Witness Name: Jenny Harries

Statement No. 1

Exhibits:

Dated: 14 April 2023

UK COVID-19 INQUIRY

WITNESS STATEMENT OF PROFESSOR DAME JENNY HARRIES

---

1. I, Professor Dame Jenny Harries, of the UK Health Security Agency, Nobel House, 17 Smith Square, London, SW1P 3JR, will say as follows:

2. I am employed by the UK Health Security Agency ("UKHSA") as the Chief Executive, a post for which I have had full executive operational responsibility since the organisation's inception on 1st October 2021. Prior to this I was formally appointed as CEO of UKHSA on 1st April 2021 supporting the organisations formation. Additionally, I took over executive operational leadership of NHS Test & Trace from 7th May 2021.

3. Before joining UKHSA, I was the Deputy Chief Medical Officer ("DCMO") for England between 2019 and 2021 and the Regional Director of the South of England within Public Health England ("PHE") between 2013 and 2019. Along with the Regional Director role I was interim Deputy National Medical Director for PHE between 2016 and 2017 providing specific support for strategic incident response. From April 2017 until July 2019 when I moved to the DCMO role, I

held the strategic incident, Deputy Medical Director role in PHE on a formal basis alongside the Regional Director role.

4. I am a clinical doctor with specialist training in public health medicine, the latter undertaken in Wales. I hold a medical degree (MB ChB) and Fellowship of the Faculty of Public Health (FFPH) by examination. I hold other formal qualifications relevant to my current role including a BSc in Pharmacology, a Masters degree in Public Health (MPH), a Masters degree in Business Administration (MBA), a Postgraduate Diploma in Health Economics Evaluation, and a Postgraduate Certificate in Strategic Planning and Commissioning. I am a Fellow of the Chartered Management Institute, a visiting Professor of Public Health at the University of Chester and an Honorary Fellow of both the Faculty of Occupational Medicine (FFoM) and of the Royal College of Paediatrics and Child Health (FRCPCH).

5. Prior to my roles with PHE and Department for Health and Social Care ("DHSC") and since 2009 I worked as a Director of Public Health in Norfolk & Waveney, Swindon and Monmouthshire and was additionally a chief officer in the two former Local Authorities. I have worked in clinical, operational, policy and health service economic and evaluation roles in the UK and globally since qualifying in medicine and have been a member of a number of national advisory groups including the Joint Committee on Vaccination and Immunisation, the National Advisory Committee on the NHS Constitution, the NHSE Clinical Priorities Advisory Group and the Women's Health Taskforce.

6. In my national work I have contributed to various significant health protection incidents including the Novichok poisonings (2018), the first cases of Monkeypox in the UK (2018), Zika (2016) and support to other global crises such as the Hurricane Irma response (2017). I was the National Programme Director for Ebola screening and the UK returning workers programme from 2014 to 2016 and the SRO for the subsequent development of the High Consequence Infectious Disease (HCID) programme. I have contributed knowledge to a number of relevant advisory groups as required during the current pandemic, chaired the SAGE Social Care Working Group from the end of the first wave of the pandemic in 2020 until leaving the DCMO post, led clinical work on the initial

shielding programme and acted as SRO for coordination of the subsequent Enhanced Protection Programme for those who may remain more clinically vulnerable to serious outcomes from COVID-19.

7. I make this statement in response to the request from the UK COVID-19 Inquiry ("the Inquiry"), dated 25 October 2022, under Rule 9 of the Inquiry Rules SI 2006/1838, requiring UKHSA to provide the Inquiry with a corporate witness statement in respect of specified matters relating to Module 1.

8. This statement is, to the best of my knowledge and belief, accurate and complete at the time of signing. Notwithstanding this, it is the case that UKHSA continues to prepare for its involvement in the Inquiry and it is possible that additional relevant information may come to light as the Inquiry progresses. In this eventuality the additional information or relevant material will be provided to the Inquiry and a supplementary statement will be made if requested by the Inquiry.

9. The matters in my statement rely on a mixture of my own experience, the records of UKHSA and its predecessor organisations, and with the input from a significant number of colleagues within UKHSA, who were employees of PHE, and those who have since left but hold relevant knowledge. These colleagues have been consulted as far as is practical, in order to provide as robust an account as possible on behalf of UKHSA.

10. While I have aimed for there to be a consistent level of factual detail provided in response to the questions posed by the Rule 9 request, as a result of the significant number of individuals that contributed to this statement, there may be some natural variation in that level of detail. I understand and expect that the Inquiry will request further detail on any matter if they require it.

11. Exhibits have been listed in this statement in response to the Inquiry's request and in order to provide context. I have not been able to review all the documents exhibited and a number of documents pre-date my own involvement or are derived outside the boundaries of my own operational sphere and in this case, I have relied upon subject matter experts to assist with the information presented.

Structure of the statement

12. 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.

13. In my statement, I use the names of organisations as they would have been referred to at the time. For example, I refer to the Heath Protection Agency ("HPA") for specific work conducted between 11 June 2009 and 31 March 2013 and Public Health England ("PHE") for specific work conducted between 1 April 2013 and 21 January 2020. However, for consistency, I refer to the Department of Health and Social care ("DHSC") throughout, rather than the Department of Health ("DH") as it was known prior to 2018. The statement refers to a large number of organisations, institutions, frameworks and guidance. As a result, the statement sets out the full name once and then reference to initials which will be used thereafter. A full set of the acronyms used with an explanation is at **[Exhibit: JH/M1 0001a - INQ000101058].**

14. This statement has 10 sections. Each section begins with a short summary of the content of that section. The headings and page references of the sections are as follows:

    Section 1: Introduction to UKHSA (paragraph 20-41)

    Section 2: Introduction to PHE and its Legacy Organisation the HPA (paragraph 42-150)

    Section 3: Overview of PHE's EPRR Functions (paragraph 151-199)

    Section 4: PHE's Public Health Services (paragraph 200-263)

    Section 5: The Civil Contingencies Act 2004 (paragraph 264-355)

    Section 6: Exercising, Institutional Learning, Training and Assurance (paragraph 356-444)

    Section 7: Vaccines, Immunisations and Countermeasures (paragraph 445-532)

Section 8: Standing up Response Plans for COVID-19 (paragraph 533-569)

Section 9: Health Inequalities and COVID-19 Disparities Data (paragraph 570-625)

Section 10: COVID-19 Lessons Identified and Future Preparedness (paragraph 626-642)

15. The global impact of the coronavirus pandemic has been unprecedented. In investigating the UK's response to this event, UKHSA fully supports the work of the UK COVID-19 Inquiry and its central focus on the devastating loss, suffering and hardship experienced by the whole nation.

16. The rapid emergence of a novel coronavirus presented an extraordinary challenge for governments, scientists and health and social care institutions around the world. At the very beginning only limited scientific knowledge was available. The subject focus of this narrative document therefore predates the majority of significant advancements made by the UK and the international scientific community in rapidly developing knowledge, understanding, treatments and vaccination to face the challenge of this new virus.

17. In this statement I provide a factual narrative of roles, responsibilities and activities of pandemic and emergency planning pre-COVID-19, and the very early stages of response, relating to the relevant public health agencies. I also lay out the organisational journey of these agencies and provide a very high-level note of relevant context for the establishment of UKHSA which was launched in October 2021, explaining changes to structures, resources, and priorities, and to the public health system more broadly.

18. The UK's response could not have been delivered without the role of the many remarkable public health professionals within and beyond these agencies together with a concerted response from the public. The unrelenting dedication of professionals to protect the nation continued simultaneously with those individuals living through their own pandemic experience along with their families and communities right across the nation. All demonstrated fortitude and

resilience in what has been the most significant public health emergency of the last century.

19. UKHSA has been born out of the learning from the pandemic and built, whilst still responding, on the strengths and expertise of its predecessors. The agency's working environment places innovation, collaboration, and continuous improvement at the heart of everything it does. With a leading role in preparing for pandemics, identifying, and learning lessons from Module 1 of the Inquiry will be crucial to UKHSA in informing its future work and how it delivers its remit to prepare for, prevent and respond to infectious diseases and other external threats to health.

Section 1: Introduction to UKHSA

20. The following is a brief narrative that provides a high-level view of UKHSA's establishment and relationship to predecessor organisations, purpose and strategy, governance, budget, staffing and organisational structure.

Establishment

21. UKHSA was formally launched on 1 April 2021 and became fully operational on 1 October 2021 combining the health protection clinical and scientific functions of Public Health England (PHE) with NHS Test & Trace (NHS T&T). The key steps leading to this are set out below.

22. PHE was established as an Executive Agency of the Department of Health and Social Care (DHSC) in 2013, to protect and improve the nation's health and wellbeing and reduce health inequalities, primarily covering England but having some UK-wide responsibilities (see Section 2 for further details). In response to the COVID-19 pandemic, NHS T&T was formally established in May 2020 to lead an additional at scale national testing and tracing service for the COVID-19 pandemic, working with PHE and others. An integral part of NHS T&T was the Joint Biosecurity Centre (JBC), which was initially established separately in the Cabinet Office.

23. In August 2020 the then Secretary of State for Health and Social Care announced that a new national body would be established to bring together the health protection elements of PHE with NHS T&T under a single leadership team. This was initially referred to as the National Institute for Health Protection (NIHP), although Ministers later changed the name to the UK Health Security Agency (UKHSA). The announcement said that the NIHP would be a new organisation whose primary focus was to ensure we have the best capability to control infectious disease and deal with pandemics or health protection crises.

24. The overall transition programme, which also included parts of PHE moving to become the Office for Health Improvement and Disparities (OHID) within DHSC, as well as to other destinations, was led by Jonathon Marron, Director General of Public Health at DHSC. A transition team was established within NHS Test and Trace to develop the structure of the new organisation.

25. In April 2021, the Community Testing Programme that had been established within DHSC to support local authorities deliver a local approach to testing was transferred into NHS Test and Trace.

26. On 1 April 2021 I was formally appointed as Chief Executive of UKHSA and Ian Peters was formally appointed as Chair (non-executive). From April to October 2021, the component organisations retained their identities, responsibilities, and structures whilst planning for transition to the new organisation continued.

27. UKHSA (renamed from the original NIHP) became fully operational from 1 October 2021. On this date staff transferred to UKHSA from PHE and NHS T&T, and the predecessor organisations ceased to be operational. Some functions and staff from PHE transferred elsewhere, most notably the health improvement functions of PHE were predominantly transferred to OHID in DHSC.

28. Over time other functions have been integrated into UKHSA. With effect from 1 April 2022, responsibility for the policy function of the Borders and Managed Quarantine Service was transferred to UKHSA from DHSC. The Managed Quarantine Service (MQS) programme had provided hotel quarantine for people legally required to isolate on return to the UK from 'Red List' countries. At the time of transfer from DHSC to UKHSA, the programme had ceased live

operations, following the Government's decision to end hotel quarantine which took effect on 15 December 2021. UKHSA took responsibility for follow-up work including litigation, as well as policy on relevant potential future health protection functions at the border.

29. With effect from 1 October 2022, responsibility for procurement and sourcing of COVID-19 vaccines that had been led by the Vaccine Task Force (VTF) with the Department for Business, Energy and Industrial Strategy (BEIS) transferred to UKHSA as the new Covid Vaccine Unit, with the Director reporting directly to me as Chief Executive. Some other functions of the VTF transferred to the Office for Life Sciences and to DHSC.

Mission and role

30. A Framework Agreement between DHSC and UKHSA was published in January 2022 **[Exhibit: JH/M1 0001 - INQ000090316]** setting out UKHSA's governance, accountability framework, core responsibilities and objectives. This document says that "UKHSA has been established by the Secretary of State for Health and Social Care as this country's permanent standing capacity to prepare for, prevent and respond to infectious diseases and other threats to health". The Annex A **[Exhibit: JH/M1 0002 - INQ000090309]** lists statutory duties that UKHSA carries out on behalf of the Secretary of State for Health and Social Care. The Framework Agreement specifies that UKHSA should develop a three-year strategic plan, with annual business plans developed from this, to be approved by the Secretary of State for Health and Social Care. UKHSA has agreed with DHSC that its first three-year strategic plan will begin in 2023/24.

31. An annual remit letter from the relevant Minister in DHSC details the government's expectations and priorities for UKHSA in the year and going forward. Remit letters for UKHSA are available for 2021/22 and 2022/23. **[Exhibit: JH/M1 0003 - INQ000090310] [Exhibit: JH/M1 0004 - INQ000090311]** DHSC consults with UKHSA when preparing the letter. The 2022/23 letter acknowledges that UKHSA is still in a development phase and is undertaking a transition of its functions in line with the COVID-19 Response: Living with COVID-19 strategy published by the Government in May 2022 **[Exhibit: JH/M1**

0005 - INQ000090312] and that the agency's budget for 2022/3 was finalised just before the start of the financial year. Budgets for 2023-2025 are not yet finalised.

32. UKHSA's mission is to provide health security for the nation by protecting the population from infectious disease and external hazards. External hazards include chemical, biological, radiological, nuclear and environmental threats. UKHSA is the nation's expert health security agency and based on its scientific expertise, it leads a system-wide effort to prevent, detect, analyse and respond to health security hazards, both delivering direct activity and working with and harnessing the capabilities of a wide range of partners.

33. UKHSA's 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. It also holds UK-wide responsibilities in areas of technical and/or specialist capability and capacity and excepted reserved competence such as specialist radiation capabilities and being the UK's designated national focal point for International Health Regulations. Responsibility for most health protection matters in Scotland, Wales and Northern Ireland rests with the devolved governments and their health protection agencies, with UKHSA carrying out the equivalent health protection functions in England. UKHSA works closely with counterparts in Scotland, Wales and Northern Ireland, and UKHSA undertakes some activities with their agreement, for example in relation to some ongoing COVID-19 surveillance activity.

34. UKHSA responds to tens of thousands of health protection situations, incidents and outbreaks in the UK and overseas each year, typically through partnerships with a range of local, national and international bodies.

35. Three strategic goals drive all UKHSA's activity whilst it aims to achieve more equitable health outcomes for all communities throughout everything it does. The strategic goals are:

    a. Prepare - be ready for, and prevent, future health security hazards.

b. Respond - save lives and reduce harm through effective health security response, protecting public services, livelihoods and the economy.

c. Build - build the capability needed as a system, and health security capacity at local, national and global levels.

36. To ensure its ability to deliver our goals, UKHSA is investing in key skills, capabilities and enabling functions such as its estates and infrastructure, digital technology, data science and surveillance capabilities. The agency will also invest and build on the collaborative working that took place during the pandemic, across sectors and professional groups, and across devolved governments, local authorities, academia, research and industry partners.

Governance and Accountability

37. UKHSA's Executive Committee is the organisation's key decision-making body and it supports me as Accounting Officer. It was established in shadow form in August 2021 and has met formally from 1 October 2021. The Executive Committee consists of UKHSA's Directors General as well as the People, Communications and Commercial Directors, and the Chief Technology Officer. From October 2022 the Director of the Covid Vaccine Unit also joined the Executive Committee **[Exhibit: JH/M1 0006 - INQ000090313].**

38. UKHSA's Advisory Board was recruited in 2021, becoming established in April 2022, with formal agreement of the organisation's remit and budget. As well as the non-executive Chair, five Non-Executive Members and three Associate Non-Executive Members appointed by the Secretary of State for Health and Social Care. **[Exhibit: JH/M1 0007 - INQ000090314]**. The first informal meeting of the Board was held in June 2022 and subsequently the first formal meetings have been held in September and November. The Board has established four committees: an Audit and Risk Committee, a People and Culture Committee, a Science and Research Committee and an Equalities, Ethics and Communities Committee. Details of the Board members can be found in the exhibited document above.

39. UKHSA is an Executive Agency of the DHSC. As detailed in the Framework Document this means that "The Secretary of State and junior minister with lead responsibility for UKHSA have ministerial responsibility for, and oversight of, UKHSA delivery and performance as an integral part of the public health system. This includes being accountable to Parliament in relation to the functions and performance of UKHSA." As Chief Executive I am responsible for the leadership and management of UKHSA and the delivery of its objectives. I have also been appointed as Accounting Officer for the agency which means that I am personally responsible for safeguarding the public funds for which I have formally received charge; for ensuring propriety, regularity, value for money and feasibility in the handling of those public funds; and for the day-to-day operations and management of UKHSA.

Organisational Structure

40. UKHSA currently comprises 6 groups led by directors general and 2 led by Directors: Clinical and Public Health; Science; Data, Analytics and Surveillance; Health Protection Operations (which incorporates Testing Operations); Strategy, Policy and Programmes; Finance, Commercial and Corporate services; People; Technology; and the COVID-19 Vaccine Unit. These span a very wide range of professions. Each group has a leader who reports to me as Chief Executive. The UKHSA model is designed in such a way that these capabilities, work together to provide an integrated all-hazards health protection capability.

41. I exhibit the leadership organogram as of the date of this statement as **[Exhibit: JH/M1 0008 - INQ000090315].**

Section 2: Introduction to PHE and its legacy organisation the HPA

42. In this section I provide an overview of the two public health organisations that I consider as predecessor organisations of UKHSA; the Health Protection Agency (HPA) (2003 -2013) and Public Health England (PHE) (2013-2021).

43. This section focuses predominantly on PHE as the agency most relevant to the scope of Module 1. However, I also provide an overview of HPA and the different

ways both agencies related to the Department of Health (DH), and latterly the Department of Health and Social Care (DHSC), as well as the key changes to the public health system, as relevant to Module 1, and PHE, and particularly those that resulted from the Health and Social Care Act (2012) ("HSCA 2012").

44. This section will set out how PHE was created in 2013 with a remit for health improvement, health care public health and heath protection underpinned by data and evidence. PHE played a central role in the major health protection challenges of the period from 2013 to January 2020, including measles outbreaks, Ebola, Zika and Novichok. The annual remit letter from the minister in DHSC set out more expectations on PHE's health improvement, healthcare services and health protection activities with specific tasks related to emergency response, vaccination and anti-microbial resistance. PHE was created with reduced government funding compared to its predecessor and there was a further reduction in funding of circa 40% between 2013/4 and 2019/20, with external income increasingly maintaining a significant part of the budget for core national capabilities.

45. I provide below a more in-depth overview of PHE, including its governance and accountability, funding and income generation, its staffing and key individuals, and the organisation's structure. This section concludes with a brief description of the transition of PHE to UKHSA.

Health Protection Agency (2003-2013)

46. In January 2002, the Chief Medical Officer for England, Sir Liam Donaldson, published a report: Getting Ahead of the Curve **[Exhibit: JH/M1 0009 - INQ000090317]** which recognised that the country faced major public health challenges from new and existing infectious diseases, antimicrobial resistance and bioterrorism threats. The report recognised the need to bring together the skills and expertise of a number of separate organisations to work in a more coordinated way and proposed the creation of a new agency for infection control and health protection, which was later named the Health Protection Agency (HPA).

47. The proposed benefits of this new agency were to provide a more comprehensive and effective response to threats to the public's health, and improve knowledge, insight, and health protection expertise through research and development, education and training, to reduce the burden and negative consequences of health protection threats or disease.

48. The HPA was established as a special health authority on 1 April 2003 and was constituted of the staff and functions of a number of arms-length bodies: the Public Health Laboratory Service (PHLS), the Microbiological Research Agency, the Chemical Incidents Response Service Unit and local health protection and emergency planning functions that were based in the NHS **[Exhibit: JH/M1 0010 - INQ000090318]**. The Health Protection Agency Act 2004 then brought together the HPA Special Health Authority and the National Radiological Protection Board (NRPB) to become the Health Protection Agency in April 2005. The agency was an executive non-departmental public body sponsored by DHSC and accountable to the Secretary of State for Health and the Minister of State for Public Health. I refer the inquiry to the "Getting Ahead of the Curve" report for detailed descriptions of HPA's predecessor organisations **[Exhibit: JH/M1 0009 - INQ000090317]**.

49. The Health Protection Agency Act 2004 and the Health Protection Agency Regulations 2005 set out the functions, duties and powers of the HPA **[Exhibit: JH/M1 0010a-0010b - INQ000147712, INQ000147713].**

50. The HPA's role was:

    a. Advising government on public health protection policies and programmes

    b. Delivering services and supporting the NHS and other agencies to protect people from infectious diseases, poisons, chemical and radiological hazards

    c. Providing an impartial and authoritative source of information and advice to professionals and the public

    d. Responding to new threats to public health

e. Providing a rapid response to health protection emergencies, including the deliberate release of biological, chemical, poison or radioactive substances

51. The HPA Board had corporate responsibility for ensuring that the HPA fulfilled the aims and objectives set by the Secretary of State for Health and promoted the efficient and effective use of staff and other resources. The Board established the overall strategic direction of the HPA within the policy and resources framework determined by the Secretary of State for Health. The Chief Executive of HPA reported to the Chair of the HPA.

52. Responsibility for delivering the HPA's objectives and running the business on a day-to-day basis lay with the Chief Executive, supported by an Executive Group, the full membership of which and specific roles are set out in **[Exhibit: JH/M1 0011 - INQ000090319].**

53. In relation to health protection, PHE initially took over the majority of the HPA's functions and its plans for developing these, which are described in a number of documents that I have provided as exhibits, namely: Leading the Way in Health Protection **[Exhibit: JH/M1 0012 - INQ000090320]**, HPA's strategic plan for 2008 to 2013 **[Exhibit: JH/M1 0013 - INQ000090321]** and the Health Protection Agency Strategic Overview **[Exhibit: JH/M1 0014 - INQ000090322]**. The Chief Executive of PHE reported to the Permanent Secretary at the Department for Health and Social Care.

Health and Social Care Act 2012 and the formation of Public Health England

54. In November 2010 the public health white paper, Healthy Lives, Healthy People **[Exhibit: JH/M1 0015 - INQ000090323]** set out the government's commitment to establish a new national service that would merge the functions of the HPA with some public health activities carried out by NHS Strategic Health Authorities and Government Offices for the regions, plus the functions of the public health observatories, cancer registries and the National Treatment Agency for Substance Misuse. Bringing together the three domains of public health (health protection, health improvement and health care public health) into a single agency reflects the discussion and changes in many countries at the time, many

of which followed the English model implemented, e.g. France, Wales and Scotland.

55. The Health and Social Care Act 2012 **[Exhibit: JH/M1 0015a - INQ000147714]** provided the foundation for this national service to be established as an executive agency of DHSC and known as Public Health England (PHE). The proposed details of PHE's structure were set out in a series of factsheets **[Exhibit JH/M1 0016 - INQ000090324]. [Exhibit: JH/M1 0017 - INQ000090325]**.

56. PHE's governance structures were developed and implemented in accordance with the requirements of the Framework Agreement with DHSC and the annual remit letter from Ministers, which taken together set out its duties and functions. They also reflected the government's expectation that, as an executive agency with operational autonomy, PHE was an authoritative voice on public health. The government acknowledged that this could include constructive mutual challenge as set out in the Framework Agreement:

57. "PHE is therefore free to publish or speak on issues relating to the nation's health and wellbeing in order to set out the professional, scientific and objective judgement of the evidence-base. Ministers will remain responsible and accountable for policy decisions."

58. In addition, the PHE Code of Conduct incorporated both the Civil Service Code, which applied to all PHE staff, and PHE's professional responsibilities as the national public health agency. This safeguarded PHE's scientific, clinical and public health professionals' right to speak and publish freely to the evidence while at the same time recognising the requirements of the Civil Service Code. I have exhibited the PHE Code of Conduct which was first produced in 2013 (reissued in 2015) and was reviewed with minor changes in 2019 **[Exhibit JH/M1 0017a-0017b - INQ000147715, INQ000147716]**.

59. The Department of Health led the transition process for the public health system, including PHE. All the changes took effect from 1 April 2013, when the HPA formally closed. Duncan Selbie was appointed as Shadow Chief Executive in July 2012 and worked on design of the agency and the public health system for

eight months. A Shadow National Executive was subsequently established to help guide the formation of the new organisation and the transition process, which was managed by DHSC.

60. PHE was set up as an Executive Agency of DHSC and came into existence on 1 April 2013. The HPA was by far the largest organisation transferring into PHE and approximately 70 other organisations sent staff to the new agency. These included the National Treatment Agency, universities, NHS Strategic Health Authorities, Primary Care Trusts and NHS Trusts.

61. As an operationally independent executive agency of DHSC, the PHE legal basis was different from that of the HPA, which was a non-departmental public body. Thus, all staff were civil servants, and the PHE Board was an advisory board rather than with decision-making powers. The Framework Agreement set out that DHSC was the lead body in policy making with PHE as its principal partner. PHE was able to make submissions to ministers, though these needed to follow the clearance policy of DHSC.

62. The Secretary of State for Health remained ultimately accountable to Parliament for the delivery of public health functions. PHE was a key vehicle through which these were delivered. Thus, the CEO of PHE was accountable to three parts of government: to the Secretary of State for Health, to Parliament via the Public Accounts Committee, select committees and other types of parliamentary processes and reporting directly to the Permanent Secretary in DHSC, and as is common for all civil servants, up via line management chains to the Cabinet Secretary.

<u>The NHS Act 2006 and the HSCA 2012</u>

63. I point the Inquiry to s2.NHS Act 2006, amended by s11 HSCA 2012 for full details of the duties placed on the Secretary of State for Health by these acts **[Exhibit: JH/M1 0017c/0015a - INQ000147717, INQ000147714].**

64. I also point the Inquiry to the Framework Agreement between DHSC and PHE **[Exhibit: JH/M1 0018 - INQ000090326]** published in 2013. The most recent version of the Framework Agreement was published in 2018 **[Exhibit: JH/M1**

0019 - INQ000090327] and of specific relevance is Annex A of the Framework Agreement **[Exhibit: JH/M1 0020 - INQ000090328]** which sets out the statutory functions that the Secretary of State for Health and Social Care instructed PHE to carry out on the Secretary of State's behalf. I highlight here the duties of the Secretary of State that PHE lead on delivering as the new public health agency, and as are relevant to Module 1, that resulted from the HSCA 2012, originally set out in the NHS Act 2006. PHE's role was as the main source of specialist public health advice and delivery working to support DHSC and other parts of the health care system at a national level, although the CMO and DCMOs were also essential sources of public health advice to ministers and senior civil servants. At a local level most broad public health expertise previously provided in NHS Primary Care Trusts (PCTs) moved into local government as a result of the HSCA 2012, though PHE's regional Health Protection Teams (which had been in the HPA) and Screening and Immunisation Teams (which had been in PCTs and SHAs) continued to provide specialist functions at a local level. Some specialist activity was reduced with the moves and returned predominantly to the NHS outside the public health system e.g. infection prevention control.

Protecting the public from infectious diseases

65. The Secretary of State was given a duty to take such steps as considered appropriate for the purpose of protecting the public in England from disease or other dangers to health. PHE was tasked with performing the function of undertaking protective and preventative work on public health matters which require a national overview. Thus, PHE had a supporting role in relation to DHSC in key parts of the delivery of this function and thus a leading role on specific tasks as allocated to it through the remit letter. For example, DHSC led on input to the National Risk Register, where necessary commissioning scientific advice from PHE. PHE led on the operational aspects of providing specialist public health advice and input to the response to incidents but DHSC's Operational Response Centre and its predecessors would run oversight groups.

66. Public health advice and expertise was not an exclusive competence only with PHE, though PHE was a critical provider of these functions. The Chief Medical Officer and team provided direct public health advice to Ministers and senior civil

servants and one of the two Deputy CMOs led on health protection. Expert scientific committees also provided advice to Ministers. PHE worked very closely with, and contributed experts to, both these sources of advice and provided the secretariat for several key committees. One important area not specifically stated in the HSCA 2012 (2006 NHS Act) was the surveillance function, here also PHE played a central supporting role alongside the Cabinet Office and other government bodies.

67. The Secretary of State's duty was also delivered through other parts of the health and care system, including the NHS and Local Government and PHE's partnerships with these bodies. NHS teams were the main providers of the clinical response requirements for outbreaks, continuing a role that they had before 2013. PHE had a supporting role to local government and the NHS which both had executive delivery responsibilities for their own organisational activities. PHE's support came from expert public health and scientific advice and the provision of specific specialist services. I provide more substantial details of how PHE met this duty in the rest of this statement.

Improving the Health of the Public

68. The Secretary of State was also given a duty to improve the health of the public in England. This duty was primarily delivered through DHSC, local government and the NHS with PHE tasked with providing national advice to ministers and DHSC and local advice and support to local bodies about measures to improve the public's health. DHSC retained policy teams in a number of health improvement areas, such as tobacco control and obesity. PHE also delivered a small number of specialist national health improvement functions on behalf of the Secretary of State such as health marketing and non-communicable disease surveillance. Thus, PHE had a central supporting role in this function with the lead responsibility for delivery of specific programmes and tasks as set out in the annual remit letter. PHE did not have exclusive competence but was a central part of the provision of advice on health improvement working alongside the CMO team (there was a deputy CMO specialising on health improvement) and specialist scientific advisory committees for some topics.

Improving the Quality of Health Services

69. The primary responsibility for improving the quality of health services under the Secretary of State's duty was with the NHS. PHE had a supportive role in providing advice to the NHS about the quality and effectiveness of services at national, regional and local levels though this would generally be focused on specific areas that had a clear direct relevance to public health (screening, alcohol etc) plus a specific function on cancer registration that came to PHE in 2013. In addition, PHE senior clinical consultants would work directly with NHS specialised commissioning teams to evaluate new therapies and interventions for the NHS and, variably, regional teams would work with NHSE counterparts on healthcare service effectiveness and efficiency. PHE also worked closely with agencies such as the National Institute of Health and Clinical Excellence in producing and aligning guidance.

Reducing Health Inequalities

70. S1c of the NHS Act 2006 (as amended by the HSCA 2012) imposed a duty as to reducing health inequalities, stating that in exercising functions in relation to the health service, the Secretary of State must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the health service. PHE had a supporting role as did all arms-length bodies sponsored by DHSC. The Health Inequalities functions worked across the whole agency while being overseen in the Directorate of Health Improvement.

71. The Equality Act 2010 which applies to public bodies that carry out public functions includes related but different legal duties. PHE published reports on how it met its duties under the Equalities Act which touches upon the related duties under the HSCA 2012. The final report was published in 2020 **[Exhibit: JH/M1 0021 - INQ000090329]**. UKHSA can provide previous reports and evidence of equalities objectives on request. Further to this, section 9 further describes work carried out relevant to Module 1 and health inequalities in health protection.

Promotion of research

72. S1e of the NHS Act 2006 (as amended by the HSCA 2012) provided a duty, insofar as this duty relates to statutory functions performed by PHE, to promote research on matters relevant to the Health Service (including public health) and the use of evidence obtained from research. Further, paragraph 13 of Schedule 1 of the 2006 Act provided a power to conduct, commission or assist research in relation to public health in order to benefit the NHS. PHE was a research active organisation participating in and receiving grants from external bodies and delivering research projects leading to approximately 1000 peer-reviewed publications each year, the majority in collaboration with partners. PHE gained Public Sector Research Establishment Status (PSRE) in 2019 and was eligible to lead on UK Research and Innovation (UKRI) funding applications since July 2019. Previously, PHE was only eligible to apply to relevant National Institute for Health Research (now National Institute for Health and Care Research – NIHR) funding calls. UKHSA has held PSRE status since September 2022. PHE research-active teams had relationships with a wide range of academic partners, as well as the NHS, other government agencies, industry and local government, for example via the NIHR Health Protection Research Units (HPRUs) further details are provided in Section 4. PHE was not allocated funding to commission research from academia and external bodies and most government research funding was held by DHSC (for the NIHR) and UKRI. Thus, PHE had an important supportive role on how this duty was delivered on behalf of the Secretary of State.

