Witness Name: Susan Hopkins

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Exhibits: SH3/01 – SH3/454

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UK COVID-19 INQUIRY

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Introduction

- 1. I, Susan Hopkins, of the UK Health Security Agency, 10 South Colonnade, Canary Wharf, London E14 4PU, will say as follows:
- 2. I am employed by the Royal Free London NHS Foundation Trust and on long-term secondment to the UK Health Security Agency (UKHSA).
- 3. Since October 2021 I have been the interim Chief Medical Advisor to the UKHSA and was appointed formally to the post in June 2022, and I am a member of UKHSA's Executive Committee. My role is to lead the Clinical and Public Health Group whose objective is to provide critical elements of professional health security, clinical and public health leadership for the UKHSA through the provision of advice, guidance, evidence, epidemiological studies and evaluation of policy across infectious diseases and other health threats.
- 4. Prior to joining UKHSA I was Deputy Director of the National Infection Service (NIS) at Public Health England (PHE) from 2018-2020, leading PHE's work on antimicrobial resistance and healthcare acquired infections. Before this, and since 2009, I worked part-time on specific projects and programmes in the Health Protection Agency (HPA) and PHE as a consultant epidemiologist.
- 5. I worked as National Incident Director [co-shared with Professor Nick Phin] from January to September 2020 and subsequently National Strategic Response Director for COVID-19 in PHE from September 2020 to September 2021 and, in addition to PHE responsibilities I acted as Chief Medical Advisor for NHS Test and Trace, advising on testing, tracing and surveillance functions from September 2020 to September 2021.
- 6. I am also Professor of Infectious Diseases and Health Security at University College London (UCL), maintain an active research portfolio, and continue to work clinically as a consultant in Infectious Diseases and Microbiology at the Royal Free London NHS Foundation Trust. I am a Fellow of the Academy of Medical Sciences, Fellow of the

Royal College of Physicians Ireland, the Royal College of Physicians London, the Royal College of Pathologists, and the Faculty of Public Health.

- I make this statement in response to the request from the UK Covid-19 Inquiry ("the Inquiry"), dated 9 May 2023, under Rule 9 of the Inquiry Rules SI 2006/1838, requiring UKHSA to provide the Inquiry with a corporate witness statement in respect of specified matters relating to Module 3.
- 8. This statement is, to the best of my knowledge and belief, accurate and complete at the time of signing. Notwithstanding this, it is the case that UKHSA continues to prepare for its involvement in the Inquiry and it is possible that additional relevant information may come to light as the Inquiry progresses. In this eventuality the additional information or relevant material will be provided to the Inquiry and a supplementary statement will be made if requested by the Inquiry.
- 9. The matters in my statement rely on a mixture of my own experience, the records of UKHSA and its predecessor organisations, and the input from a significant number of colleagues within UKHSA. 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 to provide context. I have not been able to review all the documents exhibited and some are derived outside the boundaries of my own operational sphere. In this case, I have relied upon subject matter experts to assist with the information presented.

Structure of the statement

- 12. In line with the Rule 9 Request to UKHSA, this statement focuses on the response by PHE and UKHSA, and also includes reference to NHS Test and Trace (NHSTT) and the Joint Biosecurity Centre (JBC) where relevant to issues relating to healthcare systems in the UK. Matters relating to COVID-19 vaccines have not been discussed in depth as these will be covered within Module 4 on vaccines and therapeutics. The relevant period, as specified by the Inquiry, is 1 March 2020 to 28 June 2022. I have referred to matters outside of this date range where appropriate to provide a wider context.
- 13. In my statement I use the names of organisations as they would have been referred to at the time. For consistency, I refer to the Department of Health and Social care ("DHSC") throughout, rather than the Department of Health ("DH") as it was known prior to 2018. The statement refers to a large number of organisations, institutions, frameworks and guidance. As a result, the statement sets out the full name once and then references the initials which will be used thereafter. A full set of the acronyms used with an explanation is at [Exhibit: SH3/01 INQ000348123].
- 14. This statement, where appropriate, uses evidence including exhibits from previous statements provided by UKHSA. This is stated in the relevant parts of the statement.
- 15. This statement has seven 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 and PHE page 8

Section 2 - Understanding COVID-19 page 34

Section 3 – PHE/UKHSA advice and guidance relating to health care settings page 113

- Section 4 Public health messaging page 166
- Section 5 Disparities in Risks and Outcomes COVID-19 report page 167

Section 6 – Data and analysis of impact of COVID-19 page 171

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Section 7 – Lessons learnt page 180

SECTION 1: Background

PHE's functions and role

- 16. The following narrative provides an overview of UKHSA and its predecessor organisations' formation, structures and key decision makers, main functions in relation to healthcare systems during the COVID-19 pandemic, as well as providing detail on key relationships. Section 2 of UKHSA's witness statement for Module 1 dated 14 April 2023 provided a detailed description of the establishment of PHE, its roles and responsibilities, governance structures and organisation. A summary is provided here, and the Inquiry is directed to that statement for further details.
- 17. PHE was established as an Executive Agency of DHSC in 2013, as a result of the reorganisation of healthcare provision, set out in the Health and Social Care Act 2012 [Exhibit: SH3/02 INQ000090325]. Framework Agreements, agreed between DHSC and PHE, together with the annual strategic remit and priorities letters from Ministers, set out PHE's duties and functions in relation to the healthcare system. The final Framework Agreement between DHSC and PHE was published in 2018 [Exhibit: SH3/03 INQ000090327].
- 18. Annex A of the 2018 Framework Agreement [Exhibit: SH3/04 INQ000090328] details 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. This includes statutory functions relating to the Civil Contingencies Act 2004 ("CCA 2004") which established the legislative framework for civil protection in the UK, imposing roles and responsibilities on organisations to prepare for, and respond to, emergencies.
 - As a category 1 responder under the CCA 2004, the Secretary of State for Health and Social Care has the following four duties: 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.
- 19. Annex A of the 2018 Framework agreement between DHSC and PHE, exhibited in paragraph 18, provides for PHE:

"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."

- 20. On 1 March 2020 PHE was responsible for four critical functions in respect of the public healthcare system, as set out in the 2018 Framework Agreement. These were to:
 - a. "Fulfil the Secretary of State for Health and Social Care's statutory duty to protect the public's health from infectious diseases and other public health hazards, working with the NHS, local government and other partners in England, and also working with the devolved administrations and globally where appropriate;
 - b. Fulfil the Secretary of State for Health and Social Care's statutory duty to address health inequalities by securing improvements to the public's health, including supporting the system to reduce health inequalities. It should do this through its own actions and by supporting national government, local government, the NHS and the public to secure the greatest gains in physical and mental health, and help achieve a financially sustainable health and care system;
 - c. Improve population health supporting sustainable health and care services through, for example: promoting the evidence on public health interventions and analysing future demand to help shape future services; working with NHS England (NHSE) on effective preventative strategies and diagnosis;

- d. Ensure the public health system maintains the capability and capacity to tackle today's public health challenges and is prepared for the emerging challenges of the future, both nationally and internationally".
- 21. PHE's remit letter for 2020-2021, dated 29 April 2020 [Exhibit: SH3/05 INQ000090337] from the Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care, recognised PHE's crucial role in supporting the government's response to the COVID-19 pandemic and mitigating the effects of COVID-19 on the health and care systems.
- 22. On 29 April 2020 the Private Secretary to the Prime Minister commissioned a paper outlining PHE's role in responding to COVID-19, via the private office of the Secretary of State for Health and Social Care. In response, PHE produced the document 'Introduction to Public Health England', which was presented to the Prime Minister's office on 7 May 2020 [Exhibit: SH3/06 INQ000203623].
- 23. The note to the Prime Minister's office which accompanied this document set out where it was felt that PHE could make the biggest difference to the Government's COVID-19 response. These included early warning surveillance, guidance for the public and professionals, supporting the mass mobilisation of testing and tracing, reducing infections in care homes and working with partners to implement the national vaccination strategy [Exhibit: SH3/07 INQ000203660].
- 24. Following the decision in August 2020 [Exhibit: SH3/08 INQ000223297] to create a new health protection organisation, PHE's 2021-2022 remit letter, published on 13 July 2021, included supporting the newly established (but not yet operational) UKHSA. In relation to the COVID-19 response and health protection functions, it was also expected to take action on the following health promotion activities: reducing health inequalities, obesity, healthy weight and nutrition, mental health, tackling health harms, sexual and reproductive health, public health reforms and evidence reviews [Exhibit: SH3/09 INQ000203619].

PHE's organisational structure and key decision makers

- 25. PHE's governance structures were developed and implemented in accordance with the requirements of the Framework Agreement and the annual strategic remit and priorities letters from Ministers. They also reflected the government's expectation that, as an executive agency with operational autonomy, PHE was an authoritative voice on public health.
- 26. PHE's Chief Executive Officer (CEO) was Duncan Selbie, who held this post from April 2013 until 19 August 2020. Michael Brodie was the interim Chief Executive (on secondment from his role as CE NHS Shared Business Authority) from 1 September 2020 until 30 September 2021. Exhibited here is a table which sets out the names, roles and length of appointment of PHE's senior management. [Exhibit: SH3/10 INQ000348124].
- 27. The Leadership organograms for 2018-19 and 2019-2020 are exhibited here [Exhibit: SH3/11 INQ000090360] and [Exhibit: SH3/12 INQ000090361]. These organograms provide information at Senior Civil Service level and show the changes in the senior positions, particularly in the NIS. The governance structures, in the relevant period, are also exhibited [Exhibit: SH3/13 INQ000090369] [Exhibit: SH3/14 INQ000090370].
- 28. As of January 2020, there were nine director-led teams reporting to the CEO. 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.

- 29. At January 2020, PHE's last year of operation, the Medical Director and Head of Health Protection was Professor Yvonne Doyle. The Health Protection Directorate comprised a number of key teams: 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).
- 30. The ERD led on PHE's work on Emergency Preparedness, Resilience and Response (EPRR) supported by subject matter experts drawn in for both preparedness and response from across the rest of the organisation. This EPRR work included being ready for, and acting in, emergency situations, working closely with DHSC and Other Government Departments, and delivering specific associated commissions from DHSC and NHS England and NHS Improvement (NHSE/I). The Regional Directors also had EPRR duties. Their primary role was to support the discharge of PHE's duties under the CCA 2004.
- 31. At January 2020, the Deputy CEO and Chief Operating Officer, Richard Gleave, led the Operations Directorate. The team undertook corporate tasks related to external partnerships on the public health delivery agenda and led discussions in Whitehall about funding. The NIS and the Centres and Regions Direction reported to the Chief Executive through the Chief Operating Officer/ Deputy Chief Executive, though their directors were all members of the PHE's National Executive.
- 32. The NIS was created in 2015 and, in January 2020, the NIS within PHE comprised PHE's microbiology capabilities, and core national capabilities across epidemiology, surveillance, management and research into infectious diseases. At January 2020 the Director of the NIS was Professor Sharon Peacock (on secondment from Cambridge University). From April 2020 until September 2021, Professor Isabel Oliver succeeded as the Director of the NIS.
- 33. In January 2020, the Health Improvement Directorate was led by Professor John Newton. It produced advice which informed policy, practice, and delivery of essential

services by partners, as well as coordinated research activity and led on provision of evidence to support PHE's activities. The functions it contained have now substantially moved to the Office for Health Improvement and Disparities (OHID) based in DHSC, and the majority of the PHE Screening teams that supported national screening programmes for diseases and conditions such as cancer have moved to NHSE.

NHS Test and Trace and JBC

- 34. The immediate forerunner to NHS Test and Trace (NHSTT) was the National Testing Programme (NTP), which was announced on 2 April 2020 and was initially set up within DHSC. Exhibited here is an organogram of its leadership team as of 8 May 2020. [Exhibit: SH3/15 INQ000348125]. Its aim was to provide coronavirus tests to everyone who needed them through a phased approach, starting with patients, NHS workers and their families, other critical key workers and then expanding to the wider community over time.
- 35. The NTP leadership structure saw each of the five pillars being led by a Director and reporting into the Second Permanent Secretary in DHSC. The lead Ministers were the Secretary of State for Health and Social Care, and Lord Bethell, Parliamentary Under Secretary of State.
- 36. NHSTT was formally established on 28 May 2020 to lead an 'at scale' national testing and tracing service, working with PHE and others. Exhibited here is the senior leadership, as of June 2020. [Exhibit: SH3/16 – INQ000348126]. The Joint Biosecurity Centre (JBC) was initially established separately in the Cabinet Office (CO) and then transferred into NHSTT.
- 37. The JBC was established in May 2020 to provide additional and complementary objective analysis and assessment of data and data derived evidence to build on that already in place at a local and regional level across the UK, and to inform local and national decision making in response to COVID-19 outbreaks. Exhibited here is an organogram of its high-level structure as of July 2020. [Exhibit: SH3/17 INQ000348127].

- 38. The JBC was originally conceived as a 'stand-alone' organisation. However, within its first four weeks it was incorporated into NHSTT as it became clear that the JBC played an integral part in informing the testing, tracing and local contain work of NHSTT, and JBC relied on NHSTT data and infrastructure. It was therefore integrated into NHSTT, reporting directly into the Executive Chair.
- 39. In April 2021, the Community Testing Programme (CTP), which had been established within DHSC to support local authorities to deliver a local approach to population asymptomatic testing, was also transferred into NHSTT. The CTP was announced by the government in its Winter Plan, published 23 November 2020 [Exhibit: SH3/18 INQ000137262]

UKHSA's functions and role

- 40. On 18 August 2020 the Secretary of State for Health and Social Care announced that a new national body would be established to bring together the health protection, clinical and scientific functions of PHE with NHSTT under a single leadership team.
- 41. This was initially referred to as the National Institute for Health Protection (NIHP) and the announcement, previously exhibited in paragraph 24, stated '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'.
- 42. Ministers changed the name to the UKHSA on 24 March 2021, and on 1 April 2021 UKHSA was formally launched as an Executive Agency of DHSC, becoming fully operational on 1 October 2021. Exhibited here is the press notice announcing its launch. [Exhibit: SH3/19 – INQ000223298]. It combined the health protection, clinical and scientific functions of PHE with NHSTT. From April to October 2021 the component organisations retained their identities, responsibilities, and structures whilst transition to the new organisation continued.
- 43. With effect from 1 October 2022 responsibility for procurement and sourcing of COVID-19 vaccines, previously led by the Vaccine Task Force (VTF) with the Department for Business, Energy and Industrial Strategy, transferred to UKHSA as the

new Covid Vaccine Unit, with the Director reporting directly to the Chief Executive. The onshoring vaccine manufacture programme from the VTF moved to the Office for Life Sciences (OLS) at the same time. Exhibited here is the press notice detailing these changes. [Exhibit: SH3/20 – INQ000348128].

- 44. An annual remit letter from the relevant Minister in DHSC details the government's expectations and priorities for UKHSA in the year and the future. The letter is developed in consultation with UKHSA. Remit letters for UKHSA are available for 2021/22 and 2022/23. [Exhibit: SH3/21 INQ000090310] [Exhibit: SH3/22 INQ000090311]. 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: SH3/23 INQ00086652
- 45. A Framework Agreement between DHSC and UKHSA, published on 27 January 2022,
 [Exhibit: SH3/24 INQ000203658] sets out UKHSA's governance, accountability
 framework, core responsibilities and objectives. Annex A [Exhibit: SH3/25 INQ000090309] lists statutory duties that UKHSA carries out on behalf of the
 Secretary of State for Health and Social Care.

UKHSA's organisational structure and key decision makers

- 46. On 24 March 2021 the Secretary of State for Health and Social Care announced the appointments of Dr Jenny Harries as CEO, UKHSA and Ian Peters, Chair (non-executive), of the future Advisory Board. Both appointments nominally commenced from 1 April 2021 but with the operational role beginning 1 October 2021. The Exhibit at paragraph 42 detailed the announcement. As of 1 October 2021, UKHSA comprised of 11 groups including public health and clinical, science, heath protection operations and testing, as well as functions such as finance and commercial. A senior leadership structure is exhibited here [Exhibit: SH3/26 INQ000348129].
- 47. UKHSA currently comprises five groups led by Directors General: Clinical and Public Health; Science; Data, Analytics and Surveillance; Health Protection Operations

(which incorporates Testing Operations) and Strategy, Policy and Programmes; and five led by Directors: Finance and Corporate Services; Technology; People; Commercial and the COVID-19 Vaccine Unit. These group leaders report to the CEO. The Director of Communications also sits on the Executive Committee. Exhibited here is the current senior leadership organogram [Exhibit: SH3/27 – INQ000348130].

- 48. The groups span a wide range of professions and the UKHSA model is designed so that these capabilities work together to provide an integrated all-hazards health protection capability.
- 49. UKHSA's Advisory Board, providing impartial oversight and advice, was set up during 2021/2022 and began meeting from June 2022 and in public from September 2022. Alongside the non-executive Chair, the Secretary of State for Health and Social Care appointed five non-executive members and three associate non-executive members in April 2022. [Exhibit: SH3/28 - INQ000090314].
- 50. UKHSA's Executive Committee is the key decision-making body. It was established in shadow form in August 2021 and has met formally from 1 October 2021. Its role is to oversee UKHSAs overall performance and delivery, and its Terms of Reference are exhibited here. [Exhibit: SH3/29 INQ000348131]. The Executive Committee consists of UKHSA's Directors General as well as the People, Communications and Commercial Directors, and the Chief Technology Officer. In October 2022 the Director of the Covid Vaccine Unit joined the Executive Committee.

Cross-Government Meetings during COVID-19

51. Throughout the pandemic officials from PHE, and later from UKHSA, attended various cross-government meetings as required. Senior leaders regularly attended relevant ministerial meetings to provide information, for example on epidemiology, public health advice, or operational delivery as well as providing input via DHSC, to support the Secretary of State for Health and Social Care in his attendance at other ministerial meetings.

- 52. There were also additional meetings which had PHE representation, including COVID-19 Daily Response Meeting and COVID-19 Healthcare Ministerial Implementation Group meetings. PHE representatives were also involved in the Hospital Onset COVID Working Group (HOCI), more details of which are set out in paragraphs 162-65.
- 53. In May 2020 the Prime Minister established two formal Cabinet sub-committees COVID Operations (COVID-O) to deliver the Government's policy and operational response and COVID Strategy (COVID-S) to oversee the Government's response [Exhibit: SH3/30 – INQ000147649] As Cabinet committees, formal membership was restricted to named Ministers, however, the Chief Medical Officer (CMO) and Deputy Chief Medical Officer (DCMO) and relevant senior officials, including from PHE, JBC, and NHSTT were invited to discuss wide ranging issues.
- 54. In June 2020 COVID-O approved the establishment of the Bronze/Silver/Gold (B/S/G) hierarchy of meetings of the Local Area Committee (LAC) to provide a governance framework where local, regional and national data were reviewed and operational decisions around potential local support and/or restrictions were made.

An overview of the bodies PHE/UKHSA engaged with

- 55. PHE, and subsequently UKHSA, played a significant role in supporting the government's response to the pandemic through collaboration with DHSC and delivery partner organisations to mitigate the effects of COVID-19 on healthcare systems.
- 56. Below is an overview of how we engaged with these organisations during the relevant period. Additional information will be provided, where relevant, as UKHSA's response to the Inquiry develops.

The Secretary of State for Health and Social Care and DHSC

57. Senior members of PHE staff, and subsequently UKHSA from October 2021, attended regular and ad hoc meetings as needed with the Secretary of State for Health and

Social Care during the relevant period. For example, early in the pandemic response senior PHE representatives attended daily COVID-19 meetings with Secretary of State for Health and Social Care led by Emma Reed, Director of Emergency Response and Health Protection, DHSC, who was the DHSC Incident Director and head of the DHSC Operational Response Centre (ORC). Later in 2020 DHSC convened a weekly "System Leaders" call for Secretary of State for Health and Social Care, invitees included senior staff from PHE, NHSTT and NHSE.

- 58. The regularity of meetings between PHE, and later UKHSA, and the Secretary of State for Health and Social Care shifted over the course of the pandemic response. When invited, senior PHE staff within the incident, for example the Chief Executive Officer, Medical Director, Director of NIS, attended meetings with the Secretary of State for Health and Social Care, in an advisory role, primarily to present the epidemiology and latest data on COVID-19. Other attendees included the Permanent Secretary and other DHSC officials, Special Advisors, managerial, operational and clinical leads as well as a representative from the Adult Social Care sector, who would have had an interest in decisions relating to that sector, for example testing and infection control.
- 59. Both just before and throughout the relevant period for this module, there was very frequent contact between PHE and subsequently UKHSA and officials in DHSC. For example, the DHSC ORC was established on 19 January 2020. From 20 February 2020 the DHSC ORC convened the daily ORC and Secretary of State for Health and Social Care meetings mentioned in paragraph 57 above, to review the epidemiology of COVID-19 and co-ordinate health system action.
- 60. Early in the incident response, based on previous large incident response learning, PHE convened a PHE 'DHSC liaison' function within ORC. This was composed of a team of PHE staff, co-located with DHSC teams at the DHSC's London Victoria Street headquarters (HQ), to directly align each of the operational functions of the DHSC's ORC and share situational awareness.
- 61. This liaison team supported senior PHE officials who attended meetings at DHSC's London Victoria Street HQ and facilitated rapid communication and response to the

busy 'battle rhythm' of daily meetings and requests for information or advice from DHSC or other parts of Government. The PHE 'DHSC liaison' team helped escalate urgent priorities to the PHE incident management team.

Chief Medical Officer

- 62. There are four CMOs in the United Kingdom who are appointed to advise their respective governments. The CMO for England, Professor Chris Whitty, is the UK government's principal medical adviser and chief public health adviser, and the professional head of all directors of public health in local government and of the medical profession. This includes all senior medically qualified staff in UKHSA through the UKHSA CEO and the UKHSA Chief Medical Advisor Responsible Officer role, with similar arrangements in place for its predecessor organisations.
- 63. Each CMO is assisted by one or more DCMOs. Immediately prior to her appointment as CEO of UKHSA, Professor Dame Jenny Harries was one of the DCMOs for England from 2019-2021.
- 64. PHE's two main roles were described in the Introduction to Public Health England document, previously exhibited [Exhibit: SH3/06 INQ000203623]. Working alongside DHSC, the NHS and wider government, they were:
 - a. Providing scientific advice and guidance to the CMO and government that focused on the practical application of scientific evidence and research, including translating relevant advice from the Scientific Advisory Group for Emergencies (SAGE) and other groups and committees and its own expert groups, as appropriate, into evidence-based guidance for clinicians and the public;
 - Undertaking a range of specific operational and scientific delivery tasks where it continued to deliver routine health protection response services, for example, testing and contact tracing as well as piloting new models of testing or service delivery, to adopt and implement at scale.
- 65. Scientific and medical advice was also directly provided to government by the Government's Chief Scientific Advisor and the CMO. This advice was based on the

consensus view of scientific advisory groups, primarily SAGE, sub-groups of SAGE, and other advisory groups such as the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG). A critical role for PHE, and subsequently UKHSA, was to commission and produce critical appraisals and primary research for these groups. A table of the papers PHE and subsequently UKHSA provided to both SAGE and NERVTAG is exhibited [Exhibit: SH3/31 – INQ000348133].

66. PHE, NHSTT and UKHSA worked very closely and collaboratively with the CMO and DCMOs, providing public health advice, evidence and other information. In addition to SAGE (as covered above) the CMO Senior Clinicians' group (SCG) was a key route for this engagement.

The Senior Clinicians' Group (SCG)

- 67. The SCG brought together senior clinical staff from across the health systems of the four UK nations to support the response to COVID-19. The SCG was not a decision-making body. Its main purpose was to share knowledge and provide a support base for active inquiry and working through complex clinical challenges.
- 68. The SCG was initially an England focused meeting and convened by the CMO's office. Attendees included the CMO, DCMOs, the NHSE Medical Director, NHSE Director of Emergency Planning, the PHE Medical Director (who was also the Strategic Response Director/ Senior Responsible Officer for COVID-19) and the PHE Incident Director. After the first meeting on 16 March 2020 the membership was gradually widened to include all four nations Chief Nursing Officers, CMOs and relevant DCMOs, with invited experts attending individual meetings.
- 69. The SCG had wide ranging discussions and sharing of views. In the early weeks it discussed case definitions for use in the health system, prioritisation of COVID-19 testing, COVID-19 symptoms and public communications, Infection Prevention and Control (IPC) guidance, including respiratory protection for healthcare workers (HCWs), risk factors for severe disease and HCW risk of acquiring COVID-19.

NHS England

- 70. Throughout the pandemic PHE, and subsequently UKHSA, and NHSE worked closely together, with counterparts from each organisation invited to each other's organisational meetings. From the outset NHSE representatives were invited to PHE Incident Management Team (IMT) and relevant IMT subgroups held by PHE and then UKHSA. NHSE representatives also attended Bronze/Silver/Gold meetings. These meetings provided the national governance framework for the consideration of data and local insight to inform Ministerial decisions about the potential application of localised restrictions such as non-pharmaceutical interventions. Bronze meetings looked to identify areas and key issues of concern. Silver meetings focused on the local and national epidemiology, analysis and issues raised at Bronze meetings. Gold meetings reviewed recommendations from Bronze and Silver and information from these meetings provided critical insight for further consideration and decision making, at Ministerial level, on potential necessary public health interventions including for local and regional control of COVID-19.
- 71. PHE and subsequently UKHSA attended the NHS emergency response structure meetings. The COVID-19 National Incident Response Board was the key operational arm of this with PHE Incident Director regularly attending to provide situational and organisational updates as well as other clinical or operational leaders from PHE/NHSTT/UKHSA as required.
- 72. From 10 January 2020 when the first UK IPC guidance was published by PHE, an initial information-exchange infection prevention and control working group was set up between PHE and NHSE with daily calls. The IPC cell was more formally established on 23 January 2020 after the Wuhan Novel Coronavirus IMT meetings convened by PHE.

- 73. The IPC Cell function was to provide infection prevention and control advice and review and/or develop guidance for the NHS and NHS commissioned services. NHSE was the lead organisation and acted as the secretariat Roles were discussed on 5 February 2020 [Exhibit SH3/32 INQ000348134]. The IPC Cell Terms of Reference were not formally established until several months into the pandemic [Exhibit: SH3/33 INQ000348135] [Exhibit: SH3/34 INQ000348136] [Exhibit: SH3/35 INQ000348137].
- 74. PHE's role, alongside the other Public Health Agencies, was to provide scientific evidence and act as advisers to the IPC cell. IPC cell membership included representatives from the NHSE, four nations public health agencies (including PHE), and DHSC, with representatives from equivalent bodies in Wales and Scotland joining the calls in early February 2020. Northern Ireland followed later. The Senior Responsible Officer (SRO) for the cell was initially the Chief Nursing Officer for England who was the NHSE Head of IPC. In 2021, Public Health Wales took on Chair responsibilities.
- 75. NHSE was responsible for producing the first drafts of the IPC guidance for NHS and health services, incorporating changes and was responsible for managing the consultation process with stakeholders, as well as signing off the guidance. PHE was assigned responsibility for continued publishing of the guidance, on behalf of the Four Nations IPC cell and DHSC, on gov.uk webpage. Therefore, while the IPC guidance was published by PHE on gov.uk, the content of the guidance was the consensus of the Four Nations as coordinated by the cell and chair. This was a consensus based on the majority position of the organisations contributing and, consequently, did not always fully reflect the view from PHE officials contributing to the discussions. Further information on the IPC Cell and guidance produced is provided at Section 3.
- 76. JBC produced analysis on NHS Healthcare pressures at Regional and Trust level, including forecasts for expected admissions and bed occupancy based on syndromic surveillance data. This helped inform discussions regarding where parts of the healthcare system were under increasing pressure and helped inform Local Non

Pharmaceutical Interventions (Tiering and Local COVID-19 Alert Levels). However, the NHS held the final assessment of, and operational responsibility for, NHS capacity and their ability to scale up or down to respond to the pandemic.

77. Another area where PHE worked closely with NHSE/I was on testing. On 8 March 2020 PHE set out its current and projected future availability, capacity and speed of testing in response to a request from the Secretary of State for Health and Social Care [Exhibit: SH3/36 – INQ000119505]. As NHSTT and testing are not in scope for this module further information will be provided on this area in future modules as required.

Other Bodies

78. The table below sets out an overview of other critical bodies/organisations that PHE and UKHSA engaged with during the relevant period to support the response of healthcare systems to the COVID-19 pandemic:

Name of body/organisation	PHE/UKHSA engagement during the Covid-19 pandemic
Health Research Authority	During the pandemic PHE/UKHSA worked closely with the HRA to
(HRA)	ensure public health research had adequate and appropriate
An executive non-departmental	research governance. PHE/UKHSA submitted a number of research
public body, sponsored by the	studies for HRA approval. These included the SARS-COV2 immunity
DHSC, to protect and promote	and reinfection evaluation (SIREN) in NHS staff, HRA reference
the interests of patients and the	number 20/SC/0230 [Exhibit: SH3/37 – INQ000348138], granted on
public in health research.	20 May 2020. Further information on the study itself is provided in
	the statement in the section on UKHSA and PHE's role in the SIREN
	study at paragraphs 189-203.
National Institute for Health	PHE had a variety of interactions with NICE. For example, in the
and Care Excellence (NICE)	early phase of the response input was requested from a PHE clinical
An executive non-departmental	advisor to the NICE rapid guideline on severe asthma in March-April
public body, sponsored by the	2020.
DHSC, to provide national	In July 2020 there was a PHE representative on the review panel for
guidance and advice to improve	the NICE "COVID-19 rapid guideline: arranging planned care in
health and social care.	hospitals and diagnostic services."

