 'no deal' EU Exit.
93. Infectious disease specific response capabilities were developed following incidents such as the West African Ebola outbreak, previous pandemics and responses to other emergency health threats such as the Salisbury Novichok poisoning. This has included a MEDEVAC (Medical Evacuation) capability, and specialist HCID treatment centres, including for airborne HCIDs such as SARS and MERS, and contact High Level Isolation Units for diseases such as viral haemorrhagic fevers. These HCID facilities provide care to patients with HCIDs and offer a limited number of specialist high-level isolation beds. These facilities also provide medicines and post-exposure prophylaxis where relevant and have staff trained to use the specialist equipment required for an HCID response. Should these facilities face increased demand, the UK has surge facilities for additional capacity a further two hospitals across the country. After that, they would expand out to a wider network of specialist infectious disease units. The UK's domestic MEDEVAC plans can call upon commercial providers and where necessary military assistance from the Ministry of Defence (MoD) to transfer patients both from overseas to the UK, and within the UK. The UK's MEDEVAC capability is supported by specialist NHS Hazardous Area Response Teams (HART), which provide high containment patient transfer capabilities for HCIDs and other threats.
94. Across the government, a programme of work was established which prepared for the potential disruption a 'no deal' EU Exit could cause. This was known as Operation Yellowhammer. As part of Operation Yellowhammer, DHSC established the National Supply Disruption Response (NSDR) in March 2019. The NSDR responds to supply disruptions for medicines and medical products. It coordinates between suppliers, health services, adult social care organisations, and central government across the UK and the Crown Dependencies. It does this to coordinate and manage actions to address supply incidents that might have occurred after the end of the EU Exit

transition period. The impact of EU Exit is covered in more detail in paragraphs 405-416.

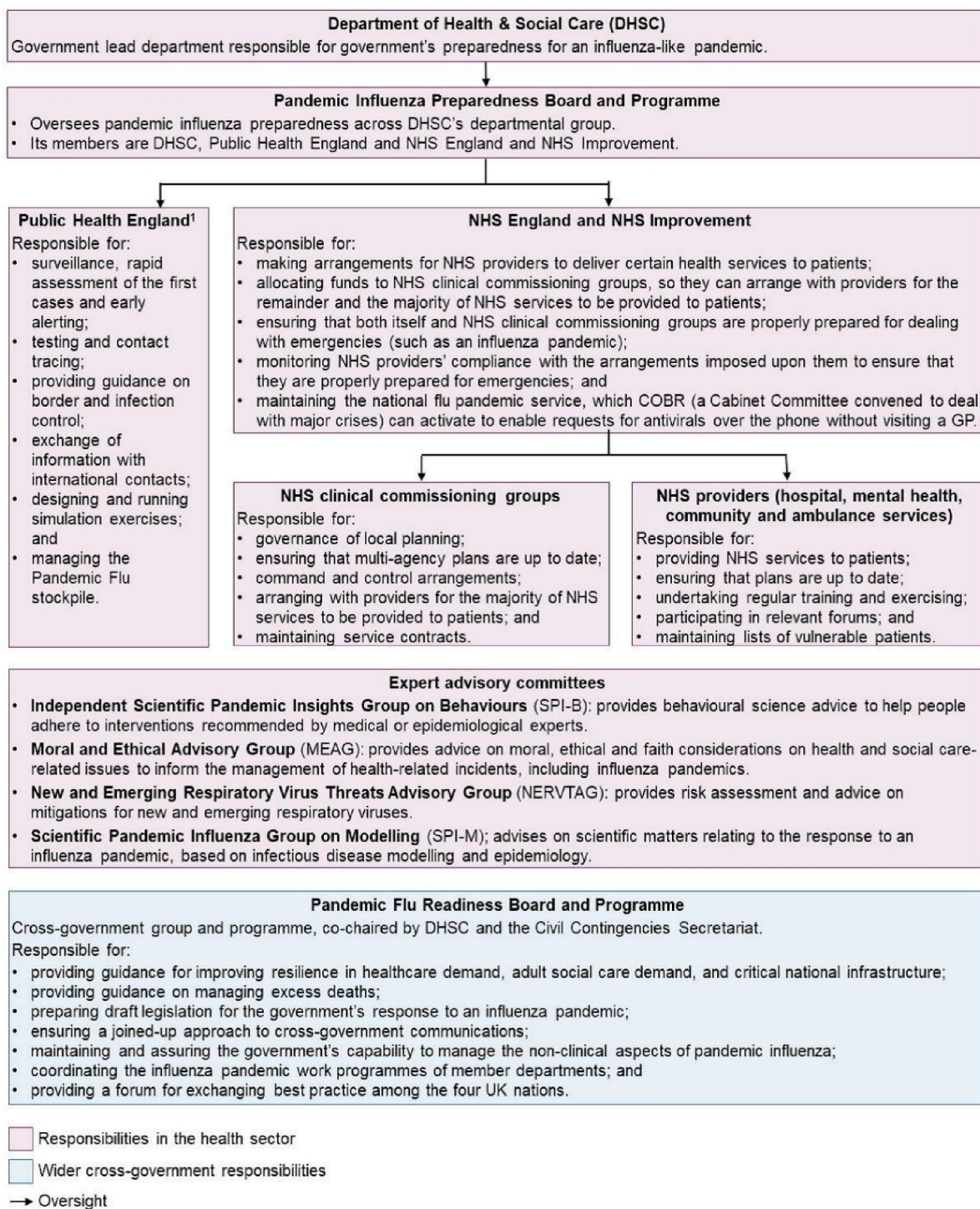
95. As a result of Operation Yellowhammer activity, response capabilities have been enhanced to improve operational practices. We have developed a UK-wide approach to emergency planning that supports mutual aid; developed coordination functions linking the NHS and wider healthcare system to wider government functions through DHSC; and incident management systems based on the concept of subsidiarity with any response being managed at the most appropriate level of the healthcare system. We continue to engage the health system to test the robustness of communications in the event that an incident occurs and to use exercises to both test capabilities and train staff.
96. In addition to responding to emergency incidents as they occur, this function also leads on policy and planning for specific risks, including both known and anticipated risks as set out in the NRR. This has included the 2012 Olympics, the 2022 Commonwealth Games, and Operation Bridges for the demise of a senior member of the Royal Family. Included as one of the risks the Department has been preparing for several years is an influenza pandemic. This is because it has been the highest risk on the NRR and the National Security Risk Assessment (NSRA) since 2008 and remains the threat with the highest impact (due to its sensitivity, CO will provide a comprehensive set of documents on the NSRA). In addition, the capabilities developed for an influenza pandemic are often the most transferable for use in response to other pandemics, should that be required (see Section 1). DHSC is the Lead Government Department (LGD) for the pandemic risk as described in the NRR and the NSRA. Further details of the pandemic and pandemic influenza planning are set out in Section 3.
97. An EPRR Partnership Group, chaired by the Director General for Global Health, with EPRR Directors from DH, NHSEI and PHE, was established in February 2013 and met quarterly until September 2018. The Partnership Board oversaw EPRR working arrangements at a national, strategic level, between DH, PHE, and NHSE, described as the 'Partnership Organisations'. In September 2018, the Partnership Group was replaced by an Operational Response Board to include oversight of 'no deal' preparedness plans for EU Exit, working with the EU Exit Assurance Board which had been established to oversee all EU Exit activity. More details on the governance for the specific pandemic influenza risk are set out in Section 3.
98. In the event of a major incident, CO may call a COBR meeting. COBR meetings are coordinated by the CO and can be chaired by the Prime Minister, any Secretary of State, or another minister. This meeting provides cross-government co-ordination

and decision making in the event of major or catastrophic emergencies, including natural disasters, terrorist attacks and major industrial accidents or disruption. COBR's purpose is to keep ministers apprised of the situation, to ensure that the wider response of the government is coordinated, to record and disseminate key decisions and updates to all relevant ministers and officials, and to provide ministers and the Prime Minister with up-to-date information on the situation for any decisions that they may need to make.

99. DHSC brought its existing EPRR function into the newly formed Operational Response Centre (ORC) in January 2019. The ORC covered all emergency response across DHSC's responsibilities, including 'no-deal' EU Exit, and infectious disease responses. ORC included enhanced capabilities, such as a system of shift-working on a rota basis and enhanced training for a wider range of emergency responders.

Pandemic preparedness

100. The main roles and responsibilities for pandemics (based on an influenza pandemic) was helpfully covered in the National Audit Office (NAO) report, 'The government's preparedness for the COVID-19 pandemic: lessons for government on risk management' (November 2021) (**CW/13**). This is demonstrated in the figure below, taken from the report.



101. DHSC is the LGD for pandemic preparedness, response and recovery, working with others in areas of their responsibility (CW/14).

102. The Pandemic Influenza Preparedness Programme (PIPP) was the central DHSC-led programme of activity for managing pandemic preparedness. More on this is in this section (paras 104-105) and in Section 3.

103. The Pandemic Flu Readiness Board (PFRB) was the cross-government group on management of pandemic preparedness activity. More on this is in this section (paras 179-182) and in Section 3.

Pandemic Influenza Preparedness Programme and Board

104. PIPP is the DHSC led programme for the health and social care system's planning and preparedness for any potential future influenza pandemic in England. The programme is governed by a programme board, the PIPP Board, which met for the first time in October 2007. The Board is currently chaired by the DG for Global Health and Health Protection. The Board is attended by representatives from NHSE, UKHSA, DHSC and the CO. The Board is responsible for setting the strategic aims and objectives of the programme and for coordinating the work of stakeholder organisations to meet these objectives. The Terms of Reference for PIPP are exhibited at (CW/15). The papers and minutes from the Board are exhibited at (CW/16) to (CW/63).

105. The PIPP Board has responsibility for delivery of the entirety of PIPP's work, including those areas where operational delivery was delegated to delivery partners such as NHSE and UKHSA. More details on the work of PIPP can be found in Section 3.

United Kingdom Health Security Agency

106. UKHSA officially operationalised in October 2021, replacing the health protection responsibilities of PHE. It is an executive agency of DHSC with operational autonomy. UKHSA is our permanent standing capacity to prepare for, prevent and respond to threats to health. Its responsibilities are for England, across the UK on reserved health matters, and in partnership with lead agencies in Scotland, Wales and Northern Ireland on devolved issues where relevant.

107. It provides national leadership on health security and health protection, and ensures a cohesive response across public health functions. UKHSA embeds effective clinical, scientific and operational functions in the public health system. I will say more on UKHSA and its predecessors in Section 4.

NHS England

108. NHSE leads and oversees the NHS. It is accountable to the Secretary of State and holds local commissioning organisations (Integrated Care Boards (ICBs) under the Health and Care Act 2022) and NHS providers, such as hospitals and trusts, to account. NHSE is an executive non-departmental public body of DHSC. It took on its statutory responsibilities on 1 April 2013. NHSE operationally merged with NHSI in

2018. NHSE is responsible for allocating budgets to ICBs (and formerly Clinical Commissioning Groups (CCGs), as discussed below at paragraph 111), holding them to account, as well as leading on commissioning specialised services and primary care. With the merger with NHSI under the Health and Care Act 2022, the organisation also became responsible for overseeing and holding NHS providers to account.

109. In the context of pandemic preparedness, NHSE's responsibilities included:
 - a. Making arrangements for NHS providers to deliver certain health services to patients
 - b. Allocating funds to NHS CCGs, so they can arrange with providers for the remainder and the majority of NHS services to be provided to patients
 - c. Ensuring that both itself and NHS CCGs are properly prepared for dealing with emergencies (including a pandemic)
 - d. Monitoring NHS providers' compliance with the arrangements imposed upon them to ensure that they are properly prepared for emergencies
 - e. Maintaining the National Pandemic Flu Service (NPFS), which COBR can activate to enable requests for antivirals over the phone without visiting a General Practitioner (GP).
110. Between 2009 and 2020, the Chief Executives of NHSE and its predecessor functions were Sir David Nicholson (2006-2014), and Sir Simon Stevens (2014-2021).

Clinical Commissioning Groups (CCGs)

111. NHS Clinical Commissioning Groups were clinically-led statutory NHS bodies responsible for the planning and commissioning of healthcare services for their local area. They were created following the Health and Social Care Act 2012 (HSCA 2012), and replaced Primary Care Trusts on 1 April 2013.
112. In the context of pandemic preparedness, they were responsible for:
 - a. Governance of local planning
 - b. Ensuring that multi-agency plans are up to date
 - c. Command and control arrangements
 - d. Arranging with providers for the majority of NHS services to be provided to patients
 - e. Maintaining service contracts

NHS providers

113. NHS providers (hospital, mental health, community and ambulance services) are responsible for:

- a. Providing NHS services to patients
- b. Ensuring that plans are up to date
- c. Undertaking regular training and exercising
- d. Participating in relevant forums
- e. Maintaining lists of vulnerable patients

The Medicines & Healthcare products Regulatory Agency (MHRA)

114. The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. It is an executive agency of DHSC.

115. The MHRA is responsible for:

- a. Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy
- b. Ensuring that the supply chain for medicines, medical devices and blood components is safe and secure
- c. Promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines
- d. Helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use
- e. Supporting innovation and research and development that's beneficial to public health
- f. Influencing UK, EU and international regulatory frameworks so that they are risk-proportionate and effective at protecting public health.

National Institute for Health Research (NIHR)

116. The NIHR is a part of DHSC. It is one of the nation's major funders of health and care research. Its mission is to improve the health and wealth of the nation through research. DHSC commissions independent research through the NIHR. The Science, Research and Evidence (SRE) Directorate senior management team provides executive leadership for the NIHR within DHSC. The DHSC CSA is the Chief Executive Officer (and until 2021 Head) of the NIHR.

117. The NIHR was established in 2006. Its remit was to "create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public".

118. Since that time, the NIHR has transformed research in and for the NHS and helped to shape the health research landscape more broadly, for example in public health and social care.

119. The NIHR is primarily funded by DHSC and as a research system it:
 - a. Funds, supports and delivers high quality research
 - b. Engages and involves patients, carers and the public
 - c. Attracts, trains and supports researchers
 - d. Invests in the healthcare infrastructure and workforce
 - e. Partners with other public funders, charities and industry
 - f. Funds applied global health research and training
120. More information about NIHR's work is at paragraphs 276-285 in Section 3.

Expert Groups

121. The Department received advice from a variety of scientific groups. These included groups that advised the department on a range of health-threats, and groups to advise specifically on pandemic influenza. I set these out below. The New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) is the primary expert advisory committee advising the Department on new and emerging respiratory viral pathogens. NERVTAG is one of several departmental expert advisory committees that advise policy officials on different aspects of infectious diseases and other threats. These include: the Advisory Committee on Dangerous Pathogens (ACDP), the Advisory Committee on the Safety of Blood, Tissues, and Organs (SaBTO), the Advisory Committee on Antimicrobial Prescribing, Resistance, and Healthcare Associated Infections (APRHAI), and the Joint Committee on Vaccines and Immunisations (JCVI). Of most relevance to the NRR pandemic and emerging infectious disease risks are NERVTAG, ACDP, and JCVI.

New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG)

122. NERVTAG, a Scientific Advisory Committee with an independent Chair, was established in 2014. Its first meeting was held on 19 December 2014. Prior to this the independently chaired National Expert Panel on New and Emerging Infections (NEPNEI) and ACDP covered aspects of emerging respiratory infection threats. ACDP continues in its role (more below).
123. The National Expert Panel on New and Emerging Infections (NEPNEI) was established in November 2003, meeting twice per year until November 2008 **(CW/64)**. Its purpose was to provide independent expert advice to the CMO on the public health risk from new and emerging infections. Between 2008 and 2014, SPI provided similar advice (see paragraphs 144-147).
124. Following the experience of the 2009 Swine Flu pandemic and the threats posed by other respiratory viruses including the outbreak of MERS in 2012, SPI (more on this group below) was disbanded in 2014 and a new threat-agnostic committee,

NERVTAG was created holding its first meeting on 19 December 2014. NERVTAG continues to provide scientific risk assessments and advice over a wide range of subjects relevant to the threats posed by new and emerging respiratory viruses. The role of NERVTAG is to advise the CMO (and, through the CMO, ministers, DHSC and OGDs) by providing scientific risk assessment and mitigation advice on the threat posed by new and emerging respiratory virus threats and options for their management.

125. On its establishment, it was agreed that the group would draw on the expertise of scientists and health care professionals, including clinicians, microbiologists and public health practitioners, and colleagues in related disciplines. NERVTAG is supported by a scientific secretariat from UKHSA and is scientifically independent. The scope of NERVTAG includes new and emerging respiratory virus threats to human health including strains of influenza virus (regardless of origin), and other respiratory viruses with potential to cause epidemic or pandemic illness, or severe illness in a smaller number of cases.
126. All minutes of NERVTAG meetings from 2014 to 2020 are published online and exhibited at **(CW/65)** to **(CW/76)**.
127. In respect of the Inquiry's specific question around meetings on 13 and 21 January 2020, I consider these are better addressed as part of Module 2.
128. The current chair is Professor Sir Peter Horby (from 2018 to the present day). Professor Sir Jonathan Van Tam was the previous chair (from 2014 to 2018).

Groups advising on wider health threats:

Advisory Committee on Dangerous Pathogens (ACDP)

129. The ACDP is a DHSC scientific advisory committee with an independent chair. Its work cuts across a number of organisations, including the Health and Safety Executive (HSE), UKHSA and Defra.
130. The Committee's purpose is to provide as requested independent scientific advice to HSE, and to ministers through DHSC, Defra, and their counterparts under devolution in Scotland, Wales and Northern Ireland, on all aspects of hazards and risks to workers and others from exposure to pathogens. Also, the Committee provides these organisations and the Food Standards Agency (FSA) as requested with independent scientific risk assessment advice on transmissible spongiform encephalopathies (TSEs).
131. The current chair of ACDP is Professor Thomas Evans (2016 to present). Previous chairs have been Professor Chris Whitty (2015 to 2016), Professor George

Griffin (2004 to 2013, and again from 2014 to 2015), Professor Roland Salmon (who was interim chair in 2014).