Education and training of health service staff

73. S1f of the NHS Act 2006 (as amended by the HSCA 2012) provided a duty as to education and training. For specialist staff this was delivered through NHS bodies, especially Health Education England (HEE). PHE worked closely with HEE and PHE also delivered its responsibilities on training and education in a wide variety of ways including hosting trainees (medicine, public health, other health professions etc.), running specific accredited programmes (such as the Field Epidemiology programme) and running training programmes and events often with Continuous Professional Development accreditation. Thus, PHE had

an important supportive role on how this duty was delivered on behalf of the Secretary of State.

Impacts of the HSCA 2012 on the Health Care system as they affected PHE.

74. In addition to creating PHE, the HSCA 2012 brought major changes to the public health system which had implications for PHE's work.

75. One of the significant changes, relevant to Module 1 and PHE, related to the employment of public health professionals and thus the mobilisation of response to outbreaks and incidents. Up to 2013 the delivery of the public health functions was undertaken by professionals who worked in the NHS Strategic Health Authorities (SHAs) (linked with Government Office regions), in Primary Care Trusts (PCTs) in the NHS or within the HPA, which was an NHS special health authority. The staff in the SHAs/regions had a direct line into the Chief Medical Officer. Staff in PCTs formed the most significant proportion of the workforce. During the 2009 flu pandemic, the NHS SHAs and PCTs were tasked by DHSC with delivering the public health response and so the HPA was able to call on these NHS public health professionals for support to assist it. Most of these staff transferred to local government, which relates to a second significant change.

76. The local EPRR arrangements changed as a result of the HSCA 2012 with most public health staff having moved into local government. Thus, new EPRR systems and mechanisms were put in place including the Local Health Resilience Partnership (LHRPs) of the local NHS and local government. PHE was a recognised key organisational input to LHRPs. The new roles of PHE and other organisations is at Annex A in the exhibited document **[Exhibit: JH/M1 0022 - INQ000090330]**.

77. The national arrangements for EPRR remained the same under the HSCA 2012. DHSC led for the health sector, for example on contributing to the national risk register and pandemic planning; and PHE took on the HPA's principle responsibilities.

78. Key interventions to public health emergencies had to be delivered through collaborations between three different types of bodies (national government,

local government and the NHS). The service and financial responsibilities of the different bodies were sometimes unclear to those working in the various organisations and this could impact the functional delivery of interventions, for example infection prevention and control arrangements and delivery of clinical interventions in an emergency response, such as vaccination and antivirals.

Public Health England (2013-2021)

79. In 2014 PHE received its first remit letter **[Exhibit: JH/M1 0023 - INQ000090331]** from the Minister for the period 2014-15. Prior to this letter, the DHSC and ministerial requirements of PHE came from the documents published as part of the public health reform programme. Within the first remit letter, the Minister stated that PHE had operational autonomy and was expected to be an authoritative voice speaking about the public's health and, as previously noted, it acknowledged that this might involve constructive mutual challenge between PHE and central government.

80. The remit letter also set out PHE's key functions as:

    a. fulfilling the Secretary of State's duty to protect the public's health from infectious diseases and other public health hazards.

    b. Improving the public's health and wellbeing.

    c. Improving population health through sustainable health and care services.

    d. Building the capability and capacity of the public health system.

    e. Developing and publishing the evidence base for public health (DHSC formally commissioned PHE to produce evidence reviews relating to alcohol, e-cigarettes, carbohydrates and obesity though PHE undertook other work on reviewing and synthesising the evidence across all three domains of public health).

81. Each year the remit letter would set out specific tasks that PHE was required to undertake, which formed the basis of the scorecard reviewed at the DHSC

quarterly accountability review meetings. The tasks reflected that the ministerial and departmental focus was usually more on PHE's health improvement activities than its health protection work with the number of specific deliverables in health improvement being more than twice the number for those focused on health protection **[Exhibit: JH/M1 0024-0030 - INQ000090332, INQ000090333, INQ000090334, INQ000090335, INQ000090336, INQ000090337, INQ000090338].**

PHE's Operating Framework

82. As set out in the Framework Agreement **[Exhibit: JH/M1 0019 - INQ000090327],** the PHE Chief Executive was appointed by the DHSC Permanent Secretary through fair and open competition in line with the Civil Service Commission Recruitment Principles.

83. Duncan Selbie, as PHE's Chief Executive from 2013 to 2020, was responsible for determining PHE's management arrangements. His responsibilities as Chief Executive were set out in both the Framework Agreement with DHSC and reported on yearly in the PHE Annual Report and Accounts, which were audited by the National Audit Office and reported to Parliament. As describe above, PHE developed a Code of Conduct that incorporated the Civil Service Code. This was published and referenced in the annual Remit Letter.

84. The Chief Executive was supported by an Advisory Board of which the non-executive Chair and non-executive members were appointed by the Secretary of State. Appointments were transparent, made on merit and managed in a way which complied with the Commissioner for Public Appointments' Code of Practice for Ministerial Appointments to Public Bodies. The Chair was accountable to the DHSC Senior Departmental Sponsor (SDS), acting on behalf of the Permanent Secretary. The Advisory Board had Audit and Remuneration sub-committees.

85. The National Executive was formally established on 1 April 2013 as the senior decision-making forum in PHE and was renamed as the Management Committee in June 2015. There were a series of sub-committees of the Management

Committee covering topics such as Resourcing & Prioritisation, Service Development, Pay, EPRR etc.

Accountability to DHSC

86. The Chief Executive had an unfettered right of access to the Secretary of State and Minister with responsibility for public health to raise any matters or concerns and to respond personally to any issues they wished to raise. There were no regular meetings with the Secretary of State though there were occasional meetings on specific topics. There were regular meetings with the Public Health Minister.

87. The DHSC Senior Departmental Sponsor (Director General) chaired quarterly accountability and partnership meetings attended by the Chief Executive and other PHE and DHSC directors. Generally, at each quarter DHSC reviewed:

a. PHE's contribution against the department's strategic objectives, and progress against the PHE business plan

b. performance against the PHE performance scorecard, on the requirements in the remit letter from DHSC, which included key metrics of overall system performance alongside delivery of PHE's key actions and internal performance metrics on people, finance and governance.

c. PHE's financial performance, governance and risk management arrangements

d. the relationship between the department and PHE, and any other key issues identified in delivery of the department's strategic objectives.

e. PHE also submitted a quarterly report **[Exhibit: JH/M1 0031 - INQ000090339]** on its all-hazards approach to incidents, outbreaks and EPRR so DHSC was sighted on the breadth of issues being handled by the agency.

88. Other accountability processes in place included:

a. the Minister for Public Health chairing an annual accountability meeting to review the performance and strategic development of PHE, discuss the annual report and inform the next set of objectives.

b. the Permanent Secretary's annual appraisal of the Chief Executive's performance, taking account of feedback from PHE's Board

c. Select Committee hearings; for example, the first hearing with the Health Committee was held in November 2013 and their subsequent report **[Exhibit: JH/M1 0032 - INQ000090340]** and recommendations were published in February 2014. These only occurred when the committee was holding an investigation.

d. regular contact between DHSC's sponsor team and PHE

e. The Tailored Review, **[Exhibit: JH/M1 0033 - INQ000090341]** led by DHSC which was published in April 2017. This was part of the standard process of how the Cabinet Office reviewed arm's length bodies.

89. As agreed between DHSC and PHE, and as set out in the Framework Agreement, PHE prepared longer-term strategic plans, **[Exhibit: JH/M1 0034 - INQ000090342]** the most recent of which was published in 2019, covering 2020-2025 **[Exhibit: JH/M1 0035 - INQ000090343]** that set out how it would deliver its core functions, described its longer-term aim and objectives, set out a strategy for achieving them and formed the agreed framework for detailed annual planning.

90. PHE also produced an annual business plan setting out how it would deliver its objectives, core functions and the government's priorities within the annual remit letter. These were also published and made available on the PHE website and are exhibited **[Exhibit: JH/M1 0036-0041 - INQ000090344, INQ000090345, INQ000090346, INQ000090347, INQ000090348, INQ000090349]** The 2016-2017 Business Plan is described on pages 17 20 of **[Exhibit: JH/M1 0034/38 - INQ000090342, INQ000090346].**

Funding

91. Over the lifetime of PHE, its funding from central Government reduced by over 40% in real terms (i.e. taking into account inflation and unfunded pay pressures). Thus, the organisation had to implement the cost savings that this required so it met its duty to operate within its budget. In addition, there were budget reductions on the level of funding in PHE's predecessor bodies for the functions that came into PHE in 2013. Below I describe in more detail how PHE was funded, both through the funding received from Government, and the income generated by its own activities, how that changed over time, and how that funding was apportioned across the organisation.

92. I exhibit the yearly funding for PHE received from DHSC as **[Exhibit: JH/M1 0042 - INQ000090350]** The exhibit includes the yearly funding for the Emergency Response Department ("ERD") which was a central component of PHE's response arrangements but which could only operate with interdependent specialist input from other parts of the organisation. I explain this further in section 3.

Funding from DHSC

93. PHE's sources of annual funding from DHSC amounted to:

    a. Core grant-in-aid funding for its general activities that was received direct from government via its sponsor department (DHSC).

    b. Non-cash funding allocations from DHSC to cover depreciation.

    c. Ring-fenced budget via DHSC to cover the costs of vaccines and countermeasures, based on the actual cost of the product and services. (but generally *not* including additional resource for clinical evaluation, data and technology or vaccine distribution and logistics oversight).

94. The PHE core grant-in-aid from DHSC for 2019/20 (and 2020/1) was £287m to cover the full range of its functions. This level demonstrates a 40% reduction in PHE's spending power from its inception, as mentioned above, between 2013/4 and 2019/20 and can be explained as follows:

A) 2013/4 (i.e. at 1 April 2013): Baseline GIA was £392.5m

B) 2019/20: GIA was £287m. By this point real pressures experienced by PHE had built up each year since inception to reach the per annum level of £157.4m, made up of a sum of £48.6m workforce costs absorbed (e.g. pay awards for staff, National Insurance, pension costs); and £18.2m non-pay inflation absorbed compared to 2013/4. The remaining pressures were from continued cash reductions in PHE's operating budgets which had to be managed through efficiency drives across the organisation. The cumulative cost pressures that PHE absorbed over the period were over £800m.

Thus the 40% reduction recognises a real terms accrual of £157.4m of pressures in 2019/20 (point B above) as a percentage of the baseline GIA in 2023/14 of £392.5m (point A).

95. To expand on point B above, the reduction in cash terms for PHE to manage through efficiencies in operating budgets was about 22% (£90.6m). The inflationary pressures such as the pay awards for staff, increases in employer's National Insurance and pension contributions and non-pay inflationary pressures these made up the other c.18%. These inflationary costs were thus absorbed along with the reduced cash sums. PHE was not unusual among government bodies in being required to manage within reduced funding levels from government.

96. In addition, PHE's core grant-in-aid funding on inception in 2013/4 was below the levels of spending in previous years in its predecessor bodies. Comparing 2013/4 funding to spending in 2010/11, the year after the swine flu pandemic, for HPA functions the reduction was £10.1m (8%) and for SHA public health staff it was £2.5m (18%).

97. PHE delivered its financial duties each year between 2013-4 and 2019-20 without overspending and this required an unremitting focus on financial management and control alongside its other priorities. With the increasing expectations and requirements, including those set out in the annual remit letter, PHE focused on ways to improve efficiency and effectiveness (i.e. "delivering more for less", "continuous improvement" and "smarter working"). PHE usually

identified organisation-wide savings projects and cost-improvement targets across all directorates. Leaders and staff worked hard to minimise the funding reductions in key health protection functions through increasing income levels and differential cost reductions within the requirement to deliver a balanced budget.

98. In addition to the core Government Grant-in-Aid funding, PHE could be in receipt of additional grant-in-aid funding on a non-recurrent basis in any given year. This was for time-limited priority deliverables essentially on a cost neutral basis, and agreed with:

    a. DHSC for areas such as for delivering the specific national programme on childhood obesity.

    b. Other Government departments as applicable, such as Official Development Assistance (ODA) funding for global health projects on health protection capabilities to meet International Health Regulations and grants related to Fluoridation.

    There was an informal understanding that DSHC would reimburse PHE for the incremental costs incurred in exceptional health protection responses such as a major national or global event e.g. a pandemic or the West African Ebola response in 2014. In such instances, this would be agreed via discussions between finance teams.

99. The funding received each year can be found in the document PHE funding and EPRR funding **[Exhibit: JH/M1 0042 - INQ000090350].** Further detail on the funding EPRR functions specifically received can be found in Section 3.

Income Generation

100. PHE had a portfolio of income generation that enabled it to maintain core national capabilities at existing levels as well as developing capabilities that though dependent on external income, could contribute to the national infrastructure and emergency response. For 2020/21, PHE's income budget was £181m which was 39% of the total operating budget of the agency (£181m income and £287m Grant In Aid). The net margin of this income above the costs

required to deliver the projects equated to c.£60m. This funding was used by PHE to mitigate some of the impact of the real terms reduction in government GIA funding and limit the effect of funding reductions on the delivery of public health and scientific functions. The majority of the income generation targets were in the health protection functions of PHE especially in microbiology services.

101. Some large contracts were with the NHS, notably of c.£60m for delivering routine NHS services for clinical microbiology (not public health microbiology which was funded from PHE grant-in-aid). Other areas such as elements of Research Microbiology and the Emergency Response Directorate team were notably self-funding from income generation activities and thus national critical infrastructure, for example, in high containment microbiology for the diagnosis of rare and imported pathogens was materially dependent on funding outside the UK government. Although income generation activity covered its costs and generated resources that could be used to help reduce the impact of reductions in government GIA funding on these services, it required significant senior and specialist staff time to make bids and deliver projects to time, quality and budget.

Staffing levels

102. I have exhibited the number of staff in each directorate as **[Exhibit: JH/M1 0043 - INQ000090351].**

103. The staffing numbers were relatively stable over the period with a 0.6% (35 WTE) increase between March 2013 and March 2020. There was a reduction in 2015 and 2016 reflecting the changes associated with an organisational change programme at that time which was a key part of delivering PHE's financial targets. Although the data is not easily available, there was a change on the grade profile (and pay profile) within PHE over this period with the numbers of staff on lower grades (and pay) increasing as a proportion of the total. It is difficult to accurately separate the workforce into the numbers working on each of the three domains of public health, but the approximate percentages were c.60% in Health Protection, which included frontline public health emergency response

services and public health laboratory staff, and c.28% combined on health improvement and health care public health with c.12% on corporate functions.

104. There is no accurate data on the breakdown by profession. There was a 2019 self-declaration as part of a civil service return. This had a partial response and the categories were developed for the civil service and so do not logically translate into PHE's operating model.

PHE's Strategic Priorities through this period

105. As referred to above, PHE produced two 3-4 year strategies in 2016 and 2019 and I have exhibited these **[Exhibit: JH/M1 0034 - INQ000090342] [Exhibit: JH/M1 0035 - INQ000090343]**. These reflected ministerial priorities from the remit letter and government strategies and PHE's assessment of priorities based on protecting and improving the public's health. Both plans set out PHE's medium-term ambitions and the 2019 strategy detailed a series of planned actions to keep the country safe, including its response to emergencies and anti-microbial resistance.

106. PHE had identified a gap in national strategy across government focusing on infectious diseases since the 2002 Getting Ahead of the Curve document. Thus, in 2018 it started work on an infectious diseases strategy which was published in autumn 2019 through a joint launch with the Chief Medical Officer **[Exhibit: JH/M1 0044 - INQ000090352]**. This identified ten strategic priorities including infectious disease surveillance, whole genome sequencing, major emergency response and health inequalities. PHE published other strategies that included specific priorities for its health protection functions such as the Global Health Strategy 2014 **[Exhibit: JH/M1 0045 - INQ000090353]**.

Key Individuals

107. A list of those who served on the HPA Executive Board, the PHE National Executive and the PHE Management Committee is exhibited as **[Exhibit: JH/M1 0046 - INQ000090354]** These three groups successively assumed the role of the most senior executive decision-making committee in HPA and PHE during the relevant periods.

108. In respect to Module 1 specifically, HPA and PHE did not make policy decisions but provided expert Public Health Advice to inform decision makers. HPA and PHE did apply decisions made where there were required public health outputs, such as public health guidance. As such the request to provide information on relevant decision makers is interpreted as those senior individuals who provided that expert advice or made operational decisions capable of materially impacting preparedness. The list of such individuals is exhibited as **[Exhibit: JH/M1 0047 - INQ000090355].**

109. From exhibits Senior PHE Management Corporate Services and Decision Makers and Witness Statement Individuals, **[Exhibit: JH/M1 0046-47 - INQ000090354, INQ000090355]** I have identified the individuals that may be best placed to provide witness statements in relation to PHE in respect of the issues outlined in the Provisional Outline of Scope for Module 1 and have described the roles and functions in which these individuals operated.

PHE's organisational structure

110. The Leadership organograms from 2013-2021 are exhibited as **[Exhibits: JH/M1 0048 - JH/M1 0054 - INQ000090356, INQ000090357, INQ000090358, INQ000090359, INQ000090360, INQ000090361, INQ000090362]** These organograms provide information at Senior Civil Service ("SCS") level.

111. The governance structure in each of the years from 2013-2014 to 2020-2021 are exhibited as **[Exhibits: JH/M1 0055 - JH/M1 0062 - INQ000090363, INQ000090364, INQ000090365, INQ000090366, INQ000090367, INQ000090368, INQ000090369, INQ000090370].**

112. PHE largely retained its core internal organisational structure but underwent some changes during its lifetime with a small number of teams moving between directorates. Below I focus on providing a description of the structures within PHE as of January 2020 and describing the functions and teams within them. In addition, I describe the most important structural change in relation to health protection functions throughout the relevant date range. Section 3 includes a more substantive description of the key EPRR functions.

113. As of January 2020, there were 9 director-led teams reporting to the Chief Executive with one directorate composed of the four regional directors. The largest volume of specific public health expertise and functions sat within three of these Directorates: the Medical Director and Director of Health Protection, the Health Improvement Directorate and the Deputy CEO & Chief Operating Officer to whom the National Infection Service (NIS) and the Centres and Regions Directorate reported (see below for full explanation of these two directorates). The remaining director-led teams comprised of other corporate functions and specialist teams such as Strategy, Marketing, Communications, Finance and Commercial, People, Corporate Affairs and Nursing, Maternity & Early Years.

Medical Director and Health Protection Directorate

114. At January 2020, PHE's last year of operation, the Medical Director and Head of Health Protection was Professor Yvonne Doyle.

115. The Health Protection Directorate comprised a number of key teams including, the Emergency Response Department (ERD), the Centre for Radiation Chemicals and Environment (CRCE), the Healthcare Public Health Team, the function of the Responsible Officer for medical revalidation and clinical governance (the latter a joint cross organisational function with the Chief Nurse Directorate. Until 2015, when the National Infection Service (NIS) was established the Health Protection Directorate also included the Centre for Epidemiology at PHE Colindale and the Field Epidemiology Service. The NIS is described extensively later in this section.

116. The ERD led on PHE's work on Emergency Preparedness, Resilience and Response (EPRR) which included being ready for, and taking action, in emergency situations, working closely with DHSC and Other Government Departments (OGDs), and delivering specific associated commissions from DHSC and NHSE/I. I provide details of its role and function extensively in Section 3 of this statement. Delivery was undertaken by all health protection functions working closely with ERD plus contributions from health improvement, health care public health and other supporting functions when needed.

Emeritus Medical Director including Global Public Health

117. In January 2020, the role of Emeritus Medical Director provided expert, largely non-operational response advice and its incumbent was Professor Sir Paul Cosford. Sir Paul had previously been the Director of Health Protection and Medical Director and had overseen the Global Public Health teams in that role. When he moved to the role of Emeritus Medical Director, the Global Public Health team moved with him. Professor Yvonne Doyle took up her position as Medical Director and Health Protection Director the same month.

118. The Global Public Health Directorate was formed in November 2016, when some internationally facing PHE teams working on Global Health challenges were merged and the Director of Global Public Health role was created. A global strategy function, that had been part of the Chief Executive's office, also moved into the Global Public Health team at that time.

Health Improvement Directorate

119. PHE's Health Improvement Directorate in January 2020 was led by Professor John Newton. The functions it contained have now substantially moved to the Office for Health Improvement and Disparities (OHID) based in DHSC, though the majority of the PHE Screening teams have moved to NHS England.

120. The Health Improvement Directorate produced data, analysis and scientific research that provided authoritative information on the significant risk factors affecting the public's health and used this evidence to influence the priorities of national and local government and the NHS in actions to improve the public's health. This data reflected the primary drivers of mortality and morbidity which were mainly addressed in the health improvement domain, and they collaborated with the teams working in the health protection domain on infectious disease and external hazard surveillance, mitigation and epidemiological data analysis to report and share data about the threats to the public's health.

121. At the creation of PHE, it was decided that there needed to be a dedicated team focused on health inequalities. This PHE-wide team was based in the Health

Improvement Directorate, but it worked across all directorates covering the three domains of public health.

122. The Health Improvement Directorate also identified and promoted effective evidence-based solutions about actions to improve the public's health. Its advice informed real-world policy, practice and delivery of essential services by partners.

123. It built capability, fostering research and innovation and supporting health and care professionals with the training, guidance and standards they needed to deliver effective interventions to improve the public's health.

Deputy CEO & Chief Operating Officer

124. At January 2020, the Deputy CEO and Chief Operating Officer was Richard Gleave who led a small team who supported his directorate known as the Operations Directorate. It undertook a number of corporate tasks related to external partnerships on the public health delivery agenda such as working with the NHS and DHSC on the Section 7A Agreement which co-ordinated the commissioning of a range of Public Health Services between PHE, NHS England and DHSC and led the discussions in Whitehall about the Public Health Grant. The National Infections Service and the Centres and Regions Directorate reported to the Chief Executive through the COO/Deputy CE though their directors were all members of PHE's National Executive.

National Infection Service

125. The National Infection Service (NIS) was created in 2015 and, at January 2020, the NIS within PHE comprised PHE's microbiology capabilities, and core capabilities across epidemiology, surveillance, management and research into infectious diseases. At January 2020, the head of the National Infections Service was Professor Sharon Peacock. The key divisions within NIS, each led by a deputy director, are described below.

NIS Divisions: Specialist Laboratories and Laboratory Operations (two divisions with two deputy directors)

126. PHE delivered specialist and public health microbiology services via its network of national and regionally located laboratories. I provide further details of PHE's standing capability for laboratory testing in Section 4.

127. At January 2020, PHE operated the following laboratory sites:

a. PHE Porton Down in Wiltshire - Porton Down was the base for Research Microbiology (which undertook a wide range of research and had key national infrastructure capabilities including in vitro and in vivo high containment microbiology), the Rare and Imported Pathogens Laboratory, Emergency Response Department (including Medical Entomology & Zoonoses Ecology), the Food Water and Environment Laboratory for the South of England, and Porton Biopharma Limited (Development and Operations in HPA/PHE prior to the creation of PBL as a limited liability company wholly owned by the Secretary of State).

b. PHE Colindale in north London - Colindale was the base for national epidemiology services, the national reference microbiology laboratories for most pathogens including key national infrastructure (including in vitro and in vivo high containment microbiology), the main centre for genome sequencing (specialist sequencing also took place at Birmingham for TB and at Porton), Food Water and Environment Laboratory for London, the East of England and part of the Midlands, and external quality assurance schemes.

c. Network of microbiology laboratories based in NHS hospitals undertaking both public health microbiology and NHS microbiology under contract with the NHS Trusts (see next section for details). There was also a Food Water and Environment Laboratory for the North based at York.

128. This division provided public health microbiology laboratory functions within PHE both on the specialist sites (Porton and Colindale) and through the network of laboratories across England.

129. PHE's laboratory services also provided the worldwide research community with unique and very rare services for example the Culture Collections are used worldwide (expertly preserved, authenticated cell lines and microbial strains of known provenance).

130. PHE also managed laboratories at Chilton, Oxfordshire and satellite sites for radiation, chemicals and toxicology and environmental testing but these did not provide microbiology services.

NIS Divisions: Data and analytical sciences

131. This division included teams that delivered bioinformatics and laboratory informatics, information management, statistical, modelling, economics analysis, and software development support to the laboratories and wider health protection function. This included aspects of primary data collection, processing, linkage, quality assurance and continuous improvement, to support further analytics, the development of models and to inform public health action and national policy.

NIS Division: Tuberculosis, acute respiratory, gastrointestinal, emerging infection and travel (TARGET)

132. This division delivered PHE's specialist national epidemiology and public health services across tuberculosis, acute respiratory infections such as Legionella, gastrointestinal diseases, emerging and zoonotic infections (i.e. diseases transferable from animals to humans) infections, and the Travel and Migrant Health Service. Under the International Health Regulations (IHR), this team has been designated the UK National Focal Point (NFP) for communications with WHO. Further details on some of the specific activity led by the TARGET division are described below.

NIS Divisions: Vaccine Preventable Diseases and Countermeasures

133. PHE's core work on tackling vaccine preventable diseases in England, including work on immunisation programmes, was undertaken across two divisions led by separate Deputy Directors, namely: the Immunisations and Vaccines Division, and the Vaccines and Countermeasures Supply and Support Division. This included PHE's professional leadership of the national immunisation

programmes in England and its management of vaccine procurement and distribution (as well as chemical, biological, radiological and nuclear countermeasures). I provide further details on PHE's role in this area of work within Section 7.

134. The team was central to all stages of the vaccination and immunisation programmes as well as advising, including to the NHS, on vaccine preventable diseases that were not part of the national programmes. The team provided the scientific secretariat and key items of scientific evidence for the independent UK Joint Committee on Vaccination and Immunisation, which delivers advice, to the Secretary of State on vaccine issues. The team worked closely with NHS England in designing the vaccination delivery programmes as specialist clinical, public health advisers. The team also produced the Patient Group Directions which allow some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or nurse prescriber) and provided the required communications materials for the public that underpin this. It was responsible for all the expert clinical documentation used by NHS health professionals that is also part of the basis for the national immunisation programmes and the supporting guidance, toolkits, training materials and Q&A services.

135. This team also undertook applied research and national surveillance of vaccine-preventable disease, including producing guidance and advice on the management of cases or outbreaks. They evaluated the impact of all the routine immunisation programmes and advised on any required changes (based on comprehensive disease surveillance; measurement of coverage of immunisation programmes, monitoring attitudes to vaccination; and studies of vaccine safety).

NIS Division: Field Service

136. PHE's Field Service was a national service comprising geographically dispersed multidisciplinary teams, integrating field epidemiology, real-time syndromic surveillance, public health microbiology and food, water and environment microbiology to strengthen PHE's surveillance, intelligence and response

functions. It undertook analysis and interpretation of surveillance data to identify disease clusters & outbreaks and changes in the epidemiology of key diseases over time. It applied epidemiological and research methods to key health protection questions to contribute to the evidence base that informed NHS, local government and public actions to control infectious diseases and health effects from exposure to environmental hazards. It also provided specialist support to the local health protection team's work on incident and outbreak investigation and control.

NIS Division: Healthcare associated infection and Antimicrobial Resistance

137. This division provided PHE's clinical, scientific and technical expertise for the surveillance, prevention and control of healthcare associated and antimicrobial resistant (AMR) infections. It was responsible for determining which complex specialist samples from the NHS were sent to the National Reference laboratories for further analysis and the epidemiological analyses that enable the national surveillance and planning of antimicrobial stewardship and infection prevention and control activities in the NHS and the wider community (including the link with animal health and DEFRA). It was the designated WHO Collaborating Centre for Reference and Research on Antimicrobial Resistance and Healthcare Associated Infections. The team produced the tools that enable GPs, schools and community groups to improve hygiene practices in the community and reduce inappropriate prescribing in primary care. The team provided specialist input to healthcare associated and AMR incidents and outbreaks reported to health protection teams. It coordinated the PHE input to the cross-government AMR strategy and led delivery of the surveillance aspects of the AMR National Action Plan with devolved administrations.

NIS Division: Blood Safety, Hepatitis and Sexually Transmitted Infections

138. This division provided evidence, advice and support to local authorities and the NHS on sexual and reproductive health and HIV prevention; and supported the development of national policy. They undertook microbiological and epidemiological services, including STI surveillance and the Blood Safety, Hepatitis, Chlamydia, HIV and AIDS screening and monitoring services, which

carry out detection and analysis of, and interventions concerning, these infectious diseases, with the objective of significantly reducing their overall incidence and health harm. They also managed national sexual health and HIV health promotion and prevention programmes including HIV Prevention England and the HIV Self Sampling Service, plus they supported local authorities and the NHS in providing local open access to sexual health services (in person or online), and their work on relationship and sex education.

Centres and Regions Directorate

139. In 2013 PHE created the Centres and Regions Directorate. As of January 2020, the structure was based on 4 regions, led by 4 Regional Directors (that aligned with the NHS regional clusters) and 8 centres with Directors who reported into the Regional Directors. The PHE London region also delivered the centre functions in London as a single unit. The Centres and Regions teams worked across all three domains of public health with both the NHS and local authorities as well as other agencies involved in the local public health system. Arrangements were put in place so that each of the c.150 upper tier and unitary local authorities had a designated Centre to work with and the Centre teams linked in with the local NHS (area teams, clinical commissioning groups, NHS trusts etc) in that footprint.

140. The regions provided support to the centres and specifically provided specialist EPRR support. Centres included the Health Protection Team's ("HPT's"), screening and immunisation teams and small health improvement and health care public health functions. The Regional Directors also played an important role providing a local perspective in PHE's work at a national level.

Health Protection Teams

141. The HPTs were a key part of the PHE Centre teams, including the combined Centre-Region team in London. It principally provided specialist health protection advice and operational support to NHS, local authorities and other agencies locally, including the third sector, in response to health protection related

incidents, including small-scale contact tracing for infectious diseases where required. The HPTs all ran acute response desks where enquiries and concerns about health protection issues were received and answered/escalated as appropriate. They also provided a 24/7 service all year round through out of hours on-call.

142. The HPTs employed professionally qualified consultants in health protection all of whom were registered with a medical or public health faculty college. In each HPT one of these registered consultants would be designated the lead consultant for working with one or more upper tier and unitary authorities within the Centre footprint. These leads were the first point of contact for important health protection issues from or to the Director of Public Health including local outbreaks and incidents. Health Protection Consultants would also have a specialist area of expertise and the patch lead consultant would call on the Centre specialist as well as the national specialist team.

143. HPT's whose patch covered key ports of entry to the country provided health protection advice and support to local ports of entry within their patch in England and there was a more specialist team based at London Heathrow that led on national issues as well as working with the London HPTs at Heathrow and Gatwick. PHE was organised to respond to incidents at all 266 entry points at which the Border Force have a presence, working with the Devolved Administration HPTs as appropriate for ports in other UK countries.

144. In England, the Animal and Plant Health Agency (APHA), the Border Force, local authorities, as designated port health authorities and the NHS also had health responsibilities and duties at the borders. There was no written document describing how these agencies should work together nor a specific meeting where they came together. As such, PHE approached DHSC with the proposal to undertake a systematic piece of work to engage with others and produce a description of the range of roles and responsibilities which would ideally lead to agreements for closer collaboration especially in an emergency situation. In November 2019, DHSC agreed to this, and a joint work programme was being commenced when the COVID-19 pandemic started.