In December 2020 PHE commented on the NICE/SIGN/RCGP rapid guideline for the 'Management of the long-term effects of COVID-19' (and its subsequent revision in September 2021). These comments were: utilising a more scientific term such as 'long-term effects of COVID-19' rather than 'long COVID', listing likely symptoms for recovery for consistent recording and how to proactively follow up those who had self-isolated without a test result. PHE also recommended that symptoms should refer to impacts on daily function and providing some epidemiological likely parameters of scale of need to help the NHS plan services, for example to aid prioritisation. There was no published review of how comments were incorporated into the guidance. PHE also submitted comments in September 2021 including: stating that hospitalisation was a risk factor for more severe Long COVID symptoms, guestioning the evidence base for some assertions (e.g. relationship to severity of long COVID) and confirmation about advice on vaccines to specific groups. NICE published collated stakeholder comments and responses for the September 2021 update, so it is not possible to determine exactly what was done with PHE input. However, several points appear to directly refer to PHE comments. For example, NICE responded they would change the wording about symptoms which "change unpredictably" to be replaced with "fluctuate" to clarify this point. PHE co-authored, with the Advisory Committee on Nutrition, NICE rapid guidance on the role of Vitamin D, published in December 2020.

A summary of NICE consultations on COVID-19 specific guidance that PHE/UKHSA's Healthcare Associated Infection and Antimicrobial Resistance division contributed to between 1 March 2020 to 28 June 2022 is provided [**Exhibit: SH3/38** – **INQ000348139**]. Nominated UKHSA staff, particularly those involved in antivirals, engaged with NICE. Further information on this and

	COVID-19 therapeutics will be provided as part of the response to
	Module 4.
Academy of Medical Royal	PHE had targeted communications, between March and July 2020,
Colleges (AoMRC)	on topic specific areas of mutual interest with the AoMRC in relation
Membership body for the UK and	to clinical guidance. For example, on the content of the PPE tables
Ireland's 24 medical royal	published in April 2020 [Exhibit: SH3/39 – INQ000339349], co-
colleges and faculties.	badged with PHE, AoMRC and other bodies.
	Other communications with AoMRC were on an ad hoc basis. A
	weekly call with AoMRC, Royal Colleges and Faculties facilitated by
	OCMO was regularly attended by the NHSE Medical Director, PHE
	Medical Director and UKHSA CEO and/or Chief Medical Advisor
	throughout the pandemic.
Medicines and Healthcare	PHE immunisation teams had extensive well-established governance
products Regulatory Agency	interaction with MHRA in relation to vaccine approvals, medicines
(MHRA)	legislation, vaccine safety and public communications. Further
An executive agency, sponsored	Information will be provided as part of the response to Module 4
by the DHSC, to regulate	relating to vaccines and therapeutics.
medicines, medical devices and	MHRA provided advice to the Covid-19 Testing Programme on the
blood components for transfusion	appropriate regulatory approach for swabs and vials for PCR test
in the UK.	and NHSTT obligations, as a manufacturer, in constructing these
	consumables into kits. This advice also included reviewing regulatory
	documents provided by swab and vial manufacturers to ascertain
	authenticity and quality of their processes.
	Similar advice and support were provided later in the pandemic for
	Lateral Flow Device (LFD) tests, along with the MHRA undertaking
	its regulatory role regarding the granting of an Exceptional Use
	Authorisation for the first approved self-test LFD.
Local Government Association	PHE worked collaboratively with the LGA and local authorities
(LGA)	through Regional Partnership Teams (RPTs), which were
National voice of local	established on an interim basis in May 2020 as part of the COVID-19
government, working with	surge response, working in partnership with local systems to deliver

councils to support, promote and	a strong and integrated, local, regional, and national response in
improve local government.	England. Prior to this PHE Centres already engaged directly with
	Directors of Public Health in LAs and had dedicated Health
	Protection links through the Consultants in Communicable Disease
	Control for the management of infectious disease outbreaks.
	In October 2021 UKHSA published a guide on how the new
	organisation could support national, regional and local partners to
	continue to work with each other and with the public, businesses,
	and other partners in their communities to prevent, manage and
	contain outbreaks of COVID-19 [Exhibit: SH3/40 - INQ000203625].
National Institute for Health	In early 2020, PHE began initial COVID-19 surveillance, research
and Care Research (NIHR)	and evaluation studies. Much initial activity, including COVID-19
Funded by the DHSC, its work	lateral flow device evaluation, was undertaken using internal PHE
focuses on early translational	resources, including the redeployment of existing research staff on to
research, clinical research and	COVID-19 studies. Studies undertaken in PHE in 2020 via this route
applied health and social care	included transmission (contact and household) studies; surveillance
research.	of health and care staff, children, adolescents, pregnant women and
	infants; evaluation of messaging, experiences, impact of quarantine,
	acceptability of testing and self-isolation interventions and evaluation
	of LFDs; and research on transmission (inc. sampling and aerosol
	studies), and research into rapid diagnostics.
	PHE worked to identify emerging knowledge and evidence gaps,
	which were prioritised and research questions developed. These
	were shared with the NIHR and UK Research and Innovation (UKRI)
	to inform their COVID-19 commissioning calls and direct
	commissioning to NIHR Health Protection Research Units (HPRUs).
	This process was undertaken centrally by the COVID-19 Research
	and Science cell to maintain independence and ensure that PHE
	researchers were able to apply for funding without conflict.
	PHE, and subsequently UKHSA, led and collaborated in various
	research, surveillance and evaluation studies, funded by the NIHR or
	the NIHR/MRC rapid response funding stream, in addition to

	research undertaken with the NIHR HPRUs. These included
	syndromic surveillance studies, the REal-time Assessment of
	Community Transmission (REACT), FluTEST, evaluation of
	therapies, research into link between ethnicity-comorbidity and
	severity of outcome, transmission studies and SIREN amongst
	others.
	The HPRUs, NIHR-funded partnerships between PHE (now UKHSA)
	and academia, support PHE/UKHSA to undertake research and
	generate evidence, enhancing our ability to protect the public's
	health and minimise the health impact of emergencies. HPRUs also
	address urgent research needs emerging from incidents through
	their responsive research mode. The HPRUs were highly responsive
	to the pandemic, tailoring their work programmes to carry out COVID
	research, repurposing studies to respond to the pandemic and
	undertaking commissioned research. Between 2020-2022, the
	HPRUs undertook 146 COVID studies, leading to 772 publications
	(399 in 2020/21 and 373 in 2021/22). An additional £2M of funding
	was allocated to HPRUs from NIHR to undertake responsive
	research for COVID-19.
	The NIHR Clinical Research Network (CRN) undertook regular
	prioritisation meetings reviewing all potential COVID-19 studies for
	urgent CRN portfolio adoption in COVID-19, and the SIREN study
	was part of this Urgent Public Health Portfolio in May 2020. I was a
	member of this prioritisation group from June 2020 until the urgent
	public health study portfolio was closed on 29 March 2021.
UK Accreditation Service	NHSTT worked with UKAS and the Care Quality Commission to
(UKAS)	establish a testing accreditation process to provide consistency in
The national accreditation body	approach across private testing and ensure that consumers could
for the UK, appointed by	easily identify which commercial testing services met appropriate
government, to assess	clinical standards. These standards brought the necessary
organisations that provide	assurances of quality for the provision of end-to-end testing services
	from customer registration to notification of results.
	5

certification, testing, inspection	Further information on this will be provided in the future module on
and calibration services.	testing and tracing.
UK Collaborative on	PHE joined the UKCDR Epidemics Preparedness and Response
Development Research	Group (also now as Epidemics Funders Group) as an attendee to
(UKCDR)	provide insight of emerging research needs and priorities from the
A group of government	COVID response to inform research investment. The UKCDR
departments and research	Epidemic Preparedness and Response Group's membership
funders working in international	includes Academy of Medical Sciences, Department of Health and
development.	Social Care, Foreign, Commonwealth and Development Office,
	Department for International Development, Welcome and the UKRI
	Research Councils. UKHSA continues to support this group to both
	provide updates on UKHSA research and emerging research needs,
	but also to learn of developments in the global research landscape of
	relevance to the UK and receive updates from funders in the area.
UKRI Research Councils	PHE provided relevant information to UKRI Research Councils, in
	particular the Medical Research Council, on emerging research gaps
	throughout the pandemic to inform the commissioning of research.
	As noted above, this was centrally coordinated to ensure PHE was
	able to receive research funding without any conflicts of interest
	arising.
	Research with PHE involvement funded by UKRI Councils (outside
	of the joint NIHR/MRC call) included the use of machine learning to
	analyse customer feedback of the contact tracing system, transport
	risk assessment for COVID, COVID anti N and S testing, mixed
	methods evaluation on advice on isolation and health care seeking to
	contain transmission of COVID, transmission in kids, adherence to
	and impact of self-isolation, amongst others.
Others	PHE also received funding as lead or collaborator in research from
	the Health and Safety Executive, WHO, Coalition for Epidemic
	Preparedness Innovations, Industry (for evaluation and
	assessments), Charity sector, Gates foundation, Learned Societies,

Cabinet Office, European Union, Department of Digital, Culture,
Media and Sport and the Scottish Government.

Working with UK Health Protection counterparts

- 79. Public health, health and social care are devolved functions. Health protection services are provided and/or led by public health agencies in respective nations. Officials in UKHSA and its predecessor organisations worked routinely with their counterparts in each of these agencies, as well as with those in the Devolved Administrations (DAs), as part of health protection planning and response prior to and during the UK government's response to the pandemic.
- 80. A critical part of the response to the pandemic has been the UK wide approach and high level of co-ordination between the senior health professionals across the UK, building on existing emergency response arrangements. For example, as previously mentioned, there were expert scientific advisory groups, such as SAGE convened at a UK level and drawing on UK wide expertise which provided advice to the CMOs of the four nations, a four nations response in diagnostics and surveillance, and the provision of services by NHSTT to support testing in all four nations.
- 81. At senior and official working level there was engagement to co-ordinate the response to COVID-19. The DAs national public health agency representatives attended the daily PHE IMT meetings from the outset, as well as other meetings, for example those relating to the development of contact tracing models and variant technical meetings.
- 82. The COVID-19 NTP, established by DHSC, included the DAs from its inception and this was carried over with the creation of NHSTT. This agreement was ratified in MOUs between the Secretary of State for Health and Social Care and his devolved counterparts [Exhibit: SH3/41 – INQ000203654]; [Exhibit: SH3/42 – INQ000203653]; [Exhibit: SH3/43 – INQ000203656].

- 83. A Strategic Testing Group was set up, with Terms of Reference agreed on 30 April 2020, to ensure there was a coordinated response across the DAs, Crown Dependencies and British Overseas Territories (DACDOTs) on the government's testing response, with alignment on approach, where possible, including on areas such as:
 - Supply and distribution of swab testing for critical key workers in the NHS, as well as key workers in other sectors;
 - b. Antibody testing and immunity detection;
 - c. Surveillance testing and the development of new tests and treatments;
 - d. Increasing mass testing capacity for the UK at an unprecedented scale.
- 84. This group also served as a forum to escalate, discuss and resolve high-level and/or strategic issues at a senior level across the DACDOTs on all aspects of the testing programme, as set out in the government's testing strategy [Exhibit: SH3/44 INQ000203655].
- 85. The JBC also established Ministerial, Steering and Technical Boards in line with their formal written agreements with the DAs. In August 2020, Health Ministers from the four nations agreed the document, "Participation of the Devolved Administrations in the Joint Biosecurity Centre" [Exhibit: SH3/45 INQ000203652]. This document, referred to as the JBC "Political Agreement", set out the principles that underpin a UK-wide JBC. NHSTT also fed into the agenda setting and briefing for the weekly UK Health Ministers' Forum. This was an informal arrangement with a focus on discussing shared priorities and developing strong relationships between the Ministers.
- 86. There was senior official oversight at the Test and Trace UK Government and Devolved Administrations Board (UKG-DA Board), which was set up as part of the agreement between the four health ministers that Covid-19 testing should be delivered on a UK-wide basis. This agreement was formalised in Testing MOUs [Exhibit: SH3/41 – INQ000203654]; [Exhibit: SH3/42 – INQ000203653]; [Exhibit: SH3/43 – INQ000203656] between each Devolved Government minister and the UK Secretary of State for Health and Social Care. The first Board meeting was held on 19 March

2021 chaired by NHSTT Executive Chair Dido Harding. The purpose of the UKG-DA Board was to establish senior permanent four nations governance across respective test, trace, contain and protect programmes, enabling the four governments' strategic oversight of UK-wide opportunities and issues. The initial Board's remit was to consider issues relating to COVID-19 including but not limited to testing policy and operations, contact tracing, containment, borders and international arrivals, selfisolation and support schemes.

- 87. The Board continues to operate in a revised form, as the UKHSA-DG Board, with a wider remit than COVID-19. It also provides a high-level forum for escalating any issues that arise in relation to activities UKHSA undertakes, including those on behalf of the DAs. The UKHSA-DG Board is chaired by the UKHSA Director General for Strategy, Policy and Programmes, with an 'open' opportunity/invitation to the UKHSA CEO to join for specific topics or at her own request or the request of the DAs. It is attended by representatives from each of the DAs and their public health agencies. The Terms of Reference are exhibited here: [Exhibit: SH3/46 –INQ000203648].
- 88. PHE also built on the extant arrangements in place with the Five Nations group (a forum for discussion, debate and collaboration between partners in England, Scotland, Wales, Northern Ireland and the Republic of Ireland) and from March 2020, PHE convened the Five Nations Health and Justice COVID-19 Contact Group meeting on a weekly and then monthly basis. These meetings covered country-specific and general situational updates. With the establishment of UKHSA a new operating model was introduced with UKHSA chairing a health protection focused group of five nations colleagues. The Terms of Reference are exhibited here [Exhibit: SH3/47 INQ000348141].
- 89. As a consequence of leaving the European Union the UK government established the UK Health Security (EU Exit) Regulations 2021. This was to ensure continuation of collaboration on health security matters within the UK and between the four countries. The Regulations established the UK Health Protection Committee (UK HPC) as the statutory body to oversee, strategically, the strengthening of UK health security. The

Public Health Protection and Health Security Framework-outline-agreement (commonly known as the 'Common Framework'), exhibited here [Exhibit: SH3/48 – INQ000106904] contains the Terms of Reference at Annex C of the document.

- 90. This formed part of a programme of work overseen by the Cabinet Office on the development of Common Frameworks on key strategic issues facing the UK. The Common Framework was agreed between all four governments and public health agencies. The Common Framework operationalises the Regulations and, to support the UK HPC, it also established the UK Health Protection Oversight Group (which is now called the Four Nations Health Protection Oversight Group (HPOG). The Terms of Reference can be found in Annex D of the Common Framework document [Exhibit: SH3/48 INQ000106904]
- 91. Membership of both groups includes representation from UK governments and agencies. The Four Nations HPOG first met in April 2021. Exhibited here is the agenda for this meeting [Exhibit: SH3/49 – INQ000348143]. The first UK HPC met in September 2021.
- 92. The HPOG and the UKHSA DG Board now work together to ensure there is strong continuity between their different agendas.

Working with UK Health Protection counterparts on testing, guidance and epidemiology data

- 93. An important aspect of delivering the testing programme UK-wide was working as equal partners with the DAs, as was the routine for smaller scale cross UK border infectious disease outbreak management. A UK-wide approach was agreed to be the most effective way to manage the epidemiological and response arrangements to break the chains of transmission.
- 94. Key elements delivered by NHSTT, on a national level, included procurement and distribution of tests (both polymerase chain reaction (PCR) and LFDs) to essential

workers (including health and social care workers), other priority and targeted groups, and the public; and providing administrative and digital infrastructure for individuals to book tests and receive test results. It did not deliver testing within hospitals or healthcare facilities as this remained the responsibility of the NHS or the private health services.

- 95. At the outset of the programme, the four nations' CMOs made a joint agreement that testing capacity would be allocated across the four nations, based on population size. LFDs were allocated to DAs at the point of procurement based on population shares for each nation to use based on their individual policy decisions. If required, DAs could request additional procurement beyond their agreed allocated percentage. Decisions on who to test in hospitals was devolved to each health administration.
- 96. Contact tracing and outbreak management were undertaken on a devolved basis, but with strong communication links across the four nations to co-ordinate approaches as far as possible.
- 97. PHE participated in regular stakeholder engagement meetings with the DAs to share information, guidance, and public health advice throughout the pandemic.
- 98. As mentioned at paragraphs 72 to 75, PHE was the publisher for guidance, standards and consensus statements developed by the Four Nations IPC cell, which sat within NHSE. The cell included representation from PHE as well as the Public Health Agencies from the DAs.
- 99. By March 2020 there were regular meetings of the Clinical Guidance Cell, an internal PHE incident Cell reporting to the PHE Incident Director, to discuss guidance issues across the DAs. For any arising issues there were often bilateral discussions with DAs on rationale and scope of guidance and approach. This was later discontinued and replaced by direct consultation on specific pieces of guidance.

- 100. The role of the JBC is set out at paragraph 37. The JBC provided data and insight about COVID-19 across all four nations of the UK and worked collaboratively with DAs. The previously mentioned JBC Ministerial Board, enabled ministers from all four nations to contribute to JBC oversight, and was supported by a JBC Technical Board that included the four CMOs established to ensure JBC products were of sufficient clinical and scientific rigour. [Exhibit: SH3/50 - INQ000203662].
- 101. The Epidemiology Modelling Review Group (EMRG), originally established in the JBC, is a UKHSA Deputy Director led group of internal and external experts which reviews model outputs, their combination and provides a consensus view for publication. The outputs include estimates of key metrics for different geographies within the UK and are published by the four nations. Following the group's move to UKHSA, consensus statements from this group have been published every two weeks with data and publication quality control clearance through UKHSA [Exhibit: SH3/51 INQ000223965].

SECTION 2: Understanding of Covid-19

102. In this section I set out PHE's and UKHSA's understanding of the nature and spread of Covid-19 at the start of March 2020, and how PHE and UKHSA's understanding of COVID-19 changed during the relevant period in relation to: modes of transmission, including aerosol and contact; asymptomatic transmission; the infectiousness of the disease; the possibility of re-infection; variants; the possibility of risks to workers in healthcare settings and the SIREN study. In relation to healthcare workers this section focuses on the specific risks outlined for this module.

PHE's Initial Understanding of Covid-19

103. On 31 December 2019, the on-duty epidemiologist in the PHE's Epidemic Intelligence team identified a report from the Wuhan Municipal Health Commission of a cluster of viral pneumonia of unknown aetiology (cause) in Wuhan City, Hubei Province of China [Exhibit: SH3/52 – INQ000119663]. Information received from WHO on 5 January 2020 reported 44 patients with pneumonia of unknown cause detected in Wuhan City, of whom 11 were severely ill, and that there was no significant evidence of human-human transmission and no HCW infections reported [Exhibit: SH3/53 – INQ000101191].

- 104. Information received from WHO on 12 January 2020 confirmed that the virus was a novel coronavirus and noted the clinical signs and symptoms reported were mainly fever and, in some instances, difficulty breathing [Exhibit: SH3/54 INQ000183385]
 By 21 January 2020, evidence of human-human transmission was emerging [Exhibit: SH3/55 INQ000101205] and WHO confirmed human-human transmission had been identified the following day. Initial symptoms were now being described as "mostly fever, cough or chest tightness and dyspnoea." [Exhibit: SH3/56 INQ00047820] [Exhibit: SH3/57 INQ000223327].
- 105. Throughout January and early February 2020 PHE worked extensively to provide advice, epidemiological updates, introduce enhanced surveillance monitoring and undertake diagnostic work. This included, but is not limited to, providing updates to NERVTAG and SAGE, the introduction of enhanced monitoring for direct flights to England from affected areas and the provision of regular updates to Ministers on the progress of contact tracing of recent returners from Wuhan. In addition, PHE worked with international collaborators to develop a specific PCR test to detect this novel coronavirus.
- 106. At the SAGE meeting on 27 February 2020, COVID-19 planning assumptions, based on SAGE's conclusions on the characteristics of the virus and transmission factors known at the time, suggested that without any mitigations, the peak of a UK epidemic would likely occur two to three months after sustained human-to-human community transmission was evident within the UK population. [Exhibit: SH3/57a INQ000074896] [Exhibit: SH3/57b INQ000106129]. The SAGE planning assumptions were based on the following assumptions regarding the characteristics of the virus and transmission factors:

- a. "Incubation period (Time between exposure to infection and symptom onset).
 Range remains 1 to 14 days, with average of 4-5 days.
- b. Duration of illness From symptom onset to hospitalisation: average of 7 days. From onset of illness to discharge from hospital: average of 23 days but may include avoidable delay in discharge. From onset of illness to death: average of 22 days for severe cases, but large variation around this. Longest time so far appears to be 41 days.
- c. Duration of infectivity likely to vary depending on severity of individual cases. 14 days as upper limit. Peak infectivity is probably around the start of symptom onset, average 2-6 days, then falling off rapidly.
- d. Transmission Current understanding is that the transmission route is respiratory and via contact. This means that viruses are transmitted via touching an infected person and spray of droplets such as coughing and sneezing. Human-to-human transmission outside China has occurred but there is as yet no definitive evidence of a sustained outbreak/epidemic elsewhere. Asymptomatic transmission cannot be ruled out and transmission from mildly symptomatic individuals is likely."

The first person recorded in the UK as infected with the virus but with no known international links, therefore suggesting community transmission was occurring, was on 28 February 2020.

How PHE obtained understanding

- 107. PHE's understanding about COVID-19 from December 2019 up to March 2020 is detailed more fully in section 3 of UKHSA's corporate statement for Module 2. The excerpt from that statement is provided for information at the end of Section two of this statement from paragraph 207 onwards.
- 108. This changing understanding was reflected in the advice and guidance PHE and UKHSA provided, as detailed in Section 3 of this statement.

WHO and International Intelligence

109. Particularly in the early stages of the pandemic, information on the virus was received from WHO, other international organisations and Ministries of Health and from official government sources in additional countries for example through travel links with FCDO. Following the first official reports, initial information about the pathogen came from China and other countries that experienced early imported cases, including the identification of the causative pathogen as a Beta coronavirus. This included some open-source information on cases, fatalities, recoveries, testing and hospitalisations, as well as restricted information. For example, WHO shared restricted information about the situation in Wuhan including Event Information Site (EIS) postings (which are restricted access information) with countries' National Focal Points (NFPs). Key information from the EIS posting shared on 5 and 12 January 2020 was later published as a public-facing Disease Outbreak News (DON) by WHO, exhibited here [Exhibit: SH3/53 – INQ000101191] [Exhibit SH3/54 – INQ000183385]. WHO also shared information between countries' NFPs.

Prior knowledge and similar viruses

110. Before robust data on SARS-CoV-2 itself became available, prior experience and knowledge from PHE and global experts about these related pathogens guided early understanding. For example, prior knowledge was incorporated into early estimates of the incubation period, which was known to be longer for coronaviruses than influenza, and of the potential for reinfections due to prior observations of waning immunity to seasonal coronaviruses.

Genomic Sequencing

111. Chinese scientists rapidly performed laboratory-based characterisation and sequencing of the pathogen from clinical samples. They first published the genome on 10 January 2020. Comparison of genome sequences with other known human pathogens demonstrated that SARS-CoV-1 was the closest related human pathogen, with around 80% genomic similarity to SARS-CoV-2. It was known that SARS-CoV-1 (commonly referred to as 'SARS') caused severe human infections.

- 112. Early recognition and detection of cases was important in supporting further research into SARS-CoV-2. After the first case was confirmed in the UK on 31 January 2020, the virus was cultured and sequenced by PHE experts within days and shared with academic partners on the Global Initiative for Sharing All Influenza Data (GISAID) website and database on 3 February 2020, enabling early virological work and supporting wider research to develop global understanding of the pathogen. With the availability of further data on the virus over the subsequent three to four months, a number of features of SARS-CoV-2 were identified as being different from SARS-CoV-1, such as in its pre-symptomatic infectiousness, levels of asymptomatic or subclinical infections and the severity of illness.
- 113. A high proportion of early cases underwent genomic analysis, which contributed to understanding viral diversity and virus evolution at this very early stage of the pandemic. This early work demonstrated the close relatedness of circulating viral strains. With little evidence of significant biological variation, sequences were used to investigate tracking chains of transmission to monitor any signals of significant virus adaptation to humans.
- 114. Meetings with the academic community were convened by the PHE Director of the National Infection Service, Professor Sharon Peacock, to agree the best way of harnessing UK academic sequencing capacity. These meetings led to the creation of the COVID-19 Genomics UK Consortium (COG-UK) in March 2020. COG-UK was established to link the public health agencies and the NHS with academic partners to develop a network of laboratories to rapidly collect, sequence and analyse genomes of SARS-CoV-2. Mass sequencing capability evolved with expansion in testing capacity.
- 115. COG-UK was a partnership of NHS organisations, the four Public Health Agencies of the UK, the Wellcome Sanger Institute and more than 12 academic institutions providing sequencing and analysis capacity. It was led by Professor Sharon Peacock who at the time was Director of the NIS. COG-UK also drew in

academic partners to develop core analysis tools on the Cloud Infrastructure for Microbial Bioinformatics.

116. COG-UK was initially funded by UK Research and Innovation (UKRI) and the Wellcome Trust and additional funding was obtained from October 2020, from NHS Test and Trace. PHE and NHS Test and Trace requested additional funding to enhance capacity and capabilities from DHSC in January 2021. In April 2021 NHSTT, and later UKHSA working with the devolved administrations contributed additional funding to extend COG-UK's sequencing output, as well as coordination of sequencing and analysis of SARS-CoV-2 genomic data for the public health response to increase the capacity for genome sequencing, improve the speed of data flows, and to continue to support and develop variant surveillance functions. The role of COG-UK is further discussed at paragraph 143.

Surveillance

- 117. At the outset of the pandemic PHE had an existing network of surveillance systems, reflecting its role to undertake surveillance of infectious diseases, as set out in the remit letter for 2019/2020 [Exhibit: SH3/58 INQ000090336]. As the likelihood of Covid-19 cases being identified in the UK increased, PHE adapted and increased the frequency of reporting of the extant surveillance systems. This included community surveillance initiatives, such as monitoring of respiratory outbreaks in certain settings, internet-based surveillance, and syndromic surveillance of NHS 111 calls reporting respiratory symptoms. PHE also undertook surveillance of primary and secondary care settings, collecting data on rates of respiratory illness. PHE undertook microbiological surveillance via testing of all suspected Covid-19 cases and seroprevalence sampling. Surveillance of excess all-cause mortality statistics on a weekly basis also helped provide a metric to help ascertain case numbers.
- 118. PHE also set up a number of new, COVID-19-specific surveillance studies during the period from January to March 2020. These included expanded sentinel GP sampling (sampling of selected population samples chosen to represent relevant

experience of particular groups) and testing patients with respiratory illness who were in critical care but who did not meet the case definition for COVID-19 at the time. This was to assess levels of community transmission in the Severe COVID-19 Enhanced Reporting study, which was replaced by the COVID-19 Hospitalisations in England Surveillance System (CHESS) in March 2020. These studies provided data to discern the rate of SARS-CoV-2 infection in the UK and how the virus was spreading and thus developed our understanding of the virus. From late February/early March 2020, in the context of reduced face-to-face contacts between patients and GP practice staff, selfswabbing kits were introduced to the primary care surveillance system with the aim to maintain the levels of data collected [**Exhibit: SH3/59 - INQ000120321**].

- 119. PHE's primary source of detailed epidemiological information on cases during the first few months after the first UK case was identified was through its enhanced surveillance of the first few hundred ("FF100" or "FFX") cases and their contacts. The FF100 is an established enhanced surveillance system designed to investigate the clinical and epidemiological characteristics of at least the first one hundred confirmed cases of an emerging infectious disease and their close contacts. In January 2020, as cases began to appear in the UK, the FF100 enhanced surveillance protocol was commissioned by PHE. The Protocol is exhibited here [Exhibit: SH3/60 INQ000061497].
- 120. Data from the FF 100 was continuously reviewed as it accrued but the first full analysis of virologically confirmed cases up to 09 April 2020 was shared with the Scientific Pandemic Influenza Group on Modelling (SPI-M-O) on 27 April and was later published online on 30 November 2020. This provided an insight into clinical presentation of the first 381 cases from 31 January to 9 April 2020: "Approximately half of the COVID-19 cases were imported (196 cases; 51.4%), of whom the majority had recent travel to Italy (140 cases; 71.4%). Of the 94 (24.7%) secondary cases, almost all reported close contact with a confirmed case (93 cases; 98.9%), many through household contact (37 cases; 39.8%). By age, a lower proportion of children had COVID-19. Most cases presented with cough, fever and fatigue. The sensitivity and specificity of symptoms varied by age, with nonlinear relationships with age.

Although the proportion of COVID-19 cases with fever increased with age, for those with other respiratory infections the occurrence of fever decreased with age. The occurrence of shortness of breath also increased with age in a greater proportion of COVID-19 cases." [Exhibit: SH3/61 - INQ000061503].

Evidence Reviews

121. PHE, and subsequently UKHSA, also undertook evidence reviews on a range of issues. These helped to inform PHE and UKHSA's advice and guidance as the pandemic progressed. Thirty seven evidence reviews were undertaken, beginning in May 2020, of which four had direct relevance to healthcare settings. These are as follows: "Rapid evidence review for Temperature screening for reducing transmission of SARS-Cov-2" dated the 1 June 2020 [Exhibit: SH3/62 – INQ000348255]; The role of face coverings in mitigating the transmission of SARS-CoV-2 published October 2021 [Exhibit: SH3/63 – INQ000348256];COVID-19 transmission from the deceased published July 2021 [Exhibit: SH3/64 – INQ000348257]; and an update on COVID-19 transmission from the deceased published February 2022 [Exhibit: SH3/65 – INQ000348258].

Understanding of the Virus's Characteristics and how this Developed over the Pandemic

122. The text below shows the evolution of PHE and subsequently UKHSA's understanding of particular characteristics of the virus over the course of the pandemic. From December 2020, changes in understanding increasingly related to new variants which were in circulation. Knowledge about the virus's severity and mortality risk is discussed later at section 6 of this statement.