132. The Group advises officials from across the UK. Its secretariat is provided by UKHSA.

The Human Animal Infections and Risk Surveillance (HAIRS) group

133. The HAIRS group is a multi-agency cross-government horizon scanning and risk assessment group. It aims to identify and risk assess emerging and potentially zoonotic infections which may pose a threat to UK public health. Since its establishment in early 2004, there has been a steady evolution and development of the risk assessment processes used by the group. Information on HAIRS is exhibited at (CW/77).

134. Members of the HAIRS group identify potential hazards (either zoonotic agents, syndromes, or emerging infections). These undergo an initial review whereby a brief overview of all currently available information on the identified hazard is compiled and provided to HAIRS group members to determine further actions. These include logging a hazard for awareness and ongoing monitoring, producing a risk review statement (where insufficient information is available for a formal risk assessment or a comprehensive risk assessment is not deemed necessary), or performing a formal risk assessment using existing zoonotic potential or emerging infections probability and impact algorithms, more information on this can be found in the HAIRS risk assessment process (CW/78).

135. The HAIRS group routinely reviews and updates HAIRS risk assessments and statements which are published online (CW/79).

136. The current chair of HAIRS is Name Redacted HAIRS was previously chaired by Dr Dilys Morgan from 2004 to 2019.

137. HAIRS membership span agencies across all four UK nations and the UK Crown Dependencies. Its secretariat is provided by UKHSA.

UK Zoonoses, Animal Diseases and Infections (UKZADI) Group

138. The UKZADI Group is an executive group from across the agricultural and public health departments that provides tactical and strategic oversight of zoonotic threats and incidents, by providing oversight, coordination and assurance of activity on emerging and zoonotic infectious diseases. UKZADI advises, as appropriate, the CMO and Chief Veterinary Officer (CVO), Departments of Health across the UK, Department for Agricultural and Rural Development Northern Ireland (DARDNI) and the FSA on important trends and observations which impact on animal and public health, including where necessary preventative and remedial action.

139. The role of UKZADI is also to provide a strategic overview to ensure overall co-ordination of public health action at the UK, national and local level with regard to existing and emerging zoonotic infections and trends in antimicrobial resistance.
140. The group makes recommendations to departments and agencies on current and future priorities, including co-ordination of surveillance, laboratory capabilities and response to incidents of zoonotic disease; consults with and receives advice, including risk assessments and identification of threats and other emerging issues, from expert groups and agrees what changes need to be considered in light of this information; and co-ordinates timely advice to ministers where needed and engages effectively with, and supports, cross-government high-level governance groups with an interest in public health.
141. Membership of UKZADI includes representatives from the FSA, DHSC, Defra, the Animal and Plant Health Agency (APHA), UKHSA and the Veterinary Medicines Directorate (VMD), in addition to at least two representatives from each of Scotland, Wales and Northern Ireland covering public health and veterinary health.
142. UKZADI is co-chaired by relevant Deputy Directors from DHSC, Defra, and the FSA, who take turns to chair the group. The current chair is the DHSC Deputy Director for Health Protection and Health Security.
143. UKZADI advises all four UK nations.

Influenza specific groups

Scientific Advisory Group (SAG)/ Scientific Pandemic Influenza Advisory Committee (SPI)

144. In 2005, as part of the UK's pandemic influenza preparation, DH established a Scientific Advisory Group (SAG) on Pandemic Influenza, to advise on the scientific evidence base for health-related pandemic influenza policies. The Scientific Pandemic Influenza Advisory Committee (SPI) was an enhanced group, covering a wider range of scientific disciplines, that replaced SAG in 2008 **(CW/80)**.
145. NERVTAG replaced the former SPI and extended the role, to cover not only pandemic influenza, but any new, emerging (or re-emerging) respiratory virus threat to the UK.
146. The modelling subgroup of the SAG on Pandemic Influenza first met in September 2005 (see **(CW/80)** above). This was the predecessor of Scientific Pandemic Infections Group on Modelling (SPI-M).
147. SAG was chaired by Dr David Harper. SPI was chaired by Professor Sir Gordon Duff. The remits of the groups were UK-wide.

The Scientific Pandemic Infections Group on Modelling (SPI-M)

148. Up to 2022, this group was called the Scientific Pandemic Influenza Group on Modelling (SPI-M). I have set out more information below on its name change, and change of remit.
149. SPI-M provides expert advice to DHSC and wider UK Government on scientific matters relating to the UK's response to a pandemic. The group may also provide advice on other emerging human infectious disease threats as required.
150. In non-emergency periods, SPI-M provides expert advice to DHSC and the wider UK Government based on infectious disease analysis, modelling and epidemiology. DHSC has sponsorship of SPI-M and determines its programme of work **(CW/81)**.
151. Advice provided by SPI-M represents a consensus view of the group, with the co-chairs responsible for reporting the scientific advice to DHSC and ensuring the scientific integrity of the group's discussion and outputs. SPI-M participants are typically drawn from the academic community and public health agencies, and contribute as experts in the field of epidemiological modelling and statistics, with relevant experience to contribute to the consensus position of the committee.
152. Prior to the COVID-19 pandemic, the work of the committee focused on pandemic influenza and included **(CW/82)**:
- a. Reviewing the available modelling evidence, and where appropriate the implications for policy.
 - b. Advising on the possible progression and severity of a future pandemic.
 - c. Providing expert challenge to epidemiological models informing procurements or those which might be used to respond to a future pandemic.
153. Further information on advice from SPI-M is given in Section 3.
154. SPI-M does not provide advice on endemic infectious diseases, such as seasonal influenza, or vaccination. Analysis of endemic diseases is led by UKHSA. Advice on the effectiveness, safety and deployment of vaccines is provided by the JCVI.
155. While SPI-M previously focused on pandemic influenza, it was formally agreed in 2018 that the group may provide advice on other areas of infectious disease modelling and epidemiology where appropriate (as detailed at **(CW/82)** above). This was later reflected in a formal revision of the group's name. The change in remit reflected operation of the group in practice, given formation of an "Ebola modelling group" which drew on the SPI-M membership and secretariat to support the government's response to the West African Ebola outbreak in 2014-2016. More on this can be found in Section 3.

156. Typically, SPI-M met three times a year. The last meeting of SPI-M prior to the COVID-19 pandemic was in July 2019.
157. During an emergency, the Scientific Pandemic Infections Group on Modelling, Operational sub-group (SPI-M-O) may be stood up to support the government's response. SPI-M-O is a separate group to SPI-M. Participants may be partly or mostly drawn from SPI-M, but with additional contributors to reflect the specific emergency and expertise required.
158. The current chairs of SPI-M are Professor Graham Medley (academic chair; 2017 onwards) and Dr Thomas Waite (executive chair; 2022). Previous chairs include Peter Grove (2005 – 2017) and Paul Allen (2017-2020) from DHSC.
159. SPI-M advises the UK Government. The secretariat for both SPI-M and SPI-M-O is provided by DHSC.

Scientific Pandemic Insights Group on Behaviours (SPI-B)

160. The Scientific Pandemic Insights Group on Behaviours (SPI-B) provides behavioural science advice aimed at anticipating and helping people adhere to interventions that are recommended by medical or epidemiological experts.
161. SPI-B advises the Scientific Advisory Group on Emergencies (SAGE). More on SAGE can be found below.
162. SPI-B for COVID-19 was stood up in February 2020. The chairs for this are therefore out of scope of Module 1.

The Moral and Ethical Advisory Group (MEAG)

163. MEAG was set up in October 2019 as a successor to the Committee for Ethical Aspects of Pandemic Influenza (CEAPI) to provide advice to policy teams. Its establishment followed the recommendations of Exercise Cygnus (2016), which found that the public reaction to a reasonable worst case pandemic influenza scenario needed to be better understood. MEAG is a group of experts and advisers who advise government on moral, ethical and faith considerations to support the development of policies and response plans both in advance of, and during, a pandemic.
164. The current chairs of MEAG are Professor Sir Jonathan Montgomery and Jasvir Singh.
165. MEAG advises the UK Government. Its secretariat is provided by DHSC.

Other groups to note:

Joint Committee on Vaccination and Immunisation (JCVI)

166. The JCVI's role is to advise UK health departments on immunisations for the prevention of infections and/or disease following due consideration of the evidence

on the burden of disease, on vaccine safety and efficacy and on the impact and cost effectiveness of immunisation strategies. It considers and identifies factors for the successful and effective implementation of immunisation strategies and identifies knowledge gaps relating to immunisations or immunisation programmes where further research and/or surveillance should be considered.

167. The JCVI is an independent Departmental Expert Committee (DEC). The JCVI is sponsored by the Routine Vaccines and Immunisations Team in DHSC and its secretariat is provided by UKHSA.
168. The JCVI provides advice and recommendations for all UK health departments based on consideration of scientific and other evidence.
169. JCVI recommendations are presented to the Secretary of State who, if a number of requirements are met, is, in accordance with the Health Protection (Vaccination) Regulations 2009, legally bound to implement those recommendations “so far as is reasonably practicable”. These requirements include that the JCVI recommendation “must be based on an assessment which demonstrates cost-effectiveness”.
170. For a number of reasons, including where no cost effectiveness analysis has been undertaken, the JCVI will publish advice, which the Secretary of State is not legally bound to implement.
171. The current chair of the JCVI is Professor Sir Andrew Pollard (2013-present). JCVI was previously chaired by Professor Sir Andrew Hall (2006-2013). A specific sub-group for COVID-19 was set up, chaired by Professor Wei Shen Lim. Professor Sir Andrew Pollard recused himself from this group due to a potential conflict of interest as a result of Professor Pollard’s role as Director of the Oxford Vaccine Group, which was developing a COVID-19 vaccine.
172. JCVI provides advice to all four UK nations. Its secretariat is provided by UKHSA.

Scientific Advisory Group on Emergencies (SAGE)

173. SAGE is responsible for providing COBR meetings with coherent, coordinated advice and to interpret complex or uncertain scientific evidence in non-technical language. Typically, SAGE meets in advance of COBR and the Government Chief Scientific Adviser (GCSA), who chairs it, subsequently represents SAGE at COBR. Where the issue is principally a health emergency, the CMO co-chairs SAGE. SAGE provides COBR with science advice at the UK level.
174. The secretariat for the Group is usually provided by CO or the GO-Science, but other departments may provide a secretariat if there is a clear Lead Government Department.

175. COVID-19 is not the first time SAGE has been activated - there have been eight previous emergencies, since its conception, when the government has sought expert scientific advice through the SAGE mechanism. Expert participants at SAGE are determined by the scientific expertise needed in that particular situation.
176. SAGE was last activated in response to the potential breach of Toddbrook Reservoir in Whaley Bridge in August 2019. A precautionary SAGE (known as Pre-SAGE) was activated to advise on the Zika virus outbreak in 2016. In 2015, SAGE was activated to advise on the Nepal earthquake, and in 2014 it was called in response to the Ebola outbreak in West Africa. It was also activated during the nerve-agent poisonings in Salisbury. SAGE also advised on winter flooding in the UK in 2013, the Japan nuclear incident in 2011, the volcanic ash emergency in 2010 and the Swine Flu pandemic in 2009.

DHSC engagement across government

Pandemic Flu Readiness Board (PFRB)

177. The PFRB was the cross-government group for pandemic preparedness. It was established following Exercise Cygnus (more on this in Section 3). CO and DHSC co-chaired PFRB meetings at Director level between 2017 and 2020.
178. The core-members of PFRB were: DHSC (co-chair); CO (co-chair); Home Office (HO); HMT; Ministry of Justice (MoJ); Ministry of Housing, Communities and Local Government (MHCLG); Department for Transport (DfT); MoD; Department for Business, Energy and Industrial Strategy (BEIS); Defra; His Majesty's Revenue and Customs (HMRC); Department for Digital, Culture, Media and Sport (DCMS); DfE; Foreign and Commonwealth Office (FCO); Department for International Development (DfID); Department for Work and Pensions (DWP).
179. In 2021, PFRB was replaced by the Pandemic Diseases Capability Board (PDCB). The PFRB Terms of Reference can be found at **(CW/83)**. The papers and minutes are exhibited at **(CW/84)** to **(CW/343)**.
180. There is more information on the work of the PFRB in Section 3.

Engagement with OGDs

181. DHSC works closely with multiple government departments on pandemic preparedness, mostly through the PFRB.
182. The Inquiry has requested detail on how DHSC worked with CO, DLUHC and the GO-Science, which I have set out below.
183. Alongside the leadership of PFRB, the Department worked closely with the CO (including the Civil Contingencies Secretariat (CCS), sitting within the National Security Secretariat (NSS)). The Department frequently engaged with the CO on

pandemic preparedness as part of wider emergency preparedness activity. DHSC supported the NSS in developing planning assumptions for the NRR, in reference to the risk of pandemic influenza.

184. DHSC and DLUHC work closely together on a number of policy areas, one of which being emergency and pandemic preparedness. We engage frequently on social care as well, given the role of LAs in this area. DLUHC are stewards for local government and support local emergency responders, such as Local Resilience Forums (LRFs), to deliver their duties under the CCA.
185. DHSC works with OGDs. This includes DLUHC and by extension local government who are responsible for the local planning and response to health related emergencies. For that reason, DHSC has worked with DLUHC's Resilience and Emergencies Department and their Resilience Advisors to engage with LRF Chiefs as and when necessary, on key risks and to discuss local and national mitigation strategies related to health and social care. The NHS also work closely with LRFs at the regional and national level, with NHS Trust representatives forming part of LRF membership.
186. Additionally, DLUHC was a member of the PFRB. One of the workstreams of the PFRB was for DHSC and DLUHC to collaborate on engagement with Local Government, to ensure robust pandemic influenza planning. This included supporting on advice on best practice, through the development of a National Resilience Standard (**CW/344**). DHSC and DLUHC worked together to engage the LRFs, who led on local preparedness planning and emergency response.
187. GO-Science is part of BEIS and advises the Prime Minister and members of the Cabinet, to ensure that Government policies and decisions are informed by the best scientific evidence and strategic long-term thinking. GO-Science is led by GCSA and supports SAGE, which provides scientific and technical advice to support government decision makers during emergencies (see paragraph 173 above).
188. As mentioned above, as part of cross-government engagement, on 15 September 2018, the CMO and I gave a presentation to Permanent Secretaries from OGDs on pandemic preparedness. This presentation is exhibited at (**CW/345**).

Devolved Governments

189. DHSC and the Devolved Governments worked together closely on pandemic preparedness. The Devolved Governments have responsibilities for pandemic response in their own territories, while emergency response is a reserved power. The Cabinet Office's Concept of Operations (CONOPS) (**CW/346**), makes clear that the Devolved Governments were to be briefed on any emergencies being led on by a UK Government Department. The Devolved Governments, and the respective

public health agencies, were crucial partners in development of policy and sat on the key governance boards, as discussed below. Below are some examples of UK-wide collaboration on pandemic preparedness.

190. The 2011 UK Influenza Pandemic Strategy (**CW/3**) was a UK-wide document, which was published by the Devolved Governments as well as the UK Government.
191. In 2016, the Devolved Governments were core participants in Exercise Cygnus (details of this Exercise are given in more detail later in Section 3). Over 950 representatives attended, including representatives from the health departments of Scotland, Wales and Northern Ireland, and NHS Wales.
192. The Devolved Governments were also involved or addressed in the following exercises (more detail about these can be found in Section 3):
 - a. January 2013 - Exercise POSE UK
 - b. December 2014 - Ebola 4 Nations Ebola Preparedness Exercise
 - c. March 2015 - Ebola Surge Capacity
 - d. February 2016 - Exercise Alice
 - e. September 2016 - Exercise Leopold
 - f. October 2016 - Exercise Cygnus
 - g. December 2016 - Exercise Theodor
 - h. October 2017 - PHE & APHA workshop
 - i. February 2018 – Exercise Cerberus
 - j. September 2019 - Exercise Tiamat
193. The Devolved Governments sat on the PFRB and were key partners in developing the draft Pandemic Influenza (Emergency) Bill (the draft Pandemic Flu Bill) (**CW/347**), which was the starting point for the Coronavirus Act 2020.

Common Framework on Public Health Protection and Health Security

194. Following the UK's decision to leave the EU in June 2016, the UK and the Devolved Governments worked together to agree a Common Framework on Public Health Protection and Health Security. The Framework is exhibited at (**CW/348**). This was to aid continuity and cooperation to avoid potentially harmful divergence in critical areas that are devolved but were previously regulated and managed at the EU level while the UK was a Member State.
195. The Common Framework on Public Health Protection and Health Security has been jointly developed and agreed in draft between:
 - a. The UK Government
 - b. The Welsh Government
 - c. The Scottish Government
 - d. The Northern Ireland Executive

e. Each of the UK's national public health agencies

196. It provides a formal basis and governance structure for collaboration between all parts of the UK on health security and health protection policy. It supports cooperation on issues which require UK-wide approaches, as well as on devolved issues where the sharing of knowledge and expertise is beneficial.

Regional and local governments

197. Prior to 2011, Regional Resilience Teams in the Government Offices for the Regions were responsible for planning and responding to civil emergencies in England. The Department of Communities and Local Government (DCLG) acted as their sponsor organisation. The core purposes of the Regional Resilience Teams were to improve co-ordination and the flow of information across and between regions, and between local areas and central government, in preparation for potential emergencies, and to support emergency responses and subsequent recovery efforts as necessary.