145. The work of the PHE regional screening and immunisation (S&I) teams were closely aligned with the work of the Health Protection teams on vaccination programmes. The S&I teams worked with the local NHS on the national vaccination programmes and the collaborative working also enabled response to outbreaks in vaccine preventable disease. These teams moved to NHS England on 1 October 2021.

Local and Regional EPRR

146. The role of the regions in EPRR functions and how they supported the work of Centres and HPTs is covered extensively in Section 3 of this statement.

Transition of PHE to UKHSA, DHSC, NHSE and NHSD

147. Following the announcement by the Secretary of State for Health and Social Care on 18 August 2020, which confirmed that a new national institute for health protection was to be established to replace PHE's health protection functions and NHS Test and Trace, Michael Brodie was appointed interim Chief Executive of PHE for overseeing the transfer of PHE's functions to the new executive agency of DHSC and other receiver organisations. Michael Brodie was appointed Accounting Officer for PHE on 1 September 2020 and remained in post until 30 September 2021.

148. Other parts of PHE moved to DHSC, NHS England (NHSE) and NHS Digital (NHSD).

149. A document setting out the transfer of PHE's functions was published by the interim Chief Executive, Michael Brodie, and Jonathan Marron, DHSC Director General for Public Health on 27 September 2021. **[Exhibits: JH/M1 0063 - INQ000090371]**.

150. A timeline of the transition to UKHSA is exhibited **[Exhibits: JH/M1 0064 - INQ000090372]**.

Section 3: Overview of PHE's EPRR functions

151. In this section I provide an overview of PHE's core Emergency Preparedness Resilience and Response (EPRR) and Pandemic Preparedness functions which included the Emergency Response Department (ERD) that sat within the Health Protection Directorate and the dedicated EPRR functions that sat within the Centres and Regions Directorate. In addition, I provide an overview of the groups that supported EPRR functions, the key EPRR documents and plans, how PHE worked with DHSC on preparedness and the funding that these EPRR functions received.

152. While the functions I describe below have a specific preparedness remit, it should be noted that the work of other directorates contributed substantially to PHE being able to respond to health incidents, not least the National Infection Service which provided significant Public Health Services that were relied upon during the COVID-19 pandemic and Health Protection Teams (HPTs) who supported local public health responses. I provide more detail on Public Health Services in section 4.

Emergency Response Department (ERD)

153. PHE's ERD, which sat within the Health Protection Directorate, was formed in 2004, combined the key public health, scientific, research, and emergency preparedness and response expertise into a single department. PHE ERD worked at international, national, regional and local levels and had links with many other organisations around the world.

154. The head of ERD was accountable to the Director of Health Protection and Medical Directorate. The ERD Senior Management Team had monthly meetings to provide strategic direction for ERD's business objectives.

155. As at January 2020, PHE ERD contained the following resources, teams and capabilities to support PHE's national incident preparedness and response. Many of these teams were very small in terms of whole time equivalent (WTE) staff capacity:

Senior Medical Advisors

156. A cadre of professionally registered public health consultants known as Senior Medical Advisers provided specialist public health advice and guidance.

Corporate Resilience Team (CRT)

157. The CRT managed the National Incident Coordination Centre (NICC) which provided national oversight when incidents required. They also 'owned' the National Incident Emergency Response Plan (NIERP) (which I describe further in section 5). The CRT therefore provided the activation of national response arrangements; the governance process for the continual review and improvement for PHE's response plan, implementation of PHE's annual EPRR assurance programme, and provided the secretariat function for PHE's EPRR governance arrangements.

Training Team

158. The Training Team delivered training to a range of agencies within the United Kingdom including the NHS, OGDs and agencies, emergency responders and local authorities. In addition, they delivered health EPRR training to EU member states, under commercial framework contracts with DG Sante and European Centre for Disease Prevention and Control (ECDC), and to international organisations such as the World Health Organization.

Exercising Team

159. The Exercise Team designed, delivered and evaluated health-led EPRR exercises. On average the Exercising Team delivered between 12 to 15 exercises a year, the majority sponsored by NHS England and DHSC. I provide significantly more detail on the work of the Exercising Team in Section 6.

Scientific Computing Service

160. The Scientific Computing team provided specialist computer systems to support the work of the mathematical modelling team as well as some developer

capabilities for software support to specialist functions such as the entomology team.

Behavioural Science and Insights

161. A Behavioural Science and Insights team provided advice, guidance, applied research and evaluation, to support a range of health protection and EPRR activities.

Geographic Information Systems (GIS)

162. A Geographic Information Systems (GIS) team provided geospatial data skills to support analysis and visualisation of public health data for EPRR.

Mathematical Modelling

163. The Mathematical Modelling team developed bespoke mathematical models to assess and predict the potential public health impact of newly emerging diseases and infectious diseases and the impacts of countermeasures and interventions.

Vector Borne Disease (VBD) threats and medical entomology team.

164. The Vector Borne Disease (VBD) team provided advice and response on emerging VBD threats through vector/pathogen surveillance, research, risk assessment, incident response, including support to international partners.

Regional EPRR Functions

165. As well as the national EPRR functions described previously, the Centres and Regions Directorate also had EPRR duties.

166. Over the course of the relevant period, there were a number of changes to the structure of the regions and therefore to the management and delivery of EPRR functions.

167. From 2009 until 2011, the HPA had 9 Regions and the specialist EPRR function was delivered by 9 Regional Health Emergency Planning Teams.

168. In 2011 HPA undertook a restructuring of its regional directorate, including the regional teams and reduced their number, staff numbers and employment grades of those staff. The result being that the EPRR function was delivered through 4 regional teams (North, Midlands and East, South and London) and each regional team worked with between 1 and 5 health protection teams.

169. In 2013 PHE completed a further regional re-organisation and the EPRR resources in each of the newly designated 9 PHE Centres varied in accordance with the anticipated health protection risk.

170. As part of an integrated resource within each of the 9 Centres, team makeup varied from Consultant EPRR Leads, Regional/Senior EPMs, EPMs and EPOs, supporting a risk-based approach to emergency planning.

171. The primary role of the EPRR teams based in the regions was to support the discharge of PHE's duties under the Civil Contingencies Act 2004. I provide further information in Section 5 on how PHE, including its Centres and Regions directorate, contributed towards this.

172. In order to carry out their EPRR functions, as described in the National Incident and Emergency Response Plan, PHE regions engaged with a broad range of key health protection partners across the regional health and social care system, which included the devolved administrations, national public health institutions, the Association of Directors of Public Health (ADPH), Local Government Association (LGA), NHS England & Improvement, local authorities, Local Resilience Forums and Local Health Resilience Partnerships. This comprehensive engagement with external partners enabled PHE's Regions and Centres to develop health protection risk mitigation measures that were appropriate to that Region; for instance, a region with a predominantly urban population (London etc) required a different health protection approach to a rural area.

EPRR Governance

173. PHE's internal EPRR governance was provided by the EPRR Delivery Group, at the operational level, and the EPRR Oversight Group provided strategic

oversight and this was strengthened by the presence of key external stakeholders such as DHSC, NHS and FSA. ERD provided the secretariat function for both meetings, which met on a regular and routine basis.

PHE EPRR Delivery Group

174. The purpose of the EPPR Delivery Group, chaired by the head of ERD, is described in its Terms of Reference (ToR) **[Exhibit: JH/M1 0065 - INQ000090380].** In summary, the Delivery Group's role was to act on behalf of and provide recommendations to the EPRR Oversight Group to provide a systematic, planned and coordinated approach to EPRR systems and processes in PHE. Specifically, the EPRR Delivery Group established task and finish groups as required to deliver specific work streams as agreed in the work programme and its members communicated key information and relevant actions across PHE areas, as appropriate. The Delivery Group was accountable to PHE's Oversight Group.

PHE EPRR Oversight Group

175. PHE's EPRR Oversight Group was chaired by the PHE Medical Director and Director of Health Protection. The purpose of the EPRR Oversight Group was to provide strategic direction, steering, assurance and governance of the organisational arrangements to implement the EPRR objectives set out in the PHE Business Plans **[Exhibit: JH/M1 0036-0041 - INQ000090344, INQ000090345, INQ000090346, INQ000090347, INQ000090348, INQ000090349]** and fulfil the organisation's statutory responsibilities as a Category 1 responder under the terms of the Civil Contingencies Act 2004. A copy of the EPRR Oversight Group ToR is detailed in **[Exhibit: JH/M1 0066 - INQ000090381]**

176. The Oversight Group was accountable to the PHE Executive Committee and provided reports to the DHSC Partnership Board for EPRR and had attendees from DHSC, NHS, FSA etc.

PHE Business Continuity Management Forum

177. The aim of the Business Continuity Management Forum within PHE was to facilitate learning, promote collaborative working in the development of document sets, and the sharing of business continuity management best practice. It reported into and was accountable to the PHE EPRR Delivery Group. The forum set the policy for how business continuity in PHE was managed, and the group was chaired by the Corporate Business Continuity Manager.

Public Health England Pandemic Influenza Co-ordination Group (PICOG)

178. To support the co-ordination of work pertaining to pandemic preparedness within PHE, in 2017 PHE set up an internal group known as PICOG. Principally, this involved co-ordinating actions that came out of DHSC's Pandemic Influenza Preparedness Programme (PIPP) Board which I describe briefly later in this section.

PHE EPRR and its relationship to DHSC

179. As an Executive Agency of DHSC with operational autonomy, PHE supported the Department in the execution of its duties. DHSC retained the system wide policy lead for health. In this capacity, PHE's Emergency Response Department acted as a specialist provider and was commissioned by the sponsor organisation to undertake the health EPRR training and exercise projects.

180. The health EPRR Training and Exercise programme was governed by the DHSC chaired EPRR Partnership Board that included key EPRR stakeholders from across the health and social care system including PHE, NHSE/I, Food Standards Agency (FSA), and Animal, Plant Health Agency (APHA) etc. The Board ceased in 2019 as the Government prepared for EU Exit.

181. Below I describe the key DHSC EPRR meetings and groups that PHE contributed to and I briefly describe PHE's role in them.

DHSC EPRR Partnership Board

182. Through the DHSC chaired EPRR Partnership Board, PHE worked collaboratively with DHSC and NHS on all health EPRR threats and hazards. PHE's representative on the Partnership Board was its Medical Director and Director of Health Protection and the Deputy CEO and Chief Operating Officer.

DHSC's Annual Exercise Programme Planning Meetings

183. An annual EPRR Training and Exercise programme was set by the DHSC EPRR Partnership Board. As part of DHSC's governance process, PHE ERD provided a quarterly report of performance against the annual EPRR Training and Exercise programme agreed by the EPRR Partnership Board.

184. I exhibit the 2019/20 Health EPRR Training and Exercises Programme paper (submitted at the end of Q4) presented by PHE's Medical Director and Director of Health Protection **[Exhibit: JH/M1 0067 - INQ000090382].** In addition to the detailed proposal for 2019/20, the paper provides a useful summary of PHE's responsibilities for health EPRR training and exercises across the health and social care system.

Pandemic Influenza Preparedness Programme ("PIPP") Board

185. PHE provided regular updates to the DHSC chaired PIPP Board. The updates related to specific activities of interest to the board such as laboratory services, countermeasures and planning for pandemic surveillance, either as general updates or by request. The updates were provided by the directorates most relevant to the subject matter.

186. As the secretariat, DHSC is best placed to provide any required documentation for this group, however on request, UKHSA can provide papers that PHE submitted to the board.

Specialist avian influenza H7N9

187. In late 2018, DHSC established a specific group chaired by their permanent secretary in response to a specific threat from the emergence of avian influenza

H7N9. PHE provided specialist technical advice to this group and was represented in these meeting by experts in influenza surveillance and representatives from the influenza reference laboratory and the countermeasures procurement teams, from NIS.

The Health Delivery Group

188. The Health Delivery Group, previously known as the tripartite group (DHSC, NHS EI and PHE) was a regular fortnightly Deputy Director level meeting held between DHSC, PHE and NHSEI to ensure shared situational awareness of current operational issues as well as management of the agreed training and exercising plan. As the secretariat and the chair, DHSC is best placed to provide any required documentation for this group.

DHSC's Operational Response Centre (ORC)

189. PHE was not directly involved in the operation of DHSC's Operational Response Centre, although PHE did routinely provide Liaison Officers into the ORC when it was activated. In addition to this, ERD Exercises Team developed and delivered a series of exercises known as the Helicoid series to help develop and implement the ORC, which was previously called the DHSC Incident Coordination Centre. I exhibit the Helicoid III exercise report **[Exhibit: JH/M1 0068 - INQ000090383].**

EPRR Funding

190. Following on from the description of PHE's funding in Section 2, I describe in further detail here the funding that EPRR activities received, PHE's role in the Public Health Grant and the impact of leaving the EU on EPRR funding.

191. As described throughout this statement, EPRR activities took place in a number of directorates, and many activities that PHE undertook, while not traditionally EPRR activities, nevertheless provided significant support and capability to incidents including the COVID-19 incident. As such, it is not possible to provide comprehensive funding figures for all activities that contributed towards preparedness. Instead, I refer again to **[Exhibit: JH/M1 0042 - INQ000090350]** as indicated in section 2, that as well as providing the yearly funding PHE

received from DHSC, it also includes the yearly funding the Emergency Response Department received, both from core allocations and through income generating work.

EPRR Funding in the context of the decision to leave the EU

192. Prior to leaving the EU PHE had significant funding streams from the EU either in the form of research grants (e.g. science and bio-science, behavioural science) and/or contracts (training and exercising). These funding streams were a significant source of income for various teams within PHE.

193. Once the decision to leave the EU had been made, PHE put in place governance and infrastructure to manage the potential consequences of the UK no longer being a Member of the EU Commission's Health Security Council (HSC) or the ECDC.

194. The work of PHE's EU and 4 Nations team that sat in the Health Protection Directorate included the assessment of the contribution of EU funding to PHE's public health capacity, with a view to determining which functions might be most impacted as a result of the arrangements to leave the EU. This work also sought to identify functions that PHE felt should actively be retained through negotiation or replaced through domestic funding.

195. The replacement of lost functionalities as a result of leaving the EU has either been mitigated by the negotiation of the MoU that is now in place between ECDC (e.g.access to EpiPulse systems) or in cases such as the of access to TESSy (The European Syndromic Surveillance System) the development of a new UK-based system funded through existing budgets across the organisation.

Public Health Grant

196. The public health grant is paid to all Upper-Tier and Unitary Local Authorities in England. Lower-Tier Local Authorities do not receive the grant. The conditions of the Public Health Grant stipulate that local authorities may utilise the public health grant to fund any activity where the primary purpose of the activity is public health. The intention of the grant is that each local authority can determine its own local public health priorities and utilise the grant accordingly.

197. Local authorities were required to report their expenditure on public health activities annually, across a number of categories, to the Ministry of Housing Communities and Local Government ("MHCLG"), via the Revenue Outturn data collection process. This data collection is publicly available on GOV.UK. One of the categories for reporting spend is "Health protection - Local authority role in health protection (prescribed functions)". This is the only category relating to Health Protection, but there are other categories within Public Health, that are not Health Protection.

Role of PHE in Public Health Grant Assurance

198. DHSC ministers decide the annual Public Health Grant allocations to local authorities and PHE was the administrative vehicle for distributing them. PHE had an annual assurance programme designed to seek that the grant was spent according to grant conditions, i.e. on Public Health. This was discussed and agreed with the NAO, to ensure that its responsibilities in assuring the Public Health Grant expenditure were discharged to a high standard. Beyond this, PHE had no role in directing local authorities' decisions about how they each utilised the grant and was strictly a matter for them to determine.

199. PHE did not have access to any data at a more granular level than is available on GOV.UK. PHE therefore had no formal knowledge of how local authorities were spending within the 'Health Protection' category, and in particular PHE would not have any data that would show whether any of this spend on Health Protection was going specifically on EPRR or on stockpiling of PPE.

Section 4: PHE's Public Health Services

200. PHE was established as a new public health service under the Health and Social Care Act as an agency of the Department of Health and Social Care to protect and promote the health of the population at national level. PHE was the expert national public health agency which fulfilled the Secretary of State for Health's statutory duties to protect health and address health inequalities and executed the Secretary of State's power to promote the health and wellbeing of the nation.

As described earlier PHE provided the national infrastructure for health protection including: an integrated surveillance system; provision of specialist services, such as diagnostic and reference microbiology investigation; management of outbreaks of infectious diseases and environmental hazards and ensuring effective emergency preparedness for health emergencies. In this section I discuss these activities with a specific focus on those that are relevant to the scope of Module 1 and the UK's preparedness.

201. PHE was responsible for providing the infrastructure for a national surveillance system for infectious diseases to detect, understand and monitor infectious diseases threats to health. Surveillance was underpinned by PHE's specialist diagnostic and reference laboratories and epidemiological teams which formed the National Infection Service.

202. The National Infection Service ("NIS") was led by a director and comprised several divisions each led by Deputy Directors: NIS Laboratories; Field Service; Healthcare Associated Infections and AMR; TARGET (TB, Acute Respiratory Infections, Gastrointestinal Infections, Emerging Infections and Travel); Blood Safety, Hepatitis, STIs and HIV; Immunisation, Vaccines and Countermeasures; Research and Data and Analytics.

NIS Laboratories - Specialist Diagnostic and Reference Laboratories

203. PHE provided specialist microbiology services from its network of laboratories to help detect and identify infectious diseases and threats to food, water and environmental safety. These comprise diagnostic and reference laboratory functions. This public health microbiology work underpins infectious disease surveillance and comprises specialist tests to characterise public health threats enabling outbreak identification and control. Public health microbiology differs from clinical diagnostic testing which is driven by a patient's clinician deciding that the individual should be tested as part of their clinical care enabling the clinician to make a diagnosis to inform clinical care decisions.

204. Clinical diagnostic testing is normally the responsibility of the NHS except for specialist tests such as those for rare and imported pathogens such as Ebola that require specialist capabilities. Specialist public health microbiology and

clinical diagnostic testing have separate funding streams between the public health system and the NHS.

205. PHE operated a network of Public Health Laboratories with the majority of reference and specialist functions based at Colindale and regional laboratories in Bristol, Birmingham, Cambridge and Manchester and the research and rare and imported pathogens laboratory functions based at Porton Down.

206. PHE Laboratories at Porton had specialist expertise in research into rare and emerging pathogens, with specialist skills in high-containment microbiology with both *in vitro* and *in vivo* testing facilities for the most dangerous pathogens in the world. PHE high containment facilities at Colindale and Porton together with those in the MoD Defence Science and Technology Laboratory (DSTL) were and remain the only Advisory Committee on Dangerous Pathogens (ACDP) containment level 4 capabilities in the UK. These highly specialist capabilities are maintained in constant state of readiness for public health response through research, for example, into vaccines.

207. PHE had built a small-scale standing capability for Whole Genome Sequencing (WGS) of bacterial and viral genomes to support surveillance and outbreak response. In addition, PHE, working with partners, led the way globally in the use of WGS as a diagnostic solution for managing TB **[Exhibit: JH/M1 0069 - INQ000090386]**.

208. PHE had also led globally in the use of WGS for the laboratory investigation and surveillance of gastrointestinal infections and to track vaccine coverage of invasive pneumococcal disease. A small amount of funding was available to apply this technology to support outbreak investigation for a broader range of pathogens. PHE had a strategic ambition to embed WGS in PHE labs and optimise the use of WGS-based information to detect and control infectious diseases as described in the PHE Infectious Diseases Strategy 2020-2025, September 2019 **[Exhibit: JH/M1 0044 - INQ000090352].**

National reference laboratory for respiratory viruses

209. The reference laboratories in PHE NIS comprised:

- the Bacteriology Reference Department (consisting of three Reference Units: (i) the Antimicrobial Resistance and Healthcare Associated Reference Unit, (ii) the Gastrointestinal Bacteria Reference Unit, and (iii) the Respiratory and Vaccine Preventable Bacteria Reference Unit).

- the Virus Reference Department (consisting of eight Reference Units: the Antiviral Unit, the Bloodborne Virus Unit, the Clinical Services Unit, the Enterovirus Unit, the Human Papillomavirus Unit, the Immunisation and Diagnosis Unit, the Polio Reference Service and the Respiratory Virus Unit),

- the Mycology Reference Laboratory,

- the Meningococcal Reference Unit.

- PHE commissioned a Malaria Reference Laboratory from an external provider and had affiliated external providers for a Parasitology Reference Laboratory and a Brucella Reference Unit.

210. Within NIS laboratories at Colindale, the virus reference department (VRD) was the national and international reference centre for a wide range of virus infections undertaking detection of viruses of public health importance. The department was made up of eight units, including the Respiratory Virus Unit, which includes the UK WHO National Influenza Laboratory. The RVU also performed tests for known coronaviruses and was one of the first laboratories in the world to develop a test for SARS-CoV-2.

211. National standard methods for microbiology investigations (UK SMI) developed by the reference laboratory provided quality assurance across early testing laboratories/network and monitored assay performance. Eligible network laboratories followed agreed referral guidelines for seasonal and unusual influenza detections. The reference laboratory provided the initial PCR method for SARS-CoV-2 detection, which was adopted in a standardised way in the early days and weeks of the pandemic.

212. PHE reference laboratories had a strong track record leading detection of respiratory virus threats to public health in the UK and the UK was the first

country to detect and communicate the emergence of resistance to oseltamivir among influenza A (H1N1) viruses in Europe in 2008. PHE's laboratories rapidly identified the first UK MERS case in 2012 and led on laboratory investigations during the 2009 H1N1pdm09 pandemic.

Laboratory based surveillance of influenza and other respiratory viruses.

213. PHE's reference laboratories worked very closely with specialist epidemiology teams. Surveillance of influenza and other respiratory viruses was undertaken throughout the year and collated on behalf of the countries of the UK by the Influenza Surveillance Team in PHE's National Infection Service. Weekly reports were normally published during the winter season between October and May.

214. A variety of data sources are collated to provide information on circulating influenza strains, resistance to antivirals, burden within the community and on the health service. These include laboratory data, GP consultations, and mortality data. PHE also undertook surveillance of seasonal influenza vaccine uptake and effectiveness. The weekly and annual influenza and respiratory virus surveillance reports included information on other respiratory viruses including emerging ones such as MERS-CoV and avian influenza.

215. Primary diagnosis of seasonal influenza is carried out by NHS laboratories. The PHE reference laboratory used a range of highly specialised molecular and genome sequencing techniques, for example, to monitor for new variants and supported adaptation of diagnostic tests where required.

216. Newly emerging influenza viruses may be considered in several different categories: new seasonal influenza strains; zoonotic influenza strains circulating in the UK in birds or mammals, and influenza viruses notified by WHO of particular pandemic threat.

217. Capacity for primary diagnosis of circulating zoonotic strains in the UK was maintained by close liaison between UK and international veterinary agencies (Animal and Plant Health Agency (APHA) and WHO) who undertake strain surveillance in domestic and wild animals coupled with targeted follow-up of suspected human exposure to non-seasonal influenza viruses.

218. The planned role of the PHE reference laboratory in an influenza pandemic is set out and described in the PHE Pandemic Response Plan (2014) **[Exhibit: JH/M1 0070 - INQ000090387]**. The laboratory was responsible for detection and surveillance of respiratory viruses including development of diagnostic assays for specific detection of any novel pandemic virus, diagnosis and confirmation of pandemic virus infections in the first UK cases, and virological surveillance of the new pandemic strain and other circulating influenza viruses. This would be followed later by roll-out of the pandemic specific diagnostic assay(s) to PHE (and possibly other) laboratories.

219. The quality assurance of assay detection was ensured across the PHE lab testing network through the provision of a standard method developed by the reference laboratory, provision of positive control reagents and proficiency testing.

220. The reference laboratory would also play an ongoing role in detecting, characterising and monitoring changes in the virus during the pandemic which impact on disease severity, changes in transmission and effectiveness of treatments. The reference laboratory used specialised testing and targeted studies to monitor disease spread and changes to effectiveness of vaccines and countermeasures. and the reference laboratory also participated in international influenza quality assurance programs and actively sought intelligence on newly emerging threats with national and international partners.

<u>Laboratory surveillance of other emerging infections</u>

221. PHE carried out national surveillance for a range of different infectious diseases of public health importance, including those considered to be high consequence infectious diseases (HCIDs), that were diagnosed in the Rare and Imported Pathogens Laboratory (RIPL) or other PHE reference laboratories.

222. RIPL provides specialist laboratory services and advice to the NHS and other healthcare providers. It provided laboratory diagnosis for a wide range of unusual viral and bacterial infections including viral haemorrhagic fevers like Ebola, mosquito-borne diseases such as Dengue and other rare and imported infections.

223. RIPL, working with partners, provided the Imported Fever Service (IFS) which was established in 2012 as a collaboration between PHE, the London Hospital for Tropical Diseases and the Liverpool School of Tropical Medicine to provide 24-hour, 7-days a week telephone access to expert clinical and microbiological advice.

224. The IFS provided advice to support the management of febrile patients, infection control and public health interventions. This included infections that may be classified as high consequence infectious diseases (HCIDs).

225. When an emerging infection or High Consequence Infectious Disease (HCID) was diagnosed in the UK, an incident response was set up within PHE to coordinate the investigation and public health response in accordance with the HCID pathway, which I describe below.

Epidemiology, Surveillance and Horizon Scanning for infectious diseases

226. The core components of PHE's infectious disease surveillance and epidemiology capability sat within NIS, which I described in some detail in Section 2. In this section I discuss the work performed by PHE, often in collaboration with partners, that covers epidemiological surveillance, horizon scanning and provides further information on specific risk assessment not covered in Section 5. I have also provided additional detail on surveillance and public health response to Middle East Respiratory Coronavirus (MERS-CoV) as specifically requested.

Horizon scanning

227. The Emerging Infections and Zoonoses (EIZ) team, which at of January 2020 was part of the TARGET division of NIS, carried out comprehensive daily horizon scanning activities that identified international emerging infectious disease threats as well as new or updated publications from a range of multilateral organisations (including WHO and ECDC).

228. This was achieved by reviewing different sources such as news and surveillance reports, scientific literature, scientific search engines, and journals, and more recently via the WHO Epidemic Intelligence through Open Source (EIOS) platform which has been used to collect and assess emerging infectious threats.

The outputs of this work were shared with approximately 200 people per day in 2019, including the relevant specialist teams within PHE and DHSC, CMOs, devolved administrations, NHS, other government departments, expert committees and international colleagues.

229. These documents were also included in the monthly Emerging Infections summaries produced by PHE and published on the PHE website.

Novel Pathogen assessment

230. The epidemiological, clinical and virological investigation of the first imported cases of a disease caused by a novel pathogen and the close contacts of these cases who may have also been exposed to the infection is essential to inform guidance and policy in directing the UK's public health response to the newly identified pathogen/disease.

231. Among other pre-existing PHE protocols to conduct enhanced surveillance of disease caused by a novel pathogen was 'The First Few Hundred (FF100) Enhanced Case and Contact Protocol'. This protocol is closely aligned to the WHO FFX protocol and has been rapidly adapted for novel pathogens. By way of **[Exhibit: JH/M1 0203 - INQ000101197]** I have provided the previous protocol designed for assessment of human cases of avian influenza A(H7N9), a novel avian influenza virus capable of infecting humans which emerged in China in 2013.This protocol was adapted and used as part of the early COVID-19 response.

232. The epidemiological methods to guide data collection for the comprehensive assessment of these confirmed cases and their close contacts are set out in the protocol. The protocol outlines the public health investigation of persons with laboratory confirmed cases, along with their close contacts.

233. When a new pathogen of public health concern emerged PHE laboratories would work to isolate it, grow it and sequence the genome. This helps characterise the pathogen, its relatedness to other pathogens and identify targets for development of specific diagnostic tools. PHE's *in vitro* and *in vivo* systems in high containment facilities were used for further assessments including

inactivation and disinfection, disease progression, transmission and interventions testing. Where the pathogen is a new variant of a known infectious agent e.g., Influenza then testing can proceed directly to look at efficacy of existing vaccines or therapeutics in established assays and models to determine possible impact on the population.

Management of High Consequence Infectious Diseases (HCID)

234. Following the Ebola outbreak in West Africa in 2014-2015, a high consequence infectious diseases programme was established in the NHS and in PHE to strengthen preparedness to future HCIDs. In the UK, an HCID is defined according to the following criteria:

a. acute infectious disease

b. typically has a high case-fatality rate

c. may not have effective prophylaxis or treatment

d. often difficult to recognise and detect rapidly

e. ability to spread in the community and within healthcare settings

f. requires an enhanced individual, population and system response to ensure it is managed effectively, efficiently and safely

235. HCIDs are further divided into contact (usually spread by direct contact with an infected patient or infected fluids, tissues and other materials, or by indirect contact with contaminated materials and fomites), and airborne (spread by respiratory droplets or aerosol transmission, in addition to contact routes of transmission). HCIDs included the SARS and MERS coronaviruses.

236. Diseases classified as HCIDs present an enhanced risk to individual and population health, and require additional measures such as enhanced infection, prevention and control measures in clinical settings, and thorough public health investigation. Pathogens with HCID status also require specific handling in the laboratory setting, such as the use of higher containment facilities. An existing list of diseases classified as HCIDs has been agreed by the UK 4 nations public

health agencies, and is informed by advice from scientific advisory committees, and is published on the UKHSA website, I have exhibited the current list as of March 2023 **[Exhibit: JH/M1 0070a - INQ000147718]**.

237. The aim of the PHE HCID programme was to support PHE to be fully prepared to lead the relevant actions (as described above) and enable the public health response to a significant outbreak of high impact /emerging infectious diseases, arising abroad or in the UK. It was designed to complement and support the NHS England HCID programme (focused on building resilience and escalation in providing acute response and treatment in secondary care for those with suspected or confirmed HCID). DHSC also collaborated and took the lead for aspects of the joint programme of work. Within PHE teams, the programme was led and coordinated by the Health Protection and Medical Directorate with PHE's National Infection Service providing the technical expertise and ERD facilitating its implementation. An overview of the work programme is described in exhibit **[Exhibit: JH/M1 0071 - INQ000090388]**.

238. A lessons identified exercise of the programme was completed in March 2017. The programme was tested via a table-top exercise, Exercise Broadstreet, in January 2018 **[Exhibit: JH/M1 0072 - INQ000090389]**. The programme was closed in April 2018, with responsibility for continuation of aspects of the programme transferred to the business-as-usual functions, with oversight by the PHE EPRR Oversight Group. The programme was reviewed as part of a stocktake in 2019.

239. Although not designed to provide a response at the capacity required for pandemics of highly infectious disease (e.g. pandemic influenza) the programme of work aimed to improve PHE's capabilities around horizon scanning and risk assessment of potential HCID threats, enhance preparedness for our public health response including our early identification and diagnostic capability.

<u>Surveillance and public health response to Middle East Respiratory Syndrome Coronavirus (MERS-CoV)</u>

240. In this section I respond to the Inquiry's specific question about PHE's role in the surveillance of MERS-CoV. I address this by covering both the work that took place in specialist epidemiology teams and surveillance within PHE laboratories.