Modes of Transmission, including asymptomatic, aerosol and contact

Early 2020	At the outset of the pandemic PHE used knowledge of other genetically similar
	viruses to identify likely routes of transmission. As a respiratory virus SARS-
	CoV-2 carried the potential for transmission via respiratory routes such as

	droplets and aerosols, direct physical contact, and indirect contact through
	contaminated surfaces or fomites. While there was a high degree of uncertainty
	about the exact mode of transmission, knowledge from genetically similar
	viruses and other respiratory infections with similar Ro [~2, that was reported
	from China] pointed to droplet transmission as the predominant route. For
	example, measles which has documented aerosol transmission was a Ro of
	15-20. However, the predominant route does not exclude other routes as
	potential modes but provides a focus to consider priority infection prevention
	and control measures. Early pandemic research into public activities which
	preceded the onset of other acute respiratory infections, sought to understand
	their relative importance for transmission and suggested a role of both
	respiratory and indirect routes of transmission and the impact of social
	distancing measures [Exhibit: SH3/66 INQ000410869 Systematic reviews
	prior to the pandemic showed that regular handwashing can reduce incidence
	of respiratory infections, implying a possible role for direct contact and/or
	fomite-based transmission [Exhibit: SH3/67 – INQ000348259].
28 January	PHE drafted a paper titled "are asymptomatic people with 2019nCoV
2020	infectious?" which assessed the current evidence for asymptomatic
	transmission of 2019nCoV (subsequently known as SARS-CoV-2) and
	compared this to what was understood of viral shedding and asymptomatic
	transmission in the closest known genetically related virus, SARS-CoV in
	humans. This paper was submitted to SAGE and discussed at the SAGE
	meeting on 4 February detailed below. [Exhibit: SH3/68 – INQ000074909].
	The paper sought to consider what proportion of transmission might come
	from asymptomatic individuals. The importance of potential asymptomatic
	infection was considered using the analogy with other respiratory viruses
	(influenza) and the conceptual framework of the mathematical relationship
	between disease control and proportion of asymptomatic infection.
	However, while individuals could have asymptomatic infection, the likelihood of
	asymptomatic individuals transmitting infection to others was assessed as
	low. This is demonstrated in the paper by the inclusion of the analogy of

	respiratory viruses, which outlines the relationship between control of virus
	transmission, the amount of asymptomatic transmission and the summary of
	early case reports for SARS-CoV-2. The paper concluded, "the currently
	available data is not adequate to provide evidence for major
	asymptomatic/subclinical transmission of 2019nCoV. Detailed
	epidemiological information from more cases and contacts is needed to
	determine whether transmission can occur from asymptomatic individuals or
	during the incubation period on a significant scale." The paper argued that it
	would be reasonable to assume that the early stages of illness may have
	lower viral load. It also noted that the current available data was not adequate
	to provide evidence for major asymptomatic or sub-clinical transmission.
3 February	PHE presented a paper to NERVTAG [Exhibit: SH3/69 – INQ000119615
2020	summarising the scientific literature regarding the survival of coronaviruses in
	the air and on surfaces. PHE used available data from both SARS and MERS
	to extrapolate for COVID-19. It concluded "the infection risk from the virus in
	the environment will decline with increasing time of exposure and PHE has
	estimated that at 48 hours the amount of virus within the environment would be
	significantly reduced to the point of acceptable risk from environmental and
	fomite transmission. After 5 days, PHE has judged that the risk would be
	almost negligible or absent and therefore decontamination would not
	necessarily be required, and general cleaning procedures would be
	acceptable." [Exhibit SH3/70 – INQ000348261].
3 February	PHE contributed to a SPI-M-O paper, 'Consensus view on the impact of
2020	possible interventions to delay the spread of a UK outbreak of 2019-nCov-3'.
	[Exhibit: SH3/71 – INQ000213043 On 4 and 13 February 2020 the paper
	was discussed at SAGE. At this stage, whilst some airborne viral transmission
	could be predicted, the relative importance of asymptomatic to symptomatic
	transmission, or of respiratory to touch modes of transmission, could not be
	assessed with precision so early in the pandemic. On the best available
	evidence and expert opinion, the paper concluded that a combination of
	voluntary home isolation of those with respiratory symptoms and school

	closures would likely have an impact in reducing the spread of the virus,
	although this would depend on timing of these interventions.
4 February	The PHE paper on asymptomatic transmission [Exhibit: SH3/68 –
2020	INQ000074909] exhibited above in the entry for 28 January 2020) was
	discussed at SAGE. It was concluded in the minutes that "asymptomatic
	transmission cannot be ruled out and transmission from mildly symptomatic
	individuals is likely". [Exhibit: SH3/72 – INQ000051925
24 February	A paper by the PHE NIS presented to SAGE a series of scenarios and
2020	proposals for contain and delay, had the underlying assumption:
	"Asymptomatic infection is now well documented, but there is very limited
	evidence of transmission from asymptomatic cases. It is assumed that the
	substantial majority of transmission is from symptomatic individuals with SARS-
	CoV-2" [Exhibit: SH3/73 – INQ000325224]. This statement was based on
	case studies and evidence shared from national organisations, pre-prints and
	the WHO. This paper considered risks to healthcare workers and outlined ways
	to contain outbreaks or to slow the spread of the virus.
	Throughout this period PHE continued to update the paper "are asymptomatic
	people with SARS-CoV-2 infectious?" to reflect the latest evidence. [Exhibit:
	SH3/74 – INQ000348264]. On 24 February a revised draft was produced
	[Exhibit: SH3/74 - INQ000348264] which noted, "the presentation of a large
	proportion of COVID-19 cases is of mild illness and minimal symptomatology"
	but that "asymptomatic infections with SARS-CoV-2 have also been reported"
	in case reports and anecdotal records. The paper continued, "the currently
	available data remains inadequate to provide evidence for major pre-
	symptomatic / asymptomatic transmission of SARS-CoV-2. Major uncertainties
	remain in assessing the influence of pre-symptomatic transmission on the
	overall transmission dynamics of the pandemic." It reiterated that detailed
	epidemiological information from more cases and contacts was needed, and
	the report would be updated as more evidence became available. On this
	basis, PHE contacted individuals in contact with a case from 2 days prior to
	symptom onset to the date the contact tracing occurred, to provide them with

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	information on isolating and symptoms and contacted them daily to assess for
	symptoms.
28 February	The WHO-China Joint Mission published its report on COVID-19 which used
2020	findings from studies, outbreak analyses, and published literature to make
	recommendations for both China and the international community [Exhibit:
	SH3/76 – INQ000218368]. The report concluded that SARS-CoV-2 was likely
	to be primarily transmitted through respiratory droplets during close
	unprotected contact, and by fomites. The report stated there was not sufficient
	evidence to suggest that SARS-CoV-2 was airborne, but that it was possible
	that aerosol generating procedures ("AGPs") in healthcare could cause
	transmission in this way.
3 March	A PHE team visited the Royal Free Hospital HCID and sampled the air around
2020	COVID-19 patients. Between 3 March 2020 and 12 May 2020, the study team
	visited eight hospitals (three on more than one occasion) and undertook
	environmental sampling in areas where patients infected with SARS-CoV-2
	were receiving care. These included 11 negative pressure isolation rooms, 11
	neutral pressure side rooms, six Intensive Care Unit (ICU/high-dependency
	unit (HDU) open cohorts and 12 non-ICU cohort bays. Results of the early
	investigations were verbally reported by PHE to NERVTAG on 27 March. The
	main points reported were: 80 surface and 28 air samples were taken; 7.5%
	positive from environmental swabs from surfaces and all air samples were
	negative. It was noted that CT values were high, suggesting low levels of virus
	[Exhibit: SH3/77 – INQ000348266]. In this study, SARS-CoV-2 RNA was
	detected in 4 (7.3%) of 55 air samples collected using a Coriolis μ air sampler.
	Virus isolation was performed on all positive surface samples where there was
	a PCR positive test with a cycle threshold (Ct) value of less than 34 [a similar
	cut off is used for isolates from humans due to laboratory assessment of the
	assays]. No cytopathic effects or decrease in Ct values across the course of
	three serial passages were observed, suggesting that the samples did not
	contain infectious virus. The paper concluded, "effective cleaning can reduce
	the risk of fomite (contact) transmission, but some surface types may facilitate

	the survival, persistence and/or dispersal of SARS-CoV-2" and "the presence
	of low or undetectable concentrations of viral RNA in the air supports current
	guidance on the use of specific PPE for aerosol-generating and non-aerosol-
	generating procedures". The early evidence from this study formed part of the
	evidence to use PPE [which included fluid resistant surgical face masks for
	general use and FFP3 for aerosol generating procedures and in areas
	considered higher risk of virus aerosolisation] more widely in health and care
	settings that was published on 2 April 2020. All results were shared with
	hospitals and SAGE-EMG through 2020 and the complete study was published
	as a preprint and in the Journal of Hospital Infection.
10 March	SAGE discussed a paper to which PHE data professionals contributed,
2020	drawing on early clinical evidence, which suggested that the clinical course of
	COVID-19 infection in younger children was milder than adults, and noting
	reports of asymptomatic infection in children, which was consistent with the
	emerging evidence. [Exhibit: SH3/78 – INQ000119702].
20 March	NERVTAG noted that, whilst there was data for people testing positive for
2020	SARS-CoV-2 without symptoms, there was very little information regarding
	transmission, and the data from reported cases of asymptomatic transmission
	was not sufficient to provide conclusive evidence at that time [Exhibit: SH3/79
	– INQ000119619
27 March	The US Centre for Disease Control and Prevention ("CDC"), published an early
2020	release of a very significant study on outbreaks in care homes in Washington
	[Exhibit: SH3/80 – INQ000348269]. This was the first reference to evidence of
	asymptomatic and pre-symptomatic transmission of the virus. The study
	concluded, "although these findings do not quantify the relative contributions of
	asymptomatic or pre symptomatic residents to SARS-CoV-2 transmission in
	facility A, they suggest that these residents have the potential for substantial
	viral shedding." The final version of the study was published on 3 April 2020.
29 March	The WHO published a briefing on modes of transmission which also concluded
2020	COVID-19 was primarily transmitted through respiratory droplets and contact

reported [Exhibit: SH3/81 INQ000300534] 1 April 2020 PHE updated its paper on evidence of asymptomatic transmission, now titled "are asymptomatic people with COVID-19 infectious?" [Exhibit: SH3/82 - INQ000348271]. It found that "overall, available evidence to date", including the CDC study in care homes, "suggests the possibility that some asymptomatic/presymptomatic transmission is occurring. However, whether this is occurring on a significant scale and how it contributes to the overall transmission dynamics of the pandemic, remains uncertain." It added, "detailed epidemiological and virological studies from cases and contacts, which combine viral genomic analysis and serological data would provide the best evidence that transmission can occur from asymptomatic individuals or during the incubation period." 2 April 2020 WHO said that there were "few reports of laboratory-confirmed cases who are truly asymptomatic, and to date, there has been no documented asymptomatic transmission". WHO reported the presence of pre-symptomatic spread in a small number of case reports and studies [Exhibit: SH3/83 [INQ000074864] 3 April 2020 NERVTAG discussed emergence of evidence around airborne transmission [Exhibit: SH3/84 [INQ000220209] and it was agreed further analysis of data would be undertaken. 8 April 2020 A briefing note was published by London School of Economics and Political Science (LSE), citing the pre-print of the Wei et al (2020) study below, on pre- symptomatic transmission and the CDC papers discussed above [Exhibit: SH3/85 - INQ000325331]. This referenced the growing asymptomatic transmission evidence base. 10 April A further study was published by the CDC, by Wei et al, 2020 (published as an early release on 1 April). The stu		routes, and that airborne transmission was possible through AGPs but not
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	base [Exhibit: SH3/86 – INQ000325253]; [Exhibit: SH3/87 –
	INQ000348274].
9-13 April	PHE identified testing capacity at Colindale Laboratory in London to allocate
2020	tests to a care homes study, referred to as the "Easter 6 Study". This was a
	PCR testing and whole genome sequencing study in 6 care homes. This study
	was the first to undertake this type of genomic sequencing study, which went
	significantly further than the research published by the CDC, studying both
	care settings with known outbreaks, those with no known cases and performing
	whole genomic sequencing. The purpose was to understand better the
	transmission of the virus in care homes and inform urgent public health
	interventions.
	As part of these studies PHE assessed SARS-CoV-2 positivity in residents and
	staff in six London care homes reporting suspected COVID-19 outbreaks
	during April 2020 and followed them daily for two weeks. [Exhibit: SH3/88 –
	INQ000089681]. The resulting data found that 44.9% of the residents and staff
	tested had COVID-19 but were asymptomatic. It was the largest international
	dataset and strongest evidence to date showing that it was likely that the virus
	was being transmitted asymptomatically and that staff played a key role as a
	vector of asymptomatic transmission.
	The available data was analysed and preliminary findings shared with the UK
	SCG and DHSC as soon as these were available, in the week commencing 13
	April 2020. [Exhibit: SH3/89 – INQ000348275], email [Exhibit: SH3/90 –
	INQ000348281 and SH3/90 A & B INQ000089658 and INQ000089659 , email
	[Exhibit: SH3/91 – INQ000348284 and SH3/91A INQ000325267 , email
	[Exhibit: SH3/92 – INQ000120155], report [Exhibit: SH3/93 –
	INQ000348289], related timeline.
	Similar studies seeking to explore asymptomatic infection were also underway
	during this period, with further studies conducted in a military barracks (440
	individuals) – see entry below for April 2020 for further information relating to
	this study, as well as screening of 5000 individuals across 11 hospitals
	[Exhibit: SH3/93a - INQ000398927] [Exhibit: SH3/93b - INQ000398933]
	[Exhibit: SH3/93c - INQ000398935].These findings are discussed in the entry
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	for 12 May 2020 on this table [Exhibit: CH2/102 INO000240150] and
	for 12 May 2020 on this table [Exhibit: SH3/103 - INQ000348150] and
	captured in the attached exhibit [Exhibit: SH3/93d - INQ000398929].
13 April	The paper [Exhibit: SH3/94 - INQ000213186 SPI-M-O stated that
2020	"other scientific information is critical for greater accuracy to be possible
	Without large-scale population level serology surveys, it is impossible to
	improve current estimates of the proportion of the UK who have been infected,
	and those that are immune. This is urgently required as it is a key source of
	uncertainty for current modelling".
14 April	The Environment and Modelling Group (EMG) which included individual
2020	experts from PHE, provided a paper to SAGE summarising evidence about the
	dispersal and environmental spread of pathogens relevant to COVID-19. The
	paper noted there was limited conclusive evidence as to where transmission
	takes place, but a study from China had suggested the majority takes place
	indoors [Exhibit: SH3/95 – INQ000189678]. The paper identified the potential
	for aerosol transmission but noted the evidence was not yet clear. The EMG
	was established to bring together a range of scientific experts to monitor best
	available evidence on transmission routes, in particular the growing evidence
	for the significant role of aerosol transmission. [Exhibit: SH3/96 -
	INQ000181693].
April 2020	PHE undertook a cross sectional investigation of a COVID-19 outbreak at a
	London Army Barracks early in the pandemic. The key finding was that high
	rates of asymptomatic SARS-CoV-2 infection were identified. They concluded
	that "Public Health control measures can mitigate spread but virus re-
	introduction from asymptomatic individuals remains a risk. Most seropositive
	individuals had neutralising antibodies and infectious virus was not recovered
	from anyone with neutralising antibodies." This outbreak setting emphasised
	the transmission potential in closed settings. [Exhibit: SH3/97 –
	INQ000348291].
24 April	Interim results and analysis from the enhanced care home outbreak study, the
2020	Easter 6 study and the Barracks study (referenced above), were presented at
	NERVTAG and further analysis presented to SAGE on 12 May 2020 [Exhibit:

	SH3/98 – INQ000120161 ; [Exhibit: SH3/99 – INQ000061543]. NERVTAG
	noted the evidence of the presence of virus was found in individuals without
	symptoms. NERVTAG concluded that there remained uncertainty around the
	level of transmissibility of asymptomatic cases and around cases that were
	truly asymptomatic as distinct from pre-symptomatic or mildly symptomatic.
	However, scientific advisors recommended that steps should nonetheless be
	taken to protect vulnerable individuals in care settings from asymptomatic
	transmission.
	This new evidence was an important milestone in our understanding of SARS-
	CoV and, in respect of the social care sector, this highlighted that staff and
	residents could be asymptomatic and potentially transmit infection. The
	evidence from emerging international and national studies was presented to
	Government and informed understanding on risk in care settings and updated
	policy recommendations in April 2020. These outbreak settings, taken
	together, emphasised the transmission potential in closed settings.
30 April	PHE produced an options paper for NERVTAG on the management of
2020	asymptomatic residents and staff in care homes. Email [Exhibit: SH3/101 -
	INQ000348145 and ^{SH3/101A, B} INQ000348146, INQ000348147 and
	INQ000089693 . The preliminary findings having been previously shared with
	UK-SCG and DHSC, as set out in the 9-13 April 2020 entry above. This
	followed a proposal from DHSC to rollout regular screening of all residents and
	staff in care homes, regardless of symptoms. It noted "early investigation has
	shown one third of staff and patients who test positive for SARS-CoV-2 are
	asymptomatic at the time of screening. Their infectiousness and role in
	transmission is unclear and such individuals are being followed to identify the
	percentage that are pre-symptomatic, pauci-symptomatic, or asymptomatic." It
	asked, "based on their knowledge of asymptomatic infection, pre-symptomatic
	and post-symptomatic detection of SARS-CoV2, does NERVTAG consider that
	there is a risk of transmission from asymptomatic individuals identified on PCR
	testing, through screening approaches as described in this paper?" This paper
	was discussed at the NERVTAG meeting on 1 May 2020, where it was agreed
	"PCR-positive asymptomatic individuals may be infectious; but the level of
	Tory positive asymptomatic marviadas may be intected, but the level of

	infectiousness compared to symptomatic individuals is uncertain" [Exhibit:
	SH3/102 – INQ000220211 and that PCR-positive staff should not provide care
	or have contact with susceptible vulnerable individuals.
12 May	PHE produced a paper for NERVTAG comparing studies of asymptomatic
	healthcare worker (HCW) testing in order to ascertain rates of COVID-19 in
	healthcare workers and patients [Exhibit: SH3/103 – INQ000348150]; and
	related email [Exhibit: SH3/104 – INQ000348151]. The paper provided a
	comparison table of HCW surveillance studies for NERVTAG based on known
	studies being recruited into. Seven studies were available. This included PHE's
	study, published rapidly in June 2020 [Exhibit: SH3/205 – INQ000348228].
	(The other studies at the time of the PHE paper being drafted (20 April 2020)
	had preliminary or unpublished results on the proportion of asymptomatic (2%
	PHE (from 207 staff), 2% SAFER (from 147 staff), 3% Cambridge (from 1,032
	staff), 16% Hospital for Neurodisability (from 12 staff), 21% Royal Devon &
	Exeter (from 120 staff), 1.5% Barts (from 396 staff)). Several studies (including
	the PHE study) included detailed exposure history on past symptoms (not just
	current symptoms) allowing for an estimation of those who may test positive
	from a recovered past illness. Those who tested positive and were
	asymptomatic but had previous compatible symptoms included 80% from the
	PHE study and 73% from the Barts study. In summary this suggested that
	asymptomatic test positivity of healthcare workers was possible, with most
	large studies coalescing from preliminary data around the 2% rate in April
	2020, and that approximately three quarters of this could be explained by
	residual PCR positivity from past infection.
	In February 2021, the COVID-19 Rapid Evidence Service (RES) received a
	commission via the Face Coverings Policy Group to review the evidence on
	long-distance (>2 metres) airborne transmission of SARS-CoV-2 in indoor
	community (non-healthcare) settings. Preliminary results of this review were
	presented to the UK IPC cell on the 10 November 2021, and the final rapid
	review (with searches updated in January 2022) was published in the BMJ
	[Exhibit: SH3/124 – INQ000348164].

	Of the 22 reports included in this rapid review, 2 reported on the outbreak at
	the Skagit Country choir practice (the initial report in MMWR by Hamner et al
	May 2020, [Exhibit: SH3/104a - INQ000347505], and a paper by Miller et al
	September 2020 [Exhibit: SH3/104b - INQ000408917]). PHE assessed this
	outbreak investigation as being of low methodological quality (using the Quality
	Criteria Checklist) and concluded that, as other transmission routes (including
	close contact and/or transmission outside this event) were only assessed
	through interviews, they could not be fully ruled out. However, PHE noted that
	the high secondary attack rate suggested that long distance airborne
	transmission might have occurred for at least some of the cases.
	To note that the 'low' quality rating of this study was due to risk of bias in
	exposure assessment and outcome assessment. However, this does not mean
	that this was not a sound documentation of a super-spreader event, particularly
	given the time when it was done, just that the assessment of the likelihood of
	long-distance airborne transmission was at risk of bias (which is in line with
	other assessments of the Skagit Country outbreak, such as the one by Axon et
	al). [Exhibit: SH3/104c - INQ000408918]. Studies that were considered at low
	risk of bias on these two aspects had typically also used Closed Circuit
	Television evidence to rule out other transmission routes and had conducted
	genomic sequencing. The Respiratory Evidence Panel (REP) work included an
	assessment of whether COVID-19 was airborne. Paragraph 334 of this
	statement refers to this.
21 May	A paper on the results of a PHE surface survival study of SARS-CoV-2 on
2020	FFP3 mask was sent to SAGE. The paper investigated the viability over time of
	SARS-CoV-2 dried onto a range of materials, and compared viability of the
	virus to RNA copies recovered and whether virus viability was concentration
	dependent. The study stated "This study shows the impact of material type on
	the viability of SARS-CoV-2 on surfaces. It demonstrates that the decay rate of
	viable SARS-CoV-2 is independent of starting concentration. However, RNA
	shows high stability on surfaces over extended periods but this does not
	necessarily correlate with viable virus that may result in transmission. This has
	implications for interpretation of surface sampling results using RT-PCR to
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	determine the possibility of viable virus from a surface, where RT-PCR is not
	an appropriate technique to determine viable virus. Unless sampled
	immediately after contamination, it is difficult to align RNA copy numbers to
	quantity of viable virus on a surface".
	These studies, funded by the MRC, continued through 2020 with the results of
	the survival studies being provided to SAGE EMG and relevant government
	departments, published as preprints, and published in the scientific literature
	[Exhibit: SH3/105 – INQ000348153].
4 June	The EMG provided a paper to SAGE on transmission of COVID-19 and
2020	mitigating measures [Exhibit: SH3/106 – INQ000192101]. It found
	"transmission of SARS-CoV-2 is most strongly associated with close and
	prolonged contact in indoor environments. The highest risks of transmission
	are in crowded spaces over extended periods", and that this suggested "close-
	range direct person-to-person transmission (droplets) and indirect contact
	transmission (via surfaces and objects) are the most important routes of
	transmission." It noted "there is weak evidence that aerosol transmission may
	play a role under some conditions such as in poorly ventilated crowded
	environments." It also noted "selection of prevention and mitigation measures
	should consider all the potential transmission routes and need to be bespoke to
	a setting and the activities carried out".
14 June	A study was initiated at the request of Cabinet Office by PHE to study the
2020	impact of facemasks on the dispersion of respiratory pathogens in an
	environmental chamber at PHE Porton Down laboratory using healthy
	volunteers and respiratory bacteria as an indicator of dispersion. [Exhibit:
	SH3/107 – INQ000069823] With a very small sample size (10 healthy
	volunteers) the findings showed that "homemade facemasks" were as effective
	as surgical masks at reducing dissemination of respiratory particles (source
	control) and both significantly reduced the dissemination of aerosol particles
	and droplets. The study also highlighted the large differences between aerosol
	dissemination within a population. A report of the study was sent to Cabinet
	Office on the 19 of June and shared with SAGE EMG on the 24 June. The
	results of the study were also shared with Health and Safety Executive and

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	Defense Oriente and Technological characteristic definition of the OAOE
	Defence Science and Technology Laboratory modellers and used in SAGE-
	EMG outputs and later published in the scientific literature. [Exhibit: SH3/108
	- INQ000192082
3 July 2020	The "Vivaldi 1: COVID-19" care homes study found that 5,455 out of 6,747
	residents who took part in the Whole Care Home Testing Programme (of all
	9,081 homes tested via pillar 2 between 11 May-7 June) and tested positive for
	COVID-19 were asymptomatic. [Exhibit: SH3/109 - INQ000106159].
9 July 2020	The WHO published a report acknowledging asymptomatic transmission, but
	its conclusion was still that the scale of asymptomatic transmission remained
	unknown [Exhibit: SH3/110 - INQ000070042].
9 July 2020	Based on a further review of the existing evidence, the WHO published a
	scientific brief which continued to recommend that direct or close contact with
	infected people via droplet remained the most likely principal route of
	transmission, and uncertainty remained about the fomite route [Exhibit:
	SH3/110 - INQ000070042]. It noted that airborne transmission could occur as a
	result of AGPs and that WHO, together with the scientific community,
	continued to actively discuss and evaluate whether SARS-CoV-2 may also
	spread through aerosols in the absence of aerosol generating procedures,
	particularly in indoor settings with poor ventilation. The brief found that there
	was no consistent evidence of this.
23 July	NERVTAG and the EMG provided a paper to SAGE on the role of aerosol
2020	transmission in COVID-19 [Exhibit: SH3/112 - INQ000070870]. It noted "the
	possibility of aerosol transmission of SARS-CoV-2 [] has recently been
	formally acknowledged by WHO and hence interest in airborne transmission
	has increase []. This paper reviews current knowledge on aerosol
	transmission mechanisms and mitigations to ensure that recommendations are
	still appropriate." It noted aerosol transmission "is most likely to happen at
	close range (within 2m) though there is a small amount of evidence that this
	could happen in an indoor environment more than 2m from an infected person.
	There is currently no evidence for long range aerosol transmission."

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12 4	DUE and the EMC provided a paper to CACE an associated destrict
13 August	PHE and the EMG provided a paper to SAGE on aerosol and droplet
2020	generation from singing, wind instruments and performance activities [Exhibit:
	SH3/113 - INQ000075020]. Following well-documented international outbreaks
	associated with choirs and performances, the paper considered the potential
	for droplet and aerosol transmission. It concluded, "aerosol generation is
	identified as likely posing an important risk" and made recommendations for
	further research and analysis.
20 August	PHE presented a paper on susceptibility and transmission risk in children to
2020	NERVTAG. [Exhibit: SH3/114 – INQ000348155]. The paper was a systematic
	review and meta-analysis, which primarily focussed on susceptibility and
	transmission in children and young people up to the age of 19. The paper
	concluded that there was 'preliminary evidence that children and young people
	have lower susceptibility to SARS-CoV-2, with 43% lower odds of being an
	infected contact'.
	At the meeting, NERVTAG discussed this paper alongside a general
	discussion on transmission in children [Exhibit: SH3/115 – INQ000239476
	Members 'noted that children are less likely to be hospitalised, need intensive
	care admission or die from COVID-19 compared to adults and, particularly,
	older adults'. They also noted that 'seroprevalence rates in children mirrored
	the longitudinal picture seen in adults.' Members noted that preliminary data
	from surveillance of schools showed 'similar seropositivity rates amongst staff
	and students' and that the 'evidence suggests children are almost as likely to
	be infected as adults, but most will be asymptomatic or have mild disease'.
	Members also noted that 'the transmission risk to and from children is
	significant in household settings' and that 'evidence from schools and other
	educational settings indicates low risk of transmission in children of nursery or
	primary school age'.
26	Paper prepared by the PHE Transmission Group, (which became part of the
November	EMG), "Factors contributing to risk of SARS-CoV2 transmission in various
2020	settings", [Exhibit: SH3/116 – INQ000224425] was considered at SAGE.
	Whilst this paper did not look at health and social care settings it did look at
	transmission and viral dynamics, finding that there were three major factors

	that influenced the risk of transmission; the contact pattern, environmental
	factors such as ventilation and socioeconomic inequalities.
28	PHE funded a study published in the Journal of Hospital Infection which took
November	place between 3 March 2020 and 12 May 2020 and investigated how SARS-
2020	CoV-2 could be spread within the hospital setting, to better understand how to
	protect staff and to implement effective control measures to prevent the spread
	of the disease in hospital settings [Exhibit: SH3/77 - INQ000348266].
	The presence of SARS-CoV-2 in the air and on environmental surfaces around
	hospitalised patients, with and without respiratory symptoms, was investigated.
	Environmental sampling was undertaken and analysed within eight hospitals in
	England during the first wave of the COVID-19 disease outbreak.
	SARS-CoV-2 RNA was detected on 30 (8.9%) of 336 environmental surfaces
	(though only 5, 1.5% of surfaces had a Virus detectable at the CT<34
	threshold). Concomitant bacterial counts were low, suggesting that the
	cleaning performed by nursing and domestic staff across all eight hospitals was
	effective. SARS-CoV-2 RNA was detected in four of 55 air samples taken <1 m
	from four different patients. In all cases the concentration of viral RNA was low
	and below the CT 34 threshold. Viral culture studies to detect the presence of
	viable (infectious) virus were undertaken and no infectious virus was isolated in
	any of the samples with CT less than 34.
	The study concluded that effective cleaning could reduce the risk of fomite
	(contact) transmission, but some surface types may facilitate the survival,
	persistence and/or dispersal of SARS-CoV-2. In addition, it found the presence
	of low or undetectable concentrations of viral RNA in the air supports current
	guidance that specific but distinct PPE was required for aerosol-generating and
	non-aerosol generating procedures.
February	PHE carried out a series of studies on the comparative surfaces survival of
2021	Variants of Concern (VoCs) through 2021, which was funded through the
	National Core Study Transmission and the Environment. Results were passed
	on to SAGE EMG and rapidly published [Exhibit: SH3/117 – INQ000348158].
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11 February	EMG produced a paper which explored the current evidence base regarding
2021	the risks of COVID-19 infection and mortality by occupation. The key findings
	included: Age is the highest risk factor associated with death from COVID-19;
	and transmission risk is a complex combination of environmental and human
	factors that are associated with the likelihood of infection. There is a clear
	interplay between occupational risk of SARS-CoV-2 transmission and
	socioeconomic inequities, which reflects the amplifying effects between the
	working environment, crowded housing, job insecurity and poverty. [Exhibit:
	SH3/119 – INQ000192159].
March 2021	A small study was carried out to assess the effectiveness of three types of
	transparent face covering in minimizing/preventing the dispersal of respiratory
	droplets and aerosol. Effectiveness was compared to that of a face shield and
	a disposable (IIR) surgical mask. The study involved 10 healthy volunteers and
	was carried out using respiratory bacteria as markers for respiratory secretions.
	In comparison to wearing no face covering, transparent face coverings (and
	surgical masks) were effective in reducing dispersal. Face shields were not
	effective. Research findings were shared with DHSC as per the attached email
	[Exhibit: SH3/120 – INQ000348160] [Exhibit: SH3/121 – INQ000348161].
21 February	UKHSA contributed to research published in the Indoor Air Journal which
2022	investigated the ability to model the dispersion of pathogens in exhaled breath
	to help describe the transmission of the SARS-CoV-2 virus and other
	respiratory pathogens. [Exhibit SH3/122 - INQ000192082 A Computational
	Fluid Dynamics model of droplet and aerosol emission during exhalations was
	developed and, for the first time, compared directly with experimental data for
	the dispersion of respiratory and oral bacteria from ten subjects coughing,
	speaking, and singing in a small unventilated room. The simulations and
	experiments both showed greater deposition of bacteria within 1 m of the
	subject, and the potential for a substantial number of bacteria to remain
	airborne, with no clear difference in airborne concentration of small bioaerosols
	(<10 μm diameter) between 1 and 2 m. The agreement between the model and
	the experimental data for bacterial deposition directly in front of the subjects
	was encouraging, given the uncertainties in model input parameters and the
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	measures in indoor settings, particularly the use of adequate ventilation.
	contributed to transmission. The results highlighted the need for mitigation
	choirs, and identified factors such as insufficient air replacement that probably
	might occur in indoor settings such as restaurants, workplaces, and venues for
	evidence suggesting that long distance airborne transmission of SARS-CoV-2
	19 January 2022. [Exhibit: SH3/124 – INQ000348164]. The research found
	might influence transmission looking at studies published between July 2020 to
	of SARS-CoV-2 in indoor community settings and to investigate factors that
2022	which sought to evaluate the potential for long distance airborne transmission
29 June	UKHSA contributed to research published in the British Medical Journal (BMJ)
	aerosol challenge models and infection prevention and control policies.
	determine SARS-CoV-2 viability following aerosolization, to help inform animal
	nebulisers with differing methods of aerosol generation were evaluated to
	CoV-2. [Exhibit: SH3/123 – INQ000348163]. In this study, a range of
2022	understand more about the impact of nebulisation on the viability of SARS-
19 March	UKHSA contributed to a study published in the Viruses Journal which aimed to
	airborne transmission of respiratory pathogens such as SARS-CoV-2".
	in the ability to model the consequences of an exhalation and hence the
	ability to predict airborne microbial dispersion and deposition gives confidence
	inherent variability within and between subjects. The research found "The