198. Following the closure of the Government Offices in 2010, the resilience and emergency function held by the Regional Resilience Teams was transferred to DCLG. DHSC supports, where relevant, in the planning and preparation for a pandemic or other health-related emergency. Local level preparations for pandemics and other emergencies are overseen by LRFs where representatives from LAs and the NHS, as well as agencies responsible for adult social care, are present. National resilience standards to inform LRF planning, including for pandemic influenza, are published on GOV.UK by the CO. These are exhibited at **(CW/349)**.

199. LRFs are multi-agency partnerships made up of representatives from local public services, including the emergency services, LAs, the NHS, the Environment Agency (EA) and others. These agencies are known as Category 1 Responders, as referred to in the CCA.

200. The PIPP Board had membership from DCLG and its successor, MHCLG. Local partners including the Local Government Association (LGA) and the Directors of Adult Social Services were also invited to attend.

201. Exercises at both the national and local level formed an essential element of developing capabilities and competences and assuring our preparedness levels.

202. Following Exercise Cygnus, in January 2017 LRFs and stakeholders in the voluntary sector were consulted on the development of guidance for the health and social care sector in England for pandemic preparedness exhibited at **(CW/350)**.

Business, Industry and Unions

203. Whilst DHSC is the Lead Government Department for pandemic preparedness, relevant government departments are responsible for preparedness arrangements within their own sectors and BEIS was the principal lead for the relationship between UK Government and industry.

Voluntary, community and social enterprise

204. Voluntary organisations were engaged as part of the development of the 2011 UK Influenza Pandemic Preparedness Strategy (CW/3) which set the strategic context for planning for an influenza pandemic across wider society. Planning was at local level involving LRFs.

205. Voluntary partners were invited to exercises which simulated response at a local, regional and UK-wide level. This helped input in our planning scenarios. As a result of Exercise Cygnus, recommendations were made that DHSC, NHSE, the Crown Commercial Service and the voluntary sector and relevant authorities in the Devolved Governments should work together to propose a method for mapping the capacity of and providing strategic national direction to voluntary resources during a pandemic.

206. They were similarly engaged in the Pandemic Influenza Communications Strategy (CW/351), as stakeholders.

International partners

The World Health Organisation (WHO)

207. As a member state, the UK attends and participates in the Governing Body Meetings of the WHO at both global and regional levels. DHSC leads the government's relationship with the WHO, working closely with the Foreign, Commonwealth and Development Office (FCDO).

208. At the global level, the UK is an active participant at the Executive Board and World Health Assembly, including prior to and during the pandemic. The UK delegation to the World Health Assembly includes DHSC ministers, and officials from both DHSC and FCDO.

209. In May 2020 the UK began a three-year term as a member of the WHO Executive Board, with Professor Sir Chris Whitty as Board Member. WHO Executive Board meetings are open to attendance by all Member States, including those which are not on the Board. Prior UK terms on the Executive Board within the timeframe covered by this request are:

- a. May 2007 - May 2010
- b. May 2014 - May 2017

c. May 2020 - May 2023

210. The UK is also currently on the Programme Budget and Administration Committee (PBAC), a sub-committee of the WHO Executive Board, with our period on the Committee running from 2021 to 2023. The UK had one additional term on PBAC during the requested timeframe from May 2014 to May 2016.
211. DHSC represents the UK at meetings of the WHO European Region, including the Regional Committee which normally meets annually in September. The UK currently has a seat on the Standing Committee of the Regional Committee (SCRC); our period on the Committee runs from September 2020-2023. The SCRC meets several times a year and meetings are usually open to all WHO European Member States. The UK had one additional term on the SCRC within the requested timeframe – September 2010 to September 2013.
212. DHSC attends the Regional Committee for the Region of the Americas, where we hold Participating Member State status reflecting our Overseas Territories in the region.
213. The timings, agendas, and papers for WHO meetings at both global and the regional level can be found on the organisation's websites.
214. Senior UK public health officials and clinicians have multiple bilateral and multilateral relationships of an informal nature in addition to formal structures.

Global Health Security Initiative (GHSI)

215. The GHSI is an informal network of countries and organisations that came together to exchange information and coordinate practices within the health sector for confronting new threats and risks to global health. The UK has been a member of the GHSI since 2001, after it was established following the 9/11 attacks. Delegations of the GHSI include Canada, the French Republic (France), the Federal Republic of Germany (Germany), the Republic of Italy (Italy), Japan, the United Mexican States (Mexico), the UK, the United States of America (the United States or USA), and the European Commission. The WHO serves as an observer. Clara Swinson, DG Global Health and Health Protection, currently co-chairs the GHSI.
216. The focus of GHSI extends across the breadth of Chemical, Biological, and Radio-Nuclear (CBRN) threats and hazards and includes a specific Working Group on Respiratory Viral Pandemic Threats. This working group was co-chaired by the UK's DCMO, Professor Sir Jonathan Van-Tam from 2017 to 2022.

Global Health Security

217. The UK is committed to strengthening the global health and health security (GHS) system to be better prepared for future pandemics and to tackle long standing

global health threats. A critical part of this is tackling the threat of antimicrobial resistance (AMR), where the UK's National Action Plan (**CW/352**), sets our comprehensive action across all sectors domestically and internationally.

218. Following the West African Ebola outbreak, DHSC established the Global Health Security programme in 2016 (previously referred to as the Ross Fund, a joint programme with DFID) (**CW/353**), drawing on UK public health and research expertise, to target Official Development Aid (ODA) investments and technical assistance to support low and middle income countries (LMICs) to be better prepared for health threats, including infectious disease outbreaks and AMR.
219. Since the 2015 spending review, DHSC has committed over £315 million on ODA, investing in surveillance systems and research and development to reduce the threat of AMR in LMICs (**CW/354**).
220. The UK delivers a number of ODA-funded projects to enhance global efforts to better prepare for and respond to health emergencies. DHSC's GHS ODA portfolio includes:
 - a. International Health Regulations Strengthening Project: Delivered by UKHSA, provides peer-to-peer technical expertise to support priority partner countries and regional organisations (e.g. Africa Centres for Disease Control and Prevention) to improve their compliance with the International Health Regulations (2005) (IHR) and strengthen global health security. If countries are unable to appropriately detect, report and respond to health threats as required under the IHR, it puts them at greater risk from the threat of outbreaks of infectious diseases and other health emergencies and has implications on a global scale.
 - b. UK Public Health Rapid Support Team (UK-PHRST): Works to address the threat posed by outbreaks of infectious disease within ODA-eligible countries through an integrated triple remit incorporating outbreak response, research to inform epidemic preparedness and response, and capacity building to help improve preparedness and response within LMICs. The team was established in response to the West Africa Ebola outbreak.
 - c. UK Vaccine Network (UKVN) Project: The UKVN invests in early-stage clinical development of vaccines and vaccine technologies to address the market's failure to develop vaccines against diseases of epidemic potential affecting LMICs (including MERS as well as 'Disease X'). The UKVN was established in June 2015 in the wake of the West African Ebola outbreak (2014 to 2016). Since its inception, the UKVN funded research into vaccine

development against emerging epidemic threats. This was pivoted to COVID-19 and enabled the rapid development of the Oxford/AstraZeneca COVID-19 vaccine. The UKVN is chaired by Professor Sir Chris Whitty. This is covered in more detail in Section 3.

- d. The UKVN also contributes funding to the Coalition for Epidemic Preparedness Innovations (CEPI) an alliance to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics.
 - e. Fleming Fund (FF): An up to £265 million fund that has invested in building AMR laboratory capacity and disease surveillance systems with a focus on AMR in over 24 countries across Africa and Asia. FF investments in biosafety, biosecurity and whole genome sequencing which supported the global response to COVID-19.
 - f. Global Antimicrobial Resistance Innovation Fund (GAMRIF): A ~£50 million fund investing in neglected areas of early-stage, innovative AMR Research & Development (R&D) for the benefit of people in LMICs. It supports research with the potential to lead to tangible innovations such as vaccines, therapeutics and diagnostics that will help to prevent, detect and/or treat drug-resistant infections in resource-poor settings. GAMRIF has supported 86 projects across nine new research partnerships and signed two bilateral Memorandum of Understandings (MOUs).
221. The UK has actively participated in discussions around strengthening health systems at G7 and G20 fora. In recent years, the UK has attended the following events focusing specifically on health emergency planning:
- a. 2017: A simulation exercise conducted by the German G20 Presidency.
 - b. 2018: A simulation exercise on AMR held by the Argentinian G20 Presidency, partially organised by the UK.
 - c. 2018: Hosted the GHSI in London (**CW/355**) to discuss emerging health security events, and to explore joint actions across sectors to protect populations, and strengthen health security globally. 2018 was the 100th anniversary of the start of the Spanish 'Flu pandemic.
 - d. 2019: A session on 'disaster risk reduction' conducted by the Japanese G20 Presidency.

The European Commission

222. As a member of the EU, the UK attended European Commission-chaired Health Security Committee meetings. The EU Health Security Committee was set up in 2001 at the request of EU Health Ministers as an informal advisory group on health

security at European level. In 2013, Decision 1082/2013/EU formalised and strengthened its role. The Committee is mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities. Member States also consult each other within the Committee with a view to coordinating national responses to serious cross border threats to health, including events declared a PHEIC by the WHO in accordance with the IHR. The Committee further deliberates on communication messages to health care professionals and the public in order to provide consistent and coherent information adapted to Member States' needs and circumstances. It is chaired by a representative of the Commission, which also provides the secretariat.

European Centre for Disease Prevention and Control

223. As a member of the EU, UK representatives sat on the Management Board of the European Centre for Disease Prevention and Control (ECDC). As an independent EU agency, ECDC reports to a Management Board whose members are nominated by the Member States, the European Parliament and the European Commission. The Management Board, as well as appointing the Director and holding them accountable for the leadership and management of ECDC, also ensures that ECDC carries out its mission and tasks in line with the founding regulation, Regulation (EC) 851/2004. The Management board approves and monitors implementation of ECDC's work programme and budget, it adopts its annual report and accounts - all in all, it acts as the governing body of ECDC. It meets at least twice a year.

SECTION 3: Planning for a pandemic

224. This section of my statement will cover DHSC's pandemic preparedness programme, its component parts and how it was governed.

225. The Department's work on pandemic preparedness comprised the following components:

- a. A dedicated permanent capability within DHSC's Director-led EPRR and Health Protection function
- b. Governance structures, primarily the Department's PIPP Board and supporting structures
- c. Cross-Government collaboration, including under the auspices of the cross-Government PFRB
- d. Pandemic preparedness programme
- e. Availability and supplies of clinical countermeasures
- f. Surveillance
- g. Scientific advice, including the role of expert advisory committees and the role of the CMO / DCMOs / CSA
- h. Investment in capabilities, including research and the role of the NIHR
- i. Operational delivery agencies (PHE/NHSE)
- j. Legislation
- k. International collaboration
- l. Incident management and exercising, including ongoing learning from both

226. The following section will describe each of these 12 components in turn to provide a comprehensive overview of the Department's work on pandemic preparedness from 2009 to the start of 2020 before going into more detail in response to specific questions asked in the Module 1 Rule 9 request.

Dedicated permanent capability within DHSC's Director-led Emergency Preparedness and Health Protection function

227. As outlined in Section 2, the Secretary of State's responsibilities as a Category 1 responder apply to all emergencies that have the potential to impact the health and social care sectors, including the public health system, the functioning of the NHS, or adult social care. For many years, the Department has maintained a dedicated EPRR function, led by the Director of Emergency Preparedness and Health Protection (EPHP) (currently Emma Reed). In December 2019, the EPHP directorate was staffed with 96 people (46 in ORC and EPRR; 28 in Global Health Security; 22 on Health Protection and Health Security). At this time, the directorate was winding

down its response to Operation Yellowhammer. By January 2020, the Directorate had transitioned to begin to respond to COVID-19, and consisted of 101 members of staff (51 in ORC and EPRR; 28 in Global Health Security; 22 in Health Security and Health Protection).

228. The EPHP directorate leads on planning and responding to all incidents where DHSC has the cross-government lead, including pandemic preparedness and emerging infectious diseases, but also coordinates the health and social care sector's response to incidents where OGDs have the lead, for example, adverse weather events, terrorist attacks, and supply chain issues. Examples of incidents that the directorate responded to include: Crimean Congo Haemorrhagic-Fever in 2012; West African Ebola Virus Disease (EVD) outbreak in 2014/16; Manchester Arena Incident in March 2017; London Bridge Attack in June 2017; Hurricane Irma and Maria September 2017; Monkeypox in 2019; the Salisbury Novichok Incident in March 2018; and the National Floods in October 2018.

229. Within the EPHP directorate is a dedicated emergency preparedness and response capability which can be stood up, as required, to lead and coordinate responses to emergencies. In addition to these emergency response teams are a number of other permanent teams which lead on policy and planning for specific risks, as mentioned in Section 2. One of these permanent teams was the pandemic preparedness team under the Deputy Director for UK Health Security, reflecting DHSC's role as Lead Government Department for the pandemic risk as described in the NRR and the NSRA.

230. This Director-led function, and the capabilities within it, have been in operation within the Department since before 2009.

Governance structures

231. DHSC is the LGD for pandemic preparedness, response and recovery, working with others in areas of their responsibility.

232. The PIPP, as mentioned in Section 2, is the DHSC-led programme of work across the health and social care sector to both prepare for and mitigate against the risk of an influenza pandemic.

233. The PIPP Board has responsibility for delivery of the entirety of PIPP's work, including those areas where operational delivery was delegated to delivery partners following the enactment of the HSCA 2012. Below the PIPP Board, both NHSE and UKHSA have their own management structures to oversee the work programme.

This includes the UKHSA chaired Clinical Countermeasures Management Board (CCMB), which DHSC attends.

234. The PIPP Board oversees the tripartite work delegated to DHSC, UKHSA and NHSE. The Board is responsible for setting the strategic aims and objectives of the programme and for coordinating the work of stakeholder organisations to meet these objectives.
235. Responsibility for some elements of the programme transferred to NHSE and PHE on 1 April 2013 following the implementation of the changes set out in the HSCA 2012.
236. In addition to the chair, the ToR from 2016 listed attendees as:
 - a. The Deputy Chief Medical Officer
 - b. Senior Civil Servants representing the Department's policy interests, including:
 - i. Director of Emergency Preparedness and Health Protection Policy
 - ii. Deputy Director, High Consequence Infectious Diseases and Immunisation
 - iii. Deputy Director, Social Care System Oversight
 - iv. Deputy Director, Commercial Medicines Unit
 - v. DHSC Principal Pharmacist
 - c. NHSE was represented by the Acting Director for Operations and Delivery, the National Lead for Emergency Preparedness Response and Resilience and their Pandemic Influenza Resilience Manager
 - d. PHE was represented by:
 - i. Director for Health Protection & Medical Director
 - ii. National Pandemic Flu Service and Infrastructure Lead
 - iii. Director, Reference Microbiology Services
 - iv. Director for Infectious Disease Epidemiology Surveillance and Control
 - v. Director, National Infection Service
 - vi. Deputy Director for Operations
 - vii. Head of Clinical Countermeasures Procurement
 - viii. Head (acting) of Respiratory Diseases Department and Head of Influenza and Other Respiratory Virus Surveillance Section
 - e. In addition to representatives from DHSC and its ALBs, CO and DCLG/MHCLG attended the Board.

f. The board also welcomed representatives from the Association of Directors of Public Health and the LGA.

237. The CCMB, a PHE-chaired Board overseeing the procurement, management, and storage of clinical countermeasures, reported into the PIPP Board. Additional time-limited governance structures may be established to oversee delivery of time-limited projects, for example, the Pandemic Specific Vaccine Project Board.

238. From December 2017 to November 2019, I was briefed on pandemic preparedness on 15 occasions, either orally or in writing. The minutes and papers from these meetings are exhibited at **(CW/356)** to **(CW/376)**. These meetings included situation and surveillance reports covering reporting of influenza and provided updates on pandemic preparedness work.

239. During the period of this statement, pandemic influenza was one of the top risks on the Department's High Level Risk Register (HLRR). This was still the case in January 2020 **(CW/377)**. Consequently, as part of its deep dives into topics on the HLRR, in September 2016 the Departmental Board reviewed the work on infectious diseases and pandemic preparedness. I chaired this meeting in the absence of the Secretary of State. The slides and briefing note from this meeting are exhibited at **(CW/378)**.

Cross-government collaboration

240. In addition to PIPP, which covers pandemic preparedness work across the health and social care sectors, DHSC and the CCS in the CO co-chaired a cross-government Pandemic Preparedness Board, called the PFRB. PFRB was established in 2017 following Exercise Cygnus (see paragraph 323) and included membership from OGDs and all Devolved Governments. Terms of reference for PFRB are exhibited at **(CW/83)**.

241. PFRB workstreams included: working across the whole of government, and with the Devolved Governments to develop draft legislation to support the response to a future influenza pandemic (the draft Pandemic Flu Bill); supporting Departments to assess and improve the resilience of their sectors to operate in a pandemic, particularly in respect to a reduced workforce; establishing a group of experts and advisers to advise government on moral, ethical and faith considerations in advance of and during a pandemic (MEAG); working with MHCLG on local engagement around pandemic flu planning including advice on best practice through the development of a Resilience Standard; and improving plans of the health and care sectors to flex systems and resources to expand beyond normal capacity levels.