241. Regular reports of global and UK numbers of MERS-CoV, drawn from WHO notifications, and UK surveillance systems, were prepared and sent to the office of UK CMO from January 2017 until June 2020. A reduction in cases globally was observed during the pandemic. The reports (e.g., in August 2019) also linked to updates in risk assessments and travel advice published on GOV.UK by PHE, and any relevant news stories, such as messaging around awareness of MERS-CoV in travellers returning from the Hajj, and in clinicians. Since 2022, reports are provided regularly to the Pandemic Preparedness Portfolio Board (known as the Pandemic Influenza Preparedness Programme Board until November 2022) chaired by DHSC and to the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG).

242. PHE had previously recommended to DHSC that notifiable disease regulations be amended to include clinically suspected MERS-CoV cases. Such a change would mean that all suspected cases of MERS-CoV would, by law, have to be reported to PHE which would help strengthen surveillance and support a rapid public health response to prevent onward transmission. This amendment has not yet been implemented (and therefore PHE continued to rely on suspected cases of this infection being reported by clinicians voluntarily).

243. PHE worked closely with the National Travel Health Network and Centre (NaTHNaC) which leads on travel health advice, to provide relevant information for MERS-CoV on the internet for travellers. In addition, both NaTHNaC and PHE published information in advance of the Hajj each year in relation to MERS-Cov related risks.

244. PHE also published guidance on clinical management, including procedures for referral and handling of clinical diagnostic specimens for MERS-CoV lab testing, advice for public health investigation and management of cases and close contacts, advice for people travelling to and returning from the Middle East and

risk assessments. This advice was published on GOV.UK by PHE and updated as appropriate in the guidance document.

Laboratory based surveillance of MERS-CoV

245. Laboratory testing for coronaviruses demonstrates capability to identify and respond to newly emerging coronavirus using a technical approach similar to that for influenza: This involves first line screening using a molecular test capable of coronavirus family detection followed by specific assay and/or genome sequencing to identify which virus is present. This approach was first developed during the SARS coronavirus epidemic in 2003, and then used to identify the first known case of MERS in 2012.

246. Due to the low incidence of MERS infection globally and in the UK, PHE's testing strategy was based on a laboratory network consisting of two specialist laboratories tasked with detection (Birmingham and Manchester) and the national reference laboratory responsible for confirmation and genetic and virological characterisation of any network laboratory detections.

Contribution to Expert Advisory Groups

247. PHE collaborated with, and contributed to the scientific expert advisory groups, who provided specific advice to government in infectious diseases risks to humans. Below I summarise PHE's interaction with those groups most relevant to Module 1.

The National Expert Panel on New and Emerging Infections (NEPNEI):

248. NEPNEI was established in 2003, with the first meeting in November that year. Its remit was as an overarching horizon scanning panel responsible for assessing the threat from new and emerging infectious diseases (which are mainly zoonoses), reporting to the CMO and advising DHSC, with the secretariat provided by the HPA.

249. Between 2003 and 2011, NEPNEI discussed a wide range of topics, some requested by the CMO, and some raised by members of the panel. It was dissolved as an expert panel in October 2012 with functions moving to other

expert groups such as the Human Animal Infections and Risk Surveillance (HAIRS) Group and the Advisory Committee on Dangerous Pathogens (ACDP).

Advisory Committee on Dangerous Pathogens (ACDP):

250. The ACDP is an independent scientific advisory committee of DHSC. Its work cuts across a number of organisations, including the Health and Safety Executive (HSE), UKHSA and the Department for Environment, Food and Rural Affairs (Defra). The Committee's purpose is to provide independent scientific advice as requested 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, to provide, as requested, independent scientific risk assessment advice on transmissible spongiform encephalopathies (TSEs) to ministers through DHSC, DEFRA, and their counterparts under devolution in Scotland, Wales and Northern Ireland, and to the Food Standards Agency.

251. The secretariat has been provided by several different Government departments including HSE, DHSC and Defra. At January 2020, PHE provided the secretariat to the ACDP main committee and sub-groups. PHE experts attended meetings as official observers, and provided updates, information and expert advice to ACDP to inform discussions and decision making. Members are appointed to ACDP by the DHSC appointments team. I have exhibited the annual reports of ACDP that were held by PHE **[Exhibit: JH/M1 0072a-0072m - INQ000147719, INQ000147720, INQ000147721, INQ000147722, INQ000147723, INQ000147724, INQ000147725, INQ000147726, INQ000147727, INQ000147728, INQ000147729, INQ000147730, INQ000147731]**

Human Animal Infections and Risk Surveillance (HAIRS) Group:

252. The HAIRS group **[Exhibit: JH/M1 0073 - INQ000090390]** is a multi-agency cross-government horizon scanning and risk assessment group that is currently chaired by Defra, but previously chaired by HPA and then PHE. HAIRS reports into the ACDP. Potentially zoonotic or animal incidents which have unknown or unrecognised human health effects are reported through the HAIRS group. The group acts as a forum to identify and discuss infections with potential for

interspecies transfer and it aims to identify, and risk assess emerging potentially zoonotic infections which may pose a threat to UK public health. I have exhibited the annual reports of HAIRS **[Exhibit: JH/M1 0073a-0073f - INQ000147732, INQ000147733, INQ000147734, INQ000147735, INQ000147736, INQ000147737]**

253. Since its establishment in early 2004, there has been a steady evolution and development of the risk assessment processes used by the group. The historic risk assessments carried out and methodology used are available on GOV.UK. The HAIRS group has not discussed or risk assessed, emerging respiratory pathogens as these have always been addressed by other groups such as ACDP and NERVTAG. I have exhibited a paper outlining the risk assessment approach taken by the HAIRS group published in 2009 in Epidemiology and Infection **[Exhibit: JH/M1 0073g - INQ000147738]** and documents describing the current risk assessment methodology for HAIRS **[Exhibit: 0073h-0073m - INQ000147739, INQ000147740, INQ000147741, INQ000147742, INQ000147743, INQ000147744].**

254. PHE sent monthly emerging infection summaries to members of both HAIRS and ACDP to support and inform the advice they provided to Government and contributed to a range of risk assessments carried out by the group. These are available online **[Exhibit: JH/M1 0074 - INQ000090393].**

255. In addition, the FCDO EpiThreats group was set up following the 2014-15 West Africa Ebola outbreak to discuss new and emerging outbreaks and associated UK responses. Information from the Emerging Infections and Zoonoses (EIZ) teams horizon scanning activities was shared with this group.

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

256. NERVTAG was established in 2014 as an advisory Group that provides the Chief Medical Officer (CMO) and, through the CMO, ministers, the DHSC and other Government departments, with scientific risk assessment and mitigation advice on the threat posed by new and emerging respiratory virus threats and on options for their management. I have exhibited the annual reports of NERVTAG

[Exhibit: JH/M1 0074a-0074e - INQ000147745, INQ000147746, INQ000147747, INQ000147748, INQ000147749].

257. NERVTAG draws on the expertise of scientists and health care professionals, including clinicians, microbiologists and public health practitioners, and colleagues in related disciplines. NERVTAG responded to requests from DHSC, PHE and the NHS. PHE provided the scientific secretariat for NERVTAG and PHE experts contributed to the work of NERVTAG as observers and would present or submit papers or provide expert input to inform discussion at meetings.

Scientific Advisory Group for Emergencies (SAGE)

258. The Scientific Advisory Group for Emergencies (SAGE) is convened to provide independent scientific advice to support decision-making in Government in the event of a national emergency. SAGE has been convened several times to provide scientific and technical advice to support government in major outbreaks. PHE representatives participated in SAGE meetings for incidents such as Zika in 2016 and Ebola in 2014.

Natural Hazard Forward Look

259. Since 2015, PHE was part of a partnership with other public sector organisations – Animal and Plant Health Agency, Public Health England, Met Office, British Geological Survey), with the aim of improving situational awareness for decision makers across government, thus supporting the UK government to be more anticipatory in its response to natural hazards and to reduce the impacts of future disasters.

260. Information on global emerging infectious threats collated through horizon scanning was fed into the International Natural Hazard Forward Look, which provides a weekly international overview of natural hazards for UK Government information on global weather, volcanic, human and animal health events and their likely impacts. It reports on new, emerging or deteriorating situations; therefore, ongoing events that are considered to be unchanged may not feature.

International contribution

261. PHE worked internationally to improve global health security and meet its responsibilities under the International Health Regulations. PHE priorities included responding to outbreaks and incidents of international concern and building public health capacity, particularly in low- and middle-income countries. PHE worked closely with international partners such as WHO, the European Centre for Disease Prevention and Control (ECDC) and the International Association of National Public Health Institutes (IANPHI) **[Exhibit: JH/M1 0045 - INQ000090353]**.

262. Following the Ebola outbreak in West Africa, the UK Public Health Rapid Support Team (UKPHRST), was established as a partnership between PHE and the London School of Hygiene and Tropical Medicine (LSHTM) (launched on 1 November 2016 following the Ebola outbreak in West Africa), to strengthen the capacity of the UK to respond to international disease outbreaks. The UK-PHRST has a triple mandate, complementing response with research and capacity strengthening to enhance response capability.

263. The UK-PHRST rapidly deploys multidisciplinary teams of public health professionals on behalf of the UK Government to support outbreak responses in areas of need in low- and middle-income countries, following direct requests for assistance from national governments or the World Health Organisation. The UK-PHRST oversees and co-leads a growing portfolio of research and capacity development projects that support and strengthen infectious disease outbreak preparedness and response with a consortium of international and national partners.

Section 5: The Civil Contingencies Act 2004

264. In this section I describe the duties imposed on the Secretary of State as a Category 1 responder, by the Civil Contingencies Act 2004 ("CCA 2004") and how relevant duties were delegated to PHE as described in the Framework Agreements **[Exhibit: JH/M1 0018/0019 - INQ000090326, INQ000090327]** discussed in Section 2. I will describe the activities undertaken by PHE in line

with the CCA 2004 as well as describing broader work conducted under these themes.

265. The CCA 2004 established the legislative framework for civil protection in the UK. It imposes a set of roles and responsibilities on those organisations with a role to play in preparing for and responding to emergencies. The Act has 2 categories of responder. Category 1 responders are those organisations at the core of an emergency response. As a category 1 responder under the CCA 2004, the Secretary of State has the following duties.

    a. to perform risk assessments of potential emergencies,

    b. maintain plans to prevent an emergency or reduce the effects of it,

    c. maintain plans to ensure business continuity should an emergency occur,

    d. maintain plans to communicate and advise the public in an emergency.

266. Section 2 of the CCA 2004 also allows a minister to make regulations that require or permit a category 1 or category 2 responder to co-operate with and share information with another responder, to enable a category 1 responder to fulfil one of the four principal duties outlined in Section 2. This duty was bolstered in The Civil Contingencies Act 2004 (Contingency Planning) (Amendment) Regulations 2012 (2012) which requires:

    a. category 1 responders to co-operate, with other category 1 responders and with category 2 responders where appropriate, for the purpose of fulfilling their duties. This co-operation expressly includes the sharing of necessary information.

267. Annex A of the 2018 Framework agreement, the agreement that was substantive going into the COVID-19 pandemic, between the Department of Health and Social Care and Public Health England **[Exhibit: JH/M1 0020 - INQ000090328]** states:

"This annex sets out the statutory functions that the Secretary of State for Health and Social Care has instructed Public Health England (PHE) to carry out on his behalf:"

"as a Category 1 responder under the Civil Contingencies Act 2004 (CCA) in respect of emergency planning, the response and resilience functions for public health. For the avoidance of doubt, these duties under the CCA shall be delegated from the Secretary of State to officials in PHE who are responsible for emergency planning, resilience and response, such that those officers operate as if PHE itself were a category 1 responder under the CCA"

Risk Assessment

268. In this section I outline the risk assessment processes that PHE engaged with, in line with the duties placed on category 1 responders, and more broadly to inform emergency preparedness particularly in relation to respiratory viruses.

269. In respect of risk assessments, the relevant wording in the CCA 2004 is that Category 1 responders having the following duties:

2(1)(a) from time to time assess the risk of an emergency occurring

2(1)(b) from time to time assess the risk of an emergency making it necessary or expedient for the person or body to perform any of his or its functions

2(1)I consider whether an assessment carried out under paragraph (a) or (b) makes it necessary or expedient for person or body to modify plans maintained under paragraph (c) or (d)

(iii) 2(1)(f) arrange for the publication of all or part of assessments made …. under paragraphs [(a) and (b)]… in so far as publication is necessary or desirable for the purpose oi) preventing an emergency,

(ii) reducing, controlling or mitigating the effects of an emergency, or

(iii) enabling other action to be taken in connection with an emergency,

National Risk Register

270. The government's National Risk Register (NRR) provides a government level assessment of the likelihood and potential impact of a range of different malicious and non-malicious national security risks, including natural hazards, industrial accidents, malicious attacks, and others, that may directly affect the UK and its interests over the forthcoming two-year period.

271. The NRR is owned by the Cabinet Office and at their request, and the request of other relevant departments, PHE contributed specialist technical advice through DHSC into the NRR via the mechanism as prescribed by the Cabinet Office to inform the decisions made about the risks relevant to PHE's expertise.

272. The NRR was considered by the DHSC chaired EPRR Partnership Board to assess risks across the health and social care system and to provide direction on their appropriate mitigation. For example, this meant that the training and exercising programme established by the Partnership Board and Health Delivery Group was prioritised according to the NRR and a principle was established in around 2018, that all exercises undertaken by PHE for the tripartite group would be focussed on risks within the NRR. Prior to this, there was more subjectivity about the risks the exercise programme was focussed on.

Local Resilience Forum Community Risk Register

273. Working with LRF partners, PHE EPRR Practitioner's within Health Protection Teams (HPTs) supported a risk-based approach to emergency planning. In doing so, PHE supported the development of the LRF owned Community Risk Registers. Local HPTs worked with specialist national teams to support the development of plans aligned to the Control of Major Accident Hazards Regulations 1999 (COMAH) and the Radiation Emergency Preparedness and Public Information Regulation 2019, dependent upon demographical risks.

PHE Corporate Risk Management

274. PHE's risk management arrangements were set out in an overarching policy **[Exhibit: JH/M1 0075 - INQ000090401]** supported by separate procedure and guidance documents **[Exhibit: JH/M1 00076 - JH/M1 0077 - INQ000090402, INQ000090403]**. These documents set out the role and responsibilities of the Management Committee, Advisory Board, Audit and Risk Committee as well as senior management teams and staff across the organisation in relation to risk.

275. Broadly speaking, PHE's high-level risks were set out in a Strategic Risk Register (SRR), which included strategic risks identified by PHE's Management Committee and risks escalated from one or more tactical risk registers owned at function, significant programme or major project level. In addition, risk registers were maintained at the operational level.

276. The SRR was owned by the PHE Management Committee who reviewed it quarterly with the PHE Audit and Risk Committee and periodically by the Advisory Board. It was also a standing item at the quarterly accountability meetings chaired by DHSC.

277. The Governance sections of the Annual Report and Accounts are at PHE Annual Report and Accounts 20-3-2021 **[Exhibits: JH/M1 0078-0085 - INQ000090404, INQ000090405, INQ000090406, INQ000090407, INQ000090408, INQ000090409, INQ000090410, INQ000090411]** for further detail on the evolving risk processes within PHE and the principal risks, for example pandemic influenza and, in 2014/15 & 2015/16, Ebola.

PHE Risk assessment of Emerging Respiratory viruses and infectious diseases

278. Risk assessments of emerging respiratory viruses and infectious diseases were undertaken within the TARGET Division *(see Section 2, NIS Division)*, with contribution from the laboratories, within the National Infection Service. Below I provide a non-exhaustive list of notable risk assessments that were carried out by PHE. In many cases, multiple updated versions of these risk assessments have been produced and published on GOV.UK. The National Archives hold

previously published versions of these risk assessments. Subsequent versions of these documents are also available via the National Archives website.

a. Middle East Respiratory Syndrome (MERS-Cov). PHE published and updated its risk assessments of MERS-Cov from 2014 **[Exhibit: JH/M1 0085a - INQ000147750]**

b. Avian Influenza A(H5N6). PHE published and updated its risk assessments of Avian Influenza A(H5N6) from 2016 **[Exhibit: JH/M1 0085b - INQ000147751]**

c. Avian Influenza A(H7N9). PHE published and updated its risk assessment of Avian Influenza A(H7N9) from 2014 **[Exhibit: JH/M1 0085c - INQ000147752].**

d. Zika Virus. Following the Zika virus outbreak in Brazil and declaration of the Public Health Emergency of International Concern (PHEIC), a risk assessment was carried out by HAIRS in 2016, of which PHE was a member. [Human Animal Infections and Risk Surveillance group (HAIRS).docx] **[Exhibit: JH/M1 0073 - INQ000090390]** PHE also published country specific risks **[Exhibit: JH/M1 0085d - INQ000147753]**.

e. Pneumonic Plague. Following a larger than usual outbreak in Madagascar in 2017, a PHE risk assessment was published Plague in Madagascar PHE Risk Assessment 2017 **[Exhibit: JH/M1 0086 - INQ000090412]**. This laid out the risk of an imported case in the UK, as well as the risk to travellers and those working in Madagascar.

f. Nipah Virus. A PHE risk assessment was carried out in 2018 due to a Nipah virus outbreak in Kerala, India **[Exhibit: JH/M1 0085e - INQ000147754].**

g. Ebola. PHE produced multiple risk assessments for Ebola since the 2014 outbreak **[Exhibit: JH/M1 0085f - INQ000147755].**

279. In addition, information on these emerging viruses and diseases were included in periodic reports to DHSC's PIPP Board and, from November 2015, this

information was shared with NERVTAG, whose members reviewed this information in their six-monthly meetings and considered their own assessment of the risk.

280. From January 2019, monthly summaries of HCIDs were published on GOV.UK for healthcare professionals who may be involved in HCID identification. These reports included a 'likelihood assessment'; the likelihood of a case occurring in the UK, based on past UK experience and the global occurrence of travel associated cases. I exhibit the final report produced during the period of relevance to Module 1 which references an outbreak of viral pneumonia of unknown aetiology from December 2019 as **[Exhibit: JH/M1 0087 - INQ000090413]** Reports continued to be produced after this time.

PHE's Understanding of the UK government's forecast of the national risk of Pandemic Influenza and Emerging Infections and HCIDs including SARS

281. As of 21 January 2020, PHE contributed specialist technical advice on the assessment of health security risks in the NRR 2017 **[Exhibit: JH/M1 0088 - INQ000090414].** The health security assessment was then incorporated into the government's overall assessment of the national risk within the wider context of the potential impact across all sectors and government departments. The NRR rated the likelihood and severity of each of the risks they identified out of 5. The NRR 2017 showed that Pandemic Influenza had a risk likelihood score of 4 and a severity score of 5. The NRR scored the risk from emerging infectious diseases with a likelihood of 3 and a severity of 3.

Incident Risks Assessments

282. When PHE stood up an incident response, it completed dynamic risk assessments (DRA) to assess the potential impact on health security and on the agency's ability to respond. This process was described in PHE's National Incident and Emergency Response Plan (NIERP) which I provide in further detail later in this section but essentially took a series of variables which were discussed and scored to establish the appropriate level of response as outlined

within PHE's NIERP. Two examples would be geographic spread of an incident and its clinical severity.

Emergency Planning

283. This part of the statement outlines the multiple emergency planning documents that PHE produced and engaged with, in line with the duties placed on category 1 responders and more broadly, with a particular focus on SARS, new and emerging diseases and HCIDs. PHE authored a number of other plans outside of this scope.

284. In respect of emergency planning, the relevant wording in the CCA 2004 is that Category 1 responders have the following duties:

> *2(1)(d) maintain plans for the purpose of ensuring that if an emergency occurs or is likely to occur the person or body is able to perform his or its functions so far as necessary or desirable for the purpose of:*
>
> > *(i) preventing the emergency,*
> >
> > *(ii) reducing, controlling or mitigating its effects, or*
> >
> > *(iii) taking other action in connection with it*
>
> *2(1)(f) arrange for the publication of all or part of …. plans maintained …. under paragraph [(d)] in so far as publication is necessary or desirable for the purpose of:*
>
> > *(i) preventing an emergency,*
> >
> > *(ii) reducing, controlling or mitigating the effects of an emergency, or*
> >
> > *(iii) enabling other action to be taken in connection with an emergency,*

Key Planning Documents

The Concept of Operations (CONOP) and National Incident & Emergency Response Plan (NIERP)

285. In 2013 PHE authored its Emergency Preparedness, Resilience and Response Concept of Operations ("CONOPs") **[Exhibit: JH/M1 0089 - INQ000090415]**, which described PHE's internal and external partner arrangements, in times of response to an incident at local, regional and national levels. This includes the provision of specialist advice and specific support to DHSC, NHS England, central and local government and Local Resilience Forums ("LRFs").

286. PHE principally discharged its emergency planning duties through the further development of this Concept of Operations (CONOPS) and National Incident and Emergency Response Plan ("NIERP"). I exhibit version 03.00 of the NIERP which was the version in use at 21 January 2020 **[Exhibit: JH/M1 0090 - INQ000090416]**. The CONOPs described the high-level principles underpinning PHE's preparedness and response and the NIERP provided the operational details of how PHE would respond to and recover from any significant public health related or business continuity incident. In 2016, these were contained in the same document.

287. The 2016 NIERP aimed to ensure a coherent and consistent preparedness, resilience and response approach, underpinned by principles set out in the CONOP, across the broad spectrum of health security risk and issues. The NIERP is an all threats and hazards plan. It is not specific to one particular health hazard, such as pandemic, and its approach is therefore equally applicable to an extreme weather event and/or a disease outbreak. The NIERP describes the core arrangements for most incident responses and describes that it is to be supported by threat and hazard specific plans where necessary; e,g.; pandemic influenza, radiation response etc.

288. It provided PHE's detailed arrangements for responding to incidents and emergencies, including the Emergency Preparedness, Resilience and Response (EPRR) arrangements in PHE's Centres. It described the mechanism for leading an incident and making decisions using a structured approach at an organisational level appropriate to the incident.

289. The NIERP includes arrangements for operating with external partners, and as such, it was discussed and created with, and distributed to key external partners across the health and social care system, including the Devolved Administrations' national public health institutes. The NIERP operating as planned therefore necessarily relies upon all of those external partners operating as agreed.

290. The NIERP was reviewed annually, and changes were made following lessons identified from incidents and exercises where these were considered improvements. The updated version was usually then tested in an internal exercise before the EPRR Oversight Group would sign off the new version and a dissemination of changes process would follow.

PHE's Pandemic Influenza Plan (2014)

291. As the lead government department for pandemic preparedness, in 2011 DHSC published the UK's Influenza Pandemic Preparedness Strategy **[Exhibit: JH/M1 0091 - INQ000090417]**. To implement PHE's responsibilities as described in this strategy, in 2014 PHE published a hazard specific Pandemic Influenza Strategic Framework and Response Plan **[Exhibit: JH/M1 0092 - INQ000090418] [Exhibit: JH/M1 0070 - INQ000090387].**

292. Following the publication of this plan, PHE continued to review its processes and learn from incidents and exercises as described in Section 6, many of which were directly related to pandemic preparedness. Updates to the 2014 PHE Pandemic Influenza Plan and Strategic Framework were underway in 2019 when planning was prioritised to manage EU exit risks and latterly the COVID-19 pandemic response.

Communicable Disease Outbreak Management: Operational Guidance (2014)

293. In 2014 PHE co-authored a "Communicable Disease Outbreak Management: Operational Guidance" plan. The plan was co-authored by PHE, Association of Directors of Public Health, Chartered Institute for Environmental Health, Food Standards Agency and Health & Safety Executive. This was important in order

to agree a combined approach to management of outbreaks of communicable diseases amongst the key agencies involved in responding to these and it was shared widely across the public health system. I exhibit it as **[Exhibit: JH/M1 0093 - INQ000090419].**

Guidelines for large-scale contact tracing 2018

294. The document "Guidelines for Large-Scale Contact Tracing" was developed after the 2014-2016 Ebola outbreak in West Africa and 2018 Novichok incidents in Wiltshire following recognition that PHE needed to strengthen its arrangements for large-scale contact tracing **[Exhibit: JH/M1 0093a - INQ000147756]**. Whilst the guidelines did not specify a specific number of contacts upon which the document was predicated, experience from those incidents and the response to the first UK cases of Mpox in September 2018 was that large scale meant 'hundreds of people'. The document was produced by the NIS Field Service and governance was provided via the PHE EPRR Delivery and Oversight Groups.

PHE Centres and Regions Operational Cell ("CROC") Operating Model 2019;

295. When an incident required multiple health protection centres or regions to be involved in the response the Centres and Regions Operational Cell ("CROC") was activated. The model for the CROC was established in 2017 during an internal PHE exercise (Typhon), to support incidents requiring a heightened response and this would be decided during the establishment of the IMT and its cells. The CROC sits within the National Incident Coordination Centre ("NICC") as defined by the NIERP, as either a physical or virtual cell.

296. The aim of the CROC was to provide a point of contact for NICC to improve co-ordination and communications with Centres and Regions (now with Regions). Its primary objective was to streamline and co-ordinate the flow of information between centres and regions and the NICC, Incident Management Team (IMT) and indirectly the Strategic Response Group (SRG).

297. When the centres became the four regions, the CROC was superseded by the Regional Operations Centre (ROC), having the same remit as the CROC.

The WHO assessment of health system crises preparedness in England in 2011 and the recommendations arising from it.

298. The HPA contributed substantially to this assessment with 9 out of the 10 authors being from the HPA. In addition, employees of the HPA were interviewed for this assessment **[Exhibit: JH/M1 0093b - INQ000147757].**

The WHO published *'Pandemic Influenza Risk Management - a WHO guide to* inform & harmonize national and international pandemic preparedness and response'.

299. An individual employed by PHE was invited by WHO to provide expert advice and contribution to this document, including peer review **[Exhibit: JH/M1 0093c - INQ000147758].**

The Global Health Security Agenda Pilot Assessment of the United Kingdom in 2015

300. The UK was an early signatory to the Global Health Security Agenda ("GHSA"), a partnership of countries involving the WHO, NGO's, private and financial organisations, when launched in 2014. The GHSA developed a tool to help countries assess their compliance with International Health Regulations ("IHR") (2005), which previously relied on country self-reporting to WHO. The UK volunteered to pilot this tool in 2015, led by DHSC as chair of the xHMG GHS steering group with the GHS team in PHE commissioned to deliver this. This tool led to WHO establishing the IHR Joint External Evaluation tool (116 countries have undertaken this to date) and associated Monitoring and Evaluation Framework. UKHSA has continued to support this key legally binding international instrument, including ensuring this is strengthened through learning from COVID-19.

The PHE review 'Public Health England and the Sendai Framework for Disaster Risk Reduction 2015-2030' published in 2015.

301. Following discussion with UK colleagues from the Cabinet Office Civil Contingencies Secretariat and related organisations and recognising the

commitment to implement the Sendai Framework, a PHE team led a review of how PHE was implementing the framework.

302. The aim of this review was to assess PHE's activities and contribution to England's performance against the Sendai Framework for Disaster Risk Reduction, providing an overview of progress to date.

WHO International Health Regulations

303. The IHR (2005) provide an overarching framework that is legally binding on 196 countries including the UK and outlines the rights and responsibilities and expected actions of countries in response to public health threats. Under the IHR, States Parties are required to develop and maintain minimum core capacities for surveillance and response, in order to detect, assess, notify and respond to any potential public health events of international concern. In addition, State Parties are required to demonstrate their progress in meeting their obligations by completing the State Party self-assessment Annual Reporting (SPAR) tool and reporting their results back to WHO on an annual basis.

304. The SPAR tool contains 15 capacities (13 prior to 2021) to reflect the need for resilience across all hazards, these include for example surveillance, key laboratory quality, capability and capacity requirements, health emergency management, health service provision, human resources, risk communication, points of entry, policy and financing. The tool requires State Parties to self-assess their capabilities for each capacity on a scale of 1-5 and provide supporting evidence to underpin this.

305. Within the UK, PHE provided the co-ordination of the SPAR tool return through the IHR National Focal Point (IHRNFP) team, on behalf of the whole UK territory. The UK has submitted SPAR tool returns annually since 2010 (and in the current format since 2016). Much of the evidence used to populate the UK return is provided by specialist teams across PHE, with additional information provided from relevant stakeholders in other sectors e.g. animal health, and from across other parts of the UK territory. The return was signed off by senior

managers and submitted to WHO for reporting at the World Health Assembly. The finalised return is shared with all collaborating teams, senior managers and other key stakeholders to inform action, and a summary of findings is published at https://extranet.who.int/e-spar/#submission-details.

Business Continuity Management

306. This part of the statement outlines the business continuity processes that PHE engaged with, both in line with the duties placed on category 1 responders and also more broadly the internal business continuity processes that PHE engaged to comply with the relevant provision of the Framework Agreement with the Department of Health.

Business Continuity under the CCA

307. In respect of business continuity, the relevant wording in the CCA 2004 is that Category 1 responders have the following duty:

> *2(1)(c) maintain plans for the purpose of ensuring, so far as is reasonably practicable, that if an emergency occurs the person or body is able to continue to perform his or its functions*

308. The NIERP **[Exhibit: JH/M1 0090 - INQ000090416]** as described earlier in this section was designed to be used for both significant public health incidents and business continuity incidents. For example it includes events that cause PHE's sites and services to be impacted in a way that threatens its ability to deliver it's delegated duties under the CCA 2004. Such incidents are likely to involve individuals from the HR, Finance, ICT or communications teams joining the Incident Management Team.

309. PHE tested business continuity arrangements during exercises. Section 6 of this statement will discuss public health exercises which PHE ran, such as Exercise Typhon which was designed to test PHE capacity to respond to two concurrent Enhanced incidents.

310. Various teams also tested business continuity arrangements in response to certain risks such as ICT testing preparedness for cyber-attacks. PHE also incorporated lessons identified from business continuity incidents such as Porton Steam in 2017 when the steam system supporting the laboratories at Porton Down failed, effectively closing a significant proportion of PHE laboratories. This business continuity incident was the catalyst for incorporating business continuity incidents formally into the NIERP in order that the same level of rigour could be applied to business continuity incidents as any other incident, given that the consequence of PHE's capacity and capability being restricted, also has an impact on protecting public health.

311. As described in the NIERP, the Deputy Chief Executive/Chief Operating Officer was normally appointed as the Strategic Director for business continuity incidents and would agree the arrangements for business continuity in health protection incidents.

Broader Business Continuity Work

312. The ability of PHE to respond effectively in a business continuity Incident, or indeed prevent one altogether, necessarily relied on the organisation having a broader business continuity management system.

313. PHE's Business Continuity Management Policy **[Exhibit: JH/M1 0094 - INQ000090420]** provided the framework for business continuity in PHE. It emphasised the need to identity what activities were business critical and what were not and outlined the need for each Directorate and PHE location to produce and implement business continuity plans, the assurance of which was carried out by the PHE Strategic Business Continuity Manager on behalf of the Director of Corporate Affairs.

314. The Business Continuity Management Procedure **[Exhibit: JH/M1 0095 - INQ000090421]** outlines that the PHE Management Committee and Board would be supported in their business continuity duties by the Audit and Risk Committee who would provide an independent perspective on the strategic processes for business continuity management. The procedure was supported

by the Guidance for Business Continuity Management System **[Exhibit: JH/M1 0096 - INQ000090423].**

315. A PHE Business Continuity Forum was established which reported to the PHE EPRR Delivery Group. The ToR **[Exhibit: JH/M1 0097 - INQ000090424]** demonstrate it was designed to bring together those from across PHE who had business continuity duties to exchange knowledge and provide recommendations for the future to develop and maintain a work programme to deliver effective internal business continuity arrangements, including contributing to the NIERP **[Exhibit: JH/M1 0090 - INQ000090416]** and horizon scanning for business continuity threats.