The Infectiousness of the Disease

PHE presented a paper at the NERVTAG meeting "Evidence base for
respiratory viral shedding in COVID-19 cases – time to remain in self-isolation"
[Exhibit: SH3/125 – INQ000119471]; [Exhibit: SH3/126 – INQ000229192
and the committee reviewed the evidence available at that time. In summary:
a. PHE reviewed the viral shedding time for the first 16 patients and found
the mean shedding time to be 11.6 days (by PCR);

	b. A review of the available scientific literature showed that on average it
	takes up to day 14 or 15 from date of onset of symptoms to when the
	PCR test becomes negative;
	c. It was suggested that at around 12 to 15 days after the date of onset
	there is reduction in viral load, acquisition of immunity and therefore
	likely to be a reduction of infectiousness associated with the reduction
	in viral load and reduced shedding;
	d. The aim during the 'delay' phase was to limit transmission, accepting
	that there will be some people that do go outside of self-isolation whilst
	still shedding. Modelling showed that isolation for 7 days gave similar
	effect to isolating for 14 days in terms of disease transmission.
	The NERVTAG recommendation was that the length of time in self-isolation
	should be between 7 and 14 days after illness onset with the NERVTAG
	preference towards the longer end of the range. Special consideration for
	longer periods of isolation was needed for those in immunocompromised
	groups and those on steroids, as the data suggested that those groups had
	more viral shedding.
27 April	An analysis of secondary attack rates (SAR) in children was presented to SPI-
2020	M-O [Exhibit: SH3/61 – INQ000061503]. This initial analysis of the FF100
	household extract provided evidence to suggest that infected children aged 18
	or younger were as capable of transmitting SARS-CoV-2 as were adults. This
	was informed from the strong association with becoming a household
	secondary case if there was a primary or co-primary case within the household
	younger than 19. In this situation, the odds of becoming a secondary case
	were 6.3 times greater (95% Cl 1.1 to 36.0) than in those households where
	the minimum age of the primary or co-primary cases was in the range 19-64. In
	contrast, those at risk of becoming a secondary case that were aged 18 or
	younger had a reduced odds of having a clinical infection. Compared to those
	aged 19-34, there was a reduction of 80% in their odds of becoming a
	secondary case. These findings suggested that children may be more effective
	transmitters of SARS-CoV-2 than adults, however, they were less likely to
	succumb to a clinical COVID-19 infection.
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30 April	PHE wrote a paper titled "Virus detection and infectivity of SARS-CoV-2 Virus
2020	detection and infectivity of SARS-CoV-2" [Exhibit: SH3/127]
2020	
	INQ000089693 The paper pointed to data to suggest that cases demonstrate
	the ability to culture virus up to day 9 post illness onset and that the peak of
	viral shedding is around the time of symptom onset and that presymptomatic
	individuals are a source of infectious virus.
30 April	PHE produced an options paper for NERVTAG on the management of
2020	asymptomatic residents and staff in care homes. More details are in the
	corresponding entry in the Transmission table above. The key findings were: "A
	high prevalence of SARS-CoV-2 positivity was found in care homes residents
	and staff, half of whom were asymptomatic and potential reservoirs for on-
	going transmission. A third of symptomatic SARS-CoV-2 residents died within
	14 days. Symptom-based screening alone is not sufficient for outbreak control".
	The Exhibit paper [Exhibit: SH3/88 - INQ000089681] also exhibited for the
	entry 9-13 April 2020 in the Transmissions table provides information.
18 May	PHE was asked to review information on the duration of infectiousness and
2020	prolonged detection of SARS-CoV-2 virus for people infected with COVID-19,
	exhibited here: Email [Exhibit: SH3/129 - INQ000348166], attached
	documents: [Exhibit: SH3/128 - INQ000120169], [Exhibit SH3/101B & SH3/101C attachments INQ000348147 and INQ000089693 . It conducted a review of
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	the available literature and produced a paper that looked at prolonged
	detection of the virus by molecular methods in May 2020, to inform guidance
	on how to manage such individuals. This was sent, via the Incident Director, for
	consideration by the Senior Clinician Group (SCG) on 18 May 2020. The
	review concluded that the duration of isolation of asymptomatic SARS-CoV-2
	PCR positive cases should be as long as for symptomatic COVID-19 cases (at
	the time from 7 days from illness onset), and that confirmed symptomatic
	COVID-19 cases and asymptomatic SARS-CoV-2 PCR positive cases should
	be excluded from subsequent 'group testing' activities for at least 4 weeks (and
	a maximum of 6 weeks) from illness onset date. The recommendation was that
	the current PHE guidance (7 days isolation) was appropriate for the delay
	phase of the pandemic, as, when there is widespread community transmission,

	it is accontable that some people may remain infectious when they and
	it is acceptable that some people may remain infectious when they end
	isolation, as they constitute a small proportion of all infectious people.
May 2020	In May 2020 the VIVALDI 1 study was commissioned by NHSTT and
	undertaken by Office for National Statistics (ONS) and University College
	London (UCL) to understand the risk factors which were contributing to
	outbreaks of infections in care homes across the whole of England. A report on
	VIVALDI 1 was published on 3 July 2020. The exhibit referenced in the entry
	for 3 July 2020 in the Transmissions table above provides information.
	The VIVALDI 2 study was launched in June 2020, in a more representative
	sample of over 100 care homes and built upon VIVALDI 1 to investigate rates
	of infection and immunity, risk factors for transmission, risk of reinfection and
	vaccine effectiveness in residential long-term care facilities. This study was
	commissioned by NHSTT and undertaken by UCL researchers and supported
	by the University of Birmingham. NHSTT also provided management and
	oversight of the studies. The initial results of VIVALDI 2 were shared by UCL
	with NHSTT and fed into the policy decisions made in relation to care homes,
	including the movement of agency staff and the regular repeat testing of all
	staff as well as all residents in residential care homes of all sizes. The VIVALDI
	2 report was published on 6 May 2021 [Exhibit: SH3/130 - INQ000220174].
	UKHSA has continued to fund the VIVALDI study, which has advanced to
	study the reinfection rates, vaccine and booster efficacy against evolving
	variants, and continues to monitor effectiveness, acceptability and feasibility of
	regularly staff testing, to protect care home residents from severe outcomes in
	future [Exhibit: SH3/131 - INQ000223935].
4 June	The following paper [Exhibit: SH3/133 - INQ000120523], produced by the
2020	Nosocomial Modelling Group, noted that based on preliminary data, "Since
	May 1st, as the number of cases in hospital has decreased, the percentage
	that are nosocomial and nosocomially-linked has increased markedly with the
	former estimated to be approximately 80% on 1st June". These findings formed
	part of a wider paper [Exhibit: SH3/131a - INQ000408919], which was
	presented to SPI-M-O on 3 June 2020, and were included in the following SPI-
	M-O consensus statement [Exhibit: SH3/132 - INQ000253876] [Exhibit:

	SH3/131b - INQ000408920], which was presented to the Healthcare Onset
	COVID-19 Infection Sub-Group of SAGE on 4 June 2020 [Exhibit: SH3/131c -
	INQ000408921], and shared with core national and regional NHS colleagues
	and IPC leads, as well as with the Incident Director. These findings highlighted
	the importance of nosocomial acquisitions to infections in hospital, and the
	importance of hospital settings to the epidemic overall. Presentation of this
	evidence led to commissions to conduct model-based evaluations of
	nosocomial infection control, including patient and HCW testing in hospital
	settings, as well as IPC strategies.
11 June	PHE contributed to a SAGE paper submitted by NERVTAG (viral dynamics of
2020	infectiousness) [Exhibit: SH3/134 – INQ000120524 [Exhibit: SH3/135 –
	INQ000120527]. The paper found:
	a. Viable virus has been recovered from pre-symptomatic patients,
	supporting the hypothesis that patients are infectious in the pre-
	symptomatic phase;
	b. Viral RNA dynamics (measured by Reverse Transcription – Polymerase
	Chain Reaction (RT-PCR)) confirm a peak in viral load around the pre-
	symptomatic/symptomatic transition time point, followed by a gradual
	decline in viral load, with RT-PCR detection extending until day 43 in
	some individuals;
	c. Beyond 14 days most, but not all, infected people shed virus at amounts
	lower than can be cultured suggesting they are no longer infectious;
	d. Viral culture data indicating likely infectiousness is limited but suggests
	most people are not infectious 12 days after symptoms onset;
	e. Antibody responses are seen as early as day 10-14 in most individuals
	and might either coincide or even account for reduced infectivity;
	f. There remains a lack of epidemiological transmission data, and a lack of
	data about shedding of infectious virus, in patients beyond day 7 post
	symptoms and in asymptomatic individuals to confirm true risk of
	infectivity to other individuals.

SAGE discussed the paper and concluded "overall this evidence indicates that
the current advice to isolate for seven days in case of mild infection, or seven
days after symptoms have ended for more severe cases remains sound."
The full FF100 analysis on transmission dynamics was shared with IMT. This
was subsequently published by MedRXiv on 22 August 2020 [Exhibit:
SH3/136 - INQ000061505].
The main findings were: an overall household SAR of 37% (95% CI 31-43%)
with a mean serial interval of 4.67 days; an R0 of 1.85 and a household
reproduction number of 2.33; lower SARs rates in larger households and SARs
were highest when the primary case was a child. A mean incubation period of
around 4.8 days was estimated, with a range of 2 to 11 days.
The SPI-M-O: Consensus Statement on COVID-19, considered at SAGE on 25
June 2020, [Exhibit: SH3/137 - INQ000253879] stated that "Modelled
estimates of incidence are generally higher than those from the ONS swabbing
surveys. The reason for this is not yet clear. It is likely to be partly explained by
the fact that the ONS survey does not include care homes or hospitals, where
infection rates are higher than the general population".
Interim analysis, from the Household Contact study (HoCo) was presented to
the PHE IMT Business meeting on 17 July 2020 and subsequently to
NERVTAG on 31 July 2020. The HoCo study was based on the WHO outline
protocol for a COVID-19 household transmission study. The initial protocol was
submitted to the PHE IMT on 5 February 2020, verbal approval for funding of
the study was given on 19 February 2020, and written approval was received
from the DCMO Van Tam on 6 March 2020.The letter confirming this is
exhibited here [Exhibit: SH3/138 – INQ000348171]
The final publication is available here: [Exhibit: SH3/139 – INQ000223873].
Key findings were a SAR among contacts of symptomatic index cases of 33%
(95% confidence intervals [CI] 25–40); lower from primary cases without
respiratory symptoms, 6% (Cl 0–14) vs 37% (Cl 29–45), p = 0.030. The SAR
from index cases <11 years was 25% (Cl 12–38). SARs ranged from 16% (4–

	28) in contacts <11 years old to 36% (CI 28–45) in contacts aged 19–54 years
	(p = 0.119).
24 August	A paper was published by the Royal Society which reported the work of the
2020	PHE/University of Cambridge modelling group. By re-purposing the
	transmission model, originally developed for influenza, the modellers were able
	to anticipate and understand the impact of lockdown and provide sequential
	updates of the dynamics of the pandemic by estimating the basic and effective
	reproduction numbers. Estimates on 10 May 2020 showed the reproduction
	number had fallen from 2.6 to 0.61 and that lockdown had reduced
	transmission by 75%. The paper is exhibited here [Exhibit: SH3/140 –
	INQ000348172].
August	PHE scientists contributed to a paper published in Eurosurveillance [Exhibit:
2020	SH3/141 – INQ000348173] – "Duration of infectiousness and correlation with
	RT-PCR cycle threshold for infectiousness and correlation with RT-PCR values
	in cases of COVID-19, England, January to May 2020." The review concluded,
	from analysis of 324 samples, that SARS-CoV-2 viral load in the upper
	respiratory tract peaks around symptom onset, and infectious virus persists for
	10 days in mild-to-moderate coronavirus disease. The probability of culturing
	the virus declined to 6% 10 days after onset and was similar in asymptomatic
	and symptomatic persons. Asymptomatic persons represented a source of
	transmissible virus.
	As this evidence evolved, this review was updated with a proposal presented
	again to the SCG in September 2020 to consider increasing the re-testing
	exemption period for people who tested positive from 42 days (6 weeks) to 90
	days (3 months). SCG endorsed this recommendation for translation into
	guidance pending four nations approval on timing of isolation for confirmed
	COVID-19 patients in healthcare settings.
4 Sept 2020	PHE contributed to a NERVTAG discussion on an update paper, requested by
	SAGE, on Immunity to SARS-CoV-2. [Exhibit: SH3/142 - INQ000120434].
	The key points were:
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	A case study of reinfection in an individual from Hong Kong led to the
	conclusion that reinfection is possible, but the frequency and the implications
	for disease transmission are uncertain. One study from Iceland found no
	decline in antibody concentrations after 4 months. National seroprevalence
	studies in the UK were being carried out using the Euroimmun assay. Internal
	observational data was that the N antibody test, the Nucleocapsid protein of
	SARS-CoV-2, based on the Abbott assay showed a decline more easily than
	other N-based assays. Other studies, such as the one from Kings found
	waning of IgG; results can depend on how the antigens for the tests are made.
	The observation was that the longer the time is from diagnosis the lower the
	antibody level.
12 January	PHE published a paper (Wiley online library) which recognised that knowledge
2021	gaps remained regarding SARS-CoV- 2 transmission on flights. A retrospective
	cohort study was conducted to estimate risk of acquiring symptomatic SARS-
	CoV- 2 on aircraft. They concluded that the risk of symptomatic COVID-19 due
	to transmission on short to medium haul flights was low and recommended that
	prioritising contact-tracing of close contacts and co-travellers where resources
	are limited, and that further research on risk on aircraft is encouraged to inform
	contact tracing and infection control efforts. [Exhibit: SH3/143 –
	INQ000348175].
5 March	PHE updated NERVTAG on work undertaken on the re-infection of people with
2021	prior exposure in outbreaks of B.1.1.7 in London Care Homes which
	experienced outbreaks prior to the emergence of B.1.1.7.[Exhibit: SH3/144 –
	INQ000120439 The original study was published in Eurosurveillance.
	[Exhibit: SH3/145 – INQ000348177].
	The conclusions were that: Field studies indicate similar levels of protection
	against B.1.1.7 infections compared to 2020 viruses. One confounder is the
	increased time from the original infection. Outbreaks in Care Homes are due to
	both old and new viruses. Boosting of antibody may represent a protective
	response against re-infection. Similar antibody titres to B.1.1.7 and older
	viruses, with a close correlation in antibody titres between the two viruses.

October	UKHSA contributed to research published in November 2021 in The Lancet
2021	Respiratory Medicine Journal which aimed to increase an understanding of the
	infectiousness of SARS-CoV-2 to inform guidance on infection control and to
	help shape future policies [Exhibit: SH3/146 – INQ000348178]. The study,
	carried out between September 2020 and March 2021, found that less than a
	quarter of COVID-19 cases shed infectious virus before symptom onset; under
	a 5-day self-isolation period from symptom onset, two-thirds of cases released
	into the community would still be infectious, but with reduced infectious viral
	shedding. The research supported a role for LFDs to safely accelerate de-
	isolation but not for early diagnosis, unless used daily.
22	UKHSA contributed to research published in The Infection Control & Hospital
November	Epidemiology Journal, Volume 23, Issue 11, to understand the transmission
2021	dynamics of SARS-CoV-2 in a hospital outbreak to inform infection control
	actions [Exhibit: SH3/147 – INQ000348179]. The findings indicated that
	respiratory exposure anywhere within a 4-bed bay was a risk, whereas non
	respiratory exposure required bed distance ≤2.5 m. Standard infection control
	measures required beds to be >2 m apart. The findings suggested that this
	may be insufficient to stop SARS-CoV-2 transmission.
14 January	UKHSA presented to NERVTAG on work between UKHSA and the
2022	Assessment of Transmission of COVID-19 in Contacts study team to try to
	improve the evidence based on the relationship between lateral flow device
	(LFD) positivity and prediction of infectiousness. [Exhibit: SH3/148 –
	INQ000348180].
	The following conclusions were presented; firstly, false negative LFDs occur
	prior to peak viral load. Secondly, LFDs become negative at the same time as
	culture; this supports guidance on testing to release from isolation and
	highlights the importance of having negative LFDs on 2 consecutive days
	before isolation ends. Thirdly, a positive LFD is better overall than PCR at
	predicting culture positivity.
	These findings are consistent with modelling data on risk of infectiousness
	which was used to develop current guidance on isolation.

The Possibility of Re-infection

- 123. PHE, and subsequently UKHSA, have undertaken a number of activities, including contributing to studies and production of papers and briefings, and contributing to meetings, to look at issues relating to reinfection, outlined in the following paragraphs.
- 124. Active identification and follow up of possible cases of re-infection was initiated by PHE's Epidemiological and Surveillance Cells, on 10 June 2020, based on positive SARS-CoV-2 samples taken more than 60 days apart in the Second-Generation Surveillance System (SGSS). SGSS is the national laboratory reporting system used in England to capture routine laboratory data on infectious diseases and antimicrobial resistance. Follow up was initially via surveillance forms sent to the microbiologist in the reporting lab to help distinguish between persistent infection, errors in data records and probable re-infections.
- 125. From 14 September 2020 Pillar 2 possible reinfection patients on SGSS were followed up directly by email through direct contact with the individual affected.
- 126. On 18 September 2020 a 90-day interval definition of re-infection was introduced, replacing the previous 60-day definition, and this was applied in the follow up of cases based on positive SARS-CoV-2 testing from 28 September 2020 onwards. The 90-day interval was introduced following reviews of data generated from people who had tested positive 30,45,60 and ultimately 90 days apart, along with data generated from the SIREN and Oxford hospital studies. Based on these reviews it was decided that the 90-day definition was likely to pick up true cases of reinfection but not cases with repeat positive testing that was from the same episode.
- 127. A paper dated 27 October 2020 was presented by PHE at NERVTAG on 30 October 2020 on the approaches to detecting SARS-CoV-2 reinfection in England [Exhibit: SH3/149 – INQ000120235 Approaches included a whole population study

(using SGSS data), Healthcare workers, via the SIREN study, Elderly (via the PHE care homes cohort), Children and the Immunocompromised. Additionally, exhibited here is a table setting out the advice provided to SAGE, its sub-groups and NERVTAG which PHE/UKHSA authored or contributed to, on the nature and spread of COVID-19 including reinfection [Exhibit: SH3/31– INQ000348133].

- 128. The earliest estimates of protective effect from previous infections were from two studies one involving staff at Oxford University Hospitals (a single centre study) with PHE collaborators [Exhibit: SH3/150 INQ000348182] and the second a UK wide multicentre cohort study the SIREN study, which is discussed in more detail at paragraphs 189-206. The Oxford study compared SARS-CoV -2 infection rates, over a six-month period, based on regular PCR testing, in healthcare workers who had evidence of prior SARS-CoV-2 infection when they entered the study with healthcare workers who did not have evidence of prior infection. The rate of infection was substantially lower in those with evidence of prior infection.
- 129. In addition, PHE scientists contributed to a retrospective study of the period from 1 March 2020 – 31 December 2020, Protective effect of a first SARS-CoV-2 infection from reinfection: a matched retrospective cohort study using PCR testing data in England [Exhibit: SH3/151 – INQ000348183]. This was a retrospective populationbased matched observational study which identified the first PCR positive of primary SARS-CoV-2 infection case tests between 1 March 2020 and 30 September 2020.
- 130. Amongst individuals testing positive by PCR during follow-up, reinfection cases had 77% lower odds of symptoms at the second episode and 45% lower odds of dying in the 28 days after reinfection. Prior SARS-CoV-2 infection offered protection against reinfection in this population. There was some evidence that reinfections increased with the alpha variant compared to the wild-type SARS-CoV-2 variant, highlighting the importance of continued monitoring as new variants emerge.
- 131. PHE also undertook a retrospective national surveillance study which aimed to assess the risk of SARS-CoV-2 reinfection in children and compare this with the risk in 68

adults, by analysis of national testing data for England. National SARS-CoV-2 testing data was used to estimate the risk of reinfection at least 90 days after primary infection, from Jan 27 2020 to July 31 2021, which encompassed the alpha (B.1.1.7) and delta (B.1.617.2) variant waves in England [Exhibit: SH3/152 – INQ000348184].

- 132. Disease severity was assessed by linking reinfection cases to national hospital admission data, intensive care admission, and death registration datasets. Reinfection rates closely followed community infection rates, with a small peak during the alpha wave and a larger peak during the delta wave. In children aged 16 years and younger, 688,418 primary infections and 2343 reinfections were identified. The overall reinfection rate was 66.88 per 100,000 population, which was higher in adults (53-72 per 100,000) than children (21.53 per 100,000). The reinfection rate after primary infection was 0.68% overall, 0.73% in adults compared with 0.18% in children age younger than 5 years, 0.24% in those aged 5–11 years, and 0.49% in those aged 12–16 years.
- 133. Hospital admission rates in children were similar for the first (64 [2·7%] of 2343) and second episode (57 [2·4%] of 2343) and intensive care admissions were rare (seven children for the first episode and four for reinfections). There were 44 deaths in children within 28 days after primary infection (0·01%) and none after reinfection. The results found that the risk of SARS-CoV-2 reinfection was strongly related to exposure due to community infection rates, especially during the delta variant wave. Children had a lower risk of reinfection than did adults, but reinfections were not associated with more severe disease or fatal outcomes [Exhibit: SH3/152 INQ000348184].
- 134. PHE contributed to articles on this topic published between January 2021 and December 2021 [Exhibit: SH3/145 INQ000348177] and [Exhibit: SH3/154 INQ000348186]. The studies exhibited looked at the duration of protection and risk of reinfection of SARS-CoV-2 in care home residents who had already been infected. The research found that the antibodies to SARS-CoV-2 protected care home residents against reinfection.

- 135. In March 2021, PHE published information on the UKHSA website which detailed the work that was being undertaken to investigate the possibility of people who had previously tested positive for SARS-CoV-2 infection being infected again [Exhibit: SH3/155 – INQ000348187] [Exhibit: SH3/156 – INQ000348188].
- 136. PHE, using national surveillance data to collect information on all SARS-CoV-2 primary infection and suspected reinfection cases between January 2020 until early May 2021, looked at reinfection cases in those who had a positive COVID-19 PCR or antigen test, 90 days after their first COVID-19 positive test. They found that deaths reported within 28 days of testing positive were 61% lower in suspected COVID-19 reinfection than primary infection cases. The paper, the abstract of which is exhibited here, was published on 22 April 2022 [Exhibit: SH3/156 INQ000348188].
- 137. In the unvaccinated cohort reinfections were associated with 49% lower odds of hospital admission in cases aged 50 to 65 years in the population not identified at risk of complication for COVID-19, and 34% in those at risk i.e. those with underlying chronic or long-term conditions. There was a 76% reduction in the likelihood of an ICU admission at reinfection compared to primary infection. Individuals at risk and those aged below 50 years, who received at least 1 dose of vaccine against COVID-19, were 62% and 58% less likely to get admitted to hospital at reinfection, respectively.
- 138. On 17 June 2021 the first routine reinfections information was published in the UKHSA national flu and COVID-19 surveillance report and updated monthly thereafter until the dashboard incorporating reinfections was launched [Exhibit: SH3/157 – INQ000348189].
- 139. On 2 July 2021 PHE contributed a paper Serological Profile of reinfection to NERVTAG. [Exhibit: SH3/158 – INQ000120358] summarising the acquired knowledge from studies at this time.

- 140. In addition, on 2 July 2021 the Reinfections/ COVID Episodes Working Group was established to review the implications of a move to reporting reinfections within SGSS and overseeing the necessary implementation changes. The Terms of Reference are exhibited here [Exhibit: SH3/159 – INQ000348191].
- 141. On 10 December 2021 UKHSA routine reinfection data were included in the SARS-CoV-2 variants of concern and variants under investigation in England Technical briefing 31 for the first time [Exhibit: SH3/160 INQ000257175]
- 142. On 31 January 2022 the COVID-19 daily dashboard, incorporating reinfections, was launched.

Variants

- 143. COG-UK, discussed at paragraph 114, played a vital role in collecting, sequencing and analysing genomes of SARS COV-2, linking the public health agencies with academic partners to develop a network of laboratories which could provide SARS-CoV-2 sequencing rapidly. COG-UK's first report was provided to SAGE on 23 March 2020 [Exhibit: SH3/161 - INQ000119488]. Subsequently COG-UK data were summarised on regular basis for SAGE.
- 144. PHE also convened regular meetings with public health and academic teams to examine joint genomic and epidemiological data. These took place on a fortnightly basis or more frequently if required if PHE judged there was significant new data or if they had received an ask for an analysis, for example from public health teams. On 8 December 2020 PHE had received a request to examine the emerging epidemiology in Kent and at the meeting the unusual mutation profile of the genomes from Kent cases was identified.
- 145. On 11 December 2020 the variant was discussed at NERVTAG [Exhibit:
 SH3/162 INQ000120390 and on 17 December 2020 at SAGE [Exhibit: SH3/163 –

- **INQ000075522**. On 18 December 2020 VUI2020012/01 was redesignated as a variant of concern with the number VOC202012/01, B.1.1.7. This was subsequently named by the WHO as the Alpha variant.
- 146. Following briefings to NERVTAG, PHE established a 'variant technical group' of PHE teams and academic partners to coordinate analyses to characterise the variant. A framework for variant risk assessment and methodologies for evaluating changes in properties such as transmissibility and antigenic properties (triggering an immune response) was established. PHE (and subsequently UKHSA) used this technical group and framework to maintain biological surveillance of the SARS-CoV-2 virus through analysis of UK and global genomic surveillance data, epidemiological studies using UK data, modelling analyses, and laboratory data from academic partners [Exhibit: SH3/164 - INQ000203642].
- 147. The Variants and Mutations Taskforce (VAM) was also established to coordinate operational delivery. The VAM Taskforce (from February 2021 the Variants of Concern Bronze level meeting) took place on a fortnightly basis or more frequently if required. [Exhibit: SH3/165 INQ000203632].
- 148. On 21 December 2020 analysis of the characteristics of VOC202012/01 was published and is exhibited. This was subsequently referred to as 'Technical briefing 1' [Exhibit: SH3/166 INQ000054364 VOC202012/01 was shown to have substantially increased transmissibility (with high confidence) with multiple different models showing that it had a higher Rt, the effective reproduction number, compared to other variants circulating at the time.
- 149. On 28 December 2020, PHE published technical briefing 2 which stated that initial analysis had found no statistically significant difference in hospitalisation and 28-day case fatality rates between the Alpha variant and comparator cases. There was also no significant difference in the likelihood of reinfection [Exhibit: SH3/167 INQ000230152] PHE continued to monitor the Alpha variant and published a further

three technical briefings relating to this variant between the 14 January 2021 and 1 February 2021 [Exhibit: SH3/168 – INQ000348197]; [Exhibit: SH3/169 – INQ000348198]; [Exhibit: SH3/170 – INQ000348199].