242. The responsibility of the PFRB was to:
- a. Oversee the delivery of the PFRB work programme and the delivery of associated outcomes and products;
 - b. Provide an interdepartmental forum to challenge and question progress against milestones;
 - c. Coordinate the work programme of constituent departments and, as appropriate, the Devolved Governments, and to provide a forum for clarifying boundaries of departmental responsibility and manage any interdependencies between departments;
 - d. Agree arrangements for maintaining and assuring the capability to manage the non-clinical aspects of pandemic influenza; and
 - e. Where policy areas are devolved, provide a forum for exchanging best practice among the four UK administrations with a view to developing common approaches where appropriate within the UK overall constitutional arrangements.
243. By 2018, the PFRB had overseen the development of:
- a. Improved plans of the health sector to flex systems and resources to expand beyond normal capacity levels;
 - b. Clear plans to prioritise and augment adult social care and community health care during a pandemic response;
 - c. Refreshed guidance for local responders on planning for large numbers of additional deaths, underpinned by a comprehensive analysis of capability across the country;
 - d. Updated planning assumptions for workforce absence and stress-tested plans from LGDs which have responsibility for particular sectors, covering both the peak and duration of workforce absence;
 - e. Confirmed UK Government policy content for a draft Pandemic Flu Bill, to be held internally and taken through Parliament if required, to support the response to a severe pandemic.
 - f. A comprehensive UK-wide pandemic influenza health-focused communications strategy; and
 - g. Options to ensure government thinking is supported by moral and ethical advice.

Pandemic preparedness programme

244. The DHSC pandemic preparedness programme was designed both to mitigate the risk of a pandemic and prepare to respond to a pandemic should one arise. Inherent uncertainty about the timing, characteristics and severity of pandemics

mean it is not possible to forecast what the next pandemic will look like, as laid out in Section 1. Consequently, DHSC's pandemic preparedness programme was informed by the agreed Reasonable Worst Case Scenario (RWCS) as set out in the NRR (**CW/379**) and NSRA, latest scientific evidence, and lessons learned since the 2009 Swine Flu pandemic. Between 2009 and 2020, programme workstreams covered clinical countermeasures, scientific and ethical advice, excess death management, legislation, RWCS impact mitigation (surge and triage), surveillance, data, strategy and guidance, communications, and governance and assurance.

Availability and supplies of clinical countermeasures

245. A core part of the Department's pandemic preparedness programme and strategy for responding to an influenza pandemic was ensuring the UK had rapid access to clinical countermeasures that could be deployed as part of the response. Through the oversight of DHSC, the UK Government maintained a centralised stockpile of relevant products together with contracts agreed in advance for the provision of further stock, the development of a pandemic specific vaccine, or the delivery of dedicated operational functions (for example, the National Pandemic Flu Service).
246. Management of stockpiles has been the responsibility of PHE since its creation in 2013, and is now the responsibility of UKHSA.
247. The end-to-end process that resulted in a pandemic preparedness stockpile comprised the following stages:
- a. Identifying the products to be held, based on expert and scientific advice (e.g. from NERVTAG, ACDP, JCVI). For example, NERVTAG advised on the Personal Protective Equipment (PPE) product mix (**CW/380**) and the specific antivirals and antibiotics to be held to treat pandemic influenza patients.
 - b. Modelling the volumes of products to be held, based on the RWCS planning assumptions for a 15-week pandemic wave. For PPE, this was to ensure enough PPE was available for the expected influx of patients requiring assessment or treatment for influenza (and related infections). Note the requirements did not include supplies for business as usual (BAU) services as these were not part of the central stockpiling programme.
 - c. Policy advice and financial approvals, including on the balance of just-in-case (JIC) and just-in-time (JIT) contracts and funding secured through government spending reviews, led by DHSC. More detail on the economic analysis is provided below in this Section.

- d. Procurement of the product, led by PHE.
- e. Storage and management of the stockpiles, also led by PHE.

248. Decisions about volume and type of products stockpiled were derived from modelling based on the RWCS for an influenza pandemic, with a majority percentage held in centralised stockpiles on a JIC basis, with separate JIT contracts in place to provide the remainder. A larger quantity was held on a JIC basis to facilitate rapid distribution in times of need and because of potential risks to supply chains in the event of a global pandemic.

249. The Pandemic Flu CCMB met on 9 October 2019 (**CW/381**) to (**CW/383**). This was their last meeting before the COVID-19 pandemic. The CCMB was scheduled to re-convene in March 2020 for their next meeting. The PHE-chaired CCMB provided governance and oversight of the necessary maintenance and management of the clinical countermeasure UK stockpiles and the agreements required to ensure that the UK was well prepared to respond effectively to a pandemic.

250. The levels within the pandemic stockpiles were reviewed as part of this meeting and the official stock levels were calculated at this point to contain approximately 323 million PPE items (including masks, aprons, gloves, respirators, eyewear, and respirators), approximately 43 million pharmaceutical items including antivirals and antibiotics, and a total approximation of 726 million clinical countermeasure consumables (including items such as boxes, syringes, paper towels, and cannulas).

251. These numbers only account for JIC stockpiles, and do not account for orders of PPE and pharmaceuticals placed and delivered prior to January 2020. Furthermore, planned deliveries of antivirals and antibiotics for 2019/20 were in most cases either completed or brought forward for delivery before 31 October 2019 to prevent any potential EU Exit disruption.

252. In October 2019, the CCMB also held an advanced purchase agreement (APA) contract to enable procurement of a Pandemic Specific Vaccine (PSV) for influenza. This provided the UK with reserved production capacity for more than enough PSV doses for the entire UK population and to be available within 4-6 months of an influenza pandemic outbreak.

253. In addition to specific products, the pandemic preparedness programme included a contract for an antiviral distribution service called the National Pandemic Flu Service (NPFs). The NPFs was designed to supplement the response provided by primary care during an influenza pandemic. If the pressures meant that it was no longer practical for all those with symptoms to be individually assessed by a doctor

or other health care professionals, patients could triage themselves via an online and telephony service in order to access antiviral medicines.

254. There is more on management of the stockpile, as well as economic analysis and the initial 2008 Outline Business Case, later in this Section.

Surveillance

255. A critical component of the health and social care system's pandemic preparedness is ongoing surveillance of pathogens with pandemic potential, including risk assessments of emerging threats. International and domestic surveillance efforts remain crucial to detecting new and emerging pathogens as quickly as possible. Responsibility for ongoing surveillance sits with UKHSA, and was one of PHE's core functions, as highlighted in PHE's annual remit letter (see Section 4). UKHSA and the other UK public health agencies work closely with international organisations to monitor and assess pathogens and the risk they pose.

256. PHE's domestic surveillance activities included active data collection and analysis through local public health laboratories based in the East of England, London, the North East, the North West, the South East, the South West, the Midlands and Yorkshire and the Humber (**CW/384**). Prior to 2013, there were four Health Protection Agency (HPA) – the predecessor to PHE – centres: at Porton Down in Salisbury, Chilton in Didcot, South Mimms in Hertfordshire, and Colindale in North London. In addition, the HPA had regional laboratories across England and administrative headquarters in Central London. On April 1, 2013, the HPA, minus the South Mimms site, became part of PHE. The National Institute for Biological Standards and Control (NIBSC) located in South Mimms was merged with MHRA.

257. PHE also operated a range of specialist microbiology tests and services delivered via the four national centres referenced above. They led the routine scanning of open-source information internationally and were members of early alerting and reporting (EAR) mechanisms such as the EU's Epidemic Intelligence Information System (EPIS) or the European Surveillance System (TESSy) tool.

258. Reflecting the focus in the NSRA on pandemic influenza, there was an increased emphasis on surveillance of influenza sub-types, including outbreaks of avian or porcine influenza as potential sources of zoonotically-derived influenza pandemics (the 2009 Swine Flu epidemic being an example here). PHE (now UKHSA) and the other UK public health agencies supported animal health responses to avian influenza detections, working with relevant animal health agencies (e.g. the APHA) to undertake risk assessment and arrange health surveillance of exposed persons.

259. Early comprehensive assessment of the epidemiological and clinical characteristics of a novel virus is essential to enable the implementation of a proportionate response to a new pandemic. The key objectives of surveillance are to:

- a. Identify key clinical, epidemiological and virological features, including transmission characteristics, and genomic sequencing of a new virus.
- b. Count severe cases and identify risk groups affected.
- c. Describe the evolving pandemic, including how the virus spreads over time and regionally, and its impact at the population level (e.g., by age-group) particularly in relation to hospitalisations and mortality.

260. One of the challenges of disease surveillance is the vast quantity of information that needs to be sifted through, analysed, and interpreted in order to focus effort and resources on those diseases that require further attention. PHE's scientific and data analytics expertise was critical to providing ongoing surveillance and assessment of pandemic risks, which is summarised in PHE's National Situational Awareness Cell (NSAC) daily report **(CW/385)**.

Scientific advice

261. Threat assessments and response planning was informed by scientific advice provided through a combination of in-house expertise within PHE (and its predecessor the HPA), independent expert advisory committees (see Section 2), and the CSA and CMO roles in the Department. More on the role of these groups can be found in Section 2.

262. I set out below a summary of how these groups supported the development of pandemic preparedness policy.

263. Besides providing advice on specific questions, SAG (and later SPI) acted as an information network for the government to ensure that it was informed of important developments in pandemic influenza related sciences, which could affect Government policy.

264. Similarly, outputs from NERVTAG fed into DHSC's pandemic preparedness arrangements, particularly through the PIPP Board and provided the main route for scientific advice on pandemic preparedness. NERVTAG documents are exhibited at **(CW/380)** and **(CW/386)** to **(CW/388)**.

Role of SPI-M

265. Advice from SPI-M prior to the COVID-19 pandemic primarily took the form of a "modelling summary". This represented the SPI-M Committee's consensus view of

the epidemiological modelling evidence available at the time and the possible implications for planning, and was periodically updated as necessary following SPI-M meetings. It was not a statement of DHSC or wider government policy.

266. The SPI-M modelling summary was published in November 2018 **(CW/1)**, and outlined key insights from the available evidence on the possible progression of an influenza pandemic from its country of origin to, and then within, the UK. It also discussed the potential severity and impact of an influenza pandemic, and the effectiveness of pharmaceutical countermeasures and social distancing.
267. Pandemics are intrinsically unpredictable. The “modelling summary” focuses on and is informed by the three significant influenza pandemics which occurred during the 20th century: 1918-19, 1957-58, and 1968-69. The 2009 swine flu pandemic had a much smaller impact and is used as an example of an event, which, at least in its early development, is difficult to distinguish from a much more severe epidemic.
268. In April 2009, SPI-M-O was activated as an operational group to support the government’s response to the 2009 Swine Flu pandemic. It reported to SAGE during this period and met on an approximately weekly basis between April 2009 and December 2009. More can be found on the 2009 swine flu pandemic in paragraphs 355-359.
269. In October 2014, an ‘Ebola Modelling Group’ was established to support the government’s response to the 2014-16 Ebola outbreak in West Africa, shortly thereafter becoming a subgroup of SAGE. The Ebola Modelling Group’s last meeting was in January 2015. Given the focus on Ebola, rather than pandemic influenza, this was not technically an activation of SPI-M-O. The group did, however, adopt the model previously established by SPI-M-O, sharing a secretariat and much of the same membership.
270. Activities undertaken by SPI-M-O during January 2020 are best considered within the scope and context of Module 2.

Reasonable worst-case planning scenario for an influenza pandemic

271. To provide a consistent basis for planning, SPI-M’s advice to DHSC also included a RWCS for an influenza pandemic. The “reasonable worst-case” is a concept developed for emergency planning. It is not a prediction or forecast of what will happen or what scenario is most likely, nor the worst theoretically possible scenario, but of the worst that might *realistically* happen. By planning for the RWCS, planners are assured that they are able to respond to a wide range of scenarios should the hazard occur.

272. The current advised RWCS for an influenza pandemic is outlined in Annex 2 of the 2018 SPI-M Modelling Summary **(CW/1)**. The scenario is based on the SPI-M's analysis of previous pandemics and seasonal influenza over the past century. It includes an indicative national planning profile for a single wave pandemic and narrative about potential local variations, as well as historical profiles from previous multiyear and multi wave pandemics. Assumptions for the proportion of the population who might fall ill during the pandemic, the hospitalisation rate, and fatality rate are also provided.

Planning scenarios

273. As discussed earlier, it is not possible to forecast what the next pandemic will look like. Consequently, DHSC's pandemic planning was informed by the agreed RWCS, latest scientific evidence, and lessons learned since the 2009 swine flu pandemic.

274. The RWCS was regularly reviewed as part of the NSRA process managed by CO. Where necessary the RWCS was supplemented with several variations exploring the impact of different rates of transmission and severities.

275. The 2011 CO publication on the scientific evidence base on pandemic influenza **(CW/389)** made clear that a new virus with pandemic potential would emerge at some stage. However, it is not possible to quantitatively estimate the precise probability of a pandemic virus emerging. The government's likelihood assessment for an influenza-type disease pandemic in the NSRA was based on empirical evidence over the past century, during which there was one influenza pandemic (1918-19) with a similarly high case fatality ratio and impact to the RWCS **(CW/392)**.

Investment in capabilities, including research and the role of the National Institute of Health Research

276. I have provided background information on the NIHR in Section 2.

277. In the period June 2009 to January 2020, NIHR invested in pandemic preparedness research, clinical research infrastructure, and "sleeping" research projects (projects put on stand-by in a maintenance-only state) ready to respond to a new health threat. Overall, funding provided for health research generally through the NIHR is over £1 billion per year.

278. The following information covers the NIHR pandemic preparedness prior to January 2020 only, and a wider suite of research followed.

Health Protection Research Units

279. Since 2014, NIHR has funded Health Protection Research Units (HPRUs) as partnerships between universities and UKHSA (previously PHE) across the whole of the health protection field. These act as centres of excellence in multidisciplinary health protection research in England.

280. In particular, the HPRU in Emergency Preparedness and Response undertook a variety of pandemic preparedness research. Rapid analyses by the HPRU informed SAGE and policy.

NIHR Infrastructure – Clinical Research Network

281. The standing NIHR research infrastructure has been established from 2006 over a number of years and had been set up with the possibility of enabling a rapid research response. The NIHR Clinical Research Network (CRN) supports patients, the public and health and care organisations across England to participate in research.

282. The CRN is comprised of 15 Local CRNs and 30 Specialties who coordinate and support the delivery of high-quality research. This system allows for central direction of resource in an emergency

283. Without the pre-existing NIHR infrastructure, it would not have been possible to rapidly set-up and recruit to COVID-19 studies and feed results into policy. For example, the Oxford/AstraZeneca COVID-19 vaccine and the RECOVERY trial.

NIHR Pandemic Preparedness “sleeping” research contracts

284. Following review of the 2009 swine flu pandemic, the NIHR commissioned a portfolio of nine 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 (**CW/390**).

285. In 2018, NIHR reviewed the studies and research teams were asked to consider how their projects could be adapted for a non-flu pandemic. Over £3.8 million was committed to “sleeping” research contracts for pandemic preparedness prior to January 2020.

The DHSC UK Vaccine Network (UKVN) Project

286. The UKVN was established in June 2015 in the wake of the West African Ebola outbreak from 2014 to 2016, which illustrated a serious market failure in the development of vaccines against emerging pathogens that cause epidemics in LMICs. It has been chaired since then by Professor Sir Chris Whitty. The UKVN has

advised DHSC on a programme of ODA-funded investments in vaccine development against emerging epidemic threats since 2016.

287. The UKVN undertook an analysis of the most likely pathogen types for which a vaccine could be useful, methods to shorten time to vaccine production in an emergency, and the epidemiological conditions under which a vaccine would be most likely to be successful.
288. The UKVN had a significant impact on both the UK's preparedness for, and rapid response to, the COVID-19 pandemic, as it:
- a. Strengthened the UK vaccine research base over the period of 2016 to 2021
 - b. Funded the scientific research on vaccine technologies that would lay the groundwork for the UK research community's rapid development of potential COVID-19 vaccines
 - c. Provided advice to the UK Government in 2016 including on:
 - i. A review of UK vaccine manufacturing capacity, which contributed to the industrial strategy decision to fund the Vaccine Manufacturing and Innovation Centre
 - ii. Production of policy tools to increase policy makers' understanding of the vaccine development process
 - d. Helped to build the UK Government's relationship with the Coalition for Epidemic Preparedness Innovations (CEPI) from 2018 onwards. CEPI became a key international organisation in the international COVID-19 vaccine response; and
 - e. Developed relationships between HMG departments and policy teams that enabled initiation of a rapid research call between MRC and NIHR in 2020.
289. The Oxford University team, funded by, the UKVN, as well as other funders, started using virus-based technology for MERS-CoV vaccine development in 2016.
290. The UKVN grant of £1.87 million supported the preclinical development and phase 1 clinical trials of a MERS-CoV vaccine using the ChAdOx1 platform. The vaccine targeted the spike protein and successfully completed phase 1 clinical trials in 2019. In January 2020, researchers showed that the MERS-CoV vaccine was a candidate to be adapted to the novel coronavirus. This became the Oxford/AstraZeneca COVID-19 vaccine. The knowledge gained from development of a vaccine for MERS on the same vaccine platform was important in allowing the rapid development of a vaccine against SARS-CoV-2, also a coronavirus.
291. UKVN investments were also made to other groups around the UK.

Operational delivery agencies (PHE and the NHS)

292. The Department's Pandemic Preparedness Programme is delivered in partnership with its ALBs, primarily UKHSA (formerly PHE) and NHSE.
293. On 1 April 2013, the HPA became part of PHE. More on the role of UKHSA and its predecessors can be found in Sections 2 and 4. I will detail specific information on their role in pandemic preparedness below.
294. Efforts to contain infectious disease outbreaks are supported by UKHSA, who have the standing contact tracing capability through regional health protection teams. Contact tracing is usually telephone based and led by regional teams, with personal contact tracing for hard-to-reach high risk contacts. The utilisation of contact tracing is determined based on the identification of cases and transmission risk relevant to the pathogen.
295. The CCA requires NHS organisations, and providers of NHS-funded services, to show that they can deal with emergency incidents while maintaining services. The NHS England Incident Response Plan is the overarching generic plan that details how NHSE responds to any health-related incident or emergency at the national level. As part of this, every acute Trust has a range of emergency plans including for HCID and epidemics. NHSE have also produced an Operating Framework for Managing the Response to Pandemic Influenza (**CW/391**). All NHS CCGs were expected to: have an executive lead to lead the CCG's pandemic preparedness activities, undertake business continuity planning, develop communications plans, develop surge plans for elective work, and ensure assurance of pandemic plans for impact on commissioned services, as exhibited at (**CW/392**). Local health protection teams within UKHSA centres work with NHSE area teams, Local Authorities, health care providers and other agencies in delivering the local pandemic influenza response.
296. When commissioned, UKHSA provides advice to those returning from high-risk countries and operates a returning workers scheme as part of arrangements to protect and monitor the health of those who travel to specific HCID-affected areas for their work. However, Local Authorities have the primary responsibility for responding at borders and UKHSA'S role is to provide public health advice and expertise. This advice may extend to appointing a UKHSA person to respond on the Local Authority's behalf. UKHSA could also provide additional interventions as required by DHSC/SofS as mitigation for new and emerging public health hazards.