316. The framework agreement 2018 **[Exhibit: JH/M1 0019 - INQ000090327]** stated that:

PHE has effective and tested business continuity management (BCM) arrangements in place to be able to respond to disruption to business and to recover time-critical functions where necessary. In line with Cabinet Office guidelines, the BCM system should aim to comply with ISO 22301 Societal Security - Business Continuity Management Systems.

Communications

317. This part of the statement outlines the communication processes that PHE engaged, in line with the duties placed on category 1 responders.

318. In respect of communications, the relevant section in the CCA 2004 is that Category 1 responders having the following duty:

> *2(1)(g) maintain arrangements to warn the public, and to provide information and advice to the public, if an emergency is likely to occur or has occurred*

319. Working alongside other executive leaders, the Communications Director was accountable for communications channels, issues and products including

publishing, media engagement, internal communications and stakeholder engagement.

320. Nationally and regionally, PHE had the following arrangements in place to directly warn, inform and advise the public and raise awareness in outbreaks and incidents. These allowed PHE to tailor the response appropriately to incidents, depending on the risk and audience:

    a. Regular seasonal marketing campaigns promoting vaccination.

    b. Production of a full suite of public information materials to support vaccination programmes, including leaflets and advice for healthcare staff. These materials were produced in a variety of formats and languages to support wide access.

    c. Communications campaigns promoting protective behaviours - e.g. hand hygiene or safe sex.

    d. 24/7 on call Communications cover to support health protection teams.

    e. Maintaining social media channels and producing high quality content to explain risks to health and how to mitigate them.

    f. Ensuring medical and scientific experts were regularly available for broadcast interviews.

    g. Working with nhs.uk to ensure information published on symptoms and advice was kept up to date and was appropriate for specific incidents and outbreaks.

    h. Publishing information for the public and healthcare professionals on GOV.UK

321. The Communications Directorate worked alongside PHE's emergency planning and preparedness teams on their activities to prepare for large scale emergencies. This typically included participating in training exercises and media training spokespeople, whenever 'communications play' was included. PHE Communications Directorate fed into the DHSC owned tripartite comms

plan for pandemic flu and also sat on the Cabinet Office pandemic flu working group.

Communications during an incident response

322. Of all the Health Protection incidents PHE responded to each year, many of them only required very targeted and local communications, such as a small outbreak of measles in a school. Other incidents required a much more significant communications response to warn and inform a larger population such as food related disease outbreaks or adverse weather. The Communications team size and composition tended to flex around the scale and the needs of the incident to provide a suitable communications response.

323. Members of the communications team were embedded locally within PHE's regional centres and led on the 'warn and inform' duties for all local incidents. This would involve working closely with partners in Local Resilience Forums and the NHS.

324. Communications professionals would be represented in national and local Incident Management Team meetings ("IMTs") and communications handling is a permanent agenda item at these meetings.

Co-operation

325. In respect of co-operation, the relevant wording in the CCA 2004 is that Category 1 responders having the following duties:

> *4(1)(a) with each other [other category 1 responders] in connection with the performance of their duties under section 2(1);*
>
> *4(1)(b) with relevant general Category 2 responders in so far as such co-operation relates to or facilitates the performance of the relevant general Category 1 responder's duties under section 2(1)*
>
> *4(4) The co-operation referred to in paragraphs (1) to (3) shall take such form as may be agreed between the relevant responders, but must include—*

4(4)(a) the provision by all relevant general Category 1 and Category 2 responders of information necessary for the performance of their functions under the Act in accordance with Part 8; and

4(4)(b) a forum of all relevant general Category 1 and Category 2 responders (referred to in these Regulations as the "local resilience forum").

326. As described throughout those sections, PHE co-operated with multiple partners such as DHSC and the NHS including other Category 1 responders.

327. I outline here additional methods of co-operation, not already mentioned, that PHE undertook with specific relevant partners in respect of EPRR and the role PHE played in the Local Resilience Forums more substantively.

NIERP

328. PHE's NIERP described the process for routine co-operation and information sharing for EPPR and the initial attendance at an acute incident management team, which routinely includes external partners such as the NHS and the Devolved Administrations public health national institutes. PHE also produced the National Situational Awareness Report (NSAC) which was sent across HMG daily covering all the active PH incidents/risks. PHE's key external stakeholders (such as DHSC, NHS England & Improvement) were also incorporated into PHE's EPRR governance arrangements such as participation in the EPRR Oversight Group as described earlier.

Directors of Public Health

329. Directors of Public Health ("DsPH") were not employed by PHE, they were employed as chief statutory officers of their respective local authority. However, PHE, on behalf of the Secretary of State played a role in the appointment of the DsPH and the DsPH had an active ongoing professional link to the PHE

Regional Director. The statutory duties of DsPH are defined in **[Exhibit: JH/M1 0098 - INQ000090425]**. PHE provided expert advice and, as agreed, shared leadership with the DsPH in local incident response arrangements.

Co-operation via the Local Resilience Forums

330. As a strategic partner, PHE regions worked collaboratively with local organisations in the production of local sector-wide health plans to respond to emergencies and contribute to multi-agency emergency planning. This co-operation was done via forums called Local Resilience Forums ("LRFs"), that were defined in the 2012 amendment to the CCA 2004, of which PHE were members.

331. LRFs work to ensure the effective delivery of those duties under the Civil Contingencies Act that need to be developed in a multi-agency environment at a local level. They work to identify potential risks and produce emergency plans to either prevent or mitigate the impact of any incident on their local communities LRFs set the strategy and objectives for the Partnership.

332. LRFs are coterminous with police force areas and are made up of multiagency partnerships and representatives from local public services. PHE's HPTs worked in an integrated way across LRF areas, with support subgroups such as Local Health Resilience Partnerships, Co-chaired by an NHS Director and a DPH.

Co-operation via the Local Health Resilience Partnerships

333. Local Health Resilience Partnerships ("LHRPs") provide a strategic forum bringing together local organisations (including private and voluntary sector where appropriate) to facilitate health sector preparedness and planning for emergencies at LRF level. They were established in 2013 to create a forum where local government public health directors and the local NHS would work together following the changes in the HSCA 2012.

334. A lead DPH is usually agreed in an LRF area to co-chair the LHRP and to co-ordinate LA public health input to preparedness and planning for emergencies

at the LRF level. They co-chaired the Partnership with one of the NHS England Area Team Directors who led on EPRR.

335. LHRPs provided support to the NHS and PHE in assessing and assuring the ability of the health sector to respond in partnership to emergencies at an LRF level. LHRPs also provide similar support to Local Authorities and Directors of Public Health and to the local NHS.

336. Concerns had been raised about the robustness of local arrangements for health protection and the Health Select Committee (Post 2013 Public Health report 2016) called for an audit of local arrangements. The NHS utilised their EPRR audit tool. Local government considered that, given these were local democratic institutions a national audit was not appropriate, and instead PHE worked with 9 other bodies to co-design and run an assurance exercise that was published by PHE in April 2018. There were plans to repeat this exercise, but this was not possible before the COVID-19 pandemic. All 36 LHRPs responded and demonstrated a variety of local arrangements around some core capabilities. The key lessons were shared back to LHRPs for local implementation, with PHE regional Health Protection Teams providing tailored feedback to individual Partnerships.

Co-operating with PHE's key partners

337. PHE worked extensively and collaboratively with a broad spectrum of external partners representing all sectors (public, private, academic, voluntary) and across all levels from local, regional, national to global and as described throughout this statement on a broad range of matters. I focus here on how PHE co-operated with these partners on Emergency Preparedness.

Devolved Government's

338. PHE worked collaboratively with their devolved administration counterparts, Health Protection Scotland (part of Public Health Scotland since December 2019), Public Health Wales and the Health Protection Service within the Public Health Agency Northern Ireland, across a range of health security preparedness and response activities for all threats and hazards. This was

achieved through regular meetings amongst EPRR colleagues within the 4 Nations as well as through DHSC convened EPRR forums which included public health agencies and devolved government officials. The DHSC commissioned training and exercise strategy was shared with the devolved governments Public Health Agencies, and they were routinely included within exercises.

339. Before the COVID-19 pandemic, the formal alignment of health security arrangements was managed through the International Health Regulations (PHE was the UK focal point delegated by DHSC) and EU Regulation 1082 (2005), with the former continuing after EU exit and the latter effectively covered by a new Common Framework for Health Security which is now agreed and active.

Expert Advisory Groups

340. As discussed throughout this statement, PHE had involvement with a number of Expert Advisory Groups such as HAIRS, NEVRTAG and ACDP as described in Section 4, with SAGE as described previously in this section and with JCVI in Section 7. In addition, PHE specialist technical experts in behavioural science, modelling and epidemiology were invited to join various expert advisory groups such as SPI-M, SPI-B etc

SPI-M

341. PHE had modelling capability based at Colindale and Porton Down, with respect to respiratory diseases, in particular pandemic influenza. Because of this, senior modelling staff (at times two from each site) were members of SPI-M where they fed in their specialist knowledge, experience and expertise.

SPI-B

342. PHE had a small Behavioural Science Team since 2005 which worked on the behavioural aspects of professional and population response to major incidents and health threats. The team worked in partnership with the National Institute for Health Research, the Health Protection Research Unit in Behavioural

Science and Evaluation at the University of Bristol, and the Health Protection Research Unit for Emergency Preparedness at the Institute of Psychiatry at King's College, London. PHE staff members worked closely with members of SPI-B.

Academic Partnerships

343. PHE, as a research-active organisation, led and contributed to a number of partnerships and collaborations with Academia, as joint applicants for numerous research funding opportunities across all of our topic areas. PHE experts were authors on over 1000 publications a year, the significant majority of which were about health protection topics.

344. The arrangements for the National Institute for Health and Care Research (NIHR) funding changed between HPA and PHE in 2013-14. HPA budgets that supported research activities were removed from HPA's budget and allocated to NIHR rather than PHE.

345. These funds were then used to create the Health Protection Research Units (HPRUs) (https://www.nihr.ac.uk/explore-nihr/specialties/public-health-and-prevention.htm). Universities then bid for HPRU status and funding and a second round of HPRU bids took place in 2019 with the new units beginning operations in April 2020. The successful university teams developed a work programme with, and to support, PHE in delivering its objectives and functions for public health protection. The current HPRUs are 15 units across 13 topic areas with the aim to retain a level of responsive research capacity to address emerging health protection research requirements. PHE utilised this recourse to support addressing our major research and evidence gaps for the COVID-19 response.

346. PHE had a wide range of academic collaborations in addition to the HPRUs. These were not formally funded by the research funding bodies but built on collaborations between PHE and universities, and sometimes included NHS and other government science bodies. The collaborations would often be the

basis for joint funding applications with both the university and PHE receiving funding if successful.

Community Network of Reference Laboratories for Human Influenza

347. From 2009 to 2013 the respiratory virus unit in HPA and subsequently PHE, was a leading laboratory participating in the Community Network of Reference Laboratories for Human Influenza in Europe (CNRL) co-ordinated by the European Influenza Surveillance Scheme (EISS) which was assimilated into ECDC as their specialist influenza laboratory network. Activities required within the laboratory network include the ability to detect circulating influenza viruses through direct detection strategies, culture, typing, subtyping and strain characterisation of influenza viruses, diagnostic serology and the creation of archives for clinical specimens and virus isolates. Engagement was defined through a series of contracts with ECDC where we provided scientific leadership and wet lab training for national level laboratories and supported the development of bioinformatic analytical skills and capability.

348. Forms of engagement included the provision of reference and quality assurance materials, development of quality assurance panels, training, conferences and networking, annual meeting organisation, scientific, technical and strategic advice to ECDC. These arrangements helped countries fulfil their statutory obligations though the International Health Regulations (IHR). CNRL meetings took place on a weekly basis with increased frequency during the Influenza pandemic in 2009 where several meetings a week and where required, daily teleconferences were held. Arrangements following withdrawal of the UK from the EU have been very much more ad hoc, though there has been very regular interaction through WHO EURO through the COVID pandemic, sharing experience and expertise. Interactions with ECDC and EU directly are currently inhibited by the position of the EU on allowing ECDC members to interact with UK.

349. Examples of significant PHE contributions were the development of diagnostic testing for the H7N9 Influenza strain between 2013 and 2015, and the support

for the development of this capability in Europe as part of response to the emerging threat of H7N9.

European Centre for Disease Prevention and Control

350. PHE established productive links with the European Centre for Disease Prevention and Control (ECDC). This included the sharing of knowledge and experience in contributing to various events and activities including health EPRR. PHE was awarded EU / ECDC contracts to undertake specific health EPRR preparedness activities. Until December 2021 (EU Exit) the UK participated in ECDC led networks for Preparedness and Response and for Threat Detection, Early Warning and Response Systems (EWRS).

351. PHE's work with the ECDC was broader than EPRR activities. The PHE Director of Health Protection and Medical Director was a member of the ECDC Advisory Forum that advises the Director of the Centre on the quality of the scientific work undertaken by ECDC and PHE actively participated in operational disease networks and consortia of public health microbiology laboratories in EU Member States. The aim of these networks is to enhance capabilities and strengthen capacity for pathogen detection, characterisation and surveillance of specific diseases and antimicrobial resistance.

352. PHE actively participated in ECDC training programmes including the two-year ECDC Fellowship programme that has two alternative paths: field epidemiology (EPIET) or public health microbiology (EUPHEM) aimed at increasing specialist capacity and developing a network of professionals across Europe.

World Health Organisation ("WHO")

353. PHE maintained the provision of knowledge and laboratory expert support to WHO through its WHO Collaborating Centres and its WHO Reference Laboratories. PHE hosted a number of WHO Collaborating Centres and WHO Reference laboratories, 16 of which had a health protection focus and continue to be provided by UKHSA, they are:

a. The WHO Collaborating centres for: Global Health Security; Applied Biosafety and Training; Public Health Management of Chemical Exposures; Virus Reference and Research (Special Pathogens); Haemophilus influenzae and Streptococcus pneumoniae; Reference and Research on Diphtheria and Streptococcal infections; Reference & Research on Antimicrobial Resistance and Healthcare Associated Infections; and Radiation Protection.

b. The WHO Affiliated laboratories: WHO National Influenza Centre; WHO MERS-CoV Reference Laboratory; WHO National Polio Laboratory; WHO RSV Laboratory; WHO Measles Reference Laboratory; WHO Prequalification evaluating laboratory; WHO Global specialised HIV Drug Resistance laboratory; and the WHO Expert reference laboratory for COVID-19

354. PHE established productive links with both WHO Head Office in Geneva and individual WHO Regional Offices. This included the sharing of knowledge and experience in contributing to various events and activities on health EPRR and also in the co-production of materials, such as WHO's work on Public Health Emergency Operations Centres. PHE was contracted by WHO to undertake specific preparedness activities, such as the series of Polio Outbreak Simulation Exercises (POSE) that PHE ERD Exercises Team, developed and delivered.

355. WHO has produced a large number of advisory documents, (which are available online) on the Public Health and Clinical Management of High Consequence Infectious Disease, in particular after the SARS (2003), MERS (2012) and West Africa Ebola (2014) outbreaks and these documents have been fed into the discussions regarding High Consequence Infectious Disease Management in the UK in both the Public Health and Hospital Management fields.

Section 6: Exercising, Institutional Learning, Training and Assurance

356. In this section I will describe the process by which PHE used health EPRR training and exercise functions to provide assurance of its CCA 2004 duties. I will describe the agency's preparedness, learning and assurance functions in three broad categories 1) those commissioned by DHSC, 2) PHE internal and 3) preparedness activity commissioned by others. I will also describe the lessons and processes PHE employed as it strived for continual improvement of its preparedness and response arrangements based on the learning from incidents and exercises, the training that PHE staff undertook to prepare for incidents and how PHE assured itself it was prepared.

357. Simulation exercises are widely used to develop and assess an organisation's preparedness for and response to incidents. The aim, objectives and scope of an exercise would be set by the commissioning organisation and then implemented by a joint PHE / commissioning organisation exercise project team. The aim of an exercise could range from test (to provide evidence of assurance and best achieved through command post exercises), to develop (to further the development of plans and arrangements and achieved through a tabletop exercise) and to train (to help organisations and individuals develop their preparedness for and response to incidents and achieved through a 'live' field exercise).

358. As a Category 1 responder, PHE had its own responsibilities to prepare for and respond to incidents and emergencies in accordance with CCA 2004. Additionally, PHE provided technical training and exercising support to DHSC to help it discharge its responsibilities across the health and social care system.

PHE's role in Exercising

359. As mentioned in section 2, PHE's ERD Team had a dedicated exercise team who designed, delivered and evaluated health-led EPRR exercises. On average the exercise team delivered between 12 to 15 exercises per year and from its inception to the closure of PHE, delivered in excess of 130 exercises at local, regional, national and/or international level. The majority of these have been

regional or national level tabletop exercises to help develop emergency response arrangements.

360. Most exercises are not held in isolation but engage partner organisations to fully explore the multi-agency response to health incidents. The success of this exercise programme has meant that PHE was frequently commissioned to deliver and run exercises for other organisations and agencies. Customers include other UK government agencies, including DHSC, the NHS, ECDC, the European Commission (DG Sante), Global Health Security Action Group, WHO, and the UK Devolved Administrations (Scotland, Wales and Northern Ireland).

361. PHE conducted exercises in preparation for a large number of hazards including infectious diseases, business continuity incidents, terrorism and CBRN events.

Identifying lessons from Exercises

362. The process of identifying lessons during and following an exercise can be summarised as follows:

a. The capture of data and information which can include capturing any facilitated discussion sessions; the exercising team taking notes at plenary sessions; capturing individual views through anonymous tools; formal evaluation forms and post exercise structured debriefs.

b. This data is then collated and reviewed by an experienced health EPRR training and / or exercise manager to author the initial impartial, unbiased and routinely anonymised, draft report. This is to encourage the open & honest sharing of ideas and maintain the approach that exercises are a safe learning space.

c. The initial draft report is then reviewed by the exercise project planning team before it is quality checked by senior management within PHE ERD before it is released to the commissioning organisation.

d. PHE ERD then distributes the report to all exercise participants and routinely uploads a summary version on ResilienceDirect™, which is an on line, cross government controlled access network that enables civil

protection practitioners to work together during the preparation, response and recovery phases of an event or emergency.

e. To ensure clarity on the responsibility for implementing any learning, PHE's exercise reports routinely included the following statement: *"It is suggested that the lessons identified are reviewed by the appropriate organisations to assess if any further action is required."*

f. On behalf of the commissioning organisation, PHE distributed the report to all exercise participants and routinely uploaded a summary version on ResilienceDirect™.

363. Responsibility sat with the team delivering the exercise to identify the learning and then getting this signed off with the sponsor/commissioner of the exercise. The commissioner of the exercise was then responsible for allocating actions - for example DHSC allocating actions across partner agencies involved in a health family exercise. PHE was responsible for implementing its own learning from such exercises.

364. The parameters of an exercise were ultimately decided by the commissioning organisation, including whether there were any Health Inequalities objectives. Any discussion on Health Inequalities that took place as a result of the exercises or the learning from them would be reflected in the exercise reports. Later in this section I provide the key reports. UKHSA-led exercises now routinely include a consideration of Health Inequalities, and UKHSA flags this important consideration to the organisations that commission it to run exercises.

Exercise Summaries and Reports

365. As requested by the Inquiry, I have described the exercises that PHE was commissioned to develop and deliver that are relevant to Module 1. In addition, I have exhibited a list of additional exercises relevant to pandemic preparedness that were conducted between 2007 and 2019 **[Exhibit: JH/M1 0099 - INQ000090427]**.

Ebola Surge Capacity Exercise, March 2015

366. Exercise was commissioned by: NHS England.

367. Purpose: The exercise, held on 10 March 2015, was designed to consider the current arrangements and capabilities of the four surge clinical case receiving centres in England and their options for surge capacity in response to multiple positive cases of Ebola Virus Disease (EVD). The four surge centres are: the Royal Free Hospital London NHS Foundation Trust; the Newcastle upon Tyne Hospitals NHS Foundation Trust; the Royal Liverpool and Broadgreen University Hospitals NHS Trust; and the Sheffield Teaching Hospitals NHS Foundation Trust. Representatives from the following Ambulance Services also participated: North East Ambulance Service; the North West Ambulance Service; the Yorkshire Ambulance Service and the London Ambulance Service

368. Learning: As the commissioning organisation, NHS England retained responsibility for allocating actions and embedding learning. Examples of learning incorporated by PHE included an extensive review of its response plans (NIERP etc) and the establishment of a High Consequence Infectious Disease (HCID) plan.

369. I exhibit the exercise report **[Exhibit: JH/M1 0099a - INQ000090428].**

Ebola Preparedness and Review Workshop, May 2015

370. Exercise commissioned by: PHE. PHE ERD's Exercise Team designed and delivered the exercise

371. Exercise purpose: The Ebola Preparedness and Response Review workshop (held on 27 May 2015) was designed to offer an opportunity for representatives from a range of PHE functions and departments involved in the Ebola Virus Disease (EVD) preparedness and response to explore their experiences and identify lessons for future incidents.

372. Learning. The learning from this workshop was incorporated into the extensive review and rewrite of the PHE CONOP and NIERP, which was issued in 2016. Key examples include,

a. the new version of the NIERP included provision of a guidance cell, this was used extensively in COVID-19 response

b. The learning identified for a forward look team resulted in the establishment of the Strategic Response Group

c. Established the requirement for consideration of port of entry activities including screening approaches where appropriate, that were used extensively during the COVID-19 response

d. Established National Situation Awareness Cell (NSAC) that continues to provide a daily situational awareness report across UKHSA and other government departments

373. I exhibit the workshop report **[Exhibit: JH/M1 0100 - INQ000090429]** and the full list of lessons identified is at Appendix A.

Exercise Valverde (for Novel Coronavirus), 2015

374. Exercise commissioned by: Global Health Security Initiative's ("GHSI") Sample Sharing Task Group which is an informal network of countries and organizations that came together shortly after the September 11, 2001 terrorist attacks to exchange information and coordinate practices within the health sector for confronting new threats and risks to global health. Delegations of the GHSI include Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States, and the European Commission. The World Health Organization (WHO) serves as an observer.

375. Exercise purpose: On 21 May 2015, member countries of the GHSI's Sample Sharing Task Group took part in a command post exercise to test the current draft arrangements in place for urgent sample sharing. Exercise Valverde was commissioned to look at the time mechanisms for urgent international sample sharing and accurately identify issues. Problems with timely sample sharing had

delayed the development of medical countermeasures in previous outbreaks/ pandemics e.g. 2009 Influenza. The GHSI's Pandemic Influenza Preparedness Framework already exists to improve and strengthen the sharing of influenza viruses with pandemic potential and implements a global approach to pandemic influenza preparedness and response. 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.

376. Learning: As the commissioning organisation, GHSI retained responsibility for allocating actions and embedding learning. There was no specific learning for PHE highlighted as a result of this exercise.

377. I exhibit the exercise report **[Exhibit: JH/M1 0101 - INQ000090430]**

Exercise Alice (for MERS), February 2016

378. Exercise was commissioned by DHSC.

379. Exercise purpose: Exercise Alice (held on 15 February 2016) was a table top exercise to explore the challenges that a large scale outbreak of MERS-CoV could present nationally to health partners in England. The exercise was prompted by a request from the CMO and was focused on two stages of response; initial actions and public health response and the health care aspects of a wider spread of cases. Participants in the exercise included representatives from NHS England, PHE and the DHSC. Additionally, observers from the Cabinet Office, the Devolved Administrations and GO-Science attended.

380. Learning: As the commissioning organisation, DHSC retained responsibility for allocating actions and embedding learning.

381. I exhibit the exercise report **[Exhibit: JH/M1 0102 - INQ000090431]**

Exercise Northern Light (for Ebola), May 2016

382. Exercise was commissioned by sponsor NHS England.

383. Exercise purpose: The NHS Royal Free's High Level Isolation Unit ("HLIU") was scheduled for capital projects during July and August 2016 and during this period the NHS Royal Victoria Infirmary (RVI) in Newcastle would be providing the NHS's first-line HLIU capability. Exercise Northern Light was designed to assess The Royal Victoria Infirmary's preparedness for and activation of its HLIU capability. The first phase of the exercise was a walk-through of the transfer and admission of a simulated confirmed Ebola Virus Disease case to be treated at the Royal Victoria Infirmary and Day 2 was a table top exercise to discuss and review the broader implications and impact on health and supporting partners. Participants in this exercise included representation from The Newcastle upon Tyne Hospital NHS Foundation Trust, The Royal Free London NHS Foundation Trust, NHS England, Ambulance Services, Public Health England, Local Authority, Police and the Royal Air Force.

384. Learning: As the commissioning organisation, NHS England retained responsibility for allocating actions and embedding learning. The actions identified for PHE were operationally focussed on the local PHE team in the North East.

385. I exhibit the exercise report **[Exhibit: JH/M1 0103 - INQ000090432]**

Exercise Cygnet (for Pandemic Influenza), August 2016

386. Exercise sponsor: DHSC.

387. Exercise purpose: Exercise Cygnet (held on 2 August 2016) was a discussion-based exercise as a preliminary to Exercise Cygnus, the Tier One pandemic flu exercise in Oct 2016. Its purpose was to provide an opportunity for colleagues from the health and social care sectors to consider the national, strategic health and social care response to an influenza pandemic. The exercise therefore included a simulated meeting of the four CMOs which was called the UK Health Delivery Board which was to simulate decisions made at the start of a pandemic with Ex Cygnus set after the first few weeks of the pandemic.

388. I exhibit a short flash report that was produced **[Exhibit: JH/M1 0104 - INQ000090433]**. The full Exercise Cygnet report was included in the main Exercise Cygnus report **[Exhibit: JH/M1 0105 - INQ000090434]**.

389. Learning: The learning from Exercise Cygnet was incorporated into the main Exercise Cygnus report.

Exercise Leopold, September 2016

390. Exercise was commissioned by PHE.

391. Exercise purpose: Exercise Leopold (held on 23 Sep 16) was a table-top exercise conducted to confirm PHE's response to multiple cases of foodborne Vero Toxin producing Escherichia Coli O104 (VTEC E.coli O104). The exercise also gave participants the opportunity to consider PHE's new draft NIERP and CONOPs. Participants were from PHE's nine Centres, four Regions, Health Protection and Medical Directorate, National Infection Service and PHE Communications

392. Much of the learning from this exercise focussed on the continued improvement of PHE's new internal response arrangements contained in the updated NIERP. This was important as a key purpose of this series of PHE internal exercises was to train, embed and disseminate changes to its preparedness and response arrangements. Examples of the learning implemented from Leopold include:

- The role of the new post-Ebola Strategic Response Director
- The requirement for a scientific cell to support an incident management team, which was applied in COVID-19 through the establishment of Public Health Advice Guidance Experts (PHAGE) cell

393. I exhibit the exercise report **[Exhibit: JH/M1 0106 - INQ000090435].**

Exercise Cygnus (for Pandemic Influenza), October 2016

394. Exercise was commissioned by DHSC.

395. Exercise purpose: As described in paragraph 387 above, Exercise Cygnus was designed to assess the United Kingdom's preparedness and response to a pandemic influenza outbreak. Over 950 representatives from Local Resilience Forums, NHS England and Public Health England at local, regional and national level, the Department of Health and 12 other government departments, the Health Departments of Scotland, Wales and Northern Ireland and NHS Wales took part in the exercise.

396. Learning. As the commissioning organisation, DHSC retained responsibility for allocating actions and embedding learning, but PHE contributed to the implementation of the cross system learning through the PIPP Board, for example, the development of the pandemic bill.

397. I exhibit the PHE authored Exercise Cygnus report as above **[Exhibit: JH/M1 0105 - INQ000090434]**, a copy of the distribution list **[Exhibit: JH/M1 0107 - INQ000090436]** and the covering letter that came with the report from the exercise sponsor, DHSC **[Exhibit: JH/M1 0108 - INQ000090437]**.

398. In addition to the formal Exercise Cygnus report, PHE held its own internal review of its internal operational level learning from the Exercise. I exhibit that report **[Exhibit: JH/M1 0109 - INQ000090438]**. This learning was considered by the PHE EPRR Oversight Group in June 2017. **[Exhibit: JH/M1 0110 - INQ000090439].** An action tracker report was presented to the PHE Advisory Board in February 2021 that shows that 27 out of the 30 lessons had been taken forward and implemented. Of the three actions for which there was no documented evidence to demonstrate completeness, all three were related to the technical delivery of exercises and the NICC.

Exercise Typhon (for Lassa), February 2017

399. Exercise was commissioned by: PHE.

400. Exercise purpose: Exercise Typhon was a command post exercise held on 22 and 23 February 2017 to review the effectiveness of PHE's updated NIERP during two concurrent enhanced incidents. The exercise explored the roles and

responsibilities of PHE in response to a major chemical incident and a confirmed positive case of a Viral Haemorrhagic Fever. Exercise Typhon was the first opportunity for Public Health England to conduct an internal 'PHE-only' command post exercise.

401. Learning. The exercise was designed to 'stress-test' PHE's 'new' NIERP that had undergone a significant process of review and change after Ebola and the Ex Cygnus-command post exercise; for example changing from the traditional response Levels 1 to 5 approach to Routine, Standard and Enhanced. This was in order to provide improved strategic oversight and incorporate wider media and xHMG interests into the dynamic risk assessment process. Prior to this, media or political interest in an incident was not considered in determining the level assigned to the response through the Dynamic Risk Assessment (DRA) process. The learning was captured in the subsequent revisions of the NIERP.

402. I exhibit the exercise report **[Exhibit: JH/M1 0111 - INQ000090440].**

PHE and APHA Workshop (for Avian and Pandemic Influenza), October 2017

403. Exercise was commissioned by: Joint sponsor between PHE and by DEFRA's Animal and Plant Health Agency (APHA).

404. Exercise purpose: The joint workshop (held on 31 October 2017) was designed to explore the health incident preparedness and response arrangements during an avian influenza outbreak with a risk of human transmission and to share an understanding of roles and responsibilities of PHE and APHA.

405. Learning: This workshop significantly helped to promote collaborative working between PHE and APHA, which has enabled both organisations to be more effective in its preparedness for and response to avian influenza (AI) outbreaks. For example, information on active AI outbreaks is now shared with PHE/UKHSA response centre in real time and disseminated to relevant health protection teams. PHE/UKHSA continue to work together with APHA on the public health control measures for the increasing prevalence of AI outbreaks.

406. I exhibit the exercise report **[Exhibit: JH/M1 0112 - INQ000090441].**

Exercise Broad Street (for Lassa and H7N9 Influenza), January 2018

407. Exercise was commissioned by: High Consequence Infectious Disease Programme Board (HCID PB)

408. Exercise purpose: Exercise Broad Street (held on 29 January 2018) was a discussion-based exercise to consider the future HCID service in England and the challenges that a HCID incident could present professional partners with the proposed 2020 HCID service in England. Participants in the exercise came from PHE and NHS England.

409. Learning: Much of the learning identified was to inform the further development of the HCID network, including out of hours alerting (which was exploited during the COVID-19 response) and continues to be iterated following a number of HCID cases.

410. I exhibit the exercise report **[Exhibit: JH/M1 0113 - INQ000090442].**

Exercise Cerberus (for Avian Influenza), February 2018

411. Exercise was commissioned by PHE.

412. Exercise purpose: Exercise Cerberus (held on 8 February 2018) was a follow-on exercise from Exercise Typhon designed to assess Public Health England's revised NIERP in enabling the organisation's preparedness and response to public health emergencies and business continuity incidents.