- 150. Between 16 November 2020 and 5 February 2021 PHE's COVID-19 Outbreak Surveillance Team contributed to a study, culminating in a paper published on 18 March 2021, which stated that the Alpha variant had the potential to spread faster, if no mitigations were applied, and to have a higher infection fatality rate than the variants previously detected to date [Exhibit: SH3/171 – INQ000348144]. This study found that this VOC was associated with two-thirds higher case fatality than the previously circulating variants in the unvaccinated population.
- 151. International monitoring of VOCs continued. By 13 February 2021, three further VOCs had been identified. VOC 202012/02 (the 'Beta' variant), first detected in South Africa, was designated as a VOC on 24 December 2020. VOC 202101/02 (the 'Gamma' variant), first detected in Japan amongst travellers from Brazil, was designated a VOC on 13 January 2021. VOC 202102/02, first detected in Southwest England on 26 January 2021, was designated as a VOC on 5 February 2021. [Exhibit: SH3/172 INQ000348200].
- 152. VOC 202104/02 (the 'Delta' variant), first detected in India, was designated a VOC on 6 May 2021. It was assessed as having at least equivalent transmissibility to the Alpha variant, with moderate confidence, based on available data. A risk assessment published by PHE on 21 May 2021 stated that transmissibility between humans appeared greater than first wave variants with some evidence of reduced vaccine effectiveness [Exhibit: SH3/173 INQ000348201]. This was updated on 27 May 2021, setting out that national vaccine effectiveness monitoring showed a reduction in vaccine effectiveness after 1 dose of vaccine compared to the Alpha variant [Exhibit: SH3/174 INQ000348202].
- 153. VOC2111/01 (the 'Omicron' variant) was designated a VOC on 26 November 2021. It was not possible to compare the risk of hospitalisation or death with other

variants at that stage as no known cases had been hospitalised or died [Exhibit: SH3/175 – INQ000262627]

- 154. UKHSA published a risk assessment for the Omicron variant on 3 December 2021 [Exhibit: SH3/176 – INQ000348204], flagging the variant as at least as transmissible as other variants and the mutations as suggestive of reduced protection from both natural and vaccine-derived immunity. The risk assessment [Exhibit: SH3/177 – INQ000348205]; [Exhibit: SH3/178 – INQ000348206]; [Exhibit: SH3/179 – INQ000348207] was updated regularly until 12 January 2022, when it was flagged that Omicron remained at least as transmissible as Delta, with substantial immune evasion properties displayed, though there was a reduction in the relative risk of hospitalisation amongst adults [Exhibit: SH3/180 – INQ000348208].
- UKHSA published details of studies regarding hospitalisation and vaccine effectiveness in respect of Omicron on 31 December 2021 [Exhibit: SH3/181 – INQ000348209].
- 156. As of 1 April 2022, UKHSA amended its variant classification system to give a clearer indication of which variants had potentially significant changes in biological properties compared to the dominant variant(s). Previous VOCs which no longer met the criteria were re-designated [Exhibit: SH3/182 – INQ000348210].
- 157. On 18 May 2022 UKHSA re-classified two sub-lineages of Omicron as VOC-22APR-03 (BA.4) and VOC-22APR-04 (BA.5) [Exhibit: SH3/183 INQ000348211]. A risk assessment for these variants was published by UKHSA on 22 June 2022 [Exhibit: SH3/184 INQ000348212]. Compared to the previously dominant variant (BA.2), BA.4/5 was assessed to have an overall growth advantage based on data from the UK and internationally. UKSHA reported with moderate confidence that antigenic change, allowing evasion of some existing immunity, was likely to be contributing to this growth advantage. There was insufficient data to say whether BA.4/5 was more transmissible than BA.2. The risk assessment for disease severity was that it was

likely similar to previous Omicron variants, with low confidence based on laboratory data with a recommendation to continue monitoring epidemiological data.

158. In total 55 technical briefings were published by PHE/UKHSA to 22 September 2023. PHE published 23 technical briefings regarding the monitoring of SARS-COV-2 variants between December 2020 and 17 September 2021. UKHSA then continued the series from briefing 24, dated 1 October 2021, to briefing 55, updated 22 September 2023 [Exhibit: SH3/185 – INQ000348213]; [Exhibit: SH3/186 -INQ000223918]; [Exhibit: SH3/187 – INQ000223919].

Assessment of Risks to Workers in Healthcare Settings

- 159. PHE, and subsequently UKHSA, assessed risks to HCWs as part of its work monitoring and modelling transmission of the virus but had no formal separate remit for occupational health review or assessment. HCWs as an occupational group were considered by those within PHE and UKHSA advising on possible interventions, such as appropriate PPE and testing strategies and producing guidance. The paragraphs below provide an account of key milestones in understanding the risks to HCWs from SARS-CoV-2. Further information on testing and PPE for HCWs, and the underlying understanding of the virus and the way it spread is provided elsewhere in this statement.
- 160. The Nosocomial Transmission Working Group, a sub-group of SAGE, was established on 3 April 2020 to provide an overview of possible nosocomial transmission of SARS-CoV-2 in hospitals and scientific advice on minimising the transmission of COVID-19 within hospital settings. The remit was narrowed to hospitals only and the group renamed the Hospital Onset COVID Working Group (HOCWG). Its terms of reference from 18 May 2020 are exhibited here [Exhibit: SH3/188 INQ000348214]. It was co-chaired by PHE's Director of NIS, Professor Sharon Peacock and the Chief Nursing Officer for NHSE. The group provided SAGE with an update paper on 13 May 2020 [Exhibit: SH3/189 INQ000348215].

- 161. As Wave One of the pandemic subsided SAGE advised that the functions of the HOCWG should, in future, be picked up by the organisation responsible for operational delivery, i.e. primarily an NHS facing group, whilst retaining a link to SAGE. Thus, HOCWG transitioned to the Hospital Onset COVID -19 Infection (HOCI) group in August 2020 led by NHSE. It was no longer co-chaired with PHE.
- 162. HOCI was set up to be an operationally focused oversight group, with four nations representation, supporting implementation of good IPC practice on a day-to-day basis and the receipt of data on local outbreaks. It is no longer a sub-group of SAGE and is now an advisory group within NHSE.
- 163. The HOCI group was the principal fora for discussion and presentation of evidence around hospital onset of COVID-19. Whilst it predominately focused on transmission to patients, it also considered transmission to healthcare workers, primarily using operational hospital onset data from the NHSE Situational Report (SitRep). This data was made available via the NHSE dashboard and verified by PHE using the patient-linked dataset PHE set up in July 2020. Metrics from this were also used for the PHE public-facing healthcare data dashboard, although this only presented patients admitted with COVID-19 and number in hospital with COVID-19; as an example, a version of the dashboard as it stood on 31 July 2020 is exhibited here. [Exhibit: SH3/189a - INQ000408922] PHE clinicians, IPC experts and modellers were members of the HOCI group and there was a two-way process between HOCI and PHE to inform epidemiology and modelling. Modelling outputs were fed through SPI-M, HOCI, and the incident response structures to inform testing policy and operations. HOCI trends both from the SitRep data and the patient linked dataset were reviewed at the monthly HOCI working group which in turn fed into other government advisory groups.
- 164. Examples of key papers provided to, and meetings held by HOCI, are provided below.

- 165. As of 1 March 2020, PHE considered the current impact of the disease and risk to the UK population was moderate. This risk level was based on a qualitative rather than a quantitative risk assessment. PHE had identified 83 HCWs as contacts of cases diagnosed in England and flagged for follow-up [Exhibit: SH3/190 INQ000348216]. PHE provided robust guidance and information for health professionals [Exhibit: SH3/191 INQ000348217] and had published guidance for HCW on 25 February 2020 [Exhibit: SH3/192 INQ000348218] [Exhibit: SH3/193 INQ000348219]. An example of this guidance is exhibited but the section below describes guidance related to healthcare settings in more detail. Work with NHSE around updates to secondary and primary care guidance around PPE usage was underway [Exhibit: SH3/194 INQ000348220].
- 166. On 25 March 2020, following a request from SAGE, PHE devised a set of surveillance initiatives to better understand infection dynamics and predict future trends in COVID-19 cases in England [Exhibit: SH3/195 INQ000348221]. These studies constituted a focused regional assessment known as the 'London snapshot.' Understanding that HCWs may be at increased risk of exposure compared to the general public due to their work environment, PHE included in the studies a seroincidence survey of NHS healthcare staff working in a clinical setting in participating London hospitals, called 'London covid' [Exhibit: SH3/196 INQ000348222]. To monitor how rapidly SARS-CoV-2 is transmitted among NHS staff working on the frontline, a blood sample was taken from participating HCWs every two weeks for 6 months. Findings of the study were eventually published in April 2021 [Exhibit: SH3/197 INQ000223812].
- 167. On 19 April 2020 a paper [Exhibit: SH3/198 INQ000120648] from the Nosocomial Modelling team which included PHE and academics from Oxford and the LSHTM was submitted to SPI-M-O. It described modelling to quantify the relative importance of nosocomial transmission and the role of HCWs. It utilised a withinhospital transmission dynamic model, developed by PHE using PHE Sitrep data along with data at individual Trust level and the available literature, and estimated that "an average of 16% (13-46%) of nosocomial infections were due to transmission from

infected HCWs, with the remainder due to direct and indirect patient to patient transmission [...], suggesting the majority of transmission within hospitals occurs via routes that could be impacted through improved IPC. Note that improved data on HCW at risk, contact patterns and HCW infection rates are required to increase certainty." The paper also noted "there are proposals for enhanced surveillance snapshots for asymptomatic infections in hospital settings".

- 168. On 20 April 2020 a paper produced by academics at Imperial College London [Exhibit: SH3/199 – INQ000348224] was circulated to SPI-M attendees, including the PHE staff in their individual capacity as experts. The paper observed, "healthcare workers (HCWs) have been disproportionately affected and infected by SARS-CoV-2, constituting between 4% and 19% of all reported COVID-19 cases in China and Europe (3.6% in the UK, 3.8% in China, 4.6% in Germany, 9% in Italy and 19% in Spain). Furthermore, absence rates among HCWs as a result of their own sickness or household isolation because of sick household members have been high. [...] This disproportionate representation of HCWs reflects their exposure to infection from patients and fellow staff, resulting in a higher incidence of infection compared with the general population (9, 10). Transmission in this high-risk group compromises both their own health and also contributes to nosocomial spread within hospitals."
- 169. In April 2020 the ONS Coronavirus (COVID-19) Infection Survey was launched to provide timely estimates on how many people were infected with COVID-19. The Survey detailed HCW infection rates alongside a range of information, with data collected through nose and throat swabs, blood samples, and participants' answers to survey questions [Exhibit: SH3/200 INQ000348225]. The initial survey data, published on 21 May 2020, reported that there was no evidence of a difference between the proportions testing positive for patient-facing healthcare or resident-facing social care roles and people not working in these roles [Exhibit: SH3/201 INQ000348226]. Survey data was published on a weekly basis throughout the relevant time period [Exhibit: SH3/202 INQ000348227] and up until 24 March 2023.

- 170. In late April and early May 2020 PHE investigated asymptomatic healthcare worker infection in a study in six hospitals [Exhibit: SH3/203 - INQ000223819]. The snapshot was set against the background of reported nosocomial transmission of SARS-CoV-2 and the need to understand the prevalence of SARS-CoV-2 transmission amongst HCWs at work, to inform the development of HCW screening programmes to control nosocomial spread. The key findings were that point prevalence of SARS-CoV-2 transmission across the study sites was 2.0% (23/1152 participants). 17 were previously symptomatic, two currently symptomatic and the remainder declared no prior or current symptoms. The findings were interpreted as the point-prevalence being similar to previous estimates for HCWs from single hospitals reported in April 2020, though a magnitude higher than in the general population. Based upon interpretation of symptom history and testing results including viral culture, the majority of those testing positive were unlikely to be infectious at the time of sampling. The findings found that "development of screening programmes must balance the potential to identify additional cases based upon likely prevalence, expanding the symptoms list to encourage HCW testing, with resource implications and risks of excluding those unlikely to be infectious with positive tests.".
- 171. On 4 May 2020 a modelling paper to which PHE contributed was presented to SPI-M-O, and then to HOCI and SAGE, including an estimation of the proportion of infectious HCW, the within-hospital R0 and contribution of patients and HCW to this within-hospital transmission. It found "we would expect a maximum of 2% of HCWs within a hospital to be infectious every day." [Exhibit: SH3/204 – INQ000231571]
- 172. On 7 May 2020 PHE provided a paper on interim findings of the London snapshot studies to HOCWG. [Exhibit: SH3/205 INQ000348228]. It found that the prevalence of PCR positivity at the time of sampling varied between 0 and 24%. Analysis of the laboratory results and questionnaire for the five individuals who had positive results suggest that they had very low levels of virus and all were very unlikely to pose an infection risk to others. HOCWG discussed the available data at its meeting that day, where it was also noted that SPI-M data suggested a risk of transfer

between HCW and patients in outpatient settings, and that further review of IPC practices may be required. [Exhibit: SH3/206 - INQ000235599].

- 173. In May 2020 PHE launched the SIREN study. While primarily focused on reinfection rates in HCWs, the study also considered absolute HCW infection rates. Detail of the SIREN study is provided below from paragraph 189 – 206.
- 174. On 12 May 2020 PHE produced a paper for NERVTAG assessing studies of asymptomatic healthcare worker testing in order to ascertain rates of COVID-19 in healthcare workers and patients. It found that there was a lack of comprehensive data relating to asymptomatic COVID-19 infection in HCWs, and that data thus far shows a wide range of asymptomatic infection rates (2-25%) in screened HCWs. This paper, [Exhibit: SH3/205 – INQ000348228] is also exhibited above at paragraph 172.
- 175. On 3 June 2020 PHE, the University of Oxford and the London School of Hygiene and Tropical Medicine (LSHTM) provided a paper to SAGE via SPI-M. [Exhibit: SH3/207 – INQ000348230]. It found that the percentage of hospitalised cases that were acquired in hospital was 20%, rising to 30% when including cases who had become infected in the community due to transmission from a discharged nosocomial infection.
- 176. On 17 June 2020 PHE provided a paper to SPI-M-O, and then HOCI, updating on its progress developing a model estimating the 'true' number of nosocomial COVID-19 cases and an individual-based model of SARS-CoV-2 transmission in hospitals. [Exhibit: SH3/208 INQ000348231]. It noted, "while the absolute number of nosocomial cases is decreasing over time, we see the proportion of cases in hospital that are hospital acquired or hospital linked to be increasing over time, particularly the percentage of cases that are readmissions. The majority of cases detected in hospital are still importations from the community, but an increasing proportion of these are due to previous nosocomial acquisition with symptom onset in the community. As previously noted, these models are reliant on a number of natural history parameters, assumptions and uncertain distributions."

- 177. It also explained the individual model "has been developed to simulate transmission dynamics in a hospital, including both community and hospital populations and patient and HCW movements between these settings, to enable for example, evaluation of alternative discharge screening strategies" and that further development was needed before it could be used to evaluate transmission and potential control strategies. A later version of this paper, by then focusing on the contribution of nosocomial cases to the first wave of the pandemic, was discussed at SAGE on 22 October 2020. [Exhibit: SH3/209 INQ00087467] [Exhibit: SH3/210 INQ000231451].
- 178. On 15 July 2020, in response to a commission from the SCG, PHE provided a paper to SPI-M which used modelling to evaluate alternative strategies for testing of healthcare workers. [Exhibit: SH3/211 – INQ000348233].
- 179. On 12 August 2020 PHE shared a paper with SPI-M-O, and then with HOCI, that simulated transmission within and between patients and HCWs in defined cohorts and used this modelling to evaluate HCW testing frequencies and patient single-room isolation. [Exhibit: SH3/212 – INQ000348234].
- 180. On 30 September 2020 PHE provided an updated paper on HCW testing to SPI-M-O, building on a paper on HCW testing previously provided on 15 July 2020 (discussed at paragraph 175). [Exhibit: SH3/382 - INQ000348580] The September paper estimated how prevalence impacts hospital transmissions and efficiency of HCW testing. It noted:
 - a. "prevalence is intrinsically linked to community prevalence; dynamics and the effectiveness of any testing strategy depends on both importations and withinhospital transmission;
 - Infections in patients are most commonly importations rather than transmissions from HCW (which contribute a maximum of ~20%), therefore the impact of reducing HCW to patient transmissions through HCW testing is limited;

- c. Furthermore, at peak HCW prevalence, community prevalence is also high and therefore a greater number of patients imported, further limiting impact;
- d. For HCW, a higher proportion of infections are transmissions from other HCW (max. ~50% under current parameters), therefore HCW testing has a greater potential to reduce onward HCW cases;
- e. Testing 1/7 staff every day gave a ~40% reduction in transmission to HCW and ~30% reduction in transmissions to patients at peak efficacy which was in a setting of high HCW prevalence and low community prevalence;
- f. Increasing testing frequency increased efficacy but decreased efficiency. Efficiency was greatest when HCW prevalence was highest." In this context, efficacy refers to how effective the testing strategy was at reducing the amount of transmission (and therefore the number of infections); while efficiency refers to how effective the strategy was at reducing transmission (and infections) per test used.

It also noted the model could be developed through dividing the population of HCWs into patient facing vs non-patient facing, and adding wards so patients are contained in hot/cold wards and staff assigned to each of those wards. The paper was then shared with HOCI on 8 October 2020 [Exhibit: SH3/214 - INQ000087607].

- 181. In October 2020, PHE and the LSHTM presented an early version of a paper on the contribution of nosocomial infections to the first wave to SAGE [Exhibit: SH3/209 INQ000087467 for discussion. It was agreed that understanding the contribution of these infections was important for understanding transmission both within hospitals and in the community. The model estimates showed:
 - a. without nosocomial transmission the duration of the first wave in hospitals may have been shortened, due to fewer COVID-19 admissions in the final quarter of the first wave (medium confidence);
 - b. As a proportion of the overall number of cases, nosocomial transmission was relatively small (just over 1%), though it made up a much more significant proportion of hospitalised cases (approximately 20-25%). As a result, due to the

age and frailty of the hospitalised population, the impact of nosocomial transmission in terms of morbidity and mortality may have been high (medium confidence) [Exhibit: SH3/210 – [INQ000231451]]. These findings were supported by research later published by members of staff at PHE on 30 August 2021 [Exhibit: SH3/215a - INQ000408923] and UKHSA on 4 December 2021 [Exhibit: SH3/215b - INQ000408924].

c. There were varied estimates of the size of the nosocomial infection proportion in hospitals, reflecting the difficulties of a robust case definition. The proportion of hospital cases deemed nosocomial depended on how expansive the case definition was. An example of the case definitions that were developed, and the range of estimates that were produced as a result, is provided in the tables below. The first table sets out the various case definitions for nosocomial transmission, and the second table summarises the number and percentage of patients with hospital acquired infections in the first wave according to each definition. The analysis was model-based and used Secondary Usage Service (SUS) hospital episode data linked with COVID-19 test data. Given the centrality of this issue, SAGE asked for a review of the paper before it was finalised. [Exhibit: SH3/210 – INQ000231451].

Type of case	Definition	
Hospital-Onset Healthcare-	Positive specimen date 15 or more days after	
Associated (HOHA)	hospital admission.	
Hospital-Onset Suspected	Positive specimen date 8-14 days after hospital	
Healthcare-Associated (HOSHA)	admission; or specimen date 3-14 days after	
	admission, with discharge from hospital in 14 days	
	before specimen date.	
Hospital-Onset Intermediate	Positive specimen date 3-7 days after hospital	
Healthcare-Associated (HOIHA)	admission, with no discharge from hospital in 14	
	days before specimen date.	
Community-Onset Suspected	Positive specimen date up 14 days before, or within	
Healthcare-Associated (COSHA)	2 days after, hospital admission, with discharge	
	from hospital in 14 days before specimen date.	

Community-Onset Community-	Positive specimen up to 14 days before, or within 2	
Associated (COCA)	days after, hospital admission, with no discharge	
	from hospital in 14 days before specimen date.	

Case Definition	Number of	Percentage of all
	cases	hospital cases
HOHA (= +ve specimen >=15d after admission)	7906	8.8
HOHA + positive specimen 8+d after admission	14635	16.4
HOHA + HOSHA	16349	18.3
HOHA + HOSHA + HOIHA	23104	25.9
HOHA + HOSHA + HOIHA + COSHA	36152	40.5

- 182. The paper was also discussed at a HOCI meeting on 22 October 2020 [Exhibit: SH3/215c INQ000235621] The paper contributed to a SPI-M-O consensus statement as well as discussions on the importance of nosocomial transmission and hospital settings to the pandemic. The initial findings led to further modelling work on transmission routes, infection protection and control strategy effectiveness evaluations and model-based evaluations of testing strategies for both patients and HCWs. Given the estimations of infectious discharges from hospital settings from the modelling work captured in the paper, model-based evaluations of various options for intervention were produced. For example, UKHSA staff contributed to evaluation of discharge testing strategies, which was ultimately published in October 2023. [Exhibit: SH3/215d INQ000408926].
- 183. In December 2020, on recognition of the Alpha variant, senior leaders within PHE requested that further work was commissioned to critically assess the evidence on the appropriate respiratory protective equipment (RPE) for HCWs in the context of the Alpha variant, the risks posed by which were still unclear. The December 2020 meetings convened by the IPC Cell about the response to the Alpha variant following a request from senior staff within PHE for a mechanism to critically appraise the evidence base. This led to the formation of the independent REP in February 2021. In

the intervening period, PHE staff recruited a chair for the panel, established a secretariat, created dedicated mailboxes, found resource to undertake a rapid literature review and agreed the Terms of Reference. This is further detailed in the section below on IPC, AGPs, and PPE at paragraph 281.

- 184. In January 2021 the finalised paper from PHE and LSHTM on the contribution of nosocomial infections to the first wave was submitted to SAGE [Exhibit: SH3/216 INQ000348237]. There have also been some retrospective studies which looked specifically at the impact of discharge policies from hospitals. The multiple available studies of this are in respect of England [Exhibit: SH3/216a INQ000234332]
 Scotland, [Exhibit: SH3/217 INQ000147514] Wales [Exhibit: SH3/218 INQ000213185] and Northern Ireland, [Exhibit: SH3/219 INQ000348240] where parallel instructions were issued in March 2020.
- 185. On 21 June 2021, based on recent findings from the SIREN study, the HOCI [Exhibit: SH3/220 – INQ000348241] [Exhibit: SH3/221 – INQ000235640] consensus was "the Delta variant is not a great concern in healthcare settings in the UK, given good vaccine coverage of healthcare workers and the general population." Further information can be found in paragraph 188.
- 186. In order to develop the evidence base for the risks to healthcare workers and appropriate countermeasures, over autumn and winter 2021 UKHSA developed a randomised controlled trial, the Winter Personal Protective Equipment Trial (WIPPET). WIPPET was intended to assess the effect of different strategies of RPE use on sickness absence among HCWs in England, which could inform both IPC guidance and occupational health policy. This was not awarded funding by NIHR and therefore could not occur.
- 187. On 9 December 2021, following the identification of the Omicron variant, HOCI met and noted "dominant transmission routes may include HCW to HCW." [Exhibit: SH3/222 INQ000235645].

188. On 3 December 2022 an updated version of the paper previously prepared by HOCI modelling the effectiveness of IPC interventions, now over three waves, was shared with the IPC cell [Exhibit: SH3/223 – INQ000348244]. The paper found that for HCW isolation of symptomatic individuals and masking around both patients and HCWs were the most effective interventions, and that interventions were most effective during the first wave of the COVID-19 pandemic when community transmission was being controlled. For patients, testing and cohorting of infected individuals and isolation of symptomatic HCWs were the most impactful interventions. The paper found the combination of interventions used averted more transmission than the sum of the effects of those individual interventions. Model findings suggest that collectively the interventions introduced over the pandemic (March 2020-July 2022) averted 400,000 (240,000 – 500,000) infections in inpatients and 410,000 (370,000 – 450,000) HCW infections in England.

PHE and UKHSA's role in the SIREN study

- 189. PHE, and subsequently UKHSA, was responsible for the conceptualisation and development of the SIREN study [Exhibit: SH3/224 INQ000320603] in spring 2020, building on early serosurveillance studies of HCWs, and has been responsible for ongoing delivery since the study was launched (i.e. open to recruitment) in May 2020. The SIREN study was established early in the pandemic with participants initially planned to undergo regular testing for one year post recruitment; with annual extensions of funding for smaller cohorts to March 2024. Analysis of these samples helps the UK to evaluate the immune response to COVID-19, build understanding of the protection offered by vaccines and provide insight into COVID-19 reinfections. A report of the SIREN study, referenced in paragraph 126, is exhibited here. [Exhibit: SH3/225 INQ00089714]
- 190. The findings showed that between 18 June and 09 November 2020, 44 reinfections were detected in the baseline positive cohort of 6,614 participants. This compared with 318 new PCR positive infections in the negative cohort of 14,173 participants. The researchers concluded that a prior history of SARS-CoV-2 infection

was associated with an 83% lower risk of infection, with median protective effect observed five months following primary infection.

January 2021 and/or prior to COVID-19 vaccines

191. In January 2021 the SIREN study preprinted its first analysis of protection following SARS-CoV-2 infection [Exhibit: SH3/226 – INQ000348249]. During study follow-up between June and December 2020, there were 44 possible reinfections in 6,600 participants with a history of infection and 318 primary infections in 14,200 participants with no history of infection (incidence density: 3.3 reinfections vs 22.4 primary infections per 100,000 person-days). The analysis showed that reinfection was possible and could occur, but that there was an 83% reduction in infection among people who had previously contracted COVID-19 compared to those who had not. Reinfection is also discussed in the section titled "The possibility of reinfection" at paragraphs 123 onwards.

Spring 2021

192. In February 2021, when the Alpha variant was dominant, the SIREN study preprinted the first analysis of the short-term effectiveness of COVID-19 vaccination on primary infections and reinfections, focusing primarily on the Pfizer vaccine. This was published in peer-reviewed literature in April, as referenced in the SIREN study exhibit in the paragraph above. Vaccinations were introduced to the cohort on 8 December 2020, and the study included follow-up from 7 December 2020 to 5 February 2021. The analysis found that, among participants with no history of infection, short-term vaccine effectiveness against infection after the first dose was 70% and rose to 85%, after the second dose. The analysis found that participants with a history of infection had 90% increased protection compared to those with no history of infection.

193. In April 2021 the SIREN study published a second reinfection analysis [Exhibit: SH3/227 – INQ000348250] with data up to February 2021, including infections from 87

the second wave when the Alpha variant was dominant. This included 155 reinfections in 8000 participants with a history of previous infection and 1704 primary infections in 17,000 participants with no previous infection (incidence density: 7.6 reinfections vs 57.3 primary infections per 100,000 person-days). Consistent with the previous results, and despite the increased infection rates, the analysis found there was an 84% reduction in infection among people who had previously contracted COVID-19 compared to those who had not.

194. In April-June 2021 the SIREN study collected data relevant to the role of the Delta variant on HCW infection. PHE noted that since April 2021, 20,000-25,000 participants had been PCR tested every couple of weeks, amongst whom only 35 cases had been detected. This was presented to HOCI on 21 June 2021. The relevant data is exhibited here [Exhibit: SH3/227 – INQ000348250].

March 2022

- 195. In December 2021 SIREN preprinted [Exhibit: SH3/228 INQ000348251] an analysis looking at the durability of protection against SARS-CoV-2 infection following both previous infection and vaccination. It looked at the durability of protection following vaccination up to 10 months following the second dose and over 18-months after primary infection. This was published in peer-reviewed literature in March 2022. [Exhibit: SH3/229 INQ000223820]
- 196. It found that in previously uninfected individuals 2 doses of the Pfizer vaccine were associated with high short-term protection against SARS-CoV-2 infection but that this protection reduced considerably after 6 months. Between 7 December 2020 and 21 September 2021, a total of 2747 primary infections and 210 reinfections were observed. Among previously uninfected participants who received long-interval BNT162b2 vaccine, adjusted vaccine effectiveness decreased from 85% (95% confidence interval [CI], 72 to 92) 14 to 73 days after the second dose to 51% (95% CI, 22 to 69) at a median of 201 days (interquartile range, 197 to 205) after the second dose.

197. Among those with a previous infection vaccination appeared to boost their immunity, providing strong and longer lasting protection. Infection-acquired immunity waned after 1 year in unvaccinated participants but remained consistently higher than 90% in those who were subsequently vaccinated, even in persons infected more than 18 months previously.

Infection/ reinfection rates impact on healthcare staff availability

- 198. SIREN investigated the burden of SARS-CoV-2 infections in English healthcare workers during the second wave, publishing this in July 2022. [Exhibit: SH3/230 INQ000212138]. This found 12.9% of susceptible SIREN participants became infected with SARS-CoV-2 during the second wave. The SIREN cohort was broadly representative of the NHS workforce but differed from the general working age population regarding gender, as a largely female cohort. The SIREN cohort was 84% female, 88% white ethnicity and a median age of 43 years.
- 199. The age profile of the SIREN cohort was consistent with the NHS workforce (median age 43 breakdown siren vs NHS: <25 years 4% vs 6%, 25-34 21% vs 23%, 35-44 25% vs 24%, 45-54 30% vs 28%, 55-64 20% vs 18%, >= 65 2% vs 2%). This was broadly similar to the UK working age population, although there were a higher proportion in the <25 years and >=65 year age groups in the general working age population. The gender profile was broadly similar to the NHS workforce, with 84% of SIREN female and 77% of the NHS workforce female. In comparison in England 47% of the population are female.
- 200. Data on ethnicity in the NHS workforce was compiled by Devolved Administrations. There was greater diversity in the English NHS workforce (74% white) than Scottish (90% white), Wales (81% white). SIREN, which is a UK cohort, with 88% of white ethnicity fits within this. In England, the NHS has greater ethnic diversity than the working age population (81% white ethnicity).

- 201. Using an individual based mathematical model to predict how large the burden could have been if vaccines had not been available from 8 December 2020, it concluded:
 - a. the rapid COVID-19 vaccine rollout from December 2020 averted infection in a large proportion of hospital healthcare workers in England: without vaccines, second wave infections in patient-facing healthcare workers could have been 21.8%.
- 202. The findings also highlighted occupational risk factors that persisted in healthcare workers despite vaccine rollout: for example, the occupational group with the strongest association with infection after adjustment was healthcare assistants, followed by bedside therapists. In univariable analysis, being of Asian or black ethnicity was associated with an increased risk of infection during the second wave compared to participants of white ethnicity. After adjustment in the multivariable model, including time to vaccination, the differences were less pronounced Asian ethnicity 1.23 (1.03 to 1.47) and the results were no longer significant for the black ethnic group 1.18 (0.86 to 1.62). The strongest risk factor for infection in the second wave was found to be time to first vaccination: disparities in vaccination coverage within our cohort are likely to account for the strong univariate association of infection risk with black ethnicity disappearing after adjustment. Infection risk varied significantly by English region, which is consistent with different regional epidemiology. Infection risk was highest in East of England and London, which is consistent with the emergence and spread of the Alpha variant in these regions before vaccine roll-out.
- 203. In multivariable analysis, factors increasing the likelihood of infection in the second wave were being under 25 years old (20.3% (132/651); living in a large household (15.8% (282/1781); having frequent exposure to patients with covid-19 (19.2% (723/3762); working in an emergency department or inpatient ward setting (20.8% (386/1855); and being a healthcare assistant (18.1% (267/1479).