297. The Food, Water and Environmental laboratories (FW&E) at UKHSA help to control incidents and outbreaks by providing evidence that leads to intervention and prevention of infections. These laboratories are geographically placed to work closely with key local authorities and port health authorities, to protect the public from the significant health threats associated with food, water and environmental hazards. The FW&E laboratories are based in 5 sites across the country and provide specialist services to the NHS, particularly in respect of the testing of water for use in medical and/or surgical procedures. As such, all FW&E laboratories are accredited through the United Kingdom Accreditation Service (UKAS) and have 'Official Control' status.
298. DHSC and UKHSA can also leverage Military Aid to the Civil Authorities (MACA) support, cross-Government support, and the voluntary sector to provide resources in the case of a national vaccination programme, or other support requirements. More information on MACA (**CW/393**). If there is an emergency in the UK, local emergency services provide the first response; however, Government departments or civil authorities may then request military assistance from the MoD. UKHSA would access MACA support via a request to DHSC. MACAs provide deployment of clinically trained staff or other military capabilities such as logistics, security and construction. Requests can be made when there are issues with human resource in the health and social care sectors due to very high levels of staff absences or a sudden and unexpected increase in demand. Once requests are granted by the MOD, military staff will be made available to the required NHS service. However, the CCA places no statutory responsibility on the MoD to plan and prepare for civil crises; the statutory responsibility rests with Category 1 and 2 responders.
299. All NHS Ambulance Trusts have the capability to deploy specially trained staff as part of a Hazardous Area Response Team (HART), who can undertake the treatment and transport of patients with HCIDs. This ensures that medical assistance and transportation can be ascribed to potentially infectious individuals prior to their arrival to an HCID hospital. HART personnel must undergo rigorous specialist training at the National Ambulance Resilience Unit Training & Education Centre before they can be deployed. This entails: training in the use of specialist PPE, Training in CBRN equipment and other resilience training.
300. NHSE have two specialist contact High Level Isolation Units in England: one at the Royal Free in London, and one at the Royal Victoria Infirmary in Newcastle. NHSE also has five specialist airborne HCID treatment centres in England: at Guy's and St Thomas' Hospital, the Royal Free London, the Royal Liverpool and Broadgreen, Newcastle upon Tyne, and Sheffield Teaching Hospitals. Once an

HCID has been confirmed these centres provide care to patients with HCIDs, including the provision of medicines and post-exposure prophylaxis where relevant. These have staff trained to use specialist equipment and a limited number of high-level isolation beds, with the ability to surge facilities if needed. As these are limited and specialist resources, they do not have capacity to contain large patient volumes.

Legislation

301. The Public Health (Control of Disease) Act 1984 (the PHA) and regulations made under it provide a legislative framework for health protection in England and Wales. The PHA was significantly updated by the Health and Social Care Act 2008, which adopted an 'all hazards' approach, in light of the IHR (see paragraph 305) and the experience of the SARS outbreak in 2002-2004. The updated PHA provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation. It includes powers to impose restrictions or requirements on people, and in relation to things and premises, for use in rare circumstances where voluntary cooperation cannot be obtained.
302. Section 45C of the PHA provides a power for the appropriate minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales. The threat can come from outside England and Wales.
303. One of the recommendations from Exercise Cygnus in 2016 (see paragraph 323) was that the government should review its legislative options to assist with the response to a pandemic, which might include relaxations to legislative requirements and/or regulatory changes. One of the workstreams under the PFRB (see paragraph 177) was the development of a draft Pandemic Flu Bill, to be held in readiness should it need to be rapidly introduced into Parliament if the need arose.
304. The draft Pandemic Flu Bill (**CW/347**) contained temporary provisions of an emergency nature to help manage the effects of a severe pandemic flu virus in the UK. It contained provisions designed to either amend existing legislative provisions or introduce new statutory powers, to help manage and mitigate the impacts of a severe pandemic – such as a reduced workforce, increased pressure on health services, and death management processes. The purpose behind the draft Pandemic Flu Bill was broadly to streamline systems, increase capacity in the healthcare system, and mitigate infection.
305. The IHR is an international instrument which is legally binding on all WHO Member States, including the UK. The IHR came into force in 2007. The IHR sets out Member States' rights and obligations for handling public health events and emergencies that have the potential to cross international borders. The IHR require

the UK to establish and maintain core capacities for surveillance and response, including at points of entry, in order to detect, assess, notify and respond to any potential public health events of international concern. Key IHR core capacities implemented by the UK since 2007 include: the appointment of a National Focal Point team responsible for rapid communications with the WHO on public health events occurring in the UK and abroad; reliable and timely laboratory testing and; a sensitive surveillance system which supports early warning and assessment during the early stages of a public health event.

International collaboration

306. I have set out more information on our work with international partners in Section 2.

307. Infectious diseases do not respect international borders and therefore an essential component of our domestic pandemic preparedness work is our engagement, collaboration, and cooperation with international partners. This is conducted through a variety of mechanisms and membership of international fora, including but not limited to being an active participating Member State and significant donor to the WHO. The UK has actively participated in discussions around strengthening health systems at G7 and G20 fora and is a member of the GHSA. As a member of the EU, UK representatives also attended EU Health Security Committee meetings, and sat on the Management Board of the ECDC. I have set out more detail on our work with international partners in Section 2.

Incidents and exercises – lessons learned

308. The Department's Pandemic Preparedness Programme was not static but constantly evolved. It developed as workstreams were completed, but also in responses to learning both from live incidents and from planned simulations and exercises to test our resilience and planning. These exercises were run both nationally and locally, across the breadth of EPRR and pandemic preparedness, both within health and social care and more widely across government. For example, Exercise Winter Willow informed the development of response plans for the 2009 Swine Flu pandemic, including stockpiling antivirals. The development of the NRR informed the Department's approach to preparedness planning (as LGD for this risk), guided by the planning assumptions within the RWCS of a risk occurring. The UK Influenza Pandemic Preparedness Strategy 2011 led to the development of a specific communications strategy. In October 2018, the CCMB pro-actively managed the risk of a 'no deal' exit from the EU by bringing forward delivery of pandemic stockpile supplies to before March 2019.

309. DHSC was involved in a number of simulation exercises, which led to the development of further workstreams, as a result of lessons identified during these exercises. For example, learnings from Exercise Cygnus included developing the draft Pandemic Flu Bill, which formed the initial basis of the Coronavirus Act 2020 and draft plans to surge capacity in the NHS and adult social care sector in the event of an extreme rise in demand for services and pressure on the workforce.
310. In addition to exercises, the Department has integrated learnings after live incidents, such as Ebola in 2015. I have set out more information on this from paragraph 333 below.

Responses to Specific questions

311. I will now provide more detail in response to the specific questions the Inquiry has asked about the Department's pandemic preparedness programme and how it evolved over time.

Chronology and Timeline of Key Policy Development

312. As the top natural hazard risk on the NRR since 2008 (**CW/2**), DHSC has been preparing for the impacts of an influenza pandemic for many years. I draw the Inquiry's attention to the following milestones in pandemic preparedness policy. Please note that this begins in 2007, as events prior to 2009 will be of interest to the Inquiry.

Establishment of PIPP in 2007

313. DHSC published the National Framework for Responding to an Influenza Pandemic in November 2007 (**CW/394**) and established the PIPP the same year to oversee delivery of our preparedness and planning. The National Framework for Responding to an Influenza Pandemic Framework superseded an existing UK-wide contingency plan from 1997 and provided information and guidance to assist and support public and private organisations across all sectors.

Publication of National Risk Register (NRR) in 2008

314. In 2008, the first iteration of the NRR (**CW/2**) was published by the CO, which identified an influenza pandemic as the highest-impact natural hazard risk to the UK. Pandemic influenza has remained on the NRR as the highest impact risk on each subsequent publication, up to and including its most recent publication in 2020. The definition of pandemic risk included in the unpublished NSRA, which supports the NRR, underpins the department's approach to pandemic preparedness planning.

The 2009 Swine Flu Pandemic (2009 to 2010)

315. In June 2009, there was an outbreak of H1N1 influenza (swine flu), which was first identified in Mexico and quickly spread globally. In the UK there were 795,000 cases. Following this outbreak, in 2010, Dame Deidre Hine led a review into the UK Government's handling of Swine Flu, publishing the Hine Review in 2010. Dame Hine concluded that the response was 'highly satisfactory' (**CW/395**). I will say more on the Swine Flu outbreak later.

Pandemic Influenza Strategy in 2011

316. Following the recommendations of the Hine Review, the Government developed and published the 2011 UK Influenza Pandemic Strategy (**CW/3**). The strategy

addressed the recommendations of the Hine Review, improving generalised capabilities that could be deployed to combat a range of outbreak sizes, increasing the emphasis on scientific evidence to inform decision making, and the government's understanding of pandemics and their impacts on society.

317. Prior to its publication, the Department led a 12-week consultation (**CW/396**) seeking views on the proposed characterisation of mild, moderate, and high-impact influenza pandemics in order to understand how best to coordinate a response in the health sector and across wider society, and the planned five-phase structure of the UK response to the threat of an influenza pandemic.
318. More generally, the consultation also invited comment on the broad approach adopted for the Strategy, organised around three principles – precautionary action, proportionality, and flexibility. The strategy publication included a full external review of the equalities impacts of the 2009 pandemic (**CW/397**), to respond to Hine recommendations. The resulting report was published alongside the 2011 strategy consultation.
319. Following feedback received during the public consultation, the final version of the Strategy was published in 2019 and divided into four phases:
- a. Detection and Assessment
 - b. Treatment
 - c. Escalation
 - d. Recovery

Pandemic Influenza Communications Strategy in 2012

320. The 2011 strategy committed to further improvements to UK pandemic influenza preparedness, including the development of a specific Pandemic Influenza Communications Strategy (2012) (**CW/351**). Other sectoral-specific guidance to help essential areas of the economy sustain their services was available online, including for telecoms and postal services, energy, finance, food and water and sewage treatment (**CW/398**). Similarly, the NHS published operational guidance that supported the health and care sector to prepare for a pandemic (**CW/399**).

Establishment of NERVTAG in 2014

321. In 2014, the Department established NERVTAG, which met for the first time on 19 December 2014. NERVTAG was established as part of the commitment in the 2011 strategy to place a stronger emphasis on scientific evidence. More detail on NERVTAG and the scientific advice provided by other expert advisory committees is provided above in this section, and in Section 2.

Ebola (2014 to 2016)

322. In 2014, there was a major outbreak of EVD in West Africa, primarily in the Republic of Guinea (Guinea), the Republic of Liberia (Liberia), and Republic of Sierra Leone (Sierra Leone). More detail on the Ebola outbreak is covered in paragraphs 362-381. In 2015, DHSC and its delivery partners identified lessons and recommendations following the government's response to Ebola which included recommendations for the management of HCIDs within the UK.

Exercise Cygnus in 2016

323. In 2016, DHSC led on the preparation for and delivery of Exercise Cygnus. Exercise Cygnus was a cross-government exercise to test the UK's response to a serious influenza pandemic. It was a multi-phase exercise with Tier 1 (national level) element of the exercise taking place from 18 to 20 October 2016 and involving more than 950 people.

324. The aim of Exercise Cygnus was to provide an opportunity for colleagues from across the health and social care sectors to consider the national, strategic health and social care responses to a pandemic-influenza outbreak ahead of the broader Tier 1 element of Exercise Cygnus. Cygnus identified several lessons, which contributed to shaping the government's approach to pandemic preparedness planning. More detail on Exercise Cygnus can be found in paragraphs 344-350.

Establishment of cross-government Pandemic Flu Readiness Board (PFRB) and associated work programme in 2017

325. The learnings from Exercise Cygnus and recommendations for how these should be taken forward as part of government's pandemic preparedness planning were presented to a meeting of the National Security Council (Threats, Hazards, Resilience and Contingencies) subcommittee on 21 February 2017. This meeting was chaired by the Prime Minister. One of the recommendations from this exercise was for the establishment of a cross-government pandemic planning oversight group, which led to the formation of the PFRB in 2017. PFRB provided cross-government oversight for a widespread programme to deliver plans and capabilities to manage the wider consequences of pandemic influenza. DHSC and the CO (through the CCS) co-chaired PFRB.

Monthly Permanent Secretary briefings on pandemic preparedness (2017 to 2019)

326. In 2017, sitting alongside the more formal PIPP and PRFB governance structures, I established a series of regular internal meetings on the Department's

work on pandemic preparedness to ensure greater visibility and momentum of key workstreams. This reflected the status of the risk in the NSRA and the associated risk in the HLRR. These meetings continued until 2019 and papers are exhibited at **(CW/356)** to **(CW/376)**.

Salisbury poisonings in 2018

327. Throughout this period, and reflected in more detail in Section 2, the DHSC EPRR function managed various incidents, including the Novichok poisonings in Salisbury in 2018. Whilst not an infectious disease outbreak, incidents such as these tested the health and social care EPRR functions, provided wider learning on the incident response and strengthened arrangements for cross-sector and cross-government working. I have provided more detail on the learnings from incidents, outbreaks and exercises at paragraph 333.

EU exit 'no deal' preparedness (including Operation Yellowhammer) from 2018

328. From 2018, the Department developed an extensive programme of activity as part of the government's planning and preparation for the risks of a 'no deal' EU Exit. Our existing EPRR function was enhanced and renamed the ORC. This brought together our capability on emergency response and responsibilities as Category 1 responder with our planning and preparedness to manage a potential 'no deal' EU Exit. I have provided more detail on the ORC in Section 2.

329. I have set out more information on the impact of EU Exit can be found at paragraph 405.

Draft Pandemic Flu Bill 2017-2019

330. One of the key achievements of the PFRB was the preparation of a draft Pandemic Flu Bill. Between 2017 and 2019, the draft Pandemic Flu Bill was developed by DHSC with support from CO and OGDs. The draft Bill was intended to provide legislative flexibilities to support the response to a severe pandemic. The draft Bill was held internally to be taken through Parliament only if required. I have provided more detail on the draft Pandemic Flu Bill in paragraph 304.

Establishment of Moral and Ethical Advisory Group in 2019

331. In 2019, DHSC established MEAG. The recommendation to establish a moral and ethical advisory group arose from Exercise Cygnus in 2016 and was established in October 2019, both as a response to the pandemic preparedness programme and as part of the department's preparedness under Operation Yellowhammer. MEAG was established by DHSC to ensure that government could receive independent

advice on the moral, ethical and faith considerations on health and social care related issues during incidents. More information on MEAG is set out in Section 2.

332. The Terms of Reference and minutes of the Group's first meeting are exhibited at **(CW/400)** and **(CW401)**. This was the only meeting before 21 January 2020, and therefore MEAG did not provide any advice on COVID-19 before this point.

Learnings from incidents and exercises

333. The Department's work on pandemic preparedness evolved over time and in response to learnings from disease outbreaks and exercise simulations. Examples where learnings have led to improvements in response planning include, from Exercise Cygnus, the development of the draft Pandemic Flu Bill which formed the initial basis of the Coronavirus Act 2020, and draft plans to surge capacity in the NHS and adult social care sector in the event of an extreme rise in demand for services and pressure on the workforce. This section summarises significant exercises and incidents over this time period and highlights some of the key learnings that were taken from each one.

Exercise Winter Willow (2007)

334. Exercise Winter Willow was the largest of several exercises undertaken in the UK aimed at testing and strengthening planning for the response to an influenza pandemic. Over 5,000 participants from government, industry and the voluntary sector were involved, and the exercise simulated response at a local, regional, and national level. The exercise took place in two phases (Winter Willow 1 and Winter Willow 2), held in January and February 2007 respectively. This built on previous exercises, especially Exercise Shared Goal in 2006, which tested response plans at WHO Pandemic Phases 4 and 5.
335. Winter Willow informed the development of response plans, including in the stockpiling of antivirals, which supported the response to the 2009 Swine Flu pandemic. The practical experience gained through Exercise Winter Willow was factored into the analysis that informed a business case for antivirals under PIPP. The Winter Willow Report is exhibited at **(CW402)**.

Exercise Valverde (2015)

336. Exercise Valverde was an international exercise delivered on 21 May 2015, which simulated the outbreak of novel coronavirus in a fictional South American country (Valverde). This exercise was commissioned and supported by member countries (including the UK) and organisations of the GHSI, an informal, international partnership among like-minded countries and organisations to strengthen public

health preparedness and response globally to CBRN threats, as well as pandemic influenza. See more on the GHSI in Section 2.