413. Participation in the exercise was restricted to Public Health England's Centres, Regions and national level organisations.

414. Learning: Much of the learning from this exercise focussed on 'tightening-up' PHE's then new internal response arrangements as described in the updated NIERP. This was important as a key purpose of this series of PHE internal exercises was to train, embed and disseminate changes to its preparedness and response arrangements. Examples of the learning implemented from Cerberus include:

- Improved coordination between public messaging and the guidance cell (which was important for the COVID-19 response)
- Improved coordination between local, regional and national incident response arrangements, which became another key factor in the Agency's response to COVID-19 and was the catalyst for the establishment of the National COVID-19 Response Centre
- The incorporation of business continuity (BC) in national response arrangements to provide a single, strategic approach to BC incidents
- Closer engagement and interface with the Devolved Administrations, specifically access to the Emergency Coordination of Scientific Advice (ECOSA) arrangements.

415. I exhibit the exercise report **[Exhibit: JH/M1 0114 - INQ000090443].** All of the lessons identified from testing the NIERP were implemented in the next version.

Exercise Pica (for Pandemic Influenza), September 2018

416. Exercise sponsor: NHS England. PHE ERD's Exercise Team design

417. Exercise purpose: Exercise Pica was held on 05 September 2018 to review and explore existing NHS primary care arrangements and processes within the context of an influenza pandemic. Its purpose was to identify lessons for the NHS primary care response to pandemic influenza over three key stages: Detect and Assess phase (first days/weeks), Treat and Escalate phase (peak of pandemic at 6/7 weeks) and the Recovery phase (months later). Participants in the exercise represented the breadth of primary care professions across representative bodies, associations, providers and commissioners, royal colleges, and regulators.

418. Learning: As the commissioning organisation, NHS England retained responsibility for allocating actions and embedding learning.

419. I exhibit the exercise report at **[Exhibit: JH/M1 0115 - INQ000090444].**

Identifying lessons from Major Public Health incidents

420. The process of identifying lessons following Major Public Health Incidents is described in the NIERP and can be summarised as follows:

a. A debrief will be carried out internally in PHE following the response to any incident or exercise, for all NIERP response levels.

b. A debrief report will be produced from the information gathered.

c. The lessons identified by the debrief report will be collated by the EPRR Delivery Group and any appropriate recommendations to embed the learning would be made to the EPRR Oversight Group and if approved incorporated into the annual review of the NIERP.

d. The Delivery Group will track their implementation progress.

e. Additionally, PHE will participate in cross-government debriefs as appropriate.

421. PHE, in the aftermath of incidents, used ResilienceDirect™ to support its learning. ResilienceDirect was a community forum for Category 1 responders that facilitated peer review, feedback, and the opportunity to identify learning from other responder agencies.

Major Public Health Incidents and the learning PHE identified.

422. In this section I will describe how the HPA and PHE learnt from major worldwide epidemics and pandemics during the relevant period.

Influenza Pandemic (H1N1) 2009

423. The HPA undertook a comprehensive lessons identified process which is described in an HPA Board paper from May 2010 **[Exhibit: JH/M1 0116 - INQ000090445].** The appendix to this board paper shows the identified lessons and their progress in being learned **[Exhibit: JH/M1 0117 - INQ000090446]**. In summary, the HPA conducted a reflections day across the organisation to initiate

a lessons process and capture learning. This was followed by structured debriefs, the information was collated into action plans which were used to implement the lessons that had been identified by that process, and by the Hine Review (2010), an independent review that took place following the 2009 influenza pandemic.

424. Following this swine-flu pandemic, the HPA developed and delivered a series of regional level exercises (the Exercise Peak Practice series) and the Cabinet Office scheduled a major Tier 1 exercise (from local to national exercise) on pandemic preparedness which resulted in Exercise Cygnus in 2016.

MERS Outbreak 2012

425. Following the MERS outbreak in 2012, the HPA conducted a lessons identified process that is described in the lessons identified report from the September and October 2012 phase of the incident **[Exhibit: JH/M1 0118 - INQ000090447].**

Ebola Virus 2013 - 2016

426. PHE undertook a lessons identified process in response to its work on the Ebola outbreak of 2013 - 2016, including workshops, debriefs and surveys, which was summarised for the Chair of the Health Select Committee in 2016 **[Exhibit: JH/M1 0119 - INQ000090448].** A copy of the update and the final update of PHE's Ebola Lessons Identified trackers are exhibited **[Exhibit: JH/M1 0120 - INQ000090449] [Exhibit: JH/M1 0121 - INQ000090450].**

427. Of note, the learning was used to significantly update and rewrite the NIERP.

Zika Virus 2015 - 2016

428. PHE undertook a lessons identified process in response to its work on the Zika Virus epidemic of 2015 2016. This involved a virtual debrief, the outputs of which were compiled into a report I exhibit at **[Exhibit: JH/M1 0122 - INQ000090451]** which includes a lessons action plan.

429. As outlined in the report, there was an identified lack of agreed national contingency plan for invasive mosquitoes, which would include specific instructions on the roles of specific teams within PHE, and with the National Travel Health Network and Centre (NaTHNaC). In response, the relevant teams arranged to produce a more co-ordinated system for alerting the health sector earlier in the development of outbreaks of infectious disease of this nature internationally, particularly when the outbreaks were producing severe adverse health effects and therefore likely to also produce significant disruption to travel and international concern. PHE led the development of the National contingency plan for invasive mosquitoes which was published in 2020, and outlines proposed actions, as agreed across government bodies, in the event of detecting non-native invasive mosquito species in England.

Embedding learning post Exercise and Incident

430. I have set out the learning from specific exercises and incidents above. In general, where PHE ran internal exercises or stood up an incident, the process to learn lessons is for the EPRR Delivery Group to collate and assess the debriefs to identify lessons and consider appropriate implementation and continuous improvement.

431. Where PHE was commissioned to conduct an exercise by another body, PHE did not play a role in assigning non PHE lessons or assuring those lessons were learnt.

Training and Exercising of Staff

432. In these paragraphs I will describe how PHE ensured that its staff was adequately trained to be able to respond to emergencies. I will describe how PHE prepared its staff for incidents and emergencies spanning all necessary roles from the operational (loggists), through tactical (incident directors) and to strategic (strategic response directors). In addition, basic 'What is EPPR' self-learning courses and 'threat' specific training was available via its e-health web-based learning platform. PHE also provided the opportunity for Diploma level qualifications in health emergency preparedness, resilience and response.

PHE Incident Director Training

433. As described in the NIERP **[Exhibit: JH/M1 0090 - INQ000090416]**, every standard incident has an Incident Director. Training for this role was provided by the ERD Training Team from 2013 onwards and the training is certified by CPD UK, the CPD certification service. The aim of the Incident Director training is to prepare participants to assume the role of a PHE Incident Director in a national or regional context and to lead an Incident Management Team ("IMT"). The training consists of theory and practical elements to include examining the role and responsibilities of an Incident Director, working with partners and using the government's Joint Decision Model. Each course has included training on the PHE NIERP. Scenario discussions gave delegates the opportunity to apply theory to practice with coaching from a member of PHE ERD's CRT when doing so.

PHE Strategic Response Director Training

434. As described in the NIERP **[Exhibit: JH/M1 0090 - INQ000090416]**, enhanced incidents require a Strategic Director and the training for this role was provided by the ERD Training Team. The aim of the Strategic Response Director training is to prepare participants for the role of the PHE Strategic Director leading and/or overseeing a national and/or complex response, including the leadership of a Strategic Response Group ("SRG"). The training consists of theory and practical elements including examining the role and responsibilities of a Strategic Response Director, dynamic risk assessment, working with partners at strategic level and the principles of upward briefing. The first SRD courses were held in 2019 and both courses covered training on the NIERP and scenario discussions for delegates to apply theory to practice with coaching input from the Director of Health Protection and Medical Director.

Scientific and Technical Advice Cell ("STAC") Training

435. Since 2007, the ERD Training Team has been delivering STAC Training to PHE public health experts who would routinely participate in and chair STAC cells as well as other LRF partners as necessary, following the Cabinet Office review of

the guidance around the delivery of health, technical and scientific advice during a major incident. The course includes opportunities for attendees to participate in a simulated STAC and SCG role play meeting. An associated online blended STAC programme was available to meet the needs of this training during the COVID 19 restrictions of face-to-face training. The course consists of an e-learning course followed by a 4-hour Adobe Connect virtual classroom.

Royal Society for Public Health Level 4 Diploma in Health Emergency Preparedness, Resilience and Response (Dip HEPRR)

436. This qualification is designed to provide the knowledge and skills necessary to participate in the development and delivery of EPRR arrangements, it is the only academic health EPRR qualification offered by the government and as such approximately 90% of learners have been from the NHS. PHE had a capacity for up to 60 learners per annual cohort.

437. The qualifications are divided into eight Units. This qualification has been mapped to the National Occupational Standards for Civil Contingencies, which describe those activities required for the provision of integrated emergency management for events or situations, within or affecting the UK, which may threaten serious damage to human welfare, the environment or national security.

eHealth

438. Launched in 2008, eHealth is an on-line Learning Management System (LMS) dedicated to health EPRR and is an online education and training tool for healthcare professionals in DHSC, NHS, Public Health England and, where appropriate, local Directors of Public Health.

439. Provided by PHE's ERD team, the online training covers the management of chemical, biological, radiological and nuclear (CBRN) incidents. eHealth hosts a series of online interactive, scenario-based training modules. PHE's NIERP **[Exhibit: JH/M1 0090 - INQ000090416]** is discussed in the Emergency Preparedness and Response Section 5.

440. The LMS currently has approximately 7000 users, and of these approximately 4500 are NHS staff, 1900 UKHSA and 600 DHSC and other organisations. Approximately 1,000 learners each year access the health EPRR training materials available on PHE ERD's e-health on-line platform.

441. The above formal training arrangements did not routinely include a learning outcome specifically linked to health inequalities. However, professional public health consultant training includes health inequalities as a core component, and all PHE staff were expected to comply with their mandatory inclusion training via Civil Service Learning which covers protected characteristics. Health inequalities is now included as an important consideration within all UKHSA health EPRR preparedness and response activities.

Assurance on Preparedness

442. PHE annually undertook an EPRR assurance process which resulted in a report. The assurance audit questionnaire (composed jointly with NHSE) set out 14 key areas of EPRR with corresponding core standards and assurance criteria to capture compliance at all levels across PHE. These assurances and standards were consistent with the requirements of the Civil Contingencies Act 2004 and related non-statutory guidance documents as well as other relevant legislation including the Health and Social Care Act 2012.

443. PHE's annual assurance report was routinely taken to the DHSC chaired EPRR Partnership Group (as was NHSE's assurance report) to provide DHSC with oversight in its assurance of preparedness and response across the health system for the Secretary of State.

444. Through emergency planning leads, all PHE Centres, Departments and specialist units were asked to provide responses using a self-assessment template which were then collated, peer reviewed and put into a PHE-wide report. All completed returns and statements of assurance were signed off by the Centre or Department Director as an accurate reflection of their current state of preparedness. A copy of the 2018- 2019 report is exhibited as **[Exhibit: JH/M1 0123 - INQ000090452]** which shows that overall compliance across core

standards was consistently high with some areas for improvement noted. The 2019/20 report was completed but did not go forward to the PHE Oversight Group or DHSC Partnership Group because these were suspended during COVID 19.

Section 7: Vaccines, Immunisations and Countermeasures

445. PHE provided expert professional support to a number of critical elements of national vaccine programmes. This included providing appropriate evidence and expert opinion to support rational policy and procurement decisions on vaccination programmes, coordinating the introduction of new programmes across the UK and monitoring uptake and evaluating the impact of the programmes overall, in specific populations and with specific vaccine products. The Immunisation and Screening National Delivery Framework & Local Operating Model **[Exhibit: JH/M1 0124 - INQ000101063]** sets out the local operational and governance arrangements for national screening and immunisation programmes.

446. For the purposes of this statement, I am going to focus on the topics most relevant to Module 1 and the questions asked in the Rule 9 request as I understand that further modules of the Public Inquiry will substantively cover vaccination, including COVID-19 vaccines further.

447. In addition, I use this section to describe the work conducted by PHE in relation to other countermeasures and stockpiling, as relevant to Module 1.

448. Specifically in this section, I will describe the work of the PHE Vaccine Preventable Diseases and Countermeasures Division within the National Infection Service (NIS) and the two PHE teams that sat within it:

    a. Immunisation Department and

    b. Vaccines and Countermeasure Response team

PHE's Immunisation Department

449. This team provided expert public health and scientific leadership to the safe and effective operation of national vaccination programmes, and their evaluation supported by a range of other groups within PHE. These supporting groups were mainly those in NIS (the other national topic specific departments leading on certain vaccine preventable infections e.g. the TB and sexual health teams and the national statistics and modelling team), the national reference laboratories based in Colindale and Manchester, the research team in Porton and the network of local laboratories that supply relevant enhanced data and support outbreak investigation. Other PHE groups key to the national role were the local Screening and Immunisation and the local Health Protection teams in regions and the communications and marketing teams.

450. The Immunisation Department team included a number of senior staff with internationally recognised clinical public health expertise in immunisation policy and in the evaluation of immunisation programmes. Their role in clinical public leadership to the immunisation programme in the UK encompassed a range of activities across the cycle of vaccine policy development and implementation which included:

a. undertaking surveillance of infection to inform vaccine development and potential vaccine strategies (including working with the national reference laboratories to describe organism diversity, estimating the burden of disease, measuring and modelling the dynamics of infection)

b. holding regular informal meetings with major vaccine manufacturers to share epidemiological information and find out about vaccine development (including advising on important outcomes that need to be measured before licensure to inform vaccine policy decisions)

c. prior to the National Institute for Health and Care Research commissioned programme in mid 2017, PHE led and conducted applied clinical trials to inform UK vaccine policy (the National Vaccine Evaluation Consortium)

d. providing expert advice to support the procurement of optimal vaccines as part of the national immunisation programme, led by NHS England

e. conducting routine and enhanced surveillance to determine the impact and effectiveness of existing vaccination programmes, publishing data on this and developing strategy options to maximise vaccine coverage

f. With the national statistics and modelling team, undertaking economic analyses of policy options to support changes to existing programmes, to support decisions around whether or not new vaccination programmes were introduced, and the procurement of vaccines

g. with the national reference laboratories, monitoring the emergence of vaccine escape strains, or of type replacement potentially fuelled by the vaccine programme

h. producing patient information leaflets, including those that are used to ensure informed consent and supporting communications campaigns,

i. authored and edited all professional advice and health care worker training and guidance to support the delivery of immunisation programmes, including:

    i. medical expertise as chief editor of Immunisation Against Infectious Disease, otherwise known as the Green Book **[Exhibit: JH/M1 0125 - INQ000101064]**

    ii. Supporting non-medical prescribing advice as lead organisation for production of patient group directions and national protocols

    iii. training of vaccinators as owners of the core curriculum for immunisers

    iv. Developing national guidance and providing ad-hoc advice on vaccine storage, stability and wastage

    v. advice on managing vaccination errors, managing safety concerns and supporting incidents and outbreaks

vi. writing and development of public information resources to be used to support informed consent.

451. This work was reviewed and monitored through a regular DHSC Chaired tripartite meeting between PHE, NHS England and DHSC.

452. PHE's vaccine uptake guidance and latest coverage data can be viewed on GOV.UK.

453. Additionally, the Immunisation department hosted the secretariat for the independent expert advisory committee the Joint Committee for Vaccination and Immunisation ("JCVI"). PHE's role in the JCVI included:

a. Providing expert medical advice to the JCVI

b. Horizon scanning for potential influenza vaccines that could be used pre-pandemic or during a pandemic

c. Sourcing evidence and epidemiological data to support decision making by the committee

d. preparing agenda, statements and minutes

e. working with analytical teams in modelling and statistics divisions in PHE as well as SPI-M and academic partners, to determine potential pandemic vaccination strategies.

454. PHE's established surveillance systems, analytical methods, and outputs for the monitoring and evaluation of pandemic vaccination programmes included:

a. assessment of population immunity through PHE's ongoing seroprevalence collection, i.e. the proportion of the population who have evidence of vaccination or infection as measured in blood serum, (with immunological assays provided by PHE's laboratories).

b. measurement of vaccine coverage by age, clinical risk and key demographics, using existing GP extraction or population registers such as Child Health Information Systems.

c. enhanced clinical and laboratory surveillance using existing systems such as RCGP, SARI-watch, Flu-watch and syndromic surveillance.

d. Developing and applying methods for estimating vaccine effectiveness using routine health service data.

e. undertaking vaccine safety investigations in collaboration with the MHRA (for example the investigation of a link between narcolepsy and Pandemrix).

Vaccines and Countermeasures Response Department

455. The Vaccines and Countermeasures Response Team ("VCR Team") transferred to PHE from DHSC in 2013 and was initially situated in the Health Protection and Medical Directorate and later moved in to PHE's National Infection Service Directorate.

456. This department's role included procuring and arranging the supply and distribution of vaccine for all the routine NHS programmes with the exception of the adult flu programme, as well as procurement and storage of a wide range of countermeasures for emergency incidents, including an influenza pandemic which will be described in detail later in this section. The routine workload included:

a. developing the outline and final business cases for procurement and working with DHSC to develop a tender including relevant clinical (supported by the Immunisation team) and other criteria for vaccine procurement.

b. Managing a contract to organise delivery direct to GPs and other providers. The team also procured and supplied rarely used vaccine and immunoglobulin, and antivenom products in small volumes for single patients.

Definitions

457. For the avoidance of confusion, I define the following terms here that will be used frequently in this section.

458. Just In Time ("JIT") contract: an agreement with a commercial supplier to provide products at the beginning or during a pandemic response.

459. Just In Case ("JIC") contract: an agreement with a commercial supplier to provide a product at an agreed time for stockpiling.

460. Personal Protective Equipment ("PPE"): Filtering Face Pieces ("FFP") respirators, gowns, gloves, aprons, fluid repellent safety masks. Designed to protect clinician/patient from infection.

461. Medical Consumables: in support of medicines e.g. cannulas, combined needles and syringes etc.

462. Countermeasures: These are medicines or consumables (PPE)

463. Pandemic Stockpile: Products that are held by PHE to be used in the event of pandemic influenza. These are JIC volumes of countermeasures. PHE were only commissioned to hold a pandemic stockpile for influenza, no other pandemic.

Summary of Role of PHE's role in procurement of Vaccines and Countermeasures

464. The DHSC Pandemic Influenza Preparedness Policy Team ("PIP Policy Team") set the UK policy and strategy for the procurement of vaccines and countermeasures, and the technical requirements including procurement volumes for England. NERVTAG and the JCVI, both support by UKHSA specialists, formally provided advice into DHSC to inform the technical requirements i.e. products and volumes. The Devolved Administrations set the technical requirements for vaccines and countermeasures in their respective countries in accordance with their individual devolved powers on the subject matter.

465. PHE's role was to deliver DHSC's policy, strategy and technical requirements for vaccines and countermeasures including the pandemic stockpile. In practical

terms, this meant PHE was instructed by DHSC on procuring, maintaining and storing the contents of the pandemic stockpile.

466. The VCR Team procured and stockpiled JIC medicines, such as antivirals and antibiotics; and consumables, such as medical consumables, PPE and liquid hygiene products, in preparedness for a future UK Influenza pandemic.

467. Additionally, PHE procured pandemic influenza stockpile products on behalf of the Devolved Administrations (DAs) through a Memorandum of Understanding (MoU) between the Secretary of State for Health and Social Care, and the Ministers for Scotland, Wales and Northern Ireland. Stocks for the DAs were received into PHE on their behalf in England and then supplied, usually annually, to each of the DAs. Each DA had responsibility for storing and onward distribution of its own pandemic influenza stockpile once received.

468. The VCR Team had a leading role in the strategic planning for, and procurement of, advance purchase agreements ("APA") for influenza pandemic specific vaccines ("PSV"). In short, this is a long-term contract or contracts with vaccine suppliers to produce vaccines against influenza should a pandemic arise which constituted a public health emergency. Under the APA, the vaccines are produced specifically against the pandemic strain once it is known. The Immunisation Department provided scientific input (e.g. as panel members) for the assessment of the clinical and scientific evidence of candidate vaccines during the influenza PSV APA procurement in 2011.

469. In January 2020, the VCR Team in PHE , activated JIT contracts for PPE to supplement the JIC stockpiled PPE.

Partnership Working - Roles and Remits:

470. In this section, I will set out how the VCR Team worked with key partners on matters relevant to the scope of Module 1.

471. The VCR Team worked in partnership with the Commercial team in DHSC ("DHSC Commercial"), particularly their Vaccines and Medical Countermeasures Team, Supply Chain Co-Ordination Limited ("SCCL"), and with the South-Central

Ambulance Service, NHS Digital and the NHS 111 Team in NHSE on the National Pandemic Flu Service, as set out below:

DHSC Commercial and SCCL

472. Prior to 1 April 2018, PHE worked with a Supply Chain Management Team in NHS Business Services Authority ("NHSBSA") that was transferred as an entire entity to SCCL. The Service Level Agreement that had existed with NHSBSA was the framework for the relationship to continue with SCCL. SCCL is a Limited Company wholly owned by the SoS.

473. SCCL's role was to act as an 'intelligent customer' to ensure that appropriate products were procured, stored and maintained in line with best industry practice and standards. SCCL also sourced storage and distribution arrangements and operated the command and control of this on strategic direction from the VCR Team. PHE worked with SCCL to ensure the stockpile remained ready to be distributed in a future UK influenza pandemic.

474. DHSC Commercial and SCCL were responsible for the sourcing of vaccines and countermeasures. They also managed the contracts for the suppliers, acting on instructions from the Procurement Team in PHE, that sat within the Finance and Commercial Directorate and the VCR Team.

475. The VCR Team chaired a Clinical Countermeasures Management Board (CCMB) which managed the procurement of clinical countermeasures and monthly procurement checkpoint meetings with delivery partners, including DHSC Commercial and SCCL, to monitor operational delivery against plans.

Other relevant companies with which PHE had a contractual relationship.

476. In addition to SCCL, NHS Supply Chain contracted a number of commercial providers on behalf of PHE, including with the following companies in the relevant time period that are mentioned later in this statement: 3M, Cardinal Health (Medline) and Tiger Medical.

National Pandemic Flu Service Partnerships

477. The National Pandemic Flu Service ("NPFS") enables access to influenza antivirals via an online and telephony channel based on the symptoms of the patient.

South-Central Ambulance Service

478. The South-Central Ambulance Service was responsible for the preparedness of the NPFS under the terms of an MoU with PHE since April 2014. Their role was and is still, to be able to mobilise this service in a future UK influenza pandemic and be responsible for its command & control, on direction from the PHE VCR team. In practical terms this would involve South-Central Ambulance Service overseeing the routing of calls, management of data and suppliers with regard to activating integrated service in response.

NHS Digital

479. An MoU dated December 2015 between PHE and NHS Digital clarifies the responsibility for the development and preparedness of the online channel of the NPFS.

NHS 111 Team

480. The NHS 111 Team in NHS England was the main party to a commercial contract with the telephony routing supplier for the 111 and NPFS service that routes the public to call centres and PHE was a party to that contract to enable appropriate telephony routing to PHE call centres from the 111 numbers. The NHS 111 team procures and contract manages that solution.

Responsibility for the Management of the Pandemic Stockpile:

481. In this section I will describe the responsibilities that PHE and the other partners mentioned previously, had in the management of the pandemic stockpile.

482. PHE worked with SCCL to ensure the pandemic stockpile was actively managed and SCCL in turn worked directly with the relevant specialist medical logistics partner.

483. To maintain the levels of the pandemic stockpile, SCCL managed the replenishment procurement processes for consumables, which involved the planning of the procurement of volumes of products to ensure in date target levels were met continuously. When a product reached the end of its shelf life, the shelf lives were either extended subject to approved testing regimes or the products removed from the stockpile and replenished as they approached the end of their shelf life. This included PPE products.

484. A table outlining the value of the assets held for the stockpiling provision for PPE from June 2009 to January 2020 is exhibited. Public Inquiry PPE Stockpiling Provision **[Exhibit: JH/M1 0126 - INQ000101065].**

Consumables

485. In this following section I will provide detail on the procurement of specific items over the relevant period, which were of particular interest during the pandemic response.

Filtering Face Pieces 3 (FFP3) Respirators

486. In this section I will set the scene of the timeline for procurement, storage and stock management of the PPE and the discussions we have with relevant partners before going on to describe:

a. Time and motion Study in FFP3

b. Shelf life extension - FFP3 Respirators

c. Shelf life extension - Fluid repellent surgical masks

d. Fit testing

e. Clinical waste bags

f. Eye protection and gowns

487. In October 2014, the target volume for the UK was to hold 34 million FFP3 respirators to be used in the event of an influenza pandemic. It was agreed that

month at the PHE operational Clinical Countermeasures Management Board (CCMB) meeting that the next procurement of FFP3 respirator face masks would be for 80% of these to be procured under a JIC contract as valved FFP3 respirators to replenish the existing stockpile and the remaining 20% would be unvalved, via JIT contracts to purchase at the time of a pandemic being declared. A copy of the meeting's minutes are exhibited **[Exhibit: JH/M1 0127 - INQ000101066]**.

488. Procurements for both the JIC and JIT FFP3 respirator contracts, as well as Type IIR (FRSM) surgical face masks on a JIC contract basis, were planned for 2016. Accordingly, the outline business case ("OBC") dated 28 October 2015 for FFP3 respirators was submitted on 2 November 2015 to the PIP Policy Team with a plan for approval. I exhibit the OBC, OBC valved JIC_JIT FFP3 Respirators (28 Oct 2015); **[Exhibit: JH/M1 0128 - INQ000101067]** and OBC JIT Unvalved FFP3 Respirators v1.0 Final **[Exhibit: JH/M1 0129 - INQ000101070],** the submission that accompanied them **[Exhibit: JH/M1 0130 - INQ000101073],** and the email serving them OBC, 02.11.2015-Approval Required Submission for OBC respirators **[Exhibit: JH/M1 0131 - INQ000101074]**

489. On receiving the OBC for the JIC procurement, DHSC Policy decided on 4 November 2015 to commission the NERVTAG committee to review the stockpile requirements for all facial PPE and paused the approval process for procurement pending this review. A NERVTAG sub-committee was subsequently convened in January 2016 and their recommendations were ratified by the full committee in June 2016. Copies of the minutes of these meetings are exhibited **[Exhibit: JH/M1 0132 - INQ000101082]** and **[Exhibit: JH/M1 0133 - INQ000101083].**

490. The NERVTAG committee made the following recommendations:

    a. a time and motion operational research study was to be carried out in an intensive care unit to better understand FFP3 usage.

    b. DHSC to commission an update to the 2009 infection control guidance to reflect the latest evidence (the PPE stockpile requirements should be informed by this guidance as it describes what PPE and how it should be used in different healthcare settings).

c. In the meantime, the stockpile contents should be reconsidered in light of their recommendations.

d. That the NERVTAG committee review their own advice once an update to the 2009 infection control guidance is developed.

491. Initially, NHS England was approached by PHE's VCR team to arrange the time and motion study based on NERVTAG's recommendations, but NHS England confirmed at the NERVTAG committee meeting on 2 December 2016 that it was not able to be taken forward at that time. The minutes of which are at **[Exhibit: JH/M1 0134 - INQ000101084].**

492. At the same time, the procurement of JIC FFP3 respirators and Type IIR (FRSM) surgical face masks was awaiting the outcome from the NERVTAG committee's review, with an aligned delay in planned stock replenishment, an agreement was reached with 3M to carry out accelerated ageing and testing on their respirators in the stockpile, in line with the strategy approved by DHSC to extend the shelf-life of stockpiled FFP3 where appropriate. The successful completion of this testing (report dated 23 November 2016) enabled 3M to extend the shelf life of their respirators by a further 3 years (from 7 to 10 years) which revised the expiration date to 2019/20 (based upon the production of the batch). This meant an immediate procurement for the replenishment of the FFP3 respirators was not needed at the time. The evidence of the proposals by 3M are at **[Exhibit: JH/M1 0135 - INQ000101085].**

493. Following this work with 3M, the Full Business Case ("FBC") for the JIT procurement for 6.84 million FFP3 unvalved respirators (20% of the total target volume) was approved by DHSC on 24 November 2016 and then agreed with suppliers with contract awarded. The JIT contract was awarded to Valmy SAS Ltd. Evidence of these meetings and decisions are exhibited. **[Exhibit: JH/M1 0136 - INQ000101086] [Exhibit JH/M1 0136a - INQ000101087] [Exhibit: JH/M1 0136b - INQ000101185] [Exhibit JH/M1 0137 - INQ000101088], [Exhibit: JH/M1 0138 - INQ000101089].**

494. The final meeting of the CCMB before the COVID-19 pandemic was held on 9 October 2019 and provides a good summary of the position with PPE at this

time. A copy of the meeting's minutes is exhibited. Draft record of CCMB meeting 9 October 2019; **[Exhibit: JH/M1 0139 - INQ000101090]** Official FW Pandemic Flu Clinical Countermeasures Board Meeting 9 October 2019 **[Exhibit: JH/M1 0140 - INQ000101091].**

Defining the Requirements - UK Study & NERVTAG sub-committee

495. As NHS England was unable to undertake the time and motion study as recommended by the NERVTAG committee, PHE undertook work to find an alternative study route.

Guy's & St Thomas' NHS Foundation Trust ("G&ST") were awarded the contract for the study in September 2018 **[Exhibit: JH/M1 0141 - INQ000101092]** and they worked with PHE in finalising the proposal. NIS approval was provided on 18 December 2017, with IASG approval following on 14 March 2018. Copies of the governance minutes and approvals are exhibited as follows: **[Exhibit: JH/M1 0142 - INQ000101093], [Exhibit: JH/M1 0143 - INQ000101094], [Exhibit: JH/M1 0144 - INQ000101095]** and **[Exhibit: JH/M1 0145 - INQ000101096] [Exhibit: JH/M1 0146 - INQ000101097].**

496. The initial timetable for G&ST to complete the study and submit the final report was by 30 June 2019. A number of factors caused some slippage to this time frame: (1) delays in agreeing the study protocol and timeline with G&ST (January to September 2019); (2) revised timelines to undertake and report the study (October and November 2019 respectively); (3) delay to GS&T prioritised clinical response to a Monkeypox incident (reported on 20 December 2019) with study report planned for January 2020.The email that records the chain of communications between PHE and G&ST and the delays to the study timeline are exhibited within the email dated 11.12.2019. **[Exhibit: JH/M1 0147 - INQ000101098].**

497. Plans for the procurement to replace the FFP3 respirators were re-started in 2019 and SCCL, with PHE, held a market engagement exercise on 20 August 2019. In the absence of results from the study and based on the CCMB recommendation in 2014, the specification for the PPE was for FFP3 valved masks. During the market engagement exercise, there was feedback from the

market that questioned the requirement for valved FFP3, explaining that valved did not protect against splashes and with recent improvements made with unvalved PHE should reconsider the specification.