- 204. The study found that both occupational and domestic exposures were associated with increased risk of infection, including increased household size and frequent exposure to COVID-19 patients. Regarding the occupational factors identified, it is likely that exposure to COVID-19 differed by role (healthcare assistant compared to doctor) and setting (inpatient wards compared to Emergency Departments) including time spent with individual patients and activities involved. It was not possible with this design to unpick these associations further, which would require more data on behavioural factors and granular details on workplace setting including IPC procedures. The results of this analysis, showing both the importance of prompt vaccination for HCWs and the persistence of demographic and occupational differences in infection rates, were presented to relevant groups including HOCI and NHSE IPC leads, to inform their risk assessment and recommendations for HCWs.
- 205. SIREN published fortnightly reports documenting infection rates, reinfection rates and COVID-19 vaccination coverage with regional stratification and shared this routinely with key experts, including to 4 nation CMOs, the UKHSA Incident Director, and presented fortnightly at the UKHSA COVID-19 surveillance Data Debrief Group for situational awareness reports to government. Interim and final analyses were regularly presented at the Vaccine Effectiveness Working Group and the Joint Committee for Vaccination and Immunisation (JCVI). Ad hoc reports were prepared and presented on request to key expert groups including SAGE and SPI-M and the HOCI group.
- 206. SIREN data was also used throughout the pandemic by the UKHSA COVID-19 nosocomial modelling group, to set model parameters to investigate different transmission pathways in hospitals. SIREN analyses were shared with researchers and other public health agencies nationally and internationally through invited presentations, including at key working groups of WHO and ECDC, and at national and international scientific conferences.

Statement Excerpt from Dame Jenny Harries' Module 2 corporate statement (INQ000251906)

207. Below is an excerpt from Dame Jenny Harries' Module 2 corporate statement (INQ000251906 – paragraphs 332 to 393), referred to above at paragraph 107.

(Statement Excerpt Starts)

- 208. This section of the statement provides my understanding of the organisational knowledge of the nature and the spread of SARS-CoV-2 and of COVID-19 between 1 January 2020 up to and including the date of first UK national lockdown on 26 March 2020. The early parts of this section primarily cover the activity of PHE, which was the only predecessor organisation to UKHSA which existed during this period. Later parts of this section cover work to increase testing capacity, and these go beyond the specified period in some instances for purposes of narrative clarity.
- 209. As detailed in Section 1 of this statement, UKHSA and its predecessor organisations' roles in the decision-making processes were predominantly through: the provision of data and other scientific information, for example, epidemiological data; the provision of scientific advice to key individuals, committees, and organisations within the established emergency response arrangements; as well as participation in meetings as subject matter experts or to fulfil prescribed roles. Our advice therefore was provided to Government through a number of routes, including directly to Department of Health and Social Care (DHSC) or the Chief Medical Officer (CMO) and through the New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG), SAGE and the SAGE sub-committees.

The emergence of SARS-CoV-2

210. In UKHSA's witness statement for Module 1 dated 14 April 2023 I provided detail on PHE activity during the initial COVID-19 response up to 21 January 2020 in Section 8, 'Standing up response plans for COVID-19'. I have included some of this detail again to aid the Inquiry's understanding and I have focused on those actions that contributed to key Government decisions within the scope of Module 2.

- 211. On 31 December 2019 the on-duty epidemiologist in the Epidemic Intelligence team, in PHE's Tuberculosis, Acute Respiratory, Gastrointestinal, Emerging & Zoonotic Infections and Travel Health Division (TARGET, part of the National Infection Service), which carried out routine epidemic intelligence activities to detect and assess potential emerging infectious disease threats to the UK, identified an unusual signal of reports from the Wuhan Municipal Health Commission of a cluster of viral pneumonia of unknown aetiology (cause) in Wuhan City, Hubei Province of China. On the same day this information was shared, via the EpiIntel briefing, which was routinely shared with a distribution list of key stakeholders via a distribution list including the PHE Medical Director and relevant colleagues in PHE Emergency response teams and National Infections Service, the DAs, CO, DHSC, other government departments and the CMO and DCMOs, plus colleagues within NHS England emergency response and the High Consequence Infectious Diseases Network [Exhibit: JH2/237 INQ000223305].
- 212. Further information on the viral pneumonia of unknown 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 European Centre for Disease Control and Prevention (ECDC), the WHO, the US Center for Disease Control and Prevention (CDC) and media over subsequent days.
- 213. PHE virologists began collaboration with WHO technical leads from 1 January 2020, building on existing emergency preparedness diagnostic development work. Following the SARS outbreak in 2003, HPA (predecessor of PHE) recognised the potential for this family of viruses to pose an emerging threat and developed detection capability using a pan-coronavirus test. This technical approach provided a viral diagnostic testing capability for coronaviruses but was not suited for mass population testing use. It was utilised in the detection of the first UK case of MERS in 2012, which was also only the second global case. However, it provided an essential diagnostic assay in January 2020 whilst a specific SARS-CoV-2 test was developed which I describe later in the statement.

- 214. On 2 January 2020 PHE sent a formal briefing to the CMO with a summary of the information known at this time [**Exhibit: JH2/238 INQ000223306**]. On 5 January 2020 the CMO emailed colleagues in DHSC and the PHE Medical director suggesting three triggers for escalation when considering the risk to the UK [**Exhibit: JH2/239 INQ000223307**]. The triggers were:
- a. Healthcare workers dying. This is often the early warning that a new infection is both severe and transmissible;
- b. Evidence of person-to-person spread;
- c. Geographical spread implying a zoonosis is spreading through animal or human transmission.
 - 215. On 5 January 2020 a WHO Disease Outbreak News (DON) notification was published highlighting that, as of 3 January 2020, 44 patients with pneumonia of unknown cause were detected in Wuhan City. Of these 11 were severely ill, and the remaining patients were clinically stable. The DON notification also stated, "no evidence of significant human to human transmission and no health care worker infections reported" [Exhibit: JH2/240 INQ000223308].
 - 216. On 8 January 2020 PHE activated its highest level of response an Enhanced National Response and established an IMT and SRG, as mentioned earlier in this statement. On the same day media sources reported an imminent announcement by China of a new coronavirus as the cause of unexplained pneumonia in Wuhan. In relation to any potential controls or specific health advice needed for travellers and/or at the border, DHSC commissioned PHE, on 17 January 2020, to set out a menu of precautionary measures that might be considered, either in a small escalation of COVID-19 (as it became known), or in a significant escalation, focused on airports that received direct flights from Wuhan [Exhibit: JH2/241 INQ000223309]. PHE shared a draft of this paper with DHSC on 20 January 2020 [Exhibit: JH2/242 INQ000051708].

- 217. In the NERVTAG meeting on 21 January 2020, the committee analysed reports from mainland China and agreed that there was clear evidence of human-to-human transmission [**Exhibit: JH2/243 - INQ000023119**]. 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 had been produced and circulated to NERVTAG members on 20 January 2020,
- b. outlined proposed changes to the existing UK risk assessment, which were supported by NERVTAG, as follows:
 - i. Impact of the disease raised from 'low/moderate', to '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 Polymerase Chain Reaction (PCR) test ("assay") was able to 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,
- d. presented an updated risk assessment to NERVTAG highlighting the emerging evidence of human-to-human spread, including from a potential 'super-spreader' event in a neurosurgical unit in mainland China, the wider geographic case distribution but without severe disease, and reviewing the modelling and other insights available from the NERVTAG members [Exhibit: JH2/244 - INQ000101205].
 - 218. Potential border restrictions were also discussed at the NERVTAG meeting on 21 January 2020. DHSC asked NERVTAG to reconsider the issue of port health 'screening' and asked it to comment on proposed interventions, some of which had been included as possible precautionary activities in the paper submitted to DHSC from PHE exhibited here [**Exhibit: JH2/242 - INQ000051708**] and in paragraph 340. NERVTAG considered that port of entry screening, as discussed in the paper, for those travelling from Wuhan was not advised at this point and that providing information to travellers and providing effective means for proper assessment of travellers who became febrile at appropriate healthcare settings was likely to be a more effective intervention.

- 219. On 22 January 2020 DHSC announced, and PHE immediately introduced, enhanced monitoring for direct flights to England from affected areas, the definition of which was updated as the virus spread [Exhibit: JH2/245 - INQ000223314] [Exhibit: JH2/246 - INQ000223315]. PHE notified the airlines directly of the new arrangements [Exhibit: JH2/247 - INQ000119494] which consisted of:
- a. Providing information to passengers in the form of leaflets and posters at airports and inflight messaging;
- b. Enhanced public health protection measures, including implementing a requirement for a General Aircraft Declaration (GAD) to be submitted to PHE's Health Control Unit (HCU) based at Heathrow Airport. If there were no symptomatic individuals on the flight, disembarkation occurred as usual. If symptomatic individuals were reported, the HCU would carry out a public health risk assessment liaising with PHE HPT colleagues for specialist public health advice as required and arrange any control actions such as isolation as necessary [Exhibit: JH2/248 - INQ000223317].
 - 220. PHE identified 1,466 passengers returning to the UK from Wuhan via direct flights from 10 January 2020 up to, and including, 24 January 2020 (when direct flights ceased) and took steps to contact them. These numbers are captured in PHE's incident response SitRep for 6 February 2020 [Exhibit: JH2/249 INQ000223324]. PHE's EpiCell routinely shared these reports with DHSC for information and the relevant extract is represented in the Port Health situational report [Exhibit: JH2/250 INQ000223325].
 - 221. On 24 January 2020 PHE representatives attended a COBR meeting from which actions for PHE to lead were noted. These included [**Exhibit: JH2/251 - INQ000223326**]:
- a. Working with the Border Force, airline carriers and the Department for Transport to ensure receipt of passenger name records where possible;
- b. Providing regular updates to Ministers on the progress of contact tracing of recent returners from Wuhan.

- 222. On 28 January 2020 PHE presented an update paper to NERVTAG providing a summary of the epidemiology of the Wuhan Novel Coronavirus [**Exhibit: JH2/252 INQ000223327**]. At this meeting PHE:
- a. Provided a summary of the current known epidemiology of the virus confirming 4,585 cases had been reported in mainland China, with 70 reported outside the country;
- b. Confirmed that at that date there was not yet any official or published evidence or sufficient case data to draw firm conclusions regarding the contribution of asymptomatic transmission to the spread of the novel coronavirus. There was further discussion by NERVTAG members with the general view taken that the force of infection from asymptomatic individuals, if present, was likely to be lower than symptomatic individuals;
- c. Confirmed the estimated reproduction number from a WHO Emergency Committee meeting on 22 January 2020 where they stated that "Human-to-human transmission" is occurring and a preliminary estimate of R0, the reproduction number of the virus of 1.4-2.5, was presented [Exhibit: JH2/253 - INQ000047820]. The reproduction number (R) is the average number of secondary infections produced by a single infected person.
 - 223. Following this meeting PHE implemented the action to send reported daily case numbers from mainland China, at a provincial level, to the Imperial College modelling team to inform the risk calculations to calculate the volume of screening that would be required if the case definition was broadened to additional provinces beyond Wuhan and Hubei. It was agreed that these calculations would be discussed at the next NERVTAG meeting to inform an update to the case definition. It was noted that any such decision would require DHSC to coordinate with external organisations such as NHS111 and the Foreign Office.
 - 224. On 30 January 2020 WHO declared the WN-CoV outbreak as a public health emergency of international concern. Internationally there had been 97 confirmed cases outside of mainland China reported from 18 countries at this point. Most of these international cases had travelled to Wuhan. However, person to person transmission events had been reported in Vietnam, Germany, Japan, and the USA. By this date, 161 people in the UK had been tested for WN-CoV all were negative.

- 225. However, on the following day, 31 January 2020, two cases of WN-CoV were confirmed in the UK. PHE's SitRep from 31 January 2020 circulated to external stakeholders including DHSC, DAs, NHS, NHSE, NERVTAG and National Travel Health Network and Centre confirmed, "As of 31/01/2020 09:00, there have been 177 individuals tested in the UK: 2 were positive and 175 were negative. Contacts of the confirmed cases are currently being identified" [Exhibit: JH2/254 INQ000119467].
- 226. The 'PHE SitRep 31 January 2020' also provided an update to the UK risk assessment (dated within the document as 21/01/2020, but the correct date is 31/01/2020):

Current impact of the disease is: Moderate

Based on limited currently available information on the transmission of the disease,

- the risk to the UK population is considered: Moderate
- the risk to UK travellers to affected areas of China is: Moderate

This is based on limited information and remains under review as more data emerges.

- 227. On 4 February 2020 PHE presented a paper to SAGE on asymptomatic transmission [**Exhibit:** JH2/255 INQ000074909]. In this paper PHE assessed the extant evidence for asymptomatic transmission of 2019nCoV (subsequently known as SARS-CoV-2) and compared this to what was understood of viral shedding and asymptomatic transmission in the closest known genetically related virus, SARS-CoV in humans. The paper noted that the available data at the time for 2019nCoV did not provide evidence for major asymptomatic or sub-clinical transmission although it also indicated the limitations of available data.
- 228. It is important to clarify that the paper presented to SAGE by PHE sought to consider what proportion of transmission might come from asymptomatic individuals. The importance of potential asymptomatic infection was recognised from the beginning in the PHE scientific advice, using the analogy with other respiratory viruses (influenza) and the conceptual framework of the mathematical relationship between disease control and proportion of asymptomatic infection. This is demonstrated in the

paper to SAGE by the inclusion of the analogy of respiratory viruses, inclusion of which outlines the relationship between control of virus transmission, the amount of asymptomatic transmission and the summary of early case reports for SARS-CoV-2.

- 229. On 11 February 2020 the Coronavirus Study Group (CSG) of the International Committee on Taxonomy of Viruses announced "severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)" as the name of the new virus. This name was chosen because the virus is genetically related to the coronavirus responsible for the SARS outbreak of 2003. While related, the two viruses are different. On the same day WHO announced "COVID-19" as the name of this new disease following guidelines previously developed with the World Organisation for Animal Health and the Food and Agriculture Organization of the United Nations [Exhibit: JH2/256 - INQ000223331].
- 230. There were four information sharing calls held between five nations (Australia, Canada, New Zealand, United Kingdom, United States) from 11 to 21 February 2020, which originated out of a bilateral call between UK and Australia where joint discussion on emergent issues was felt useful. These calls compared models of investigation and control between the different countries. Attendees were largely medical consultants from PHE involved in incident response. The first call focused on border control measures, case investigation and case definition, contact tracing, and cruise ships. Subsequent calls focused on issues arising from repatriation of citizens from the Diamond Princess cruise ship, quarantine arrangements arising from repatriation, and control measures on return. For example, one meeting dealt specifically with the epidemiological follow-up of repatriation cohorts, including developed protocols for repatriation and management approaches (email examples below). Much of the information was received via International Health Reporting or other routes (e.g. publicly available from Japan), however there were details shared about approaches each country was taking to repatriation, such as pre-flight assessment and quarantine periods on return [Exhibit: JH2/257 - INQ000223332] [Exhibit: JH2/258 -INQ000223333] [Exhibit: JH2/259 - INQ000223335] [Exhibit: JH2/260 -INQ000223338].

- 231. PHE presented a further paper to SAGE on 18 February 2020 showing very early virological analysis of samples from UK cases of SARS-CoV-2. This paper set out current understanding regarding viral shedding from humans infected with the virus, although data remained limited at this stage as only nine cases of SARS-CoV-2 had been detected in the UK. All cases were identified through detection of SARS-CoV-2 in upper respiratory tract samples. Lower respiratory tract material was available in very few cases and no blood samples demonstrated the presence of SARS-CoV-2 RNA [Exhibit: JH2/261 INQ000074915].
- 232. Work to understand the transmission dynamics of SARS-CoV-2 developed over the next few months, as demonstrated in the tracking of cases through First Few Hundred ("FF100") epidemiological studies, establishing household contact studies and outbreak investigations in different settings, such as in the military and the "Easter 6" study in care homes, as well as regular sampling of returning traveller cohorts, including UK nationals from Wuhan and cruise ships which were quarantined. Further information and evidential exhibits on FF100 can be found at paragraphs 656-667 in Section 5 of this statement.
- 233. A paper by PHE was presented to SAGE on 24 February 2020, considered three scenarios for action if evidence of an epidemiologically linked group of COVID-19 cases in the UK (an "outbreak") were to be recorded. The scenarios considered were i) a community-based outbreak, ii) a hospital outbreak and iii) an outbreak on a ship in a UK port. These scenarios were outlined for the containment phase of the pandemic at a point where there was no sustained community transmission in the UK. Recommendations for containing the outbreak and slowing the spread included standard public health outbreak measures such as contact tracing, isolation of cases and closures of individual settings such as a school or care home [Exhibit: JH2/262 INQ000074910]. The paper was incorrectly dated 2019.

"Guidance for social or community care and residential settings on COVID-19" – Care Sector

- 234. On 25 February 2020 "Guidance for social or community care and residential settings on COVID-19" was published on PHE's website (the "February PHE Guidance") [Exhibit: JH2/263 INQ000223341]. This guidance was commissioned by DHSC and brought together contributions from across government, NHSE/I and the adult social care sector, to articulate clearly: infection prevention protocols; when to notify the PHE HPTs; decontamination advice; and current understanding of symptoms and isolation requirements.
- 235. PHE based its guidance on the information and evidence known at the time. As such, the February PHE Guidance began with the following paragraph: "This guidance is intended for the current position in the UK where there is currently no transmission of COVID-19 in the community. It is therefore very unlikely that anyone receiving care in a care home, or the community will become infected. This is the latest information and will be updated shortly."
- 236. Whilst the risk was perceived as low, the guidance stated what measures care homes should take to protect residents so that they could plan and prepare. It provided detailed guidance on the virus and its management, including section 17, which was headed "Specific actions for social and community care staff visiting patients...providing care to residents".
- 237. PHE had pre-existing guidance on management of cases and outbreaks of acute respiratory infections in care homes (and other settings) which informed the actions of Health Protection Teams [Exhibit: JH2/264 INQ000223342]. Care homes were familiar with this guidance and its recommendations. This included advice on isolation of infected patients and on testing suspected cases and management of contacts. The February PHE guidance approach built on existing good practice for managing infectious disease in care homes, including guidance on the circumstances in which self-isolation was required, both in respect of staff and care home residents, infection prevention protocols and decontamination advice.

- 238. The February PHE Guidance was following the "case definition" applicable at the time, in line with WHO data and UK surveillance. The case definition was based on whether a person had travelled to, or worked in, one of fifteen specific countries/regions which had been particularly affected by COVID-19, as set out the Chief Medical Officer Alert issued on 25 February 2020 [Exhibit: JH2/265 INQ000087259]. The CMO Alert linked to guidance that PHE had developed collaboration with the NHS on: initial assessment and investigation of cases; infection prevention and control guidance; guidance on diagnostics; guidance for primary care.
- 239. The scientific understanding at the time was that there was very limited evidence of transmission from asymptomatic cases and the February PHE Guidance stated, "there is currently little evidence that people without symptoms are infectious to others." It was not until April 2020 that the scale of asymptomatic transmission between individuals was better evidenced and understood.
- 240. The February PHE Guidance built on existing PHE outbreak and flu guidance for care homes and applied this to the current available evidence regarding COVID-19. 375. At this stage the UK was still in the 'contain' phase (i.e., seeking to isolate all contacts through pre-existing methods of local contact tracing and isolation of suspected cases), and this guidance reflected the state of knowledge of the virus and transmission rates within the country at the time. It was not until 12 March 2020 that the government announced that it was moving its COVID-19 response from the 'contain' to the 'delay' phase, after the UK's CMOs raised the risk to the UK from moderate to high. As a result, on 13 March 2020 the February PHE Guidance was withdrawn, and superseded by the March PHE Guidance, which reflected the changing phases of the pandemic.
- 241. Advice and proposals for guidance for the sector, in preparation for the move from contain to delay, were already in development by PHE by 29 February 2020. In fact, over 29 February 2020 and 1 March 2020, PHE had circulated internally three proposed versions of updated guidance on social care which was being prepared for the "delay" phase of the pandemic. This reflected the need to update the February 102

PHE Guidance to ensure care settings had appropriate up to date advice on mitigations to reduce transmission and advice on how to manage suspected or confirmed cases if there was the possibility of increased cases in the community. The guidance was initially sent to the Secretary of State for Health and Social Care and CMO on 4 March 2020. The exhibited minutes of the IMT meeting on 4 March confirm that '5 pieces of guidance sent to CMO and the Secretary of State for Health and Social Care and are ready to be put up. These are education, employment, cleaning, transport and social care and these will be looked at by 12.00 with aim to get back to PHE by 17.00' [Exhibit: JH2/266 - INQ000223344]. But, as the guidance provided advice relating to the delay phase, publication was delayed until 13 March on the basis that the move to the delay phase was imminent [Exhibit: JH2/267 - INQ000223345], The Government wanted to communicate all changes to policy as a result of this move together where possible, as set out in the Protocol for Moving from Contain to Delay described below. Further details are below at paragraph 374.

Update to case definition and move to Delay phase

- 242. On 25 February 2020, with emerging epidemiology and the agreement of the CMO, PHE revised the geographical component of case definitions and the recommended management of individuals with recent travel to specific locations in China, Republic of Korea and Italy. PHE was asked to provide visual materials, including maps specifying the "containment areas" (areas for which enhanced suspected case management applied) in these three countries, so they could be used in public press briefings and made available on the GOV.UK website, to support public and clinical awareness of changes in case management. A formal CMO alert was also issued to ensure immediate distribution to and awareness in frontline staff [Exhibit: JH2/268 INQ000119491].
- 243. At the SAGE meeting on 27 February 2020, initial modelling, based on the characteristics of the virus and transmission factors known at the time, suggested that without any mitigations, the peak of a UK epidemic would likely occur two to three months after sustained human-to-human community transmission was evident within 103

the UK population. The first person recorded in the UK as infected with the virus but with no known international links, therefore suggesting community transmission was occurring, was on 28 February 2020.

- 244. On 4 March 2020 a meeting was held to advise the four UK CMOs on the deteriorating COVID-19 epidemiological situation in Italy. A paper for PHE representatives to present at that meeting was prepared on 3 March 2020 [Exhibit: JH2/269 - INQ000223347].
- 245. The approach to port health changed in response to the frequent changes in geographic case definitions. Previously, direct flights from affected areas were required to provide a General Aircraft Declaration (GAD) even if there was no one who was symptomatic on board. On 4 March, given the frequency of flights and volume of passengers, airlines and airports from Northern Italy which were now classed as an "affected area" under the case definition, PHE, DHSC, DfT, and the aviation industry agreed a pragmatic approach, in that a GAD was required only when there was illness on board a flight [Exhibit: JH2/270 INQ000223348]; [Exhibit: JH2/271 INQ000223350].
- 246. On 5 March 2020 the geographic case definition was further revised with the whole of Italy being classed as Category 2 (travellers do not need to undertake any special measures, but if they develop symptoms they should self-isolate and call NHS 111) [Exhibit: JH2/272 INQ000223351]; [Exhibit: JH2/273 INQ000223352]; [Exhibit: JH2/274 INQ000223353]; [Exhibit: JH2/275 INQ000223355]; [Exhibit: JH2/276 INQ000223354]. The adjusted approach and protocol were to be implemented immediately with the expectation that it would be rolled out across all airports and airlines by 11 March 2020. PHE set out the approach in a paper for DHSC on 6 March 2020 [Exhibit: JH2/277 INQ000223360]; [Exhibit: JH2/278 INQ000223361].

- 247. Of the more than a quarter of a million passengers who went through enhanced monitoring between 22 January 2020 and 12 March 2020 when the approach next changed, 129 ill passengers were identified through this process, with 59 of this group being taken for further assessment. No confirmed COVID-19 cases were identified through this process [Exhibit: JH2/279 - INQ000223363].
- 248. In 2018 PHE had developed guidelines for large scale contact tracing if required for a public health incident. The document set out principles to be applied and how coordination was planned to work, rather than operational detail which would inevitably vary depending on the specific nature of the incident [Exhibit: JH2/280 -INQ000148388]. PHE set up a designated contact tracing cell as part of its incident response and this appeared on the daily SitRep report from 19 February 2020 [Exhibit: JH2/281 - INQ000223365].
- 249. The government's initial plan [Exhibit: JH2/282 INQ000057508] for dealing with the pandemic, launched on 3 March 2020, consisted of four phases, the first of which was "contain". This phase was aimed at detection of early cases, follow up of close contacts and prevention of the disease moving to sustained community transmission if reasonably possible. Prior to this, in February 2020, PHE worked to identify potential evidenced points where it might be decided that contact tracing and isolation were no longer effective interventions for control of the pandemic during the Containment phase [Exhibit: JH2/283 - INQ000087180].
- 250. On 7 March 2020, the Civil Contingencies Secretariat circulated the 'Protocol for moving from Contain to Delay' following a discussion at COBR(O) the previous day [Exhibit: JH2/284 - INQ000223368]; [Exhibit: JH2/285 - INQ000223370].
- 251. On 8 March 2020 PHE provided input to DHSC into a submission to be sent to the Secretary of State for Health and Social Care the following day titled, 'Transitioning from Contain to Delay: advice in advance of COBR(M) on 9 March'. PHE provided advice in Annex A on how interventions would change from Contain to Delay on port

health, testing, surveillance, contact tracing, with more detail on PHE's approach in Annex B, which had been sent to DHSC previously [**Exhibit: JH2/286** -**INQ000223371]** (DHSC owns the submission. The document provided is a draft sent to DHSC with PHE's contribution). For contact tracing PHE proposed that it should 'aim to contain as many cases as possible for as long as possible, however, as contact tracing capacity is reached there will be a need for contact tracing to be targeted.' The targeted population was to be determined by available evidence and expert opinion and focused on 'areas which will reduce morbidity and mortality and limit situations which have high potential for spread.' PHE continued to carry out targeted contract tracing, focused on localised outbreaks, throughout the pandemic, alongside the work of NHS Test and Trace.

- 252. On 10 March 2020 SAGE discussed a paper to which PHE data professionals contributed, drawing on early clinical evidence which suggested that the clinical course of COVID-19 infection in younger children was milder than adults, and noting reports of asymptomatic infection in children, which was consistent with emerging evidence in adults [Exhibit: JH2/287 INQ000119702].
- 253. By this date the scale of the global spread of the virus was also becoming clearer and, having studied the outbreaks in Europe, SAGE estimated that without mitigation the peak of the first wave was likely to occur at the end of May/early June 2020.
- 254. Upon case numbers increasing with community transmission PHE advised an evidence-based approach to targeting public health interventions with available resources to maximise protection of the public's health. Recommendations included critical management of case identification including surveillance, contact tracing, testing and treatment as:
 - a move to a national surveillance system combining laboratory and community (via sentinel GP practices) surveillance;
 - b. targeted contact tracing;
 - c. testing according to prioritisation of clinical need;

- d. moving to a 'warn and inform' model at ports and airports [Exhibit: JH2/288 INQ000223373].
- 255. The 'PHE SitRep 14 March 2020' [**Exhibit: JH2/289 INQ000251900**] provided an update to the UK risk assessment stating it was reviewed and raised on 12 March 2020 as:
 - Current impact of the disease is: High
 - The risk to the UK population is considered: High
- 256. On 12 March 2020, following the Prime Minister's announcement [Exhibit: JH2/290 INQ000223374] that the UK was moving into the 'delay' phase of the response, individuals with mild symptoms were asked to self-isolate at home, and PHE published stay at home guidance for individuals who had symptoms (new continuous cough, and/or high temperature) [Exhibit: JH2/291 INQ000223375].
- 257. International reports between January and March 2020 noted differential transmission characteristics within and between different countries. Some European countries saw large, confirmed outbreaks earlier and sometimes more localised than in the UK, whereas genomic sequence data suggested the UK experienced multiple rapid introductions nationwide. However, there was a limit on national testing capacity at this stage and more granular understanding of the UK epidemiology progressed through the duration of the pandemic. Global epidemiological COVID-19 data were collated from official open sources and via the PHE International Health Regulations National Focal Point and were disseminated to DHSC by PHE from the start of the enhanced response via standard reporting mechanisms. The previously exhibited SitRep from 14 March 2020 exhibited here [Exhibit: JH/M2 0289] and in paragraph 379 showed that, at this time, cases were rising significantly on a daily basis in Italy, Spain, France and Germany.
- 258. Between 12 and 31 March 2020 the recurrent review of both UK and global epidemiology, on an ongoing basis, indicated very rapid progression of the pandemic

in the UK, even with interventions implemented to 'flatten the curve', with ICU cases doubling every three to five days. This evidence led to a significant change in the scientific advice that informed policy. SAGE discussed a 'Reasonable Worst-Case Planning Scenario' paper on 29 March 2020 [**Exhibit: JH2/292 - INQ000119708**]. The paper was prepared by the CO and endorsed by the Scientific Pandemic Influenza Group on Modelling (SPI-M-O) to which PHE also contributed through individual technical experts. Reasonable worst-case scenarios are not forecasts but are required to ensure Government has agreed planning assumptions in place to enable respond to a range of scenarios.

- 259. In the early phase of the pandemic, including during March 2020, a number of recognised parameters helpful to forward prediction of infectious disease transmission were unavailable for use by experts. In early March 2020 the likely level of spontaneous reduction in social mixing, the compliance rate for social distancing interventions, including stay at home guidance and some other key parameters were not known. Projected case numbers and deaths varied significantly according to the values of these parameters across modelling approaches.
- 260. On 20 March 2020 NERVTAG noted that, whilst there were data for people testing positive for SARS-CoV-2 without symptoms, there was very little information regarding transmission, and the data from reported cases of asymptomatic transmission was not sufficient to provide conclusive evidence at that time [Exhibit: JH2/293 INQ000119619].
- 261. The COVID-19 Genomics UK (COG-UK) Consortium tabled a report for SAGE on 23 March 2020 which was discussed at the SAGE meeting on 31 March 2020. The report analysed 260 SARS-Cov-2 genomes with initial findings confirming 'a large number of independent SARS-CoV-2 introductions to the UK from multiple locations around the world.' The Executive Chair of COG-UK was the PHE Director of the NIS , and the consortium included representatives from PHE. The genomics work was expanded over the next few months and was a notable part of the 'Easter 6' study in care homes in April 2020 [**Exhibit: JH2/294 - INQ000223378**].