337. This exercise was commissioned by the GHSI's Sample Sharing Task Group (SSTG) under the Risk Management and Communications Working Group to test the current draft arrangements of member countries for the rapid sharing of laboratory samples of non-influenza pathogens and related specimens during a public health emergency.
338. Participants in the exercise included representation from the member countries and organisations of the GHSI's SSTG; Ministries of Health; national level designated laboratories; and other relevant stakeholders and government departments that are involved in the process of sample sharing across international borders. Members of the SSTG include representatives from Canada, the European Commission, France, Germany, Italy, Japan, Mexico, the UK, and the United States. Italy and Mexico did not participate in the exercise, and although France did not actively participate in the exercise, they engaged in the teleconferences and received all the exercise material. The WHO was aware of the exercise and party to all material.
339. The exercise tested the arrangements that were in place for urgent sample sharing. The new frameworks tested involved the Operational Framework and the Material Transfer Agreement (MTA) for sharing non-influenza pathogens, as the Pandemic Influenza Preparedness Framework was already in existence to share influenza viruses of pandemic potential. The purpose of this exercise was to identify and aid in addressing the major policy, regulatory and logistical challenges associated with the rapid sharing of laboratory samples and critical biological materials of non-influenza pathogens in the context of a public health emergency.
340. The exercise was a valuable opportunity for participants to walk through the process required for the requesting, sending and receipt of samples using the Operational Framework and MTA that has been developed by the SSTG for the purpose of facilitating sample sharing during a public health emergency.
341. The exercise also helped demonstrate the complexity of the current arrangements in place and the broad network of stakeholders who need to be involved. It also clearly showed that not all of these stakeholders lie within the health sector (e.g. customs and border force agencies, legal and business departments) and that the process requires wider engagement across many government departments and agencies.

342. Exercise Valverde was successful in achieving its objectives and progressing the work necessary for urgent sample sharing. The report from Exercise Valverde is exhibited at **(CW/403)**. All recommendations were actioned by the UK and the utility of this exercise was in the development of a fully functional MTA. Following Exercise Valverde, a voluntary agreement was developed between GHSI members to facilitate the rapid sharing of non-influenza biological materials, such as virus and serum samples during a public health emergency.

343. This agreement helped to facilitate fast sample sharing during the COVID-19 pandemic and the UK benefitted from expedited access to samples due to the work undertaken after Exercise Valverde. The GHSI Sample Sharing Framework was used by the UK for every SARS-CoV-2 variant of concern (received into UK or shipped to other countries). This work developed the draft MTA into a fully operational mechanism and the assurance that this multilateral agreement did not impinge on the Nagoya Protocol.

Exercise Cygnus (and Cygnet) (2016)

344. Exercise Cygnus was a cross-government exercise commissioned by DH to test the UK's response to a serious influenza pandemic. It was a multi-phase exercise with Tier 1 (national level) element of the exercise taking place from 18 to 20 October 2016 and involving more than 950 people. The aim of Exercise Cygnet was to provide an opportunity for colleagues from across the health and social care sectors to consider the national, strategic health and social care responses to a pandemic-influenza outbreak ahead of the broader Tier 1 element of Exercise Cygnus.

345. The other phases were the Exercise Cygnus Health Delivery Board meeting (May 2014) and Exercise Cygnet – a discussion-based exercise (August 2016) **(CW/404)**.

346. DH and 12 other government departments, as well as NHS Wales, NHSE, PHE, local public services, several prisons, and staff from the Scottish and Welsh governments and the Northern Ireland Executive took part in the exercise. The Secretary of State and the Minister for the Cabinet Office chaired meetings as part of the exercise, and ministers from Devolved Governments participated. During the exercise, participants considered their capacity and capability to operate at the peak of a pandemic affecting up to 50% of the UK's population and which could cause between 200-400,000 excess deaths in the UK. The exercise assumptions included a staff absence rate of approximately 3%, and a case fatality of around 1.5% across the UK population.

347. Cygnus identified several lessons, which contributed to shaping the government's approach to pandemic preparedness planning. The full report is exhibited at **(CW/405)**.
348. Cygnus found that the UK's command control and emergency response structures provided a sound basis for the response to an influenza pandemic. However, it also found that the UK's preparedness and response, in terms of its plans, policies and capability, were not sufficient to cope with the extreme demands of a severe pandemic that would have a UK-wide impact across all sectors. Exercise Cygnus identified 22 recommendations, all of which were accepted by the Government.
349. There were four key learning outcomes:
- a. The development of a Pandemic Concepts of Operations would assist in managing a cross-Government and multi-agency response, i.e. how government works with responders
 - b. The introduction of legislative easements would assist with the implementation of measures that might be employed during a pandemic
 - c. Public reactions in response to a reasonable worst-case pandemic influenza needed to be better understood; and
 - d. An effective response would require capability and capacity to surge services to meet demand.
350. These four outcomes sat over the 22 recommendations. The PFRB took forward these recommendations in its workstreams between 2017 and 2019.

Exercise Alice (2016)

351. Exercise Alice was delivered on 15 February 2016, and was supported by DH, NHSE and PHE. This exercise considered the planning and resilience arrangements required to respond to an outbreak of MERS, a HCID in England. The exercise was commissioned by DH in response to concerns raised by the CMO about the planning and resilience to respond to a large-scale outbreak of MERS in England. The exercise was an opportunity to explore the policies, response and issues associated with the outbreak by the NHS and PHE.
352. Exercise Alice was not intended to test elements of preparedness for a pandemic scale event, but rather to assess the UK's readiness for a potential outbreak of MERS. As set out above in Section 2, MERS-CoV, which causes MERS, is a different virus to SARS-CoV-2, which causes COVID-19. MERS-CoV does not transmit as easily as SARS-CoV-2, has a much higher case fatality rate and outbreak sizes are comparatively small.

353. Recommendations from Exercise Alice included the development of a set of guidelines for the health and social care system on the treatment of patients and the production of updated PPE guidance for frontline health practitioners **(CW/406)** to **(CW/415)**. The learnings from Exercise Alice have been incorporated into ongoing planning work conducted by DHSC, UKHSA and NHSE to respond to HCID outbreaks in the UK. The report from Exercise Alice is exhibited at **(CW/416)**.

Other exercises of note

354. The Inquiry may be interested in these other exercises, which DHSC either led or participated:

- a. Exercise Peak Practice - September 2009: Multiple regional flu exercises on behalf of DH were delivered by the Strategic Health Authorities and designed by HPA. The report is exhibited at **(CW/417)** to **(CW/424)**.
- b. Exercise Spinner - March 2012: To ensure mutual understanding of roles and responsibilities in public health scenarios during the Olympic Games. There were three scenarios. The first was a measles outbreak in the Athletes' Village; the second, a food contamination incident; and the third, a SARS like outbreak.
- c. Ebola Surge Capacity - March 2015: A discussion-based exercise considered the current arrangements and capabilities of the four designated NHS surge centres in England to respond to multiple positive cases of Ebola in England. DH observed this exercise. The report is exhibited at **(CW/425)**.
- d. Exercise Northern Light - March 2016: Designed to assess the Royal Victoria Infirmary's preparedness for and activation of its High-Level Isolation Unit capability. DH was not involved in this exercise. The report is exhibited at **(CW/426)**.
- e. Exercise Theodore - December 2016: A tabletop exercise held to review the coordinated strategic response required to a national outbreak of foodborne Shiga-toxin producing Escherichia coli, serotype O104:H4 disease, as well as promoting multiagency cooperation and information-sharing between organisations and the public.
- f. Exercise Typhon - February 2017: Exercise Typhon was a command post exercise held on 22 and 23 February 2017 to review the effectiveness of PHE's National Incident & Emergency Response Plan (NIERP) during two concurrent enhanced incidents. The report is exhibited at **(CW/427)**.
- g. Exercise Broad Street - January 2018: The exercise considered the agreed approach to managing the end-to-end patient pathway for known HCID (including suspected and confirmed) cases to ensure an appropriate response

is in place. Further, the exercise considered whether the proposed HCID pathways and algorithms were efficient and actionable by identifying gaps or limitations. The report is exhibited at **(CW/428)**.

- h. Exercise Cerberus - February 2018: Exercise Cerberus was designed to assess PHE's draft revised NIERP, enabling the organisation to respond to public health emergencies. The report is exhibited at **(CW/429)**.
- i. Exercise Pica - September 2018: Exercise Pica reviewed and assessed pandemic influenza preparedness and response within primary care by providing an opportunity to review and explore the existing processes and arrangements. The report is exhibited at **(CW/430)**.
- j. TTX EBOLA MEDEVAC Protocol - October 2019: CCS, DHSC and PHE delivered a cross-government tabletop exercise of the specialist MEDEVAC protocol, designed to test and rehearse the Government's policies and contingency plans for the medical evacuation of a patient from the DRC and surrounding regions.

2009 H1N1 (Swine Flu) Outbreak and the Hine Review (2010) (respiratory transmission)

- 355. First identified in Mexico in April 2009, the H1N1 (swine flu) virus spread rapidly on a global scale, largely due to a low immunity to the virus amongst younger people. The WHO declared Swine Flu a pandemic on 11 June 2009.
- 356. There were two waves in the UK. Most cases in the UK were relatively mild, although more serious cases occurred amongst younger adults and children, particularly those with underlying health problems, and pregnant women. Academic studies suggest an infection mortality rate of between 1 and 10 per 100,000 infected. The pandemic caused 457 deaths in the UK **(CW/395)** and 795,000 were infected **(CW/431)**. The WHO declared the pandemic over on 10 August 2010.
- 357. Following the 2009 Swine Flu pandemic, the government commissioned an independent report conducted by Dame Deirdre Hine into how the pandemic spread across the world and here in the UK **(CW/395)** and **(CW/432)**. The report also covered how the UK Government responded to prevent a major outbreak in this country. The review found that:
 - a. The planning for a pandemic was well developed
 - b. The personnel involved were fully prepared
 - c. The scientific advice provided was expert
 - d. Communication was excellent; and
 - e. The NHS and public health services right across the UK and their suppliers "responded splendidly and the public response was calm and collaborative".

358. The review made several recommendations for the UK and Devolved Governments to improve the 2007 Pandemic Flu Framework. Recommendations included: taking into account greater variations in severity rather than focusing solely on the RWCS, considering differences of clinical impact on different age groups, and adopting behavioural science advice to assess the impact of how people may feel, think, and behave during a pandemic.
359. All recommendations were addressed in various documents, such as: the 2011 UK Influenza Pandemic Strategy (**CW/3**), the CO's Civil Emergency Concept of Operations CONOPS (2013) (**CW/346**), Enhanced SAGE Guidance (October 2012) (**CW/433**), the Health and Social Care Response document (April 2012) (**CW/399**), and the 2012 Pandemic Influenza Communications Strategy (**CW/351**).

2012 MERS outbreak

360. The MERS outbreak was relatively small, with the only cases in the UK resulting from overseas travel. However, the learning from the response to this outbreak informed the design of Exercise Alice in 2016 referred to in paragraph 351 above.
361. An outbreak in South Korea in 2015 demonstrated sustained person-to-person spread was possible, especially in healthcare settings from symptomatic cases, and also significantly influenced South Korean thinking in addressing nosocomial respiratory outbreaks.

2014 Ebola Virus Disease

362. The 2014–2016 outbreak in West Africa was the largest Ebola outbreak since the virus was first discovered in 1976. This was the seventh outbreak of EVD since its discovery. There were more cases and deaths in this outbreak than all previous EVD outbreaks combined. It started in Guinea then quickly spread to neighbouring countries Sierra Leone and Liberia. By July 2014, it had reached the capital cities of these three countries and in August 2014, the WHO declared the outbreak a PHEIC.
363. Over the course of the epidemic, the disease was imported to seven additional countries: Italy, the Republic of Mali (Mali), the Federal Republic of Nigeria (Nigeria), the Republic of Senegal (Senegal), the Kingdom of Spain (Spain), the UK and the USA. Secondary infections occurred in Italy, Mali, Nigeria and the USA. The three UK cases were all cases where infection had occurred outside the UK with no onward spread.
364. The UK Government provided considerable assistance in a joint DFID, MoD, CO, DH and PHE mission (Operation Gritrock) in support of the Government of Sierra Leone. Over 1,000 individual NHS, medical, academic and other staff volunteered to

work in West Africa during the epidemic. Joint civil-military planning proved successful.

365. This collaboration with Sierra Leone in support of their response led to significant experience for some UK medical, public health nursing and laboratory personnel in managing highly infectious patients, rapid deployment of contact tracing and isolation as a successful control measure and interactions with armed forces in times of medical emergency.
366. The epidemic occurred at a time when there were no vaccines or treatment for Ebola. The control effort had to rely on case findings and isolation to which the UK contributed planning and operational expertise. This was effective because almost all transmission was from symptomatic cases. Several scientific disciplines had to be integrated in support of this effort.
367. The contribution of social, and specifically anthropological sciences was important in informing the response, in addition to epidemiology, clinical science, engineering, virology and others.
368. Since the UK sent clinical staff to the region some of them required MEDEVAC due to exposures to Ebola. These evacuations required support from the Department and treatment in one of the UK's specialist infectious disease centres.
369. During the 2014-2016 Ebola outbreak, PHE provided 'port of entry' screening for Ebola to travellers arriving from high-risk countries. Screening teams were focused on London's Heathrow and Gatwick airports where more than 90% of relevant passengers entered the UK, including all identified higher risk workers. Screening enabled PHE to:
- a. Identify returnees from the affected countries;
 - b. Assess passengers' state of health and in-country activities;
 - c. Provide passengers with information about Ebola and the public health system in place for addressing it should symptoms develop; and
 - d. Facilitate rapid access to treatment if needed, and rapidly follow up high-risk passengers within the UK.
370. The outbreak led to the development of integrated care pathways for management of suspected EVD patients by NHS hospitals and primary care services across the country. Individuals who met suspected case criteria underwent clinical assessment at NHS hospitals across the UK. Clinical algorithms and guidelines were made available by PHE to assist UK clinicians with safe assessment and management of suspected cases.
371. NHSE and LRFs also developed plans for the sampling of possible HCID cases in the community, and the transfer, treatment and/or potential community

management of individual cases diagnosed outside of a healthcare facility. They also developed resources for frontline staff to ensure understanding about Ebola and developed Ebola specific infection prevention and control (IPC) guidance for emergency departments and primary care.

372. Contact tracing was also set up where in the case of a positive case of Ebola, hospital clinicians would inform the local Health Protection Team who would follow up on all possible contacts. In addition, many nursing, medical and microbiology departments took on extra workloads for colleagues who were granted time in West Africa. These activities are expected to have left a legacy of improved risk assessment and management.
373. Following the Ebola outbreak NHSE, PHE and DH took forward an HCID programme which included surveillance to ensure that appropriate preparation and response arrangements were in place for any future HCID's. While NHSE had developed a commissioned pathway for some airborne HCIDs at this stage there wasn't a commissioned pathway for others, such as SARS and MERS. The resulting HCID service has been operational since April 2018 **(CW/434)**. NHSE maintains the HCID network ready for activation in scenarios agreed with UKHSA. This network is responsible for coordinating the safe transfer (with the National Ambulance Resilience Unit), isolation and clinical management of cases.
374. In June 2016, the outbreak was declared over. More than 28,600 people had been infected and 11,325 people had died from this outbreak.
375. This Ebola disease outbreak led to an extensive review of the way the UK prepares for an incursion of a HCID. In 2015, DH and its delivery partners identified lessons and recommendations following the government's response to Ebola **(CW/435)**. Actions were implemented to address the recommendations, including improved data sharing (led by PHE), and developing a central register of contact details for healthcare volunteers travelling from the UK to affected countries, which was completed through NHSE's HCID programme.
376. The UK-PHRST, a specialist team ready to respond to disease outbreaks around the world, was also established as a result of the lessons learned from the government's response to Ebola. The UK-PHRST is a partnership between the London School of Hygiene & Tropical Medicine and PHE (now UKHSA), with contributing academic partners.
377. As mentioned in Section 2, the Ebola outbreak led to DH establishing the Global Health Security Programme (previously referred to as the Ross Fund, a joint programme with DfID) in 2016.

378. The Ebola outbreak in 2014-2016 led to initiation of the HCID Programme in 2015.
379. The aim of this was to consolidate learning from the Ebola experience and incorporate it into a long-term resilience plan to enable NHSE to deliver care safely and effectively for a wider range of known and unknown HCIDs.
380. The UKVN was established to identify vaccines with the potential to mitigate epidemics and pandemics. One of its funding priorities was the MERS vaccine, which was subsequently adapted to become the Oxford/AstraZeneca COVID-19 vaccine. More on the UKVN can be found above in this Section.
381. The experience of the 2014 Ebola outbreak led to extensive work on safe medical evacuation, reviewing the ability of commercial providers to deliver these services, ensuring their equipment is interoperable with the NHS and their HART ambulance isolation units.

Zika virus epidemic (2015 to 2016)

382. In 2015 Brazil reported a large outbreak of rash illness, which was later identified as Zika virus infection as causing microcephaly (very small heads) and other neurological disorders of new-borns where the mother was infected in pregnancy. It is transmitted by Aedes mosquitoes. WHO declared this constituted a PHEIC. To date, a total of 86 countries and territories have reported evidence of mosquito-transmitted Zika infection.
383. The UK was assessed as very low risk due to no local Aedes mosquito species capable of sustaining transmission of the infection.
384. The UK's response to the Zika virus was informed by the response to the Ebola outbreak, where it was noted that different government departments and other national and international agencies were working together very closely, which ensured a coordinated and effective response.
385. International networks, such as the GHSI, were valuable during health emergencies as a forum for sharing information quickly on global health challenges, including on the Zika virus, COVID-19 and the current Monkeypox outbreak. Early, rapid information sharing on the emerging Zika virus was facilitated through the GHSI, which informed the UK's decision making and approach. Through the GHSI, the UK was able to share and receive Zika virus samples with the purpose of developing diagnostics, using the GHSI Sample Sharing Framework, which was tested during Exercise Valverde (see above in this Section). This information sharing process via the GHSI, and Sample Sharing Framework, were used successfully during the COVID-19 response. A Zika virus report is exhibited at **(CW/436)**.