498. As uncertainty remained as to whether PHE should procure valved or unvalved FFP3 respirators, PHE informally asked the Chair of the NERVTAG sub-committee for advice on the valved and unvalved issue. The DCMO, Jonathan Van Tam, expressed that he was concerned that at that stage, advice had been shared across emails and should be commissioned formally. Subsequently, DHSC Policy suggested to the Chair of NERVTAG that they would require formal advice from NERVTAG to provide a response to ensure that the specification of the FFP3 respirators being procured was correct. DHSC commissioned NERVTAG on 11 October 2019 and in November 2019, NERVTAG's sub-committee was asked to confirm whether valved (standard or shrouded) or unvalved respirators were an appropriate specification. A copy of the commission to NERVTAG is at. **[Exhibit: JH/M1 0148 - INQ000101099].**

499. NERVTAG were unable to respond to this request as they needed the outcome of the study being undertaken by G&ST. They stated that the results of the FFP3 study would inform and support the sub-committee's recommendation. This is evidenced in the meeting minutes of a NERVTAG meeting dated 17 December 2019 at item 2. **[Exhibit: JH/M1 0149 - INQ000101100].**

500. PHE received the draft report from the G&ST study on 27 January 2020, which was quickly followed by the NERVTAG's sub-committee recommendation on 2 February 2020 to procure unvalved FFP3 respirators, based on a one-hour usage/tolerance, in the volume estimates modelled on the NERVTAG committee's previous advice in 2016. The final report from the G&ST study was received on 28 August 2020. Copies of the correspondence between PHE and G&ST are exhibited as follows: **[Exhibit: JH/M1 0150 - INQ000101101], [Exhibit: JH/M1 0151 - INQ000101102], [Exhibit: JH/M1 0152 - INQ000101104]**, **[Exhibit: JH/M1 0153 - INQ000101105]**, **[Exhibit: JH/M1 0154 - INQ000101107]** and **[Exhibit: JH/M1 0155 - INQ000101108].**

501. The G&ST study, which was undertaken at the recommendation of the NERVTAG committee, as deferred to by DHSC, provided the evidence of tolerability/usage of FFP3 in an ITU setting which was used subsequently to calculate the total volume requirement for FFP3 respirators in the pandemic influenza stockpile as 31 million for the UK, of which 26 million was allocated for England **[Exhibit: JH/M1 0155a - INQ000101109].**

Shelf-Life Extensions - FFP3 Respirators

502. Given these significant delays in being authorised to procure respirators and surgical face masks PHE undertook a number of steps with manufacturers to ensure the existing stockpile remained viable should it be required in a future UK influenza pandemic.

503. In addition to the agreement reached with 3M in 2016 which extended the shelf life of the FFP3 stockpile (as detailed in the section above), an agreement was reached with Medline in 2019 for the accelerated aging and testing of the 3M FFP3 respirators and subsequent appropriate shelf-life extensions by a further 3 years and 5 years following receipt of batches in October 2019. This, together with the JIT framework, sought to provide some contingency. A copy of the Agreement is exhibited **[Exhibit: JH/M1 0156 - INQ000101110].**

Shelf-Life Extensions - Fluid Repellent Surgical Masks

504. The Fluid Repellent Surgical Mask (FRSM) facemasks (type 2R) were purchased in 2009/10 and the stock was mostly procured from 3M, Cardinal Health (Medline) and Tiger Medical.

505. The stock initially had a labelled 5-year shelf life, except for the Tiger Medical FRSM which had no shelf life or labelled expiry date.

506. As with all stockpile products, these were continually held in temperature-controlled storage facilities in the original packaging.

507. A strategy to extend the usable life of the stockpiled FFP3 respirators and FRSM masks where appropriate was developed in 2012 and a paper was presented to the Pandemic Influenza Preparedness Programme (PIPP) Board in November

2012. A decision was made by the Board to seek a shelf-life extension on all 3M and Medline products. A copy of the proposal to the Programme Board and the PIPP Board Minutes are exhibited **[Exhibit: JH/M1 0157 - INQ000101111]** and **[Exhibit: JH/M1 0158 - INQ000101112].**

508. Following accelerated aging and successful testing by 3M of their masks in May 2013, 3M extended the 3M facemasks for a further 2 years to 7 years, which gave them an expiry date in the calendar year 2016/17. No further testing beyond 7 years would be carried out by 3M and the stock was retained in quarantine at the end of its shelf life in 2016/17. Copies of the shelf-life extension and the final expiry being set at this period are exhibited **[Exhibit: JH/M1 0159 - INQ000101113]** and **[Exhibit: JH/M1 0160 - INQ000101114].**

509. Following accelerated aging and successful testing of the Cardinal Health masks by Medline (AT74535 / BWM028), Medline extended the expiry date of their Cardinal masks in September 2013 for a further 7 years to 2021/22. A copy of the report issued by Medline and the related agreements are exhibited at **[Exhibit: JH/M1 0161 - INQ000101115], [Exhibit: JH/M1 0162 - INQ000101116]** and **[Exhibit: JH/M1 0163 - INQ000101117].**

510. NHSBSA approached Medical Engineering Technologies Ltd (MET) an independent testing house, to undertake testing of the Tiger Medical masks in November 2014. Direct work with Tiger Medical was not possible at the time due to supplier relationship issues.

511. Following this testing in April 2015, NHSBSA submitted their summary and recommendation:

    a. The results of the QA and accelerated ageing suggest that the stock of Tiger facemasks remained fit for purpose and should be retained within the PIPP stockpile for a further 2 years. At that time the product should be re-tested.

    b. In the meantime, PHE should plan to replace all 89m Tiger facemasks in the final year of the next replenishment, as a best-case scenario (2021/22)

512. A copy of the summary report from NHSBSA and the Terms and Conditions of Sale are exhibited **[Exhibit: JH/M1 0164 - INQ000101118]** and **[Exhibit: JH/M1 0165 - INQ000101120].**

513. Two batches ("lots") of Tiger Medical masks did not successfully pass the testing. These were Lot numbers: 08212009CS and 06192009CO. Accordingly, this stock was quarantined and then disposed of.

514. The DHSC Health Protection Analytical Team reviewed the PIPP stockpile target volumes ("derivations") for the FRSM facemasks in or around June or July 2016. The original assumptions and methodology were revised by the DHSC analysts in collaboration with PHE and NHS England, and the updated calculations resulted in a reduction in the FRSM UK target volume from 236m to 180m. A PHE submission was sent to DHSC Policy recommending a reduction in the stockpile. This was eventually approved by the Parliamentary Under Secretary for Health (PHI) on 21 July 2017. As a result, the expiring 3M facemasks did not require replenishment as there were sufficient stocks of Tiger Medical and Cardinal (Medline) facemasks to maintain the revised target volume. Evidence of the correspondence is exhibited. **[Exhibit: JH/M1 0166 - INQ000101121], [Exhibit: JH/M1 0167 - INQ000101130], [Exhibit: JH/M1 0168 - INQ000101137], [Exhibit: JH/M1 0169 - INQ000101138].**

515. The Tiger Medical facemasks were tested in 2017 and accelerated aged tested to 2019. Two batched lots did not meet all the testing criteria and these batches were quarantined and then disposed. Documentation relating to the testing is exhibited as follows: (File Names MET Test Report Appendix 1 BFE and BR results (June 2017); **[Exhibit: JH/M1 0170 - INQ000101139]** MET Test Report - Accelerated aged 2 year (June 2017); **[Exhibit: JH/M1 0171 - INQ000101140]** MET Test Report Time Zero (June 2017); **[Exhibit: JH/M1 0172 - INQ000101062]** MET Test Report Accelerated 1 year (June 2017); **[Exhibit: JH/M1 0173 - INQ000101141]** Surgical Mask DHL Stock Verification **[Exhibit: JH/M1 0174 - INQ000101142].**

516. A business case for the testing of the Tiger facemasks was submitted for approval in May 2019 and approved by DHSC in June 2019. The contract was

awarded to Medline. Testing was carried out in January 2020 and all Lots of the Tiger facemasks passed the testing carried out by Medline (notification by email). A request was then made by PHE to cease accelerated testing as at this stage the facemasks were all going to be used in the pandemic and had all passed the baseline tests at that time. A copy of the correspondence and business cases and the related approvals is exhibited: **[Exhibit: JH/M1 0175 - INQ000101143], [Exhibit: JH/M1 0176 - INQ000101144], [Exhibit: JH/M1 0177 - INQ000101145], [Exhibit: JH/M1 0178 - INQ000101146], [Exhibit: JH/M1 0179 - INQ000101147], [Exhibit: JH/M1 0180 - INQ000101155], [Exhibit: JH/M1 0181 - INQ000101156], [Exhibit: JH/M1 0182 - INQ000101157], [Exhibit: JH/M1 0183 - INQ000101158], [Exhibit: JH/M1 0184 - INQ000101159], [Exhibit: JH/M1 0185 - INQ000101160], [Exhibit: JH/M1 0186 - INQ000101161].**

Fit testing

517. In October 2019, the VCR team and NHS England explored the potential of including Fit Test Training of FFP3 respirators as part of the procurement for respirators, given users of FFP3 respirators must undertake fit testing for each brand of FFP3 respirator they use. Establishing a fit test training provision that could be called upon at the time of need was felt to be beneficial to the end users (particularly considering that the stockpiled FFP3s may be an unfamiliar brand/product). A meeting was held between PHE and NHS England on 24 October 2019 to discuss NHS fit testing requirements. The feedback received from this meeting was used in developing the tender requirements for such a service.

Clinical Waste Bags

518. Investigation work carried out by PHE and SCCL in 2019 on the clinical waste bags purchased in 2009 by DHSC and held in the stockpile at that time, discovered they were the wrong colour specification for use in a pandemic (they were yellow when they should be orange), and that they didn't conform with the latest 2015 EU standards (REACH 2015). A proposal was made to DHSC on 28 January 2019 to write off and recycle the stocks and then replace them with new

stock. DHSC approved this proposal on 31 January 2019. Evidence of these approvals and related documentation is exhibited at **[Exhibit: JH/M1 0187 - INQ000101162]** and **[Exhibit: JH/M1 0188 - INQ000101163].**

519. An OBC and FBC for the procurement of replacement stocks of clinical waste bags from the SCCL/NHS SC NHS Framework was submitted to DHSC on 12 August 2019 and approved on 22 August 2019. This was to purchase an increased volume of bags from the previous 7.27m target to 15m, split between 75% JIC and 25% JIT. Orders were placed in September 2019 and stock deliveries commenced in January 2020 and continued through the early stages of the pandemic. Given the urgency, an arrangement was made for the DAs to receive their allocations of stock directly from the manufacturer. A copy of the OBC / FBC and related approvals are exhibited as follows: **[Exhibit: JH/M1 0189 - INQ000101167], [Exhibit: JH/M1 0190 - INQ000101168], [Exhibit: JH/M1 0191 - INQ000101169], [Exhibit: JH/M1 0192 - INQ000101170].**

Eye Protection and Gowns

520. The eye protection glasses held in the stockpile were purchased in 2009 and had no recorded shelf life. On 9 November 2016, PHE asked the Health and Safety Executive (HSE) for advice at what product life age eye protection glasses should be tested. Their advice was to contact the manufacturer. On 15 November 2016 this information was passed to NHSBSA, who at the time held the contract for the responsibility of monitoring the stock and the eye protection glasses remained in the stockpile. Detailed further information on stock testing action taken by NHSBSA may be directed to that organisation. But a copy of the enquiries made by PHE is exhibited at **[Exhibit: JH/M1 0193 - INQ000101181].**

521. At its meeting on 17 June 2019, the NERVTAG Committee advised the procurement of visors - to be purchased at the time of replenishing stocks of eye protection glasses as and when they required replacement rather than to replace the existing usable stocked eye protection glasses. I exhibit the minutes as **[Exhibit: JH/M1 0194 - INQ000101182].**

522. The VCR team built up subject matter knowledge through their collaborative work in this field. As such on occasion, the team was able to ask relevant partners

informed questions to try and ensure the stockpile was fit for purpose. As such, on 2 July 2018, the VCR team asked the Chair of the NERVTAG PPE sub-group whether to include gowns in the pandemic stockpile. A copy of the correspondence is exhibited at **[Exhibit: JH/M1 0195 - INQ000101183].**

523. In January 2019, PHE began working with SCCL in preparation for a procurement of gowns, in confirming the requirements (sterile vs non-sterile) and carrying out market analysis. This information was provided to NERVTAG to assist with their review and recommendation at their next meeting in June.

524. At its meeting on 17 June 2019, the NERVTAG committee recommended the procurement of gowns consistent with the infection control guidance. Additional feedback from the NERVTAG subcommittee on PPE was that the gowns selected for procurement should be blood/body fluid repellent as a minimum standard. A copy of the minutes of the meeting, covering the items mentioned, are exhibited at **[Exhibit: JH/M1 0194 - INQ000101182].** NERVTAG also sent a letter to DHSC **[Exhibit: JH/M1 0195a - INQ000103064]** formally recommending that gowns were procured and for DHSC to confirm its policy position based on the NERVTAG committee's recommendations.

525. There was insufficient time for completion of procurement of visors and gowns, including business cases and approvals, from the time of NERVTAG's formal recommendations in June 2019, before the start of the COVID-19 pandemic.

Pharmaceuticals

526. The replenishment procurement processes for Pandemic influenza pharmaceutical products (medicines and vaccines) and associated contract management services were performed by DHSC Commercial through a service level agreement between DHSC Commercial and PHE.

527. Under this Agreement, PHE was responsible for:

c. confirming DHSC's requirements to meet the policy and strategy requirements,

d. developing the business cases; and

e. gaining appropriate spending approvals.

528. Product requirements were reviewed by the VCR team prior to each replenishment exercise which was detailed in a business case that needed approval before a procurement could commence.

529. NERVTAG would often carry out clinical and scientific review of the requirements and make recommendations to DHSC. If these were accepted by the DHSC Policy Team, they would be considered as part of the business case prior to procurement.

530. SCCL (consumables) or DHSC Commercial (medicines) would then develop a commercial strategy in partnership with PHE based on the policy requirements.

531. The medicines (influenza antivirals and antibiotics) were purchased for a JIC stockpile and were stocked in their entirety. One of the contracts was on a JIT basis which prioritised the UK's access to vaccines made for the specific strain of the influenza pandemic. This was effectively an insurance policy should an influenza pandemic occur.

532. SCCL was responsible for the holding of these stocks, when required, and for all ambient and chilled protocols to maintain efficacy.

Section 8: Standing up response plans for COVID-19

31 December 2019 to 21 January 2020

533. In this section I provide an overview of the structures and processes that were in place throughout the relevant date range for Module 1, and as at 21 January 2020, which enabled PHE to coordinate its emergency response at local, regional and national levels. I also describe on a chronological basis, some of the key activities taking place within PHE in response to the evolving novel coronavirus outbreak. I do not go into extensive detail of events beyond 21 January 2020, due to the expectation that this will be covered in future modules.

Initial response activity

534. On 31 December 2019, PHE's routine Epidemic Intelligence (EI) scanning identified reports from the Wuhan Municipal Health and Health Commission, of a cluster of viral pneumonia of unknown aetiology in Wuhan City, Hubei Province of China. On the same day, this information was shared with key stakeholders including relevant colleagues in PHE, the Devolved Administrations, Cabinet Office, DHSC, other government departments and the CMO and DCMOs.

535. Further information on the viral pneumonia of unknown aetiology (cause), (later confirmed as a novel coronavirus) was gathered from a range of open sources (for example: Ministries of Health and other official government sources from other countries; international organisations such as ECDC, WHO, and CDC; and media) over subsequent days. PHE virologists began collaboration with WHO technical leads from 1 January 2020, building on existing diagnostic development work for diagnostic assays for coronavirus.

536. On 2 January 2020, PHE sent a briefing to the CMO with a summary of the information known at this time **[Exhibit: JH/M1 0196 - INQ000101189]**. On 5 January 2020, the CMO suggested to PHE three triggers for escalation when considering the risk to the UK: (this was shared at the 9 January 2020 Strategic Response Group meeting which was overseeing PHE's formal incident response for the novel respiratory virus) **[Exhibit: JH/M1 0197 - INQ000101190].**

    a. Healthcare workers dying, (often the early warning that a new infection is both severe and transmissible (eg SARS, MERS, Ebola)).

    b. Evidence of human-to-human transmission, e.g. within families.

    c. Geographical spread implying a zoonosis is spreading.

537. Also on 5 January 2020, the WHO shared information with Member States via the Event Information Site (EIS) regarding pneumonia of unknown aetiology in Wuhan, China. A WHO Disease Outbreak News (DON) Item and initial WHO Risk Assessment about the cases in Wuhan were also published on the same day. At that point, the DON stated there were 44 patients with pneumonia of unknown aetiology, that the causal organism was unknown, and some

individuals were linked to the Huanan Seafood market. At that point it also stated "no evidence of significant human to human transmission and no health care worker infections have been reported" **[Exhibit: JH/M1 0198 - INQ000101191]**. The Wuhan Municipal Health and Health Commission report stated "respiratory pathogens including influenza, avian influenza, adenovirus, infectious atypical pneumonia (SARS) and the Middle East respiratory syndrome (MERS) have been excluded".

538. On 6 January 2020, PHE conducted a meeting in which a dynamic risk assessment was recorded based on the information available at the time **[Exhibit: JH/M1 0199 - INQ000101192]**. The overall risk that the reported cluster of infections in Wuhan being a new pathogen was considered Moderate and the current impact of the disease was rated low/moderate, however the meeting noted that that risk would need to be reviewed as new information becomes available. At this point, there was no reported evidence of international spread.

539. On 7 January 2020, PHE issued a briefing note **[Exhibit: JH/M1 0200 - INQ000101193]** for the NHS, private healthcare providers and DAs on a cluster of cases of pneumonia of unknown aetiology associated with Wuhan City which possibly represent the emergence of a novel pathogen, and guidance to follow for patients who present with pneumonia and had travelled to China and Wuhan City 14 days prior to an onset of symptoms.

540. On 7 January 2020, PHE also provided the CMO with a briefing on the latest situation including an update on the advice it had issued for infection specialists and travellers around the Chinese New Year **[Exhibit: JH/M1 0201 - INQ000101194]**.

541. Over the period of review and throughout the pandemic period, the International Health Regulations (IHR) National Focal Point (NFP) in PHE had regular contact with WHO EURO to request additional details of the testing being carried out in China, and with the European Centre for Disease Prevention (ECDC) to enquire whether they would be carrying out a rapid risk assessment of this event.

542. On 8 January 2020, media reports (including on promedmail.org) quoted an imminent announcement by China of a new Coronavirus as the cause of unexplained pneumonia in Wuhan.

Standing up PHE's COVID-19 response

543. On 8 January 2020, on the basis of the expected imminent announcement of a new coronavirus, and with PHE's prior experience with SARS and MERS, PHE activated its highest level of response (designated as an Enhanced Response), as per the National Incident Emergency Response Plan **[Exhibit: JH/M1 0090 - INQ000090416].** The first meeting of the Incident Management Team (IMT) was scheduled for the next day.

544. The IMT began to establish the 'cells' it required to manage the incident as well as setting the objectives for the IMT and proposals for the Strategic Response Group SRG. Cells are specialist teams established for incident response to provide operational delivery and expertise. It is normal practice to tailor the response cells required to the specific incident being managed and five initial cells were activated, namely epidemiology, communications, diagnostics & virology, guidance & case management and port health.

545. This IMT meeting on the 9 January 2020 initiated the following actions: **[Exhibit: JH/M1 0202 - INQ000101196]**

a. To recommend to NHSE&I that this novel coronavirus infection was managed within the NHS as a high consequence infectious disease (HCID)

b. To develop and adapt the first few hundred (FF100) protocol, previously developed for new and emerging infection and pandemic influenza to provide enhanced epidemiological surveillance to allow the detailed characterisation of cases and contacts **[Exhibit: JH/M1 0203 - INQ000101197]**

c. To develop a diagnostic pathway and work with international partners to develop an appropriate diagnostic test, noting that PHE had already

developed a pan-coronavirus PCR assay that had been able to detect MERS-CoV.

d. Develop clinical and public health guidance for this infection, adapted from current SARS and MERS-CoV.

e. Work with international partners to seek further information about this virus to further develop the risk assessment.

f. Provide a recommendation to DHSC to convene an emergency meeting of NERVTAG.

546. Following the initial IMT meeting, the SRG met for the first time, also on the 9 January and established the following strategic objectives: **[Exhibit: JH/M1 0204 - INQ000101198]**

a. Monitor and assess the risk to public health in the UK

b. Facilitate detection, immediate case management and isolation to prevent transmission in the UK

c. Develop suitable diagnostic assays for novel strain

d. Provide robust guidance and information for health professionals and the public

e. Facilitate PHE's cross-government communications and actions.

<u>First public statements and guidance</u>

547. Over the next 24 hours, PHE developed guidance on diagnostic infection prevention and control for clinicians on the investigation and initial clinical management of possible cases of COVID-19 (then known as Wuhan Novel coronavirus) infection and did not advise changes to travel plans. This guidance was published on GOV.UK and communicated via a briefing note **[Exhibit: JH/M1 0205 - INQ000101199]** issued by PHE to NHS (for Primary and Secondary care distribution), Port Health, private healthcare providers and DAs. Exhibits as follows:

a. Guidance for clinicians on the investigation and initial clinical management of possible cases of Wuhan Novel coronavirus infection **[Exhibit: JH/M1 0206 - INQ000101200].**

b. Wuhan Novel coronavirus (WN-CoV) infection prevention and control (IPC) **[Exhibit: JH/M1 0207 - INQ000101202],** this guidance utilised existing guidance developed in response to MERS-Cov and SARS-Cov. It was aimed at NHS Acute Trusts who would be responsible for monitoring and treating patients with COVID-19 in the event that cases reached the UK. It provided advice around environmental cleaning, infection prevention and control precautions including hand hygiene, case identification and management, as well as PPE - all of which proved appropriate in the context of COVID-19 at the time.

548. On 10 January 2020, PHE issued a press statement on GOV.UK to the public which provided public health advice to travellers to China on both avian influenza and COVID-19 **[Exhibit: JH/M1 0208 - INQ000101201]**. In accordance with WHO recommendations, it did not recommend any border or travel restrictions.

549. China released the first viral genome sequence on 10 January and deposited four further genomes on 12 January 2020 in the viral sequence database curated by the Global Initiative on Sharing All Influenza Data (GISAID). Using this genome sequence and other information from related viruses, PHE colleagues worked with international collaborators and subsequently went on to develop a specific PCR test to detect this novel coronavirus. This was achieved without any virus material and required global collaboration between laboratories in Europe, PHE and Hong Kong with coronavirus expertise.

550. Over the subsequent 9 days an assay was developed, and the methodology was shared publicly on 23 January 2020 in a peer reviewed publication. PHE then started to develop workflows to implement and scale this methodology within its internal network and shared the detection methodology with the NHS. In order to be compliant with the existing UK regulatory framework governing laboratory health and safety overseen by the Health and Safety Executive and Advisory Committee on Dangerous Pathogens, this work needed to be performed at

Biosafety Level 3, which limited the number of laboratories that could perform sample handling to prepare clinical materials for testing.

551. PHE's Executive Team agreed that PHE specialist virology laboratories (that had this resource) would assist the WHO in helping countries confirm their suspect cases of coronavirus where they lacked expertise.

552. On 13 January 2020, WHO issued an updated Disease Outbreak Notification (DON) on the novel coronavirus. PHE noted initial media reports of a case in Thailand (with travel from China).

553. The first NERVTAG meeting regarding the novel coronavirus was held on 13 January 2020 and was attended by NERVTAG members plus public health experts and officials from PHE, DHSC, NHSE and GO-Science. At this stage, NERVTAG was cautious to draw conclusions about human-to-human transmission but stated that 'with the evidence that is currently available, the novel virus does not look to be very transmissible'. At the meeting PHE:

a. Summarised the current epidemiology and provided a virology update

b. Presented the PHE risk assessment for this virus which was then endorsed by the Committee **[Exhibit: JH/M1 0209 - INQ000101203].**

c. Presented travel advice which was endorsed by the Committee. *"Travellers should practise good general hygiene measures, such as regular hand washing with soap and water at all times" and that "Travellers should follow the advice of local health authorities. There are currently no travel restrictions to or from Wuhan City, China. Travellers developing fever and a cough within 14 days of travel from Wuhan City, China should seek medical advice and must report their travel history so that appropriate infection control measures and testing can be undertaken. People who are acutely ill with an infectious disease are advised not to travel but to seek health advice immediately".*

554. From 16 January 2020 **[Exhibit: JH/M1 0210 - INQ000147760]** reports of international cases of novel coronavirus were included in the PHE Weekly National Influenza Report (which reported on influenza and other seasonal

respiratory illnesses) . These reports include a range of syndromic surveillance indicators of respiratory disease as well as reports of acute respiratory infections incidents (outbreaks and clusters) reported by health protection teams.

555. Following review of the limited data available and potential high mortality, the UK's four public health agencies formally recommended to the NHS that the management of this pathogen should be included in the HCID airborne list and initial cases managed within the HCID network in the NHS.

556. On 19 January 2020, DHSC stood up its Operational Response Centre (ORC) to lead and coordinate the health response across the UK. On 20 January 2020, DHSC declared a major national incident. On 21 January 2020, ORC began Daily National Incident Calls to coordinate the response. This included attendance by PHE as the public health agency for England, the NHS and other related health bodies in all four health administrations in the UK.

557. On 21 January 2020, PHE published guidance for primary care professionals outlining actions to be taken for dealing with potential COVID-19 patients in primary care settings, when transferring them to other settings, and environmental cleaning. **[Exhibit: JH/M1 0210a - INQ000101204].**

558. On 21 January 2020, PHE also presented an updated risk assessment to NERVTAG, highlighting the emerging evidence of human-to-human spread with a potential 'super-spreader' event in a hospital overseas, wider geographic case distribution but without severe disease and reviewed the modelling and other insights available from the NERVTAG members **[Exhibit: JH/M1 0211 - INQ000101205]**.

559. In relation to any potential controls or specific health advice needed for travellers and/or at the border, DHSC had commissioned PHE to set out a menu of interventions that might be needed, either in a small escalation of COVID-19 as it became known, or in a significant escalation. PHE acknowledged the NERVTAG position that was reached in the same 21 January 2020 meeting that port of entry screening for those travelling from Wuhan was not advised, and that providing information to travellers and providing effective means for screening febrile travellers attending healthcare settings, was likely to be a better option.

560. In the NERVTAG meeting, the committee analysed reports from mainland China and agreed that there was clear evidence of human-to-human transmission. However, at this stage the extent of transmissibility between people was not clear. At this meeting PHE:

a. Provided an update on epidemiology and outlined that the situation was rapidly changing since the written update was produced and circulated to NERVTAG members on 20 January 2020.

b. Presented to NERVTAG the existing UKHSA risk assessment undertaken by PHE and outlined proposed changes to the existing UK risk assessment as follows:

i. Impact of the disease - raised to 'moderate' from 'low/moderate'

ii. Risk to UK population - raised from 'very low' to 'low'

iii. Risk to UK travellers to affected parts of China - raised from 'low' to 'moderate'.

c. outlined progress on diagnostics, including confirming that the pan-coronavirus PCR assay would detect the novel coronavirus and the progress that PHE had made with global collaborators to develop a specific PCR assay to detect this novel virus.

561. Also on 21 January 2020 WHO/WPRO tweeted to state "at least some human-to-human transmission", and that infections among health care workers strengthened the evidence for this. WHO then convened the first meeting of the global expert network on infection prevention and control.

562. PHE provided expert input into travel and risk assessments for travellers which informed case definitions, including travel advice. On 22 January 2020, a joint statement from PHE and DHSC was published setting out updated travel advice and measures **[Exhibit: JH/M1 0212 - INQ000101206].**

563. Over the next week, PHE continued to develop the relevant specialist guidance for the NHS, including clinical and diagnostic management pathways for

ambulance, primary and secondary care health services. This included contributing to the drafting of the Tripartite Coronavirus Letter which was sent as a CAS Alert to NHSE staff.

564. Given the evidence of widening geography and human-to-human spread PHE virology experts were invited to the initial SAGE meeting held on the 22 January 2020, to share knowledge with other academic and public health external experts convened by the CMO and GCSA. At this meeting SAGE confirmed the current understanding of SARS-CoV2 and COVID-19, reviewed and supported the advice from NERVTAG about port screening. SAGE noted that there was good centralised diagnostic capacity for SARS-COV2, and a specific test, scalable across the UK was imminent. SAGE agreed DHSC and PHE criteria for testing potentially infectious individuals, noting that they should be prepared to revise the criteria as the situation evolved. SAGE also noted that DHSC and PHE were preparing plans for isolation and follow-up of contacts.

565. On 23 January 2020, critical points were discussed at PHE's IMT. The latest international epidemiology was reported: 571 confirmed cases in China, 17 reported deaths only from Wuhan; 32 provinces reporting cases. There were 10 confirmed cases outside mainland China 1 Japan, 1 Macau, 2 cases Republic of Korea, 1 Taiwan, 4 Thailand, 1 USA. No ongoing transmission was confirmed to be happening outside mainland China. In the UK, five individuals had been assessed and test results were negative, a further nine individuals were being tested that day and it was recognised that other patients had been identified for testing and results were continuously being added.

566. Given the fast-moving changes in epidemiology with increased numbers of suspected cases on 23 January 2020, PHE's National Incident Coordination Centre (NICC) and cells moved to 12 hour working Monday to Friday with on call arrangements at the weekend. On 25 January 2020 the NICC went to 7 days a week working due to an escalation in workload and response activities.

567. By 24 January 2020, PHE had delivered 11 negative tests and were testing 19 others on that day at the national virus reference laboratory utilising the pan-coronavirus assay. PHE teams had provided support to the NHS services

assessing the cases and providing isolation advice for individuals awaiting their results. The Port Health Team were meeting flights from Wuhan and China to provide advice (and leaflets) on symptoms and who to contact if symptoms developed.

568. In this time PHE had adjusted its response arrangements to surge the organisation into 7-day week working across all areas from local Health Protection Teams to its specialist laboratories, to national capabilities, which included its National Incident Coordination Centre.

569. In summary in less than 4 weeks from the initial reports of cases from China, PHE had provided the NHS with guidance for clinical management, developed and validated an assay for a novel coronavirus assay working with international partners, provided evidence, expertise and advice to NERVTAG, DHSC, and the NHS, initiated a port health pathway to meet flights from Wuhan and provide information to travellers, developed a protocol to study the detailed epidemiology of cases and contacts (this critical information would be shared with modellers and academics to inform nowcasts and models for government), developed contact tracing protocols, and worked with global partners to share information, while continuing to deliver essential services for other infectious diseases and non-communicable disease.

Section 9: Health Inequalities and COVID-19 Disparities Data

570. In this section, I:

a. briefly describe PHE's health inequalities duties
b. describe how PHE fulfilled its roles and responsibilities to address health inequalities in emergency planning and risk assessments, in relation to pandemics such as COVID-19, up to 21 January 2020.
c. describe action taken by PHE in relation to health inequalities related to COVID-19 up to 21 January 2020.
d. summarise the findings of key health inequalities publications PHE contributed to throughout the pandemic until the point PHE was abolished.

e. exhibit analysis describing data on deaths from COVID-19 with inequalities breakdowns and describing the way in which our understanding of reported inequalities changed throughout the course of the pandemic.

571. This is not a comprehensive description of the wider work on health inequalities delivered by PHE prior to the pandemic, nor comprehensive of other work related to health inequalities conducted throughout the pandemic as I understand this will be considered in more detail in subsequent modules.