Declassifying Covid-19 as a High Consequence Infectious Disease (HCID)

- 262. The following paragraphs provide an explanation of PHE's role in decisions to classify and declassify Covid-19 as a HCID in the UK. A 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.

263. HCIDs are further divided into contact and airborne groups:

- a. contact HCIDs are 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,
- *b.* airborne HCIDs are spread by respiratory droplets or aerosol transmission, in addition to contact routes of transmission.
 - 264. 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 public health agencies of the four UK nations and is informed by advice from scientific advisory committees. It is published on the UKHSA website [**Exhibit: JH2/295 - INQ000148350**].

- 265. At the start of the pandemic the four nations public health HCID group was responsible for making recommendations on HCID classifications that went to the Advisory Committee on Dangerous Pathogens (ACDP) to consider, and where appropriate, endorse. The group was made up of representatives from PHE and health professionals from across the UK, as well as experts from the HCID Clinical Network.
- 266. On 10 January 2020 the interim recommendation of this group was to classify COVID-19 as an HCID while more was learnt about the disease. This was based on consideration of the UK HCID criteria and the evidence available about the virus and disease during the early stages of the outbreak and was circulated to the Incident Director at PHE on 10 January 2020 and discussed at the Incident Management meeting on 13 January [Exhibit: JH2/296 - INQ000223380]; [Exhibit: JH2/297 -INQ000223381]. The NHS HCID commissioned units providing specialist beds to care for patients with HCIDs and prevented nosocomial transmission when there were no community cases of infection. There are commissioned contact and airborne HCID beds (contact 4 beds and airborne 14 beds), and there are surge capabilities for exceeding routine HCID bed numbers, for example in the Royal Free Hospital there are power respiratory hoods and a dedicated infectious diseases ward that can be transferred to HCID use. The surge capacity and commissioning are the responsibility of the NHS.
- 267. As COVID-19 cases started to emerge in February 2020, all contacts of cases were also identified and closely monitored by local HPTs who followed up by telephone to assess subsequent development of any symptoms. PHE advice on clinical management of cases at this time was therefore tailored to HCID centres. Additional guidance sought to provide information around early identification, referral, and preventive measures, which utilised standard infection prevention and control precautions [Exhibit: JH2/298 INQ000223382].
- 268. On 16 March 2020 a group of infectious disease experts from the four nations reviewed up to date information against the UK HCID criteria. They determined that

further data on cases meant that there was more information available about mortality rates (lower overall than most other current HCIDs), and there was greater clinical awareness as well as a specific and sensitive laboratory test.

269. As a result, the group forwarded a recommendation to the ACDP to declassify COVID-19 as an HCID. This was endorsed by ACDP [Exhibit: JH2/299 -INQ000115534] [Exhibit: JH2/300 - INQ000223384] and agreed by NHSE and the CMO. From 19 March 2020 COVID-19 was no longer considered an HCID and cases could be treated at all hospitals rather than specialist HCID units. The following exhibit details the original and updated review [Exhibit: JH2/301 INQ000257933

(Statement Excerpt Ends)

SECTION 3: Advice and guidance provided by PHE / UKHSA in relation to healthcare settings

Overview

- 270. This section sets out a summary of the areas for which PHE and UKHSA were responsible for providing advice or guidance as part of the response of healthcare systems to the COVID-19 pandemic.
- 271. Guidance teams in UKHSA and its predecessor organisations were involved in the drafting and publication of the government's COVID-19 guidance and were consulted for advice on guidance produced by a number of other government departments that was ultimately owned by those departments.
- 272. At the start of the pandemic, in PHE, COVID-19 guidance was drafted and published by the Clinical and External Guidance Cells set up in January and February 2020 respectively and these merged to become the Advice and Guidance team in September 2020. An overarching function for PHE's Advice and Guidance team, Behavioural Science, Modelling, Rapid Evidence Service and Senior Medical Advisors and Senior Public Health Advisors (PHAGE) was stood up on 19 October 2020.

PHAGE aimed to maximise the expertise of the different specialist teams, ensuring public health outputs were evidence-based, aligned, and consistent.

- 273. PHAGE published guidance documents on GOV.UK for the public, for clinical audiences and for specific settings. Between September 2020 and December 2022, the team alone produced over 60 separate detailed evidence-based guidance documents, in addition to those produced by OGDs. PHAGE also published the UK Infection Prevention and Control (IPC) guidance on behalf of the Four Nations IPC cell. Further details can be found in paragraphs 288 onwards in this section.
- 274. In the early months of the pandemic, guidance for the public and non-clinical settings was cleared through the Incident Director, PHE's Director of Health Protection and Medical Director [who was also the COVID-19 Strategic Director and subsequently the Senior Responsible Officer for COVID -19 in PHE] and Department of Health and Social Care and No.10 [Exhibit: SH3/231 INQ000224010]. Initially, clinical guidance was cleared through the Incident Director with wider input provided from PHE, NHSE, DHSC, CMO and DCMOs, and DAs, where requested.
- 275. From 25 May 2020, the cross-government Triple Lock clearance process was introduced so that all government guidance relating to public health was cleared through PHE, OCMO, the Government Digital Service and No.10 in a process coordinated by the Cabinet Office Guidance Coordination team [Exhibit: SH3/232 INQ000224011]; [Exhibit: SH3/233 INQ000224012].
- 276. PHE and UKHSA published a large volume of advice and guidance during the COVID-19 incident response. This was produced by different teams and not held in one central repository. The documents attached contains two lists of guidance: the first is of guidance badged by PHE or UKHSA alone; the second includes guidance badged by PHE/UKHSA alongside other government departments [Exhibit: SH3/234 INQ000348293] and [Exhibit SH3/235 INQ000120379]. The input from PHE/UKHSA into these co-badged guidance documents will have varied depending on the piece of guidance. These lists are as complete as possible however, due to the

high volume of guidance, published by the cells and teams within UKHSA and its predecessor organisations, which was not held in one central repository and not all published by PHE or UKHSA, they may not be fully comprehensive.

- 277. Advice PHE or UKHSA authored or contributed to which was provided to SAGE, its sub-groups and NERVTAG is exhibited here [**Exhibit: SH3/31 INQ000348133**] and also at paragraphs 65 and 127. This has been produced to be as complete and accurate as possible but may not be comprehensive.
- 278. Changes in understanding of SARS-CoV-2 virus and its transmission influenced ongoing advice and guidance provided by PHE and subsequently UKHSA in relation to healthcare settings. The EMG, a sub-group of SAGE identified and steered the role that environmental modelling, data analysis and environmental sampling played in understanding COVID-19 transmission, with a view to understanding transmission routes, factors that influenced this and the impact of environmental and behavioural interventions and mitigations at an operational level. The work of this group was heavily informed by PHE's activities to understand transmission. From November 2021, the membership of the EMG included individuals from UKHSA including, Isabel Oliver, Chief Scientific Officer at UKHSA.
- 279. Details of how PHE, and subsequently UKHSA's, understanding of COVID-19 changed over time is provided within Section 2 of this statement. A table setting out the guidance which was amended to reflect our changes in our understanding of COVID-19 is exhibited. The document again is intended to be as complete as possible [Exhibit: SH3/236 INQ000348295].
- 280. Included within this section are the following:
 - a. An overview of IPC, AGP and PPE guidance
 - Healthcare Systems Guidance Timeline (including IPC, AGP, PPE and management of exposed healthcare workers guidance). The timeline is broken down into five time periods: Pre 2020, January to March 2020, April to November 2020, December 2020 to November 2021, and December 2021 to June 2022

- c. Guidance relating to rules for visiting patients in hospital
- d. Guidance relating to testing the adequacy or suitability of PPE to protect the wearer
- e. Guidance relating to the use of PPE out of date or not marked with the CE standard in healthcare settings
- f. Guidance relating to the availability of testing for healthcare staff, broken down into the following time periods: March 2020 to November 2020 and December 2020 to June 2022
- g. Guidance relating to utilising or maximising critical care capacity/availability of beds
- h. Guidance relating to the capability of the different sectors of the healthcare systems to scale up or down to respond to areas of need broken down into two sections: supporting the NHS 111 lines and setting up the 119 test contact centre
- i. Guidance relating to the decision to cancel or pause routine care
- j. Guidance relating to the routine vaccinations and immunisations: maintenance of the childhood immunisation programme
- k. Guidance relating to the need for and availability of ventilators and the use of technology to reduce face to face contact within healthcare settings

Overview of IPC, AGPs, and PPE guidance

- 281. The WHO defines IPC as "a practical, evidence-based approach preventing patients and health workers from being harmed by avoidable infections." [Exhibit: SH3/237 INQ000348296]. IPC involves systems and guidance through which healthcare workers can reduce the risk of infection transmission by applying standard and transmission-based precautions as appropriate, including personal protective equipment (PPE). IPC may involve additional precautions for healthcare workers conducting AGPs, which the WHO defines as "medical procedures that have been reported to be aerosol-generating and consistently associated with an increased risk of pathogen transmission." [Exhibit: SH3/238 INQ000114293]
- 282. Prior to the COVID-19 pandemic IPC guidance was developed by a range of organisations including PHE, DHSC, the NICE and the HSE. PHE published a range 114

of pathogen specific guidance on gov.uk, which included IPC precautions to minimise transmission of acute respiratory tract infections and MERS-CoV: infection control for possible or confirmed cases. [Exhibit: SH3/239 - INQ00001222] Criterion 9 of the Code of Practice [Exhibit: SH3/240 - INQ000130549] for the prevention and control of infection sets out the requirements for registered providers to have policies in place for the prevention and control of infection. As part of the UK Antimicrobial Resistance National Action Plan, the forward view for IPC in England was for NHSE to develop the national NHS IPC guidance and policies, adopting the Scottish IPC resources.

- 283. From 5 February 2020, the NHSE/I-led Four Nations IPC Cell was responsible for coordinating and agreeing the consensus IPC policy on behalf of the four nations. The guidance would be jointly issued by DHSC, Public Health Wales, Public Health Agency Northern Ireland, Health Protection Scotland and PHE. PHE published the consensus guidance on behalf of all these bodies as it was hosted on gov.uk. NHSE/I provided the secretariat function for the cell and hold the Cell's records.
- 284. The Four Nations IPC Cell developed consensus on what IPC should be recommended by having regular meetings to share evidence and insights from other countries, WHO guidance, pre-existing evidence for other respiratory infections to build consensus within the Cell, using evidence and literature reviews. Where the Cell could not reach consensus the majority decision was taken. The Cell also updated the guidance as the pandemic progressed from one phase to another, in line with pre-agreed policies. Finally, the Cell also amended the guidance in response to feedback from stakeholders. Other changes to the guidance are outlined in the chronology from paragraphs 288-370. PHE's role alongside the other Public Health Agencies was to provide scientific evidence and advice into the IPC Cell for consideration. The IPC cell reviewed all evidence provided and consensus guidelines were developed.
- 285. The list of procedures considered to be AGPs was also revised as the pandemic progressed and further evidence became available and was reviewed.

- 286. PHE, and subsequently UKHSA, was responsible for developing guidance on the stepdown of IPC measures. PHE and subsequently UKHSA was also involved in developing setting-specific guidance on IPC, PPE, and AGPs. For example, PHE advised on AGPs in special schools and provided guidance on PPE in prisons and places of detention. We will detail this advice and guidance in later modules.
- 287. Another central piece of healthcare guidance led by PHE and UKHSA was guidance on the management of HCWs who had been exposed to COVID-19. Key milestones in the development of this guidance are provided in the timeline below.

Healthcare Systems Guidance Timeline

Pre-2020

- 288. In September 2016, PHE published Infection Prevention and Control Guidance for Middle East Respiratory Coronavirus (MERS-COV) [Exhibit: SH3/239 INQ000001222 Prior to this, the Health Protection Agency had developed guidance on SARS-CoV-1 [Exhibit: SH3/241– INQ000348299].
- 289. In October 2016 PHE published guidance, "Infection control precautions to minimise transmission of acute respiratory tract infections in healthcare settings," which included a list of AGPs. [Exhibit: SH3/242 – INQ000348300].

January-March 2020

- 290. On 10 January 2020, the following key pieces of advice and guidance were issued:
 - a. The four nations public health High Consequence Infectious Disease (HCID) group (the group responsible for making recommendations on HCID classification) made an interim recommendation that COVID-19 be classified as an airborne HCID with immediate effect. Their recommendation was based on consideration of the UK HCID criteria and the evidence available about the virus and disease

during the early stages of the outbreak. [Exhibit: SH3/243 - INQ000223380]. This recommendation was circulated to the Incident Director at PHE on 10 January 2020 and discussed at the IMT meeting on 13 January 2020. [Exhibit: SH3/244 - INQ000090510];

- b. On 10 January 2020, PHE published guidance on the investigation and clinical management of possible cases of COVID-19 (then known as Wuhan novel coronavirus) [Exhibit: SH3/245 INQ000348301]. This provided information on conducting a clinical assessment, COVID-19 symptoms and testing actions to take if a possible case requires hospital admission and de-escalation of IPC measures in hospital. Updates to this guidance were made as detailed in the exhibited table in line with the case definition changes between January and March 2020 and then after COVID-19 became declassified as an HCID on 19 March 2020;
- c. On 10 January 2020, PHE published the first COVID-19 IPC guidance, "Wuhan novel coronavirus (WN-CoV) infection prevention and control guidance" [Exhibit: SH3/246 INQ000101202]. This was less than two weeks after the Chinese authorities declared the incident in Wuhan, at which point there was little (COVID-19 specific) evidence available. Therefore, the guidance was based on the extant PHE MERS-CoV guidance from 2016 [Exhibit: SH3/239 INQ00001222] also exhibited at paragraphs 282 and 288. This guidance 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 recommendations around IPC precautions including environmental cleaning, hand hygiene, identification and management of cases, as well as PPE. It provided the following advice about PPE:

"The following PPE is to be worn by all persons entering the room where a patient is being isolated (either before definitive assessment, or once assessed as a possible case):

- long sleeved, fluid-repellent disposable gown wearing scrubs underneath obviates problems with laundering of uniforms and other clothing
- gloves with long tight-fitting cuffs

- FFP3 respirator conforming to EN149 must be worn by all personnel in the room. Fit testing must be undertaken before using this equipment and a respirator should be fit-checked every time it is used
- eye protection, such as single use googles or full-face visors, must be worn (note prescription glasses do not provide adequate protection)"

This guidance also included a section about AGPs, again based on the extant PHE MERS-CoV guidance. The guidance did not list all AGPs but pointed to specific examples. It stated:

"Procedures that produce aerosols of respiratory secretions, for example bronchoscopy, induced sputum, positive-pressure ventilation via a face mask, intubation and extubation, and airway suctioning carry an increased risk of transmission. Where these procedures are medically necessary, they should be undertaken in a negative-pressure room, if available, or in a single room with the door closed".

As part of general IPC guidance, on 10 January, PHE included advice on what PPE was to be used for AGPs.

- 291. On 28 January 2020, PHE presented a paper to NERVTAG, "High Consequence Infectious Diseases PPE for assessing suspected cases". [Exhibit: SH3/247–INQ000348302] [Exhibit: SH3/56 INQ000047820] This paper described the new PPE ensemble for healthcare workers involved in the care of individuals with suspected HCIDs and contained illustrated appendices for donning and doffing PPE. The new ensemble had been in development over the past year but was not yet actively used within the NHS. NERVTAG were asked if they would recommend accelerating the roll out. At that time, NERVTAG did not support an accelerated roll-out of the new HCID PPE ensemble.
- 292. On 14 February 2020, PHE published updated IPC guidance on behalf of the Four Nations IPC Cell. This guidance amended the description of AGPs [Exhibit: SH3/249 INQ000348304] to 'Procedures that produce aerosols of respiratory secretions, for example bronchoscopy, induced sputum, non-invasive ventilation

positive-pressure ventilation via a face mask, intubation and extubation, sputum induction, manual ventilation, tracheostomy procedures, high frequency oscillatory ventilation and airway suctioning carry an increased risk of transmission'. The Four Nations IPC Cell did not consider coughing, sneezing, or breathing by patients or staff as possible AGPs. It adopted the list of AGPs provided in the extant PHE MERS-CoV guidance, which was derived from a list the WHO published in 2007 following SARS-CoV-1 and updated in 2014. [Exhibit: SH3/238 - INQ000114293]. Given the uncertainty about the transmission of SARS-CoV-2 in mid-February 2020, as stated above, it was considered reasonable to adopt the WHO list of AGPs.

- 293. On 19 February 2020, PHE published posters for donning and doffing PPE.
 [Exhibit: SH3/250 INQ000348305] [Exhibit: SH3/251 INQ000348306].
- 294. On 3 March 2020, PHE published quick guides and videos for donning and doffing of PPE. [Exhibit: SH3/252 – INQ000348307] [Exhibit: SH3/253 – INQ000348308].
- 295. On 6 March 2020, PHE published an updated version [Exhibit: SH3/254 INQ000348309] of IPC guidance on behalf of the Four Nations IPC Cell. The guidance advised that FFP3s should be used by healthcare workers conducting AGPs or in contact with confirmed cases, and that fluid resistant surgical masks (FRSMs) should be used for close patient contact of a possible case. The guidance also expanded the AGP list to include:
 - a. intubation, extubation and related procedures such as manual ventilation and open suctioning;
 - b. tracheotomy/tracheostomy procedures (insertion/open suctioning/removal);
 - c. bronchoscopy;
 - d. surgery and post-mortem procedures involving high-speed devices;
 - e. some dental procedures (such as high-speed drilling);
 - f. non-invasive ventilation (NIV) such as Bi-level Positive Airway Pressure and continuous Positive Airway Pressure Ventilation;

- g. High-Frequency Oscillating Ventilation;
- h. High Flow Nasal Oxygen, also called High Flow Nasal Cannula;
- i. induction of sputum.

296. On 13 March 2020, NERVTAG met and discussed the proposed adaptation of the pandemic influenza IPC guidance into a COVID-19 version. PHE published the pandemic IPC guidance on behalf of the Four Nations IPC Cell. [Exhibit: SH3/255 - INQ000325314]. DCMO Jonathan Van Tam had commissioned this pandemic coronavirus IPC guidance from a small group in NERVTAG based on the extant Pandemic influenza IPC guidance. [Exhibit SH3/256 – INQ000348310] [Exhibit: SH3/256a - INQ000212195]. NERVTAG worked with the Four Nations IPC Cell on the guidance which was reviewed, finalised and approved by the DCMO. The attached email trail demonstrates PHE input into the draft guidance, but the Four Nations IPC Cell held the pen on the guidance. NERVTAG endorsed the recommendations in the guidance to move to the use of FRSMs outside of AGP 'hotspots' as per pandemic flu as opposed to the HCID recommendations of FFP3 respirators at the meeting on 13 March 2020 [Exhibit: SH3/257 – INQ000224002]; [Exhibit: SH3/258 - INQ000224003].

297. The guidance stated the following:

a. Healthcare workers were recommended to use FFP3 respirators when conducting AGPs and in AGP hotspots such as critical care (AGP hotspots were a new concept as advised by NERVTAG in 2020) and FRSMs for all other scenarios. This followed the same principles as the pandemic influenza guidance (prior to this the COVID-19 IPC guidance was based on PHE MERS-CoV guidance) and the guidance cited the WHO 2014 publication on IPC of epidemic-and pandemic prone acute respiratory infections in healthcare and a Health Protection Scotland COVID-19 literature review. This literature review was published on 19 March 2020 and included the review of studies and reports investigating the transmission, presentation, incubation and infectious periods of COVID-19, as well as the use of infection prevention control

methods on similar pathogens. A number of these studies and reports included cases of COVID-19 [Exhibit: SH3/266 – INQ000348313].

- b. That the predominant modes of transmission were assumed to be predominantly droplet and contact and that during AGPs there is an increased risk of aerosol spread of infectious agents irrespective of the mode of transmission (contact, droplet, or airborne). This advice was also based on the Health Protection Scotland review. The guidance also replicated the list of AGPs from the guidance published by PHE in October 2016. There is no mention in the above review on comparison groups relied on to establish that AGPs pose an increased risk. [Exhibit: SH3/242 INQ000348300].
- 298. On 13 March the Advisory Committee on Dangerous Pathogens (ACDP) [Exhibit: SH3/260 - INQ000115534] [Exhibit: SH3/261 - INQ000223384] unanimously recommended that COVID-19 be declassified as a HCID and wrote to the DCMO.
- 299. On 16 March 2020, a group of infectious disease experts from the four nations the four Nations HCID Definition and list group reviewed up to date information against the UK HCID criteria. They determined that further data on cases meant that there was more information available about mortality rates (lower overall than most other current HCIDs), and there was greater clinical awareness as well as a specific and sensitive laboratory test. As a result, the group recommended that COVID-19 was not considered an airborne HCID. This was agreed by NHSE and the CMO. From 19 March 2020 COVID-19 was no longer considered a HCID and cases could be treated at all hospitals rather than specialist HCID units. The following exhibit details the original and updated review. Further information regarding the declassification of COVID-19 as an HCID can be found in paragraphs 262 269. [Exhibit: SH3/262 INQ000119498].
- 300. On 17 March 2020 NHSE/I issued a letter requesting every part of the NHS to free-up the maximum possible inpatient and critical care capacity. [Exhibit: SH3/263 INQ000087317] and on 19 March 2020 the Government's COVID-19 Hospital Discharge Service Requirements set out the actions that should be taken to enhance

discharge arrangements [**Exhibit: SH3/264 - INQ000049702**]. PHE was not formally consulted regarding these requirements nor their impact on the wider system.

- 301. On 19 March 2020, NHS Scotland published a "Rapid review of the literature: Assessing the infection prevention and control measures for the prevention and management of COVID-19 in health and care settings." [Exhibit: SH3/265 INQ000413471] [Exhibit: SH3/266 INQ000348313]. This document was updated throughout the pandemic with the final version published on 7 April 2022.
- 302. It aimed to provide a rapid review of the scientific evidence base to determine if the infection prevention and control measures applied in Scotland were suitable for the prevention and management of COVID-19 in healthcare settings and was used by the IPC cell. The review found:
- "Currently there is no clear evidence of airborne transmission of SARS-CoV-2. Aerosol generating procedures (AGPs) have been associated with an increased risk of transmission of previous coronaviruses (SARS-CoV and MERS-CoV) and a number of AGPs (mostly airway management) have been implicated as risk factors for SARS-CoV2 Therefore airborne precautions should be put in place for all AGPs performed on suspected/confirmed COVID-19 patients."
- 303. On 21 March 2020, PHE published a poster to accompany IPC guidance on "when to use a surgical face mask or FFP3 respirator" [Exhibit: SH3/267 INQ000410868] t advised that healthcare workers use FRSMs unless performing an AGP or working in an AGP hotspot such as critical care, in which case FFP3 respirators should be used.
- 304. On 24 March 2020 PHE published two videos added for donning and doffing PPE specific to COVID-19 for AGPs. [Exhibit: SH3/268 – INQ000348314]. Further information on PPE posters and videos is set out in the exhibited table [Exhibit: SH/M3 0269 – INQ000348315].

305. On 28 March 2020 PHE shared a consultation paper with NHSE, DHSC, CMO's Office, settings and the AoMRC, email [Exhibit: SH3/270 - INQ000348316 and SH3/270 A & B INQ000348318 and INQ000348319] and [Exhibit: SH3/271 -

INQ000348320]. The AoMRC coordinated dissemination to and feedback from all Medical Royal Colleges, the British Medical Association and the Royal College of Nursing. This proposed changes to PPE guidance to more general PPE use given the widespread community transmission of SARS-CoV-2 and more general precautionary use of PPE, at all times, while delivering patient care in healthcare settings. The exhibited document from 30 March 2020 [**Exhibit SH3/272 – INQ000348321**] shows consultation responses, which were reviewed and where appropriate incorporated into the draft guidance.

- 306. On 29 March 2020, the WHO published a scientific brief, titled "Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations" [Exhibit: SH3/81] INQ000348322]. This concluded that its recommendations for droplet, contact and airborne precautions were consistent with those currently being used in the UK:
- "Based on the available evidence, including the recent publications mentioned above, WHO continues to recommend droplet and contact precautions for those people caring for COVID-19 patients. WHO continues to recommend airborne precautions for circumstances and settings in which aerosol generating procedures and support treatment are performed, according to risk assessment. These recommendations are consistent with other national and international guidelines, including [...] those currently used in Australia, Canada, and United Kingdom."

April - November 2020

307. On 2 April 2020, PHE published a quick guide for putting on and taking off standard PPE. [Exhibit: SH3/274 – INQ000348323]. PHE, DHSC, and NHSE also issued a joint press release on the publication of new PPE guidance for NHS teams.

Generally, however, NHSE was responsible for disseminating information around AGPs to healthcare settings [Exhibit: SH3/275 – INQ000348324].

308. On 2 April 2020, on behalf of the Four Nations IPC Cell, PHE published updated "Covid-19 Personal Protective Equipment" guidance as part of broader IPC guidance. [Exhibit: SH3/276 – INQ000348325]. PHE had led the production of this guidance. widely consulting on it including with unions and the AoMRC and getting the endorsement of all four nations' CNOs and CMOs. The updated guidance provided enhanced PPE recommendations, advice on both sessional use of PPE (that is, use of specific items of PPE by a health and social care worker during a single period of time where they are undertaking duties in a specific clinical care setting or exposure environment, such as a ward round, which ends when they leave the clinical care setting or exposure environment) and guidance on the use of PPE in a range of scenarios, including during periods of sustained community transmission. It outlined the advice to all health and social care staff to utilise PPE, including fluid repellent surgical masks, gloves, and aprons when delivering all close contact care (i.e., within 2 metres) for both individuals with confirmed and suspected COVID-19 and those with no symptoms. It advised that respirators, type IIR FRSMs, eye protection and longsleeved disposable fluid repellent gowns could be subject to single sessional use in specific, outlined circumstances. This guidance also made recommendations for PPE when case status was unknown or high levels of COVID-19 were circulating. Providers were advised to undertake a risk assessment within the setting, and "where staff consider there is a risk to themselves or the individuals they are caring for they should wear a fluid repellent surgical mask with or without eye protection".

309. The guidance included four tables:

- a. Table 1 Recommended PPE for healthcare workers by secondary care clinical context [Exhibit: SH3/277– INQ000117822
- b. Table 2 Recommended PPE for primary outpatient and community care [Exhibit: SH3/278 – INQ000348327];

- c. Table 3 Recommended PPE for ambulance, paramedics, first responders and pharmacists [Exhibit: SH3/279 INQ000117824
- d. Table 4 provided further advice on PPE where there was sustained community transmission. It advised the use of PPE for all direct episodes of care both within hospital settings and in the wider community whether or not an individual was known to be symptomatic. [Exhibit: SH3/280 INQ000348329].
- Further detail on the updates to PPE guidance is set out in the exhibited table here [Exhibit: SH3/269 – INQ000348315] and also at paragraph 304.
- 310. On 4 April 2020, PHE published "COVID-19: management of exposed healthcare workers and patients in hospital settings" [Exhibit: SH3/281 - INQ000325260] guidance. This superseded the guidance "COVID-19: actions required when a case was not diagnosed on admission [Updated 14 March]" [Exhibit: SH3/282 -INQ000348330]. For HCWs, it advised, firstly, they could remain in work if they came "into contact with a COVID-19 patient or a patient suspected of having COVID-19 while not wearing personal protective equipment (PPE)". Secondly, they should "not ... attend work if they develop symptoms while at home" and should "self-isolate and immediately inform their line manager if symptoms develop while at work". And finally, that they should only return to work "on day 8 after the onset of symptoms if clinical improvement has occurred and they have been afebrile (not feverish) for 2 days". The guidance also provided advice to HCWs on what to do if symptoms persist beyond seven days, and where to find further information on PPE and infection prevention control. For patients, it recommended that on discharge, they "should be given written advice to stay at home and referred to the stay-at-home guidance if less than 14 days has elapsed since their exposure." The guidance was shared with the DAs, email [Exhibit: SH3/283 - INQ000348331 and SH3/283A INQ000348332], for review on 3 April 2020 and shared with the Four Nations IPC Cell [Exhibit: SH3/284 -INQ000348333] for comment on 9 April 2020.

- 311. On 9 April 2020, PHE published "Guidance for stepdown of infection control precautions and discharging COVID-19 patients." ("Stepdown guidance") [Exhibit: SH3/285 INQ000106344]. The guidance aimed to complement existing infection control guidance to provide advice, on appropriate IPC precautions for COVID-19 patients recovering or recovered from COVID-19 and remaining in hospital or being discharged to their own home or residential care. It specifically provided clarity for clinicians around the necessary periods for isolation of COVID-19 positive cases and testing requirements.
- 312. The Stepdown guidance recommended, "a precautionary approach with more stringent rules for ending isolation and infection control precautions". The need to ensure safe discharge was explicitly outlined: "it is important to note that patients can and should be discharged before resolution of symptoms provided they are deemed clinically fit for discharge in a rapid, but safe, manner". It outlined that patients should be given clear safety-netting advice for what to do if their symptoms worsened, that individuals must follow the "stay at home guidance" and complete the recommended isolation periods.
- 313. The Stepdown guidance was drafted with input from individuals with specialist knowledge in Microbiology, Virology and Infectious Diseases and developed with consultation from NHSE. During the development of the guidance, alongside clinical input, NHSE was also consulted on the content, wording and format, email [Exhibit: SH3/286 INQ000348334 and SH3/286A INQ000383775]. Between 28 March 2020 and 8 April 2020 PHE received feedback from NHSE regarding whether information contained within the guidance was required given recently published Infection Control Guidance, email [Exhibit: SH3/287 INQ000348336 and SH3/287A]
 INQ000348337 In emails on the 5 April 2020 PHE highlighted continued requests from infection control clinical leads for the publication of the guidance in order to support safe discharge. [Exhibit: SH3/288 INQ000348338]. The draft guidance was sent to the Four Nations IPC Cell for review and comment on 9 April 2020 and PHE received confirmation of signoff from NHSE on the same day. [Exhibit: SH3/289 -

INQ000348339]. PHE and subsequently UKHSA updated the Stepdown guidance throughout the pandemic.