Clinical countermeasures

386. As mentioned above, a critical component of the Department's Pandemic Preparedness Programme was pro-active stockpiling of clinical countermeasures to ensure the UK had ready access to critical products in the early stages of a response to an influenza pandemic. The economic case to support procurement of the pandemic influenza clinical countermeasure stockpile was developed in 2008 to support the 'Defence in Depth' approach to pandemic preparedness (see below in this Section and Section 4).

387. Clinical countermeasures held or contracted for included:

- a. Antivirals stockpiled for treatment of pandemic influenza, to treat 50% of the UK's population (the proportion expected to develop symptomatic infections in the RWCS for pandemic influenza) **(CW/437)**.
- b. Antibiotics stockpiled for treatment of secondary bacterial infections in an influenza pandemic. Secondary bacterial infections have been a significant cause of mortality in previous influenza pandemics.
- c. A contract (APA) for supply of a pandemic-specific influenza vaccine when available (estimated to be approximately four to six months from the start of a pandemic). The contract provided the UK Government the option to order enough doses to vaccinate 70% of the UK population under a two-dose schedule at a pre-agreed unit price.
- d. Clinical consumables held to support the deployment of medicines and vaccines, such as needles and sharps bins.
- e. PPE for frontline health and social care staff, and additional clinical consumables to support infection prevention and control (including disinfectants and clinical waste bags).

Economic analysis to support pandemic countermeasure procurements

388. DHSC conducted economic analysis to support procurements for pandemic programme clinical countermeasures, in line with the guidance on economic appraisal and evaluation set out in the HMT Green Book. To reflect the large degree of uncertainty, the economic costs and benefits were assessed against a range of pandemic scenarios. The analysis built on the outputs from detailed epidemiological modelling conducted by PHE. PHE would then assist DHSC analysts with modelling target volumes for procurements.

389. Economic analysis supporting the procurement of pandemic countermeasures and consumables was typically presented in respect of a 4% probability of an influenza pandemic with any severity occurring in any year, emphasising high

uncertainty. This aligns to the occurrence of four influenza pandemics over the previous century (1918-19, 1957-58, 1968-69, and 2009-10).

Outline Business Case for Pandemic Influenza Clinical Countermeasures 2008

390. As mentioned above, an overarching business case was developed in 2008 (**CW/438**) to underpin delivery of a coherent programme of pandemic influenza clinical countermeasure and supply deliverables (represented in specific intervention Final Business Cases) that, when linked together, would realise the most effective response on behalf of the UK population and reflect a value for money outcome based on the precautionary principle.

391. The business case focused on a series of countermeasures, and on an intervention strategy, for use in the event of a pandemic, based on the need for 'Defence in Depth'. This strategy aimed to:

- a. Minimise illness and death;
- b. Reduce the burden on the NHS; and
- c. Reduce economic impact of a pandemic.

392. There were four layers to the 'Defence in Depth' strategy:

- a. Reduce the spread of the virus - through good public hygiene habits, social distancing measures and the use of face masks;
- b. Reduce the number of symptomatic cases - through the use of vaccines and antiviral prophylaxis;
- c. Reduce the number of complications; and
- d. Reduce chronic illness and death.

393. The commercial case was targeted at the delivery of a coherent programme of pandemic influenza clinical countermeasures and supply deliverables, which when linked together and distributed in a timely manner to appropriate recipients provides the most effective response.

394. In the UK, the Department's SAG completed comprehensive reviews of the evidence supporting the use of antivirals and antibiotics in 2006/07 which were broadly in line with the international consensus described above. These were subsequently peer reviewed by a group of national and international experts in a Colloquium convened by the Secretary of State. The policy on the use of vaccines, antibiotics and antivirals fully reflected the work completed by the SAG.

Funding for pandemic preparedness clinical countermeasures

395. Programme funding for pandemic preparedness clinical countermeasures is provided for from within a broader DHSC-owned Vaccines and Countermeasures

Response (VCR) budget. The VCR budget encapsulates funding for three programmes:

- a. The national vaccines and immunisations programmes
- b. The pandemic preparedness programme (PIPP)
- c. The emergency preparedness (CBRN) programme

396. The table below shows the spend (budget outturn) against the Pandemic Preparedness Programme (component (b) of the VCR budget) from 2013/14 to 2019/20. This reflects the actual cost incurred against the budget.

397. This table reflects the cost of products covered by the PIPP budget. Detail of the PIPP stockpile is set out at the start of Section 3 (paragraph 245). This includes the National Pandemic Flu Service (NPFS – at ~£2 million/year), the Antiviral Exchange Programme, the APA (at circa £40 million/year) and the storage and distribution of PIPP items among other pandemic flu related costs. Spend fluctuates year on year dependent on what procurements are made, stock expiry / disposal costs. This variation in the budget overrun reflects the underlying profile of the PIPP stockpiles and is not due to changes in the prioritisation of pandemic preparedness. For example, in financial year (FY) 16/17 there was an increased spend of circa £50 million to replace expired antivirals as part of the Antiviral Exchange Programme, in FY 18/19 there was a spend of circa £50 million to replace stock, and in FY 19/20 there was a significant cost increase in commencing the initial response to COVID-19.

Year	PIPP Budget Outturn £ million
19-20	164.995
18-19	102.033
17-18	53.244
16-17	106.415
15-16	63.264
14-15	64.516
13-14	104.93

Pandemic risk assessment

398. As mentioned in Section 1, the threat of an influenza pandemic has been captured as the highest natural hazard risk in the NRR since its first iteration in 2008.

The threat description and analysis of the risk (in terms of both likelihood and impact) has been kept updated in subsequent iterations of both the public-facing NRR and the internal NSRA. Both the NRR and NSRA are updated regularly, with NRR editions appearing in 2008, 2010, 2012, 2013, 2015, 2017, and 2020. The Department is identified as the LGD for both the pandemic risk and the closely aligned emerging infectious disease risk (see Section 1).

399. Risks in the NRR are represented as RWCS. Based on expert advice, these RWCS represent the worst plausible manifestation of that particular risk once highly unlikely variations have been discounted. Following comparative assessment of these RWCS, pandemic influenza was identified as the risk on the matrix with the highest impact. This assessment informed the department's approach to preparedness planning (as the LGD for this risk), guided by the planning assumptions within the RWCS for the reasonable worst-case scenario of a risk occurring.
400. The NRR was first published in 2008 (although pandemic influenza had been a published risk by the Department before this). The NRR also sets out advice to individuals, communities, and families on preparing for human disease and reducing the risk of viruses spreading.
401. CO's NSRA underpins the NRR and is a sensitive and unpublished document. The NSRA was first produced in 2019. DHSC contributes to the NSRA to determine the risk outputs on the NSRA and NRR. NRRs up until 2017 were underpinned by the National Risk Assessment (NRA). The NSRA and NRR are usually updated every two years. The risk of a pandemic has been high on the risk matrix on every update of the NSRA and NRR since it was first established.
402. In 2012, the government commissioned the Blackett Review of high impact, low probability risks to advise on how to reflect planning scenarios in the NSRA. This is exhibited at **(CW/439)**.
403. Prior to the COVID-19 pandemic, the last Global Health Security Index exercise was completed in October 2019 **(CW/440)**. The GHS Index found that the United Kingdom scored second overall in the world, with a score of 77.9/100, behind only the United States. It ranked the UK number 1 in the world with a score of 91.9/100 for our ability to provide a rapid response and mitigation to the spread of an epidemic.
404. The GHS Index is a comprehensive assessment and benchmarking of health security and related capabilities across the 195 countries that make up the Member States subject to the IHR. The GHS Index benchmarks health security in the context of other factors critical to fighting outbreaks, such as political and security risks, the broader strength of the health system, and country adherence to global norms.

Impact of EU Exit

405. In December 2018, Cabinet agreed that a 'no deal' EU Exit was the government's 'principal operational focus' and this was communicated to departments. Consequently, DHSC, along with all OGDs, changed its priorities. However, EU Exit planning and preparation had already been underway before this point, and the Department had focussed resources to prepare for a range of scenarios.
406. On 28 July 2019, the Chancellor of the Duchy of Lancaster announced that "planning for no deal is now this government's No. 1 priority". When Boris Johnson MP became Prime Minister in July 2019 the new Cabinet agreed that 'no deal' was the government's 'central focus', with additional actions to ramp up preparations including daily meetings of the EU Exit Operations (XO) Cabinet Committee.
407. As is usual practice across government, departments re-balance their resource when there is a major new government commitment to ensure there is sufficient focus on the new work. This was the case with EU Exit preparations, where the department needed to prepare for a number of different scenarios. Both 'deal' and 'no deal' scenarios required work which increased the resilience of the health and care system, including some elements which were then of direct use in the pandemic response.
408. Following the scale up of EU Exit related work that took place across government in 2018, the Department's ExCo agreed to deprioritise other work in order to move resource to focus on EU Exit. This affected work across the breadth of the Department's responsibilities. For example, the Department scaled back some work on the social care green paper in 2018. Similarly, work was paused on new consultations on obesity policy, as well as a roundtable on Hepatitis **(CW/441)** to **(CW/444)**.
409. In October 2018, the PIPP Board was notified of DHSC's decision to scale back some work related to pandemic preparedness and HCID **(CW/62)**. Work was paused on the development of guidance for NHSE on managing surges in the healthcare system, as well as on operationalising plans for adult social care. Furthermore, a refresh to the Influenza Pandemic Strategy from 2011, and the 2012 Communications Strategy, was paused. Similarly, the PFRB met in November 2018 and agreed to pause meeting until February 2020 (although the Board met in January 2020).
410. The Department continued to progress work on the development of the draft Pandemic Flu Bill, as well as continuing plans to re-procure a pandemic specific vaccine APA. DHSC also advanced plans to establish a programme of Tier 1

pandemic flu exercises to test the improvements made to preparedness since Exercise Cygnus. The PIPP Board met again in October 2019.

411. Some elements of EU Exit preparations created additional public health and system resilience. In 2018, the Department developed an extensive programme of activity as part of the government's planning and preparation for the risks of a 'no deal' EU Exit. Our existing EPRR function was brought together with our work on preparing for a 'no-deal' EU Exit into the newly formed ORC. This brought together our capability on emergency response and responsibilities as a Category 1 responder with our planning and preparedness to manage a potential 'no deal' EU exit.
412. The DHSC ORC led the health and social care preparedness and response for Operation Yellowhammer. The work developed under the Operation Yellowhammer programme provided great benefits to the Department that were realised during the COVID-19 response, including improved emergency response capability and a better understanding of supply chains and impacts of supply chain disruptions.
413. A new Continuity of Supply programme was established to mitigate the risk of border disruption to the import of medicines and medical products from the EU. The UK is heavily reliant on imports from or via EU member states and the short straits (the routes between Calais/Dunkirk/Coquelles and Dover/Folkestone) for medical supplies: around three quarters of medicines have an EU touchpoint, with the vast majority via the short straits. For more detail on EU Exit and the NSDR, see paragraph 94. The government's published RWCS planning assumptions noted the "unready Heavy Goods Vehicles (HGVs) could reduce the flow rate [at the short straits] to 40-60% of current levels" **(CW/445)**. Working closely with industry, the NHS, and OGDs, a multi-layered approach was implemented **(CW/446)**, which consisted of stockpiling around 6 weeks' worth of medicines and supplies (both government and private owned), supporting suppliers to get trader ready for new border checks, alternative ferry routes to avoid the short straits (equivalent of 2,603 HGVs per week of Government Secured Freight Capacity for medical products procured by DfT) **(CW/447)**, regulatory flexibilities and a dedicated emergency response function, including DHSC procured Express Freight Service for emergency product movements by air from the EU **(CW/448)**. The programme was UK-wide and covered six product areas (medicines, medical technologies, vaccines, clinical trials, substances of human origin, and non-clinical goods and services, such as food and laundry).
414. The Department identified 10 workstreams in the EU Exit portfolio, which were:

- a. Continuity of supply – Ensure uninterrupted patient care in the health and care system by ensuring there is a sufficient supply of medical products across the UK.
 - b. Reciprocal healthcare - Seek to establish alternative reciprocal healthcare arrangements between the UK and the EU27/ European Economic Area (EEA) countries as soon as possible and minimise the disruption of transition to any new arrangements
 - c. Adult social care - Ensure continued care services for recipients (both publicly and privately funded) of adult social care services across England.
 - d. MHRA readiness - Ensure effective and uninterrupted regulation processes from day one in the UK
 - e. Workforce - Protect the health, safety and interest of patients and staff by mitigating or responding to disruption to the health and social care workforce and strengthening the resilience of the sector.
 - f. Data - Ensure alternative transfer mechanisms are in place to enable data transfer from the EEA to England for the health and care system, including transfer of data stored in the EEA and access to data contained in EEA databases, systems and networks; and to be ready to respond to any issues after exit-day where data is not flowing.
 - g. Health security - To maintain the UK's capability to prevent, detect, prepare for and respond to cross-border threats to health.
 - h. Overseas Visitor Cost Recovery - Put in place a legal framework for England and Northern Ireland and support implementation of the National Health Service (Charges to Overseas Visitor) Regulations 2015 in England.
 - i. Public health - Ensure continued functioning of the statute book for the UK.
 - j. Operational readiness and response - Ensure local, regional and national preparations are in place for adult social care services in England before day one of EU Exit; and development of emergency response arrangements.
415. When the date of EU Exit was confirmed in January 2020, there was some uncertainty as to the impact of the UK's withdrawal from the EU on public health cooperation. The Department agreed with the EU Commission on 30 January 2020 that information-sharing and participation in relevant meetings on COVID-19 would continue during the Implementation Period **(CW/449)**.
416. While it is a matter of judgement, the Department's view is that the UK was better prepared for health-related emergencies as a result of the work conducted on EU Exit. For example, on supply, the Department had a far deeper understanding of global medical supply chains and stronger relationships with industry, heightened

stockpiles of critical medicines and medical products which provided an increased buffer to disruption, and an improved emergency response function, including provision for emergency logistics to mitigate disruption (since re-procured to enable imports from anywhere in the world, and not just the EU) **(CW/450)**. During the COVID-19 pandemic, the department was able to use its existing stockpiles, the NSDR service, and could quickly identify specific drugs that came from Wuhan, thanks to these capabilities.

SECTION 4: Public health services

417. This part of my statement covers the structure and responsibilities of public health services and the funding of the system.

Structure and responsibilities of public health services

418. From 2009 to 2013, responsibility for public health services in England rested primarily with the HPA. The HPA was created on 1 April 2003 as a special health authority in England and Wales, and was established as a UK-wide non-departmental public body on 1 April 2005 by the Health Protection Agency Act 2004. The HPA's functions in relation to health included the protection of the UK public against infectious disease and other dangers to health, and the prevention of the spread of infectious disease. The HPA exercised these functions alongside NHS Primary Care Trusts (PCTs) who commissioned a range of services to improve or protect the public's health. Policy responsibility for public health services sat with the Secretary of State, supported by DH. The Secretary of State retained the power to direct the HPA to take on other functions in relation to health.

419. The HPA's functions included providing impartial expert advice and information to professionals, the public and government on health protection matters. It was also responsible for acting, as well as supporting other organisations (such as the NHS) to act, to protect the public from infectious diseases, CBRN hazards and other public health threats.

420. One of the HPA's roles was to help ensure that the nation was ready for future threats to health that could happen naturally, accidentally or deliberately. The HPA incorporated the functions of the Public Health Laboratory Service, the Centre for Applied Microbiology and Research and the National Focus for Chemical Incidents.

421. Information on responsibilities and arrangements for pandemic preparedness, including stockpiling of equipment and countermeasures, for the period 2009-2019 is covered in Section 3 of this statement.

422. In 2010 the government embarked on a health reform programme which included significant changes to public health responsibilities (**CW/451**). The HSCA 2012 made significant changes to the NHS Act 2006, including a duty on the Secretary of State for Health to take such steps as the Secretary of State considers appropriate to protect the public in England from disease or other dangers to health (s.2A NHS Act 2006), and a duty for unitary and upper-tier local authorities to take such steps as each considers appropriate for improving the health of the people in its area (s.2B NHS Act 2006). Section 2B also gave the Secretary of State power to take such steps as the Secretary of State might consider appropriate for health improvement.

Functions of the HPA, which was abolished, were transferred to the Secretary of State. There were also substantial changes to the organisation of the NHS with the creation of NHSE and CGS (and the abolishment of PCTs). I will cover these changes to public health responsibilities in turn.

423. To support exercise of these new functions:

- a. PHE was established as an Executive Agency of the DH. PHE was the principal route for discharge of the Secretary of State's public health protection duty (s.2A NHS Act 2006), and it also acted under the Secretary of State's public health improvement power (s.2B NHS Act 2006). For the first time, health protection and health improvement responsibilities were combined in the new agency.
- b. PHE was a distinct delivery organisation with operational autonomy. It provided government, local government, the NHS, Parliament, industry, public health professionals and the public with evidence-based professional, scientific and delivery expertise and support, and carried out some statutory functions of the Secretary of State. PHE had responsibility for four critical functions:
 - i. Fulfil the Secretary of State's duty to protect the public's health,
 - ii. Secure improvements to the public's health, including supporting the system to reduce health inequalities,
 - iii. Improve population health supporting sustainable health and care services,
 - iv. Ensure the public health system maintains the capability and capacity to tackle today's (and future) public health challenges.
- c. Both PHE and DHSC had responsibilities for planning for and managing the response to emergencies and health protection incidents and outbreaks in an extended team that worked across government.
- d. DHSC and PHE worked together to provide assurance that PHE's responsibilities were being discharged. To that end, DHSC and PHE (with other bodies) developed a protocol on assurance for emergency planning, resilience and response. The protocol was reviewed at least annually.
- e. PHE drew together functions from a number of pre-existing bodies which had performed health improvement and health protection functions, including the HPA. Core health protection functions of PHE included: hosting national

expertise and research capability; operation of high containment laboratories and other nationally important scientific facilities; and managing local health protection teams which provided specialist advice and support to local Government, the NHS and other agencies. PHE's health protection brief encompassed infectious diseases and other hazards to health, such as chemical, radiation and environmental risks. HPA functions which were associated with the NIBSC transferred to the MHRA. PHE was funded by a Grant in Aid from DH, and it also generated income from its activities.