Health Inequalities Duties

572. In addition to PHE's duty to reduce health inequalities in accordance with the Health and Social Care Act 2012 and the Equality Act 2010 as set out in section 2, PHE was also bound by, and delivered in accordance with, the Public Services (Social Value) Act 2013 and the Accessible Information Standard.

573. In September 2019, PHE published its forward look Infectious Diseases Strategy 2020 to 2025 this is at **[Exhibit: JH/M1 0044 - INQ000090352]**. In it, health inequalities were highlighted as a strategic priority. It highlighted that many pathogens disproportionately affect groups already experiencing health inequalities, including the homeless. It highlighted that it would draw on PHE's experience working on health inequalities with noncommunicable diseases and continue to develop PHE's capability in behavioural science techniques. "*Through Strategic priority 6, we will turn our attention to the infectious diseases burden associated with health inequalities, building evidence through research to characterise specific areas and develop strategies to reduce their impact on health.*"

Health Inequalities in Risk Assessments

574. This section describes how health inequalities were considered as part of the risk assessment processes that PHE fed into, with a particular focus on risk assessments concerned with infectious diseases.

575. As discussed in Section 5, PHE contributed specialist technical advice into the Cabinet Office's National Risk Register (NRR) when requested to do so. This included advice on health inequalities.

576. As discussed in Section 5, PHE supported the development of Local Resilience Forum Community Risk Registers. These included a vulnerability assessment considering emerging infectious diseases, hazards and threats relating to local areas and taking into account that the impact of any response or threat will differ depending on population demographics, the prevalence of underlying health conditions and chronic disease, and the environment in which people and communities live and work.

577. As I also describe in Section 5, in line with the PHE NIERP **[Exhibit: JH/M1 0090 - INQ000090416]**, when an incident is stood up a dynamic risk assessment (DRA) is completed in the initial alerting phase. The extant DRA methodology in 2020 included an assessment against five core criteria:

Severity: Dynamically assessed risk of the degree of foreseeable harm that may be caused to: individuals; the population or; disruption to PHE's operating capability and possible issues with recovery.

Confidence: Knowledge, derived from all sources of information that confirm the existence and nature of the threat and the routes by which it can affect the population or PHE.

Spread: The size of the actual and potentially affected population.

Interventions: The availability and feasibility of interventions to alter the course and influence the outcome of the event.

Context: The broad environment, including media interest, public concern and attitudes, expectations, pressures, strength of professional knowledge and external factors including political decisions.

578. While health inequalities were not explicit in the extant guidance in early 2020, specific variables were included within the demographics to understand who in the population was affected. The DRA also included collected, analysed and published information on age, ethnicity, pregnancy and underlying health conditions, including data collected as part of previous FF100 studies where relevant, in order to ensure that interventions were developed for the population affected. Data on sexuality and other factors would also be collected if considered important for the threat including its mitigation and management.

579. While the implications of the incident on those people with protected characteristics (as defined by the Equality Act 2010 these are; age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex, and sexual orientation) and those subject to health inequalities were included in each assessment the UKHSA DRA, updated since the start of the pandemic, is now directed to explicitly consider such parameters. This informs UKHSA's response levels as well as any impact on the wider population.

580. Risk assessments (see Section 5), which considered data on identified populations at risk, including those relating to health inequalities, were shared with the relevant advisory groups and government departments.

Health Inequalities in Emergency Planning

581. This section describes how health inequalities were considered as part of the emergency plans that PHE developed and implemented, with a particular focus on plans concerned with infectious diseases.

582. PHE's primary relevant emergency planning documents as discussed in Section 5, are the NIERP **[Exhibit: JH/M1 0090 - INQ000090416]** and the Pandemic Influenza Plan (2014) **[Exhibit: JH/M1 0070 - INQ000090387]**. The NIERP is an all-hazards plan that describes how PHE stands up its incident response, which includes the requirement to conduct a DRA as discussed previously in this section. The Pandemic Influenza Plan (2014) defines the public health activities

in each phase of an influenza pandemic, which includes conducting the FF100 protocol.

583. As mentioned in Sections 4 and 8, PHE published a protocol called the First Few Hundred (FF100) which was ready to deploy for new and emerging infections, including pandemics. This was applied routinely for surveillance of novel respiratory viruses, and specifically in the case of COVID-19, collected data on demographics, ethnicity, country of birth, and pre-existing health conditions to obtain an understanding of those in the population who had been infected by COVID-19. I have exhibited versions of the protocol utilised for avian influenza **[Exhibit: JH/M1 0203 - INQ000101197]** and for MERS-CoV **[Exhibit: JH/M1 0203a - INQ000147759]**

584. The FF100 has been deployed on a number of occasions, including as part of the 2009 influenza pandemic, to examine the prevalence of underlying medical conditions amongst cases compared to the general population, alongside demographics and access to antivirals. *Pandemic (H1N1) 2009 influenza in the UK: clinical and epidemiological findings from the first few hundred (FF100) cases. McLean et al (2010).* **[Exhibit: JH/M1 0213 - INQ000101211].**

585. As data became available in the 2009 H1N1 pandemic, the HPA produced and disseminated analysis on:

a. risk of death from influenza in the first 12 months of the pandemic amongst people with different medical conditions and compared the risk of death between the over 65s and those younger. *Pandemic Influenza A (H1N1) 2009 and mortality in the United Kingdom: risk factors for death, April 2009 to March 2010. Pebody et al. (2010).* **[Exhibit: JH/M1 0214 - INQ000101212]**

b. risk of death by ethnicity and deprivation due to the pandemic. *Ethnicity, deprivation and mortality due to 2009 pandemic influenza A (H1N1) in England during the 2009/2010 pandemic and the first post-pandemic season. Zhao et al (2015).* **[Exhibit: JH/M1 0215 - INQ000101213]**

c. data on deaths, including by age, sex and prior medical conditions/health, with the CMO. *Donaldson et al (2009).* **[Exhibit: JH/M1 0216 - INQ000101214]**

586. Beyond these published plans, PHE conducted other relevant work projects that had a bearing on Health Inequalities in preparation for pandemics. I provide two examples here:

Improving communication with the public about antivirals and vaccination during the next pandemic

587. Between 2013 - 2015, the PHE Behavioural Science Team, that sat within ERD, in collaboration with King's College London and other academic partners, led the DHSC Policy Research Programme-funded INfluENCE project, titled, "Improving communication with the public about antivirals and vaccination during the next pandemic'. Across five work packages, the project sought to identify ways of communicating better with the public about vaccination and antivirals during a future pandemic. The project concluded and reported to DHSC on 16th October 2015. A number of the project outputs have been published in peer-reviewed academic journals to be accessible nationally and internationally. An end of INfluENCE project event brought together stakeholders from across government to hear the outcomes of the project and their implications and applicability for future work. The project outputs were shared with the funder the DHSC Policy Research Programme in final reports, for review and dissemination within their networks.

Health Inequalities and Public Health Risk, Guidance and Information Communications

588. PHE developed a Publications Standard in January 2016 which covered both professional and public-facing materials It aimed to ensure all content was produced to a high quality, and in a consistent and evidence-based way.

589. Along with other standards listed, the standards stated that publications must meet the known needs of stakeholders.

590. In line with those standards, prior to the pandemic, PHE aimed to ensure commissioners, providers, and relevant healthcare professionals had access to the necessary resources in order to communicate public health information to patients and the public including a wide range of groups in the population.

591. In particular, a range of information leaflets and promotional materials about the different vaccination programmes were available online, co-branded with the NHS and included HTML, translations in a range of languages, easy read for people with a learning disability, simple text for low literacy and braille, BSL, large print and audio versions of guidance for parents.

592. PHE provided patient facing leaflets written in plain English to a reading age of 7-11 years and resources were often translated into the most common languages in the UK. For example, related to measles, mumps and rubella vaccination, PHE had published a leaflet in plain English and translated it into Bengali, Polish, Romanian, Somali, Ukrainian and Yoruba for download. The resources were available on GOV.UK (MMR for all general leaflet), and information was cascaded to NHS and local authority staff for them to use for patient and public interactions.

593. PHE also worked with stakeholders, to produce a range of tailored resources for prisons, migrants, people who inject drugs (PWIDs), Gypsy Roma and Traveller groups, to make sure that each community had suitable resources and could be encouraged to take up the offer of vaccines. Resources that were co-produced with stakeholders were distributed through their networks and on their channels and the publications PHE produced can be found on the PHE Health Publications website, on GOV.UK and on the PHE Campaign Resource Centre (CRC). These were particularly welcomed by Directors of Public Health.

594. PHE worked with the NHS to prioritise other groups with disparities and improve vaccine uptake an example of this is within the 2014/15 PHE Winter Flu Plan **[Exhibit: JH/M1 0217 - INQ000101215]** requesting that GP practices and other immunisation providers 'prioritise the improvement of vaccine uptake' among people with learning disabilities as well as other clinically vulnerable groups.

Addressing Inequalities in the National Immunisation Programme

595. PHE developed a strategy, conducted a health equity audit and a template for a local action plan for addressing inequalities in the national immunisation programme in 2019. Due to COVID-19 pandemic work pressures, this publication was delayed until February 2021. **[Exhibit: JH/M1 0218 - INQ000101216]**.

Work conducted by 21 January 2020 by PHE to reduce Health Inequalities as a consequence of COVID-19

Advising on the prioritisation of routine Vaccinations and Immunisations

596. It was understood prior to 2020 that during a pandemic routine primary care services such as general practice could potentially be overwhelmed by clinical demands as there was a risk of serious outcomes such as critical care admissions and death related to secondary bacterial pneumonias. In addition, primary care staffing itself would be depleted due to pandemic illness among health professionals. There would therefore be potential for the delivery of routine immunisation programmes to be adversely affected during a pandemic. The scale of this disruption would be dependent on the clinical severity of the pandemic and the age groups affected.

597. However, disruption to coverage for non-pandemic vaccination programmes, such as childhood vaccinations, would risk co-circulation of other vaccine-preventable infections, with the possibility of outbreaks, and hospitalisation. As influenza predisposes to secondary bacterial infections, it was considered particularly important to preserve programmes that provide both direct and indirect protection against such infections - this would include vaccines against pneumococcal infection, meningococcal infection and haemophilus influenzae. If approached, PHE would therefore have recommended to DHSC that continuation of most existing vaccination programmes would be desirable to

avoid additional strains on health services and public health agencies at a time of historic peak activity.

598. As such and given that as of the 21 January 2020 there were no confirmed cases of COVID-19 in the UK, PHE had not provided any advice in relation to pausing or continuing vaccination programmes.

599. During the early stages of, and throughout, the pandemic the PHE Immunisation team continued to work with the NHS to ensure that routine immunisation coverage was maintained. Further information on this work can be provided in subsequent modules.

Pausing young person and adult screening programmes, continuing antenatal and newborn screening programmes

600. Given that at the 21 January 2020 there were no confirmed cases of COVID-19 in the UK, PHE had not provided any advice in relation to pausing or continuing screening programmes as a result of COVID-19. However, there is a well-developed and used-in-practice process by which screening can be paused as a result of quality concerns. **[Exhibit: JH/M1 0219 - INQ000101217].**

601. In March 2020 PHE supported NHSE&I in making a decision about pausing some aspects of some national screening programmes. It also provided advice on the issue to the CMO and ministers. These programmes were commissioned by NHSE&I under a statutory delegation from the Secretary of State. Further information on this work can be provided in subsequent modules.

Mapping evidence of Mental Health Impacts of COVID-19

602. Given that at the 21 January 2020 there were no confirmed cases of COVID-19 in the UK, PHE did not have data to conduct analysis on the mental health impacts of COVID-19.

Highlighting Health Inequalities - Summaries of key PHE Health Inequalities publications

603. Given that as of the 21 January 2020 there were no confirmed cases of COVID-19 in the UK, PHE did not have data to conduct analysis on the impacts of COVID-19 on different groups. However, the Inquiry has asked for a summary of PHE publications that identified and highlighted health inequalities during the pandemic, outside the relevant period of Module 1.

604. Specifically, the Inquiry has requested a summary of the findings of 3 publications as follows, 1) Disparities in the risks and outcomes of COVID-19 (June 2020) **[Exhibit: JH/M1 0220 - INQ000101218]** 2) Beyond the data: Understanding the impact of COVID-19 on BAME groups (June 2020) **[Exhibit: JH/M1 0221 - INQ000101219]** and 3) Analysis of the relationship between pre-existing conditions, ethnicity and COVID-19 (December 2020). The summaries are provided towards the end of this section.

605. In addition, I have also provided summaries of the following:

a. Review of the available data on the deaths of people with learning disabilities in England during the COVID-19 pandemic (November 2020) **[Exhibit: JH/M1 0222 - INQ000101220]**
b. COVID-19 Health Inequalities Monitoring Tool for England (CHIME) tool, (launched May 2021) available on the government website **[Exhibit: JH/M1 0222a - INQ000147761]**
c. Wider Impacts of COVID-19 on Health (WICH) **[Exhibit: JH/M1 0222b - INQ000147762]**
d. Excess mortality in England and English Regions **[Exhibit: JH/M1 0222c - INQ000147763]**
e. Health profile for England 2021

<u>PHE's 'Disparities in the risks and outcomes of COVID-19'</u>

606. This report **[Exhibit: JH/M1 0220 - INQ000101218]** was an early descriptive review of surveillance data on disparities in the risk and outcomes from COVID-19. It presented findings based on surveillance data available to PHE at the time of its publication in June 2020, including through linkage between health data

sets. The review looked at different factors including age and sex, where people live, deprivation, ethnicity, people's occupation and care home residence.

607. The review confirmed that the impact of COVID-19 replicated existing health inequalities and, in some cases, increased them. These results improved our understanding of the pandemic and formulating the future public health response to it.

608. The review also stated that "The largest disparity found was by age. Among people already diagnosed with COVID-19, people who were 80 or older were seventy times more likely to die than those under 40. Risk of dying among those diagnosed with COVID-19 was also higher in males than females; higher in those living in the more deprived areas than those living in the least deprived; and higher in those in Black, Asian and Minority Ethnic (BAME) groups than in White ethnic groups. These inequalities largely replicate existing inequalities in mortality rates in previous years, except for BAME groups, as mortality was previously higher in White ethnic groups. These analyses take into account age, sex, deprivation, region and ethnicity, but they do not take into account the existence of comorbidities, which are strongly associated with the risk of death from COVID-19 and are likely to explain some of the differences".

Beyond the Data: Understanding the Impact of COVID-19 on BAME Communities

609. The Disparities report was accompanied by this report commissioned by the Chief Medical Officer. **[Exhibit: JH/M1 0221 - INQ000101219]** This report was described as "a descriptive summary of stakeholder insights into the factors that may be influencing the impact of COVID-19 on BAME communities and strategies for addressing inequalities". The report included a literature review. The executive summary highlights the findings from the literature review, the themes emerging from the stakeholder sessions and provides seven recommendations. The PHE CEO wrote a letter to the Equalities Ministers highlighting the findings along with the recommendations from the report.

Analysis of the relationship between pre-existing conditions, ethnicity and COVID-19

610. The Race Disparity Unit in the Cabinet Office commissioned this report **[Exhibit: JH/M1 0223 - INQ000101221]** to determine whether a high prevalence of pre-existing health conditions was a contributory factor to poor outcomes from COVID-19 in some ethnic groups. The report was published in December 2020. This report concluded that, in the first wave of the COVID-19 pandemic in England, ethnic inequalities in survival following diagnosis of COVID-19 were not explained by differences in pre-existing health conditions between ethnic groups. However pre-existing conditions were defined as those with a hospital admission related to their condition in the previous 5 years and the study therefore excluded individuals who were routinely only attending primary care.

Deaths of people identified as having learning disabilities with COVID-19 in England in the Spring of 2020

611. DHSC commissioned PHE to review the available data on the deaths of people with learning disabilities in England during the COVID-19 pandemic. The report **[Exhibit: JH/M1 0222 - INQ000101220]** was published in November 2020 and included possible (ie unconfirmed) COVID-19 related deaths. Using extrapolated data it found that between 21 March and 5 June 2020, people registered as having a learning disability had a death rate involving COVID-19 4.1 times higher than the general population after adjusting for other factors such as age and sex. However, as not all deaths in people with learning difficulties are registered on the available databases, it is estimated the real rate may have been as high as 6.3 times higher. This study was unable to differentiate risk between underlying cohorts already known to have higher mortality rates, for example those with Downs Syndrome.

The COVID-19 Health Inequalities Monitoring Tool for England (CHIME) tool

612. This tool was an interactive data display tool developed by PHE to build on the Review of disparities in the risks and outcomes of COVID-19 by providing monthly analysis. It was launched in May 2021 with indicators for deaths involving COVID-19 and hospital admissions where COVID-19 was the primary

reason for admission and focussed on inequality breakdowns by age, sex, ethnic group, level of deprivation and region. This tool continued to be developed and was transferred to OHID in October 2021. It is available to view on the government website.

Wider Impacts of COVID-19 on Health (WICH)

613. The Wider Impacts of COVID-19 on Health (WICH) monitoring tool was launched in July 2020. This data tool provided a wide range of metrics to consider their possible interaction in relation to wider impacts of the COVID-19 pandemic on health and health inequalities. For example, it includes information on associations which may represent impact on behaviours such as smoking, drinking, gambling and physical activity by a range of factors such as age, sex, ethnicity and disability. It also included information on health service use and the social determinants of health such as employment. Responsibility for publishing WICH transferred to OHID on 1 October 2021. The WICH tool is available to view on the government website.

Excess mortality in England and English regions

614. Monitoring excess deaths provides the most comprehensive overview of the impact of the pandemic on mortality. Excess deaths are the number of deaths over and above what would be expected, based on trends in previous years. Because monitoring excess deaths captures deaths from all causes not just COVID-19 it gives us an idea of both the direct and indirect impact of the pandemic.

615. These reports were updated weekly on GOV.UK, and therefore I have only exhibited the most recent report as of 16 March 2023 [**Exhibit: JH/M1 0223a - INQ000147764**]. They present all cause excess deaths by age, sex, region, local authority, deprivation and ethnicity. They were produced weekly from July 2020 until May 2022 and are now produced monthly. Responsibility for producing the reports transferred to OHID on 1 October 2021.

616. Between 21 March 2020 and 1 October 2021, deaths were 1.13 times higher than expected across England, based on data from the nearest five-year period

before the pandemic, 2015 to 2019. Deaths were higher than expected in all age groups over 25, but were highest in those aged 50-64, 1.19 times higher than expected. Deaths were particularly higher than expected in those who live in deprived areas (1.17 times higher) and in the Black and Asian population (more than 1.4 times higher), reflecting the disproportionate impact of the pandemic on these groups.

Health Profile for England 2021

617. The 2021 edition of the Health Profile for England, published in September 2021 **[Exhibit: JH/M1 0224 - INQ000101222]**, provided a comprehensive overview of the health of people in England and updated indicators presented in previous reports. It also contains a summary of the wider impact of the COVID-19 pandemic on many aspects of health and health inequalities. In addition, the report makes comparisons with health in a selection of other countries (US, Canada, Japan, France, Italy, Germany, Spain, Poland) where possible.

Deaths from COVID-19 with inequality breakdowns

618. Over the course of the pandemic, there were marked differences in COVID-19 deaths by age, sex, ethnicity, and deprivation. These disparities were observed consistently throughout the pandemic. Older adults were disproportionately affected by COVID-19 deaths: 92% of deaths were in people aged 60 and over; and over half (58%) were aged 80 or older. Men were at greater risk of COVID-19 death, particularly during the first wave when the age-standardised mortality rate for men was double that of women.

619. By ethnicity, while people of white ethnicity comprised 84% of COVID-19 deaths, after age-standardising within the population, COVID-19 mortality rates were highest in non-white ethnic groups; particularly in Black, Asian and Other ethnic groups. Likewise, there was a clear difference by deprivation, with age-adjusted death rates being highest in the most deprived quintile of areas.

620. Some disparities were passing, such as differences in COVID-19 mortality by region and population density. For example, the most notable regional difference in COVID-19 deaths was in London during the first wave, with almost double the age-standardised mortality rate observed in other regions. Likewise, in the first wave there was a clear relationship with higher mortality rates in areas with higher population density. However, after the first wave, trends by region and population density became less clear as COVID-19 spread through different geographies. Please see **[Exhibit: JH/M1 0225 - INQ000101223]**, for more detailed information.

Changing Trends in COVID-19 cases and deaths

621. Trends in COVID-19 cases and deaths varied significantly over the course of the pandemic. It is important to note that changes in testing practice and policy influenced case ascertainment, particularly in the period before April 2020 and after March 2022 when widespread community-based testing was not available. This means case data may not be representative of all infections during this time, and caution in interpretation is warranted.

622. Given these caveats, differences were seen in cases by age group. During the first wave, confirmed cases were highest in oldest ages because health outcomes of infection was more severe and testing was available in hospitals and care homes to detect and treat the cases. This likely masked significant transmission in younger ages due to lack of testing to detect the cases. After the first wave, case rates in the rest of 2020 and in spring 2021 remained lowest in the youngest and oldest age groups, as cases were largely driven by working age population age 20-60. From summer 2021 until the end of the year, the trends were highest among children and young people and younger adults; in autumn of 2021 case rates were highest in 1019-year-olds. Case rates remained lowest in the oldest ages (80+), likely due to success of vaccination programme (with very high uptake) and non-pharmaceutical interventions and risk messaging for these groups.

623. Age-standardised case rates were highest among women, with the exception of July 2021 when cases were briefly higher for males. By ethnicity, trends in cases

varied over the course of the pandemic: in 2020 age-standardised case rates were highest in non-white ethnic groups, but thereafter trends were less clear with highest rates occurring among different ethnic groups at different time points. The same is true for difference in cases by deprivation and population density: initially more deprived, more densely populated areas were disproportionately affected but this trend became less clear after 2020 as COVID-19 spread through different geographies. In addition, uptake of interventions to mitigate serious outcomes and death similarly showed differential and persistent ethnicity patterns, with vaccination rates continuing to remain lower in Pakistani populations and in the black ethnic group as a whole.

624. As described in previous paragraphs, disparities in COVID-19 mortality (less impacted by testing practice) were clear and consistent for people of older age, males, people of non-white ethnicity and people living in most deprived areas. Whereas disparities in COVID-19 mortality by region and population density were observed more clearly in the first wave when more deprived, more densely populated areas were disproportionately affected by COVID-19 deaths. Please see **[Exhibit: JH/M1 0225 - INQ000101223]**, for more detailed information. However, after the first wave, trends in COVID-19 mortality by region and population density became less clear as COVID-19 spread through different geographies. Please see the attached report for more detailed information

Additional data on COVID-19 Published by PHE

625. PHE also published regular data outputs, which included breakdowns down by demographics, on GOV.UK: the COVID-19 Dashboard and the National Flu and COVID-19 Surveillance report. UKHSA continues to publish these weekly.

Section 10: COVID-19 Lessons identified and future preparedness.

COVID-19 Lessons Identified Activities

626. From the outset of the COVID-19 response in early 2020, PHE, NHS T&T and JBC initiated a multi-modality programme of lessons identification activity. PHE

incident response cells conducted rolling improvement/lessons identification discussions which were recorded and tracked to support response interventions. Debriefs, surveys and internal audits during the main phases of the response as the organization evolved in to UKHSA identified further tactical and strategic successes and challenges. A comprehensive repository of lessons identified has been collated during the period and now forms the basis of formal lessons identified activity in UKHSA. An itemised list is included in **[Exhibit: JH/M1 0226 - INQ000101059]**.

627. In June 2020, the Government Internal Audit Agency conducted an audit review of the effectiveness of the point in time arrangements in place to manage multiple incidents (including Novichok, Ebola, Listeria and Grenfell Tower) and business as usual activities in PHE (20200611 Major Incident Response Final Report_101_) **[Exhibit: JH/M1 0227 - INQ000101060].** Due to the ongoing nature of COVID-19 the recommendations from this audit were not formally implemented but were fed into an internal process focusing on key findings around PHE's organisational remit, preparedness and business continuity, incident management, decision making, data, people and communications, prior to the creation of UKHSA.

628. UKHSA's creation on 1 October 2021, brought together different organisations to provide a more integrated health security capability, and resilience in national public health response arrangements than at pre-pandemic levels. UKHSA also integrated the COVID-19 Vaccine Taskforce, now Covid Vaccine Unit (CVU) in October 2022 to ensure the UK remains protected from COVID-19 and best engages with the new global COVID-19 vaccine market as well as amplifying opportunities with other UKHSA directorates to support research and development of wider vaccine opportunities.

629. In addition to UKHSA's organizational learning, in my role as Chief Executive of UKHSA as well as my former role as Deputy Chief Medical Officer (DCMO), I co-authored the recent "Technical report on the COVID-19 pandemic in the UK", published by DHSC, which summarises high level technical and professional learning for future UK Chief Medical Officers, Government Chief Scientific

Advisers, National Medical Directors and public health leaders in any future pandemic **[Exhibit: JH/M1 0227a - INQ000147765]**.

630. UKHSA is committed to being a learning organisation, focused on continuous improvement. An internal assurance process for lessons identified within UKHSA is currently being developed to monitor and report on implementation of technical, structural, operational and cultural lessons that have been identified both prior to and during the COVID-19 Pandemic. This builds upon routine incident response arrangements, which include after-action debriefs, evaluations and continual integration of evaluation findings.

Reflections on UKHSA's current state of preparedness

631. UKHSA has scaled back its operational response to COVID-19 in line with the government's "Living with Covid" strategy and an overall reduction in population infection rates. A core plank of the strategy was ensuring ongoing surveillance and contingency capability to detect and respond to new variants or waves that were more serious or threatened to overwhelm the NHS.

632. UKHSA has maintained robust surveillance systems developed during the pandemic, monitoring new variants and variants of concern (VoCs) and is assessing the continued effectiveness of vaccines against emerging variants. Vaccination will remain key to the overall COVID-19 response and this is led by UKHSA's Covid Vaccines Unit.

633. UKHSA has developed and exercised COVID-19 contingency plans for both a variant of concern or a new wave of infection which may threaten to overwhelm health services and tests our capacity to respond to multiple concurrent incidents. UKHSA has engaged with other Government Departments and delivery partners to explain this plan and ensure that it informs their own sectoral contingency plans. This will be a proportionate response in line with the risks posed by the virus during the course of 2023/24 and will continue to be reviewed for relevance and response needs.

634. The organisation's current state of preparedness embeds learning to date from the pandemic and stands ready to respond to all potential external threats as outlined in the government's remit letter. The following context should be noted:

a. we remain in response mode for the current pandemic as well as managing a significant number of new or unseasonal variations in health protection risk

b. we are in the very early phase of building a complex, new organisation where only one third of our staff were permanently recruited at inception and organisational structural change will necessarily take further time

c. we are taking on new responsibilities as we form - for example the previous COVID-19 Vaccine Task Force, now the UKHSA Covid Vaccine Unit

d. the organisational budget is nearing completion for future preparedness and response capacity and capability provision

e. we continue to work, and compare our capability and capacity, with other international health protection agencies many of which are also reviewing standards, capacity and national and international expectations in light of the recent pandemic and;

f. we anticipate there will be considerable learning from this public inquiry itself against which we should - and wish to - benchmark ourselves against expectations of future UK health threat preparedness.

635. UKHSA has led the world in the identification and/or handling of many recent health protection incidents including the Mpox outbreak, the assessment of new variants of SARS-CoV-2, salmonella infections in chocolate products and the increased prevalence of invasive Group A streptococcal disease. Other examples of response and preparedness can be found on a daily basis in the media or UKHSA online which also contains lists of ongoing surveillance work of global importance stretching from antimicrobial resistance rates (ESPAUR report) to vaccine effectiveness studies.

636. **Preparedness for other health threats:** Within its first year and in addition to the ongoing response to COVID-19, UKHSA responded to address multiple, concurrent and complex health security risks such as Monkeypox, avian influenza, Strep A, hepatitis in children, polio, and extreme weather. UKHSA is seeing increased demand on its health protection operational response system due to an increased number of health incidents from pre-pandemic levels.

637. Building on learning from the pandemic, UKHSA's Emergency, Preparedness, Resilience and Response ('EPRR') function is being re-developed to provide integrated situational awareness and horizon scanning and to respond effectively to incidents at an operational level (including early detection of emerging infectious disease which could lead to a pandemic). A significant project is underway across UKHSA to map an updated incident management system, surge mechanism and governance framework, which will enhance the coordination of the response and operations across the local and national response system and ensure UKHSA is able to meet the strategic goals of providing a strong, capable and prepared response system.

638. In addition, UKHSA has established a new Centre for Pandemic Preparedness ('CPP'), with the core purpose to ensure the UK can help prevent future pandemics, respond faster where they occur, and is more effective and efficient in reducing the negative impacts of health threats to the UK. The CPP's role is to co-ordinate the identification of gaps in the UK's preparedness across the health protection system and the strategic opportunities to enhance our readiness providing leadership across UKHSA and working with industry, academia, and the international community.

639. The CPP is systematically integrating lessons from the scale down of COVID- 19 response into its workplan, developing recommendations that can be shared with government and public health institutions around the world to tackle future pandemics. Through provision of the UK 100 Days Mission secretariat, and through UKHSA's data and surveillance, vaccination, immunology, clinical and science teams – it is co-ordinating the UK contribution to the 100 Days Mission, **[Exhibit: JH/M1 0228 - INQ000101061]** which focuses on global collaboration with the goal that vaccines in particular but also, diagnostics and therapeutics for

a novel virus could be available within 100 days of confirmation. DHSC as the lead department maintains leadership and responsibility for the Government's overall pandemic preparedness policy and portfolio management.

640. **Health inequalities:** COVID-19 demonstrated how health threats can very frequently disproportionately impact certain groups, and the importance of addressing health inequalities in our response to health threats. We know that some people and places are at greater risk of external health threats; more vulnerable to their effects; and less likely to benefit from interventions designed to prevent, detect and respond to those threats. To fulfil our mission as an organisation, UKHSA is developing a health equity strategy, focusing on how best to support those who face a disproportionate burden in relation to external health threats. Doing so will enable us to protect those at higher risk, but also provide more effective protection for the wider public and protect our economy and public services. Our focus for this strategy is making sure we have the right approach, capability and processes in place as an organisation to deliver this key critical objective. In driving efforts to provide health security for every person in every community, we will develop our role as a system leader working with partners to tackle the disproportionate burden of health hazards on specific communities and/or populations.

641. **Collaboration with industry:** UKHSA also recognises that collaboration with industry was critical during the pandemic to ensure we had rapid access to the tools needed for both response and mitigation measures to scale up at pace but also building blocks of preparatory work over previous years to call on when needed in an emergency. This same collaboration will be critical in ensuring preparedness and response to future health threats. Therefore, UKHSA is developing a new commercial framework to facilitate engagement with industry including guidance on whom to engage with and when, and consistent and structured operating models and guidance for managing partnerships. UKHSA has launched a new *Centre for Vaccine Development and Evaluation* to be a focal point for partnerships with industry and international bodies, helping us bring new investment to the UK and develop the UK as a science and health protection global leader.

642. **Data analytics and surveillance:** Data was central to the pandemic response. The way that we collected, managed and shared data across the UK and globally had a major impact on the domestic and global pandemic response. We are currently retaining the capabilities developed in JBC within our DAS team, and transparently putting health and non-health data in the hands of those who need it thereby enabling the health protection ecosystem through the provision of high calibre analytics capability to inform health protection activities, decision-making, action and outcomes.

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

Signed: … **Personal Data**

Dated: ……14 April 2023……