- f. PHE's Regional Directors (RDs) provided regional leadership for both health protection and health improvement activities in PHE, and were professionally and managerially accountable within the organisation. The number, configuration and reporting arrangements for these regional roles evolved in the years following PHE's establishment, with a seven region model in place by 2019. During 2019, PHE and NHSE were working together to establish joint RD roles spanning their respective public health remits, with RDs remaining PHE employees accountable to the organisation's Medical Director but also operating as part of NHSE's regional leadership structures.
 - g. PHE's primary remit was for England, but it worked closely with other UK public health agencies, including to co-ordinate knowledge and action on protecting the public's health, and was active internationally in countering global health protection threats such as specific disease outbreaks overseas.
 - h. DH further supported discharge of the Secretary of State's functions in respect of policy development and implementation both for the protection and improvement of the public's health. This included holding PHE and NHSE to account for the performance of their functions.
424. As outlined in paragraph 422, the HSCA 2012 established a duty for each unitary and upper-tier local authority to take such steps as the LA considers appropriate for improving the health of the people in its area. This was accompanied by a power which transferred responsibility for appointing Directors of Public Health (DPH) from PCTs to both unitary and upper-tier LAs and the Secretary of State (s.73A NHS Act 2006). The HSCA 2012 also abolished PCTs and transferred commissioning responsibilities for a range of health services from PCTs to other health bodies such as CCGs, the NHS Commissioning Board or LAs.
425. The duties placed upon local DPHs, as chief statutory officers in Local Government, align with the corporate public health duties of their LA; in addition, the DPH is under a duty to publish an annual report on the health of the local population. PHE's RDs represented the Secretary of State in appointing local DPHs, and

provided them with ongoing professional support and advice. DPHs were managerially accountable to their employing authority, though the Secretary of State could require the employing LA to review the performance of a DPH with regard to the performance of Secretary of State's delegated public health responsibilities. DPHs were expected to undertake continuing professional development and to maintain an appropriate professional registration. DH issued guidance on the role and appointment of DPHs, which was updated in January 2020. This is exhibited at **(CW/452)**.

426. The Local Authorities (Public Health Functions and Entry to Premises by Healthwatch Representatives) Regulations 2013 imposed duties on local authorities to exercise prescribed public health functions of the Secretary of State and to take prescribed steps in exercise of public health functions of their own, in particular their duty as to the improvement of public health (s.2B NHS Act 2006). This included a duty for the LA to provide information and advice to specified people and bodies to promote the preparation of appropriate local health protection arrangements.

427. LAs' new public health functions were funded by a ring-fenced grant from central government, the public health grant, which amounted to £2.66 billion in 2013/14 **(CW/453)**. There was a requirement for LAs to use this funding only to meet eligible expenditure incurred or to be incurred by LAs when exercising their public health functions under s.73B(2) of the NHS Act 2006. In 2015 LAs took on responsibility from NHSE for commissioning additional public health services for young children, accompanied by a further transfer of funding, and in 2019/20 the public health grant stood at £3.134 billion **(CW/454)**. The grant was distributed to LAs by PHE, and PHE's Chief Executive was the national Accounting Officer for this funding. LAs reported spend against a number of different public health activities: the biggest categories of spend have consistently been sexual and reproductive health, treatment and prevention of addictions, and (from 2015) children's public health. Against health protection, LAs reported spend of £34 million in 2013/14 and £29.4 million in 2019/20.

428. The Secretary of State also has a power under section 7A of the NHS Act 2006 to delegate the exercise of public health functions to NHSE, CCGs and LAs. This power was used from 2013 to delegate responsibility for commissioning certain national public health services to NHSE, including national immunisation programmes for influenza and childhood illnesses **(CW/455)**. Funding for these services was identified from within the overall mandate funding total for the NHS. Immunisation programmes were jointly planned by DHSC, PHE and NHSE, in line with advice from the JCVI. Procurement and storage of vaccines and provision of

expert advice was largely undertaken by PHE; and service delivery was managed by the NHS. There was coordination across the four nations on the programmes but decisions and delivery were devolved.

Funding

429. As mentioned in Section 3, the national pandemic preparedness approach is based on a 'Defence in Depth' strategy to minimise spread of infection and treat individual cases. In addition to plans to surge NHS provision, including critical care, the strategy involves measures to reduce the demand on those NHS services by reducing the risk of transmission and minimising serious illness, including through the stockpiling of personal protective equipment and antivirals.
430. As the Defence in Depth strategy is multi-faceted and involves many organisations and departments, it is difficult to provide one figure that accurately represents our spend on pandemic preparedness. However, some of the key elements of the strategy are outlined below. In terms of funding, this translates into two specific elements within the health system:
- a. Funding, managed by PHE (now UKHSA) for the management of PIPP stockpiles and associated infrastructure (for example the NPFS); and
 - b. Funding to the NHS which supports the provision of services, for example critical care beds, that are used to treat patients with other conditions between pandemics.
431. The DHSC Group outturn tables below demonstrate these figures, as well as Public Health Grants provided to LAs, between 2009 and 2020. The tables are in both cash and real terms (real terms are in 2019/2020 prices).
432. PHE brought together public health functions from over 70 national, regional and local sender bodies, including the HPA and DH. The figures in the tables below for PHE cover the full range of its functions, including health protection and health improvement. They are net of income which PHE generated through its activities, reported as £243m 2019/20. PHE's published annual reports and accounts attributed spend in each year to a range of activities, including protection against infectious diseases and environmental hazards. These data do not readily support the provision of a directly comparable time-series for PHE's spend on health protection vs its other responsibilities, as the organisation's financial reporting included a number of cross-cutting areas of spend – such as business support, facilities, research and global – which related to multiple PHE functions.

DHSC Group Figures - Cash basis

1. Revenue Departmental Expenditure Limit (RDEL) Outturn Figures in £ms	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
					Note 1						
RDEL, of which	98,781	96,582	99,368	101,645	105,477	109,533	113,710	117,031	120,650	125,278	134,183
<i>NHS England and NHS Providers</i> ²					93,754	97,713	102,187	105,089	108,933	112,806	122,936
<i>Health Protection Agency</i> ³	193	154	146	142							
<i>Public Health England</i> ⁴					413	351	354	315	304	325	432
<i>Public Health England - Vaccines and Countermeasure Response</i> ⁵					402	453	551	557	504	676	481
<i>Grants to Local Authorities (mainly Public Health Grant)</i> ⁷					2,705	2,863	3,088	3,433	3,091	3,011	2,932
<i>Other</i>	98,588	96,429	99,222	101,502	8,203	8,153	7,529	7,637	7,819	8,460	7,403

2. Capital Departmental Expenditure Limit (CDEL) Outturn Figures are in £ms	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
					Note 1						
CDEL, of which	5,173	5,045	4,669	4,708	5,367	4,971	4,652	4,556	5,238	5,941	7,015
<i>NHS England and NHS Providers</i>					3,411	3,496	3,124	3,093	3,273	4,150	4,764
<i>Health Protection Agency</i> ³	50	36	28	28	-	-	-	-	-	-	-
<i>Public Health England</i>					57	50	40	65	105	69	86
<i>Public Health England - Vaccines and Countermeasure Response</i> ⁶					11	16	53	13	34	139	55
<i>Research and Development</i>		887	898	925	1,018	1,020	1,021	998	1,063	1,103	1,169
<i>Other</i>	5,123	4,122	3,744	3,755	870	421	521	414	831	759	942

DHSC Group Figures - Real Terms basis (19-20 prices) ⁸

1. Revenue Departmental Expenditure Limit (RDEL) Outturn Figures in £ms	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
					Note 1						
RDEL, of which	117,202	112,713	113,944	114,570	116,468	119,630	123,210	124,258	125,999	128,536	134,183
NHS England and NHS Providers ²	0	0	0	0	103,524	106,720	110,725	111,578	113,763	115,740	122,936
Health Protection Agency ³	229	179	168	160	0	0	0	0	0	0	0
Public Health England ⁴	0	0	0	0	456	383	384	334	317	333	432
Public Health England - Vaccines and Countermeasure Response ⁵	0	0	0	0	444	495	597	591	526	694	481
Grants to Local Authorities (mainly Public Health Grant) ⁷	0	0	0	0	2,987	3,127	3,346	3,645	3,228	3,089	2,932
Other	116,972	112,534	113,776	114,409	9,058	8,904	8,158	8,109	8,165	8,680	7,403

2. Capital Departmental Expenditure Limit (CDEL) Outturn Figures are in £ms	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
					Note 1						
CDEL, of which	6,138	5,888	5,354	5,307	5,926	5,429	5,041	4,837	5,470	6,096	7,015
NHS England and NHS Providers	-	-	-	-	3,766	3,818	3,385	3,284	3,418	4,258	4,764
Health Protection Agency ³	59	42	32	32	-	-	-	-	-	-	-
Public Health England					63	55	44	69	110	70	86
Public Health England - Vaccines and Countermeasure Response ⁶					12	18	58	14	36	143	55
Research and Development	-	1,035	1,029	1,043	1,124	1,114	1,106	1,060	1,110	1,132	1,169
Other	6,078	4,811	4,293	4,232	961	460	564	439	868	779	942

1. In 2013-14, the DHSC Group structure changed: Primary Care Trusts and Strategic Health Authorities ceased and instead, NHS England, Public Health England, Health Education England, NHS Property Services LTD and Community Health Partnership LTD were created. Therefore a detailed breakdown by Group entity prior to 2013-14 has not been provided.

2. The NHS RDEL timeseries excludes some income/expenditure transactions with DHSC (i.e. dividends paid by NHS Providers to DHSC).

3. Health Protection Agency figures are provided from 2009-10 to 2012-13. Most of HPA's functions transferred into PHE from its creation from 2013-14.

4. In 2019-20, PHE incurred £49m of expenditure relating to Covid-19.

5. PHE Revenue Vaccines and Counter Measure Response (VCR) figures are taken from PHE's published Annual Report and Accounts "overall results against budgets" table.

6. PHE's VCR capital figures are taken from the data supplied by PHE to feed into the DHSC Group Annual Report and Accounts. This capital expenditure includes the net movement of Vaccines and Countermeasure Response (VCR) inventory (including the Pandemic Influenza Preparedness Programme - PIPP). Net movement in inventory comprises new inventory bought, less inventory used/impaired. In some years, inventory used/impaired was higher than new inventory bought resulting in a negative capital outturn.

7. The public health grant was introduced from 2013-14. Figures from 2015-16 reflect a change in scope of the Grant, to include funding for commissioning of 0-5 years public health services which moved from the NHS to local authorities from 1

8. The figures in the second set of tables are in real terms (2019-20 prices) based on the Office for National Statistics Quarterly National Accounts release of 30 September 2022. <https://www.gov.uk/government/collections/gdp-deflators-at-market-prices-and-money-gdp>

SECTION 5: Planning for future pandemics

433. In this section I offer some high-level reflections on what we have learnt from this pandemic. I will set out more detail on lessons learned and planning for future pandemics in a separate statement to the Inquiry.
434. My first reflection is that there is a difference between planning and capability to respond. Planning is essential, and I have set out the facts of our preparations before 2020 and refer to the external validation of the UK's position in the Global Security Index as described in Section 3. Planning does not in itself determine the capability of a large system to respond. Capability in the public health workforce, the NHS and in adult social care is dependent on a large number of other factors. The baseline and surge capacity of these services is also a relevant factor for the ability to respond.
435. My second reflection, which is related to the first, is that the response was strongest in the areas in which the UK was already strong. The UK's science-base, research, and universal health services led to obvious successes, for example, in running clinical trials and the vaccine roll-out. In areas where the UK is not a world-leader, such as large-scale manufacturing capacity, application and availability of diagnostics, and adult social care, the capacity to respond at speed was more limited.
436. These reflections are high-level and I will provide more detail on lessons learned on DHSC's preparedness activity up to January 2020, as well as planning for future pandemics during and after the COVID-19 pandemic, in a separate statement.

Statement of Truth

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

Signed: Personal Data

Dated: 25/11/2022

Glossary

Acronym	Full name
ACDP	Advisory Committee on Dangerous Pathogens
ALBs	Arm's Length Bodies
AMR	Antimicrobial resistance
APA	Advance purchase agreement
APHA	Animal and Plant health Agency
APRHAI	Advisory Committee on Antimicrobial Prescribing, Resistance, and Healthcare Associated Infections
ARC	Audit and Risk Committee
BEIS	Department for Business, Energy and Industrial Strategy
CO	Cabinet Office
CBRN	Chemical, Biological, and Radio-Nuclear
CCA	Civil Contingencies Act 2004
CCG	Clinical Commissioning Groups
CCMB	Clinical Countermeasures Management Board
CCS	Civil Contingencies Secretariat
CEAPI	Committee for Ethical Aspects of Pandemic Influenza
CEPI	Coalition for Epidemic Preparedness Innovations
CMO	Chief Medical Officer
CNO	Chief Nursing Officer
CONOPS	Cabinet Office Concept of Operations
COVID-19	Coronavirus disease
CRN	Clinical Research Network
CSA	Chief Scientific Adviser
CJD	Creutzfeldt – Jakob Disease
CVO	Chief Veterinary Officer
DARDNI	Department for Agricultural and Rural Development Northern Ireland
DCMO	Deputy Chief Medical Officer
DCMS	Department for Digital, Culture, Media and Sport
DEC	Departmental Expert Committee
Defra	Department for Environment, Food and Rural Affairs
DfE	Department for Education
DfT	Department for Transport

DG	Director General
DHSC	Department of Health and Social Care
DLUHC	Department for Levelling Up, Housing and Communities
DWP	Department for Work and Pensions
EA	Environment Agency
EAR	Early alerting and reporting
ECDC	European Centre for Disease Prevention and Control
EPHP	Emergency Preparedness and Health Protection
EPIS	Epidemic Intelligence Information System
EPRR	Emergency Preparedness, Resilience and Response
EVD	Ebola Virus Disease
ExCo	Executive Committee
FCDO	Foreign, Commonwealth and Development Office
FCO	Foreign and Commonwealth Office
FF	Fleming Fund
FSA	Food Standards Agency
FW&E	Food, Water and Environmental
GAMRIF	Global Antimicrobial Resistance Innovation Fund
GCSA	Government Chief Scientific Advisor
GHS	Global health security
GHSI	Global Health Security Initiative
GP	General Practitioner
HAIRS	Human Animal Infections and Risk Surveillance group
HART	Hazardous Area Response Team
HCID	High Consequence Infectious Diseases
HLRR	High Level Risk Register
HMRC	His Majesty's Revenue and Customs
HMT	His Majesty's Treasury
HO	Home Office
HPRU	Health Protection Research Units
HR	Human Resources
HSAG	Health Strategic Advisory Group
HSE	Health and Safety Executive
IHR	International Health Regulations
IRMA	Information Risk Management & Assurance

JCVI	Joint Committee on Vaccines and Immunisations
JIC	Just-in-case
JIT	Just-in-time
LGA	Local Government Association
LGD	Lead Government Department
LMIC	Low and middle income country/countries
LRF	Local Resilience Forums
MACA	Military Aid to the Civil Authorities
MEAG	The Moral and Ethical Advisory Group
MERS	Middle East Respiratory Syndrome
MHCLG	Ministry of Housing, Communities & Local Government
MHRA	Medicines & Healthcare products Regulatory Agency
MoD	Ministry of Defence
MoJ	Ministry of Justice
MOU	Memorandum of Understanding
MTA	Material Transfer Agreement
NAO	National Audit Office
NEDs	Non-executive director
NERVTAG	New and Emerging Respiratory Virus Threats Advisory Group
NHS	National Health Service
NHSE	NHS England
NIBSC	National Institute for Biological Standards and Control
NIHR	National Institute for Health Research
NPI	Non-pharmaceutical interventions
NPFS	National Pandemic Flu Service
NRR	National Risk Register
NSAC	National Situational Awareness Cell
NSRA	National Security Risk Assessment
NSS	National Security Secretariat
ODA	Official Development Assistance
OGDs	Other Government Departments
ORC	Operational Response Centre
PBAC	Programme Budget and Administration Committee
PFRB	Pandemic Flu Readiness Board
PHE	Public Health England

PHEIC	Public health emergency of international concern
PIPP	Pandemic Influenza Preparedness Programme
PPE	Personal protective equipment
PSV	Pandemic specific vaccine
PSVP	Pandemic Specific Vaccine Project
R&D	Research & Development
RWCS	Reasonable Worst Case Scenario
SaBTO	Advisory Committee on the Safety of Blood, Tissues, and Organs
SAG	Scientific Advisory Group
SAGE	Scientific Advisory Group for Emergencies
SARS	Severe Acute Respiratory Syndrome
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SCRC	Standing Committee of the Regional Committee
SPI	Scientific Pandemic Influenza Advisory Committee
SPI-B	The Independent Scientific Pandemic Insights Group on Behaviours
SPI-M	Scientific Pandemic Infections Group on Modelling
SSTG	Sample Sharing Task Group
TESSy	European Surveillance System
TSEs	transmissible spongiform encephalopathies
UKAS	United Kingdom Accreditation Services
UKHSA	UK Health Security Agency
UK-PHRST	UK Public Health Rapid Support Team
UKVN	UK Vaccine Network
UKZADI	UK Zoonoses, Animal Diseases and Infections Group
VMD	Veterinary Medicines Directorate
WHO	World Health Organization