- On 10 April 2020, PHE published guidance on gov.uk relating to putting on PPE.
 [Exhibit: SH3/290 INQ000348340] [Exhibit: SH3/291 INQ000348341].
- 315. On 11 April 2020, the Four Nations IPC Cell met to discuss a shortage of disposable fluid resistant gowns, as requested by NHSE members of the cell. [Exhibit: SH3/292 INQ000348342] and email [Exhibit: SH3/293 INQ000348343]. Following this meeting, NHSE cell members produced a paper noting that organisations should undertake a local risk assessments if experiencing a shortage of gowns and recommending that wherever possible gowns should be prioritised for aerosol generating procedures.
- 316. On 11 April 2020, NHSE indicated that the DHSC supply chain would not provide sufficient gowns to equip staff in many trusts with the level of PPE recommended in the current IPC guidance, [Exhibit: SH3/293a INQ000408929]. On 12 April 2020, senior clinicians from PHE attended a meeting of the UK CMOs, CNOs, and NHSE/I chaired by the CMO for England. It was agreed at this meeting that in the context of very limited stocks of gowns, a communication to the NHS should be prepared setting out the options in case of failure of supply of gowns, as set out in the exhibited submission DHSC staff sent to [Exhibit: SH3/293b INQ000408930] the Secretary of State later that day. At the request of NHSE, in order to provide consistent advice to the NHS and its trusts to help protect health and care workers appropriately from Covid-19 where items of PPE were unavailable, PHE began developing a draft document setting out options for PPE usage where there were shortages. [Exhibit: SH3/242 INQ000348300]
- 317. On 13 April 2020, PHE circulated the draft document to the HSE, the NHS, and the CMOs for input, especially considering the health and safety of these approaches. Email [Exhibit: SH3/294 INQ000348345 and SH3/294A] INQ000348346], email [Exhibit: SH3/295 INQ000348347 and SH3/295c] INQ000348352]. The document

included options for longer use and where necessary of re-use of elements of certain items PPE and made clear when certain items of PPE should be disposed of. It also made recommendations around the safe fit and storage of items of PPE, and when IPC procedures such as hand washing should be conducted. It considered the balance of risks of no PPE and the safety of re-using PPE, as outlined in the WHO and CDC NIOSH guidance documents [**Exhibit: SH3/295a - INQ000408932**] [**Exhibit: SH3/295b – INQ000408933**] when there were severe shortages. This was approved by the CMOs, CNOs, HSE and the NHS. In addition, given that this was outside routine processes, DHSC sent a submission to the Secretary of State for Health and Social Care to secure approval to move to longer use and re-use of PPE [**Exhibit: SH3/296 &** INQ000339154 related email [**Exhibit: SH3/297 - INQ000348354 and SH3/296 &** INQ000339154 and INQ000339153 further email [**Exhibit: SH3/298 -**INQ000348357].

- 318. On 17 April 2020 PHE published "Considerations for acute personal protective equipment (PPE) shortages" [Exhibit: SH3/299 INQ000068845]. This document recommended "the sessional use and reuse of personal protective equipment (PPE) when there are severe shortages of supply." In relation to masks, it advised "sessional use," "the use of masks for one [healthcare worker] to use in one work area." A central alerting system alert was issued to highlight the publication of the guidance. [Exhibit: SH3/300 INQ000106357].
- 319. On 24 April 2020 NERVTAG published its evidence review and consensus on AGPs [Exhibit: SH3/301 INQ000257933] NERVTAG observed the scientific evidence base was "extremely weak and heavily confounded by an inability to separate out specific procedures performed as part of CPR." It noted a systematic review found that chest compressions and defibrillation were not significantly associated with an increased risk of SARS infection and that while it was biologically plausible that chest compressions could generate an aerosol, this would only be in the same way that an exhalation breath would do, which was not currently considered a high-risk event or an AGP. It concluded, "we do not consider that the evidence

supports chest compressions or defibrillation being procedures that are associated with a significantly increased risk of transmission of acute respiratory infections."

- 320. On 24 April 2020 PHE added the clarification that chest compression was not an AGP to the PPE page on gov.uk [Exhibit: SH3/302 INQ000348359].
- 321. On 27 April 2020 PHE added a statement to the IPC guidance in response to NERVTAG's review of cardiopulmonary resuscitation as an AGP:
 "based on this evidence review, the UK IPC guidance therefore will not be adding chest compressions to the list of AGPs. Healthcare organisations may choose to advise their clinical staff to wear FFP3 respirators, gowns, eye protection and gloves when performing chest compressions but we strongly advise that there is no potential delay in delivering this life saving intervention."[Exhibit: SH3/303 INQ000257949]
- 322. Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) Scotland published a rapid review, 'Assessing the evidence base for medical procedures which create a higher than usual risk of respiratory infection transmission from patient to healthcare worker'. The review concluded that previously listed AGPs should not be removed from the list and confirmed this was agreed in collaboration with experts from NERVTAG and PHE. It noted that evidence regarding AGPs was constantly being assessed. The review was updated throughout 2020 and 2021 as new evidence emerged and formed a significant part of the evidence base used by the Four Nations IPC Cell during this period. This review is exhibited here [Exhibit SH3/304 INQ000348361].
- 323. On 27 July 2020 the first meeting of the Independent Panel on High-Risk AGP was held [**Exhibit: SH3/305 INQ000348362**]. This was a UK-wide, independent, non-executive expert advisory panel commissioned by the CMO for England. It aimed to provide practical and scientific advice to the CMOs for the four nations on specific high-risk AGPs in the context of the pandemic. PHE provided the secretariat for the panel but did not attend as a member and was not involved in the decision-making

process of the panel. The Terms of Reference for this panel are exhibited here. [Exhibit: SH3/306 – INQ000300663

324. On 21 August 2020, PHE published updated IPC guidance on behalf of the Four Nations IPC cell. [Exhibit: SH3/307 – INQ000299582]. In recognition of 'new ways' of working required as healthcare services remobilised, NHSE developed the concept of three different COVID-19 pathways – high, medium, and low risk – through which patients were to be managed. [Exhibit: SH3/308 – INQ000348366] [Exhibit: SH3/309 – INQ000348366 and SH3/309A] INQ000348367]. Reflecting this, the guidance stated patients on a low risk pathway required standard IPC precautions for surgery or procedures, and set out enhanced protections for medium and high risk patients.

December 2020-November 2021

- 325. In December 2020, the Southeast of England began to demonstrate alarming and accelerating rates of change in case numbers, driven by the emergence of a new variant (subsequently known as "Alpha"). In response to this and the identification of other new variants of concern, the Four Nations IPC Cell produced a position statement based on the available scientific evidence/opinion on whether any changes were required to the current IPC guidance regarding RPE by HCWs. [Exhibit: SH3/310 INQ000348368]. The cell's position was that it should maintain the current recommendations set out in the guidance.
- 326. PHE members of the Four Nations IPC Cell agreed that the IPC guidance should consider a more precautionary approach to PPE for HCWs in light of the Alpha variant and articulated this view at an extended Four Nations IPC Cell meeting on 22 December 2020, and then sent an email to the Four Nations IPC Cell on 23 December 2020, recommending the sessional use of FFP3 masks and visors for red/high risk pathways. PHE IPC staff developed a draft recommendation paper for internal review on 24 December 2020 advocating "a pre-cautionary approach in the absence of evidence" and recommending "the sessional use of FFP3 masks for staff caring for suspected and confirmed patients in non-AGP settings, where additional controls of

hierarchy such as increased ventilation, cannot be immediately improved". [Exhibit: SH3/310a - INQ000408934] [Exhibit: SH3/310b - INQ000408935]. The published consensus review of the cell exhibited in the paragraph above stated, "a review of current available evidence has not identified a change in the mode of transmission between this variant strain and previous circulating strains of SARS-CoV-2". It concluded that the evidence warranted "no change to the PPE recommendations i.e., wider use of FFP3 respirators when AGPs not being performed." The statement committed to continue to review the emerging evidence and update the IPC guidance if required.

- 327. On 4 January 2021, following the publication of the Four Nations IPC Cell's position statement, PHE infection prevention and control colleagues recommended the establishment of a PHE-led expert group to review the emerging evidence on FFP3 use to inform the Four Nations IPC Cell and a weekly review of the available evidence on the new variant. [Exhibit: SH3/310c - INQ000408936]. This was discussed at a PHE Strategic Response Group meeting on 7 January 2021, and agreement to formally commission an expert panel was conveyed on 29 January 2021, with formal scope finalised by 4 February 2021, [Exhibit: SH3/310d - INQ000408938] [Exhibit: SH3/310e - INQ000408939] followed by recruiting of a chair, establishing a secretariat, creating dedicated mailboxes, finding resource to undertake a rapid literature review, agreement on terms of reference, and making initial and formal approaches to key experts and designated bodies. This was completed by 22 February 2021. [Exhibit: SH3/313 - INQ000348386]. The Panel included experts from a range of organisations and disciplines such as infectious disease, hygiene, virology, microbiology, respiratory infection, engineering, occupational safety, and IPC.
- 328. On 11 January 2021 the Independent High Risk AGP panel published a summary paper containing recommendations [Exhibit: SH3/311 INQ000348384]. This summary paper presented the outputs from three separate elements (1) an evidence review of medical procedures which at the time of review were confirmed not to meet the WHO definition for high risk AGPs, commissioned and funded by the NIHR and produced by the Evidence for Policy and Practice Information and Co-ordinating

Centre (2) an international review of high-risk AGP lists worldwide produced by the panel (3) a background briefing document produced by the panel The panel published an updated review of high-risk AGP lists worldwide in July 2021 [Exhibit: SH3/312 – INQ000348385].

- 329. The paper concluded that for the following medical procedures, not on the AGP list, the available evidence was not strong enough to demonstrate that significantly more aerosols were generated than other types of care or that exposure to the aerosols resulted in infection. These procedures were: nasogastric tube insertion, cardiopulmonary exercise and lung function tests, spirometry, swallowing assessment, nas(o)endoscopy and suction in the context of airway clearance (not associated with intubation or mechanical ventilation). The panel recommended the need for further clinical studies as a priority ideally from a broader AGP perspective but with the recognition that guidance was needed for the COVID-19 pandemic.
- 330. On 28 February 2021, the Royal College of Nursing (RCN) published an "Independent review of guidelines for the prevention and control of Covid-19 in health care settings in the United Kingdom" [Exhibit: SH3/312a - INQ000114357]. The RCN review concluded the methodology of the rapid reviews undertaken by ARHAI Scotland to inform UK IPC guidelines did "not meet contemporary standards for the conduct of rapid reviews and consequently the UK infection prevention and control guidelines that draw on it have not been appropriately updated to meet the needs of this pandemic situation, now progressing into its second year. In particular, the evidence relating to airborne transmission, the ventilation of health care premises and the implications for the use of face-protection need to be re-considered." The review went on to argue specifically in relation to droplet versus aerosol transmission, that UK IPC guidelines, and the rapid reviews of the literature which underpin them, "still identify droplet spread as the major route" of transmission, despite updated evidence indicating that "aerosol spread is much more significant". This "outdated evidence", the RCN review argued, was having an impact on recommendations for face-protection.

- 331. On 1 March 2021, the expert REP, convened by PHE to critically assess the evidence on the role of face coverings in mitigating COVID-19 transmission to inform guidance and recommendations met for the first time [Exhibit: SH3/313 INQ000348386]. The Panel met three times between March and May 2021 to discuss and assess the evidence. Given the expert AGP panel was in existence at this time, the REP did not explicitly consider specific AGPs.
- 332. On 25 March 2021 SAGE considered a paper, "Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2," authored by members of the Hospital Onset COVID-19 Working Group and Environment and Modelling Group sub-groups [Exhibit: SH3/314 INQ000075022] both of which had participants from PHE in their capacity as expert advisors. The paper assessed the evidence base on SARS-CoV-2 transmission and mitigation in UK health and care settings with a focus on small particle aerosols and HCW facemasks. It recommended that transmission risks should be managed to be as low as possible and that "improved understanding of aerosol risks supports the need for a greater consideration of this route of transmission within risk assessment and IPC strategies, including ensuring compliance with wearing of FRSM as source control by staff and patients (as far as possible) and paying specific attention to the effectiveness of ventilation in both clinical and non-clinical areas." The paper was updated following SAGE input and finalised on 9 April 2021.
- 333. On 6 April 2021 ARHAI Scotland published a response [Exhibit: SH3/315 INQ000348388] to the RCN's independent review of IPC guidance [Exhibit: SH3/312a INQ000114357]. Their response identified "a number of factual inaccuracies" with the RCN review. With regards to UK guidance, they argued: "The RCN report [...] incorrectly assumes the UK IPC guidance is based on this ARHAI rapid review. The RCN report did not reflect that the UK COVID-19 IPC Guidance is based on the UK IPC pandemic response guidance, agreed by NERVTAG, and is fully aligned with that of the World Health Organisation IPC guidance recommendations published to date [...] The UK IPC cell draw on a broad evidence base to inform the development of this guidance, rapid reviews carried out by ARHAI Scotland are only one part of the evidence from the 4 UK country advice being reviewed by the UK IPC Cell." This was

reviewed at the Four Nations IPC Cell who decided not to make any changes to face masking advice. Notes of this meeting are held by NHSE.

- 334. On 17 May 2021 the evidence from the REP, that PHE convened, was presented to the PHE Face Coverings Group (which was established in January 2021 by PHE, in partnership with the Health and Safety Executive and DHSC, to provide a forum for discussion between expert scientists, public health officials and policy advisers, in order to shape research, inform policy and promote action about face coverings during the COVID-19 pandemic). [Exhibit: SH3/316 – INQ000348389] [Exhibit: SH3/317 – INQ000348390].
- 335. At the meeting on 17 May the REP assessed review-level evidence to consider the potential effectiveness of face masks in mitigating transmission of SARS-CoV-2. The findings presented included:
 - Airborne transmission beyond two metres was possible and contributory factors include poorly ventilated indoor settings, prolonged exposure and activities that may generate more aerosols;
 - b. Certain VOCs are likely to have increased transmissibility although the magnitude of the increase was subject to variations in the modelling approach taken and control measures in place;
 - c. Evidence to date suggested modes of transmission of VOCs had not changed so it was likely that the same IPC measures should be adequate;
 - d. The evidence suggests all types of face mask are, to some extent, effective in reducing transmission of SARS-CoV-2 in both healthcare and public, community settings. N95 respirators are likely to be the most effective, followed by surgical masks, and then non-medical masks, although nonmedical masks (such as cloth masks) made of 2 or 3 layers may have similar filtration efficiency to surgical masks;

e. Evidence (usually of low or very low certainty) from SARS-CoV-2 and other respiratory viruses suggests that, in healthcare settings, N95 respirators (or equivalent) might be more effective than surgical masks in reducing the risk of infection in the mask wearer.

The PHE Face Coverings Group advised sharing the evidence summary and panel recommendations with the Four Nations IPC Cell, email [Exhibit: SH3/318 - INQ000348391 and SH3/318A INQ000348392] [Exhibit: SH3/319 – INQ000348394].

- 336. On 25 May 2021 PHE sent its position paper in response to the HOCI and EMG paper to the Four Nations IPC Cell and to DHSC, email [Exhibit: SH3/321 INQ000348396] and [Exhibit: SH3/320 INQ000348395]. The paper followed a request by the DHSC Patient and Public Involvement (PPI) policy team for a response from the Four Nations IPC Cell on their position following the publication of the HOCI and EMG paper. It was reviewed by the Four Nations IPC Cell, medical and guidance experts within PHE who considered the findings of the paper in the context of the current pandemic landscape (including VOCs) and aimed to provide PHE's views and recommendations in relation to the Four Nations IPC Guidance.
- 337. In the paper PHE recommended a more precautionary approach for HCW (including those working within social care) where there remained areas of uncertainty (around variants of concern, the exact role of short and long-range aerosols and transmission dynamics) caring for patients who had suspected or confirmed COVID-19 in poorly ventilated areas. It recommended that HCW should wear (or have the option of wearing) FFP3 masks or other appropriate respiratory protective equipment as part of sessional use. More generally PHE recommended that more explicit guidance was issued to support organisations and HCW in undertaking and applying the hierarchy of controls risk assessments in all sectors.
- 338. On 26 May 2021 the initial findings and draft high level position statement produced by the REP was circulated to members of the Four Nations IPC Cell, email

[Exhibit: SH3/322 - INQ000348398 and SH3/322A INQ000348401] [Exhibit: SH3/323 – INQ000348402] [Exhibit: SH/M3 0324 – INQ000348403]. In addition to the conclusions presented on 10 May, the statement also noted the evidence specific to COVID-19 was still limited and does not allow for firm conclusions to be drawn for specific settings and type of face coverings. Wider evidence from other respiratory viruses suggests that, in healthcare settings, N95 might be associated with a risk reduction while this might not be significant for surgical masks.

- 339. Also, on 26 May 2021 the Four Nations IPC Cell met and discussed the REP evidence statement and PHE's position statement and recommendations. [Exhibit: SH3/325 INQ000348404]. The IPC Cell majority view was there was no need to change the approach to respiratory protective equipment based on the findings or the REP, since the risk assessed approach they had recently entered in the guidance would mitigate the findings sufficiently: "airborne PPE (when undertaking or if AGPs are likely, when working within a cohort of COVID positive patients or when risk assessed as required) was not supported for inclusion into the guidance by the Cell members." email [Exhibit: SH3/326 INQ000348405 and SH3/326A & B] INQ000348406 and INQ000348407].
- 340. In June 2021 a discussion with NHS Scotland, NHSE/I and PHE took place where it was agreed that the ARHAI Scotland review of the AGP list should be paused pending the feedback from consultation that a UK-wide review was needed [Exhibit: SH3/327 - INQ000348408].
- 341. In August 2021 NHSE led a consultation on transitioning COVID-19 specific IPC guidance to more general respiratory guidance at a time when health and care services were moving towards a recovery phase. [Exhibit: SH3/328 INQ000348409] [Exhibit: SH3/329 INQ000348410] [Exhibit: SH3/330 INQ000348411] and related email [Exhibit: SH3/331 INQ000348412].
- 342. On 9 August 2021 a modelling paper, to which PHE staff contributed, was shared with the Four Nations IPC Cell. This paper modelled the effectiveness of IPC

interventions to reduce nosocomial transmission during the first wave. [Exhibit: SH3/332 – INQ000330923

- 343. On 12 August 2021 the paper modelling the effectiveness of IPC interventions in the first wave was shared with HOCI Working Group.
- On 31 August 2021 findings on the effectiveness of IPC interventions during the first wave captured in the 9 August paper were presented to the SCG. [Exhibit:
 SH3/333 INQ000339939
- 345. On 27 September 2021, following a commission from the Secretary of State for Health and Social Care, UKHSA published three recommendations for changes to IPC guidance to help ease operational pressure on the NHS. [Exhibit: SH3/334 – INQ000348418]. The recommendations were for implementation in low risk areas such as planned or scheduled elective care and were designed to free up capacity in the NHS and Social care as understanding of infection transmission and containment improved and vaccination coverage increased. They included:
 - a. a reduction of physical distancing from 2 metres to 1 metre with appropriate mitigations where patient access can be controlled;
 - b. removing the need for a negative PCR and 3 days self-isolation before selected elective procedures as currently advised by the NICE;
 - c. re-adopting standard rather than enhanced cleaning procedures.
- 346. On 14 October 2021 the REP published its statement [Exhibit: SH3/335 INQ000120649] and evidence review [Exhibit: SH3/336 INQ000120671] on the role of face coverings in mitigating COVID-19. The panel found that:

- a. Airborne transmission beyond 2 metres is possible and that contributory factors to airborne transmission of SARS-CoV-2 include poorly ventilated indoor settings, prolonged exposure and activities that may generate more aerosols;
- b. Effective ventilation as part of the implementation of the hierarchy of risk controls should be used to reduce airborne exposures beyond 2 metres;
- c. Certain variants of concern are likely to have increased transmissibility;
- d. Evidence suggests that the modes of transmission of VOCs has not changed compared to other variants, so it is expected that the same infection prevention and control measures should be appropriate, including ventilation, hand hygiene, face coverings and, in high-risk settings, respiratory personal protective equipment PPE;
- e. Evidence suggests that all types of face coverings are, to some extent, effective in reducing transmission of SARS-CoV-2 in both healthcare and public, community settings;
- f. Epidemiological evidence (usually of low or very low certainty) from SARS-CoV-2 and other respiratory viruses suggests that, in healthcare settings, N95 respirators (or equivalent) may be more effective than surgical masks.
- 347. On 22 November 2021 UKHSA published updated IPC guidance on behalf of the Four Nations IPC Cell, broadened to address IPC for seasonal respiratory infections rather than solely COVID-19. [Exhibit: SH3/337 – INQ000348420].

December 2021-June 2022

348. On 1 December 2021 the Four Nations IPC Cell met to develop a consensus position statement following the identification of the Omicron new variant of concern on whether any changes were required to the current IPC guidance. Based on the available scientific evidence, and in particular the lack of evidence that the transmission mode for this variant had changed, the cell agreed that no changes were required to the extant IPC guidance based on the identification of Omicron but that this

would be kept under review. [Exhibit: SH3/338 – INQ000348421 and SH3/338A INQ000348422] [Exhibit: SH3/339 – INQ000348423] and related email [Exhibit: SH3/340 - INQ000348424].

- 349. On 3 December 2021 the UK CMOs discussed whether guidance on FRSM,
 FFP2 and FFP3 should be reviewed and if there was anything further that could be done to protect staff in light of the finding of the Omicron variant. [Exhibit SH3/341 INQ000348426 and SH3/341A INQ000348427]. On 6 December they asked the Four Nations IPC Cell to consider this and report back to the SCG.
- 350. On 8 December 2021, at a meeting of the Four Nations IPC Cell, UKHSA members flagged their opinions based on the output of the REP and the limited evidence regarding the emergence of the Omicron variant highlighting a greater need for FFP3 mask use: "this is a rapidly evolving situation and in the absence of scientific certainty, as previously recommended by PHE for Alpha variant, a more precautionary approach including the wider use of FFP3 respirators by staff caring for suspected and confirmed SARS-CoV-2 patients should be considered by the UK IPC Cell." The Cell discussed this, but the majority view was that this was disproportionate. The cell agreed that the advice on risk assessment with regards to crowding and ventilation would be made a key message, and the message that if mitigations around crowding and ventilation were considered inadequate the need for RPE would be made clearer. [Exhibit: SH3/342 INQ000348428], email [Exhibit: SH3/343 INQ000348429].
- 351. On 4 January 2022 UKHSA applied for NIHR funding for a randomised control trial, called WIPPET, which it had designed over the course of autumn and winter to answer the critical question on FFP3 versus FRSM [Exhibit: SH3/344 INQ000348431]. The trial was intended to address the evidence gap in real world settings on the best protection for healthcare workers caring for patients with respiratory infections. This was intended to enable better decision making on types of masks and usage (i.e. sessional versus targeted) that should be recommended. UKHSA proposed using a cluster randomised control trial design, involving hospitals

where FFP3 use was not routine outside of aerosol generating procedures (AGPs). Participating staff would be randomised (at the hospital site level) to use either a) FRSM (except for AGPs), the current UK standard of care or b) FFP3 respirators for all encounters with patients.

352. On 7 January 2022 Professor Dame Jenny Harries chaired a roundtable discussion on respiratory protective equipment. [Exhibit: SH3/345 – INQ000348432]. Attendees included representatives from DHSC, the Four Nations IPC Cell, NHSE, the public health agencies of the four nations, and the Health and Safety Executive. The minutes state:

"It was agreed by attendees on the call that there was sufficient guidance already in place to allow the appropriate clinical use of FFP3s, but that in response to ongoing questions on this matter, messaging within the guidance could be more 'enabling'. Notably, even if future evidence did suggest more universal advice was needed, there would be practical challenges in wide staff deployment (including fit testing at scale)."

Actions were taken away for UKHSA to work with the UK IPC Cell on messaging in the UK IPC guidance to ensure it is more 'enabling' of FFP3 use in appropriate settings, and to review any more recent evidence relevant to RPE, with respect to Omicron transmissibility.

353. On 17 January 2022 UKHSA, on behalf of the Four Nations IPC Cell, published an updated version of the IPC guidance [Exhibit: SH3/346 – INQ000348433]. The wording, suggested by UKHSA, added and published in the guidance was: "where a risk assessment indicates it, RPE should be available to all relevant staff. The risk assessment should include evaluation of the ventilation in the area, operational capacity, and prevalence of infection/new SARS-CoV-2 variants of concern in the local area. Staff should be provided with training on correct use." The Four Nations IPC Cell also made additional edits to the existing text, removing the word "wholly" in relation to transmission and use of RPE as follows:

"A respirator with an assigned protection factor (APF) 20, that is, an FFP3 respirator (or equivalent), must be worn by staff when: caring for patients with a suspected or confirmed infection spread [wholly] by the airborne route (during the infectious period)."

The removal of this word "wholly," combined with no text in the guidance on transmission routes of SARS-CoV-2, generated significant confusion, with many concluding that this means RPE should be used for all patient encounters for those with suspected and confirmed SARS-CoV2 infections. [Exhibit: SH3/347 – INQ000348434], email [Exhibit: SH3/348 - INQ000348435 and SH3/348A INQ000348437].

- 354. On 31 January 2022 the NIHR rejected UKHSA's application for funding for WIPPET. [Exhibit: SH3/190 INQ000348216] However, the NIHR stated that they would be willing to review a revised application based on feedback provided by the funding committee.
- 355. On 9 February 2022 a review of the list of AGPs completed by NHSE/I at the request of the Four Nations IPC Cell was presented to the Cell. The specific research question for this review was: what is the available evidence to support the removal of any procedures currently included on the UK AGP list? NHSE/I's review recommended that some AGPs could be declassified as such in the guidance iteration. UKHSA's view was that the findings of this review, although focused on AGPs, had potential practical implications for potential airborne transmission in healthcare settings and required further consideration on the impact of the review on PPE guidance.
- 356. On 11 February 2022 the CMO received a letter, co-signed by Royal Colleges, Professional Bodies and Trade Unions, regarding inconsistencies between public messaging on airborne transmission of COVID-19 and IPC guidance across the UK. [Exhibit: SH3/349a - INQ000074820]. Firstly, the letter argued that while there was "now significant scientific consensus" that COVID-19 was "transmitted by the airborne route as well as by droplets and fomites", the latest version of UK IPC guidance, dated

17 January 2022, "no longer gives any indication of the transmission route." This omission, the letter argued, was leading to confusion and "differences of interpretation" across healthcare organisations and made "Infection and Prevention Control decisions and risk assessment less easy to carry out in an appropriate fashion." Secondly, it argued that "current IPC guidance gives no indication of the increased risk" of COVID-19 for healthcare workers working in close quarters, "except in the context of AGPs", and that clarification was needed on "the appropriate use of RPE" for those healthcare workers in close contact with COVID-19 infected patients. Thirdly, it argued that IPC guidance on airborne transmission was "out of alignment" with guidance produced by the Department for Education for the education sector, which highlighted SAGE advice that the Omicron variant might show more airborne transmission. Finally, the letter argued that there needed to be clarification on the use and "limitations of FRSM on protection from infection for healthcare workers" [Exhibit: SH3/350 – INQ000348439]. The letter was shared with UKHSA on 14 February 2022.

- 357. On 16 February 2022 UKHSA members at a meeting of the Four Nations IPC Cell stated more time was needed to review the NHSE's review of the AGP list in greater detail. UKHSA staff were concerned the evidence presented in the review was too limited to base critical decisions about potential changes to the list which would have significant implications for PPE recommendations and potentially the risk of HCW and patient infection.
- 358. On 22 February 2022 UKHSA produced a paper [Exhibit: SH3/351– INQ000348440] setting out its response to the NHSE/I review of the list of AGPs. UKHSA found that the evidence to support downgrading certain procedures as AGPs was not robust and that, on this basis, "the precautionary principle should apply before potentially removing protection from staff and patients." The paper also detailed UKHSA's interpretation that "this AGP review highlights the production of aerosols by normal respiratory activity in a graded and proportionate way," and that "the logical consequence of this conclusion is that those delivering close care to patients with suspected or confirmed COVID-19 should be provided with the highest grade of respiratory protection."

- 359. On 23 February 2022 UKHSA provided advice on RPE to be worn in an increased number of settings at a meeting of the Four Nations IPC Cell, email [Exhibit: SH3/352 INQ000348441 and D & E INQ000348445, INQ000348446, INQ000114315 INQ000348448] and previously exhibited documents [Exhibit: SH3/320 INQ000348395] [Exhibit: SH3/343 INQ000348429 and SH3/343A INQ000348430].
- 360. On 1 March 2022 representatives from UKSHA, Public Health Wales, and DHSC met at the Chief Medical Advisor's request to discuss inconsistencies between public messaging and IPC guidance across the UK. [Exhibit: SH3/353 INQ000348451] [Exhibit: SH3/354 INQ000348452].
- 361. On 3 March 2022 UKHSA shared its response to the NHSE/I's review of the list of AGPs with the Four Nations IPC Cell [Exhibit: SH3/355 - INQ000348454] and attachment [Exhibit: SH3/351 - INQ000348440].
- 362. On 9 March 2022 the authors of the NHSE/I review of the list of AGPs replied to UKHSA's response. NHSE/I stated: "there is high quality new evidence supporting the initial objective of the review - to recommend removal of several procedures. This is the view of both the review authors and the clinical consultancy group, and this has been strongly affirmed by an independent peer review of the findings. There are large consequences to keeping procedures on the list that are not a high risk for aerosol generation specifically in terms of inappropriate use of RPE, delays to healthcare, cost, environmental harm, communication problems, stress and fatigue. These are all huge downsides to an overly conservative interpretation of the evidence that will have major impacts on the ability of the NHS to remobilise and to deliver good quality healthcare to patients. We agree there are still evidence gaps that a number of research groups are actively working to close for some of the other procedures and making explicit the link to transmission and its mitigation. However, this should not delay revision of the list as the emergent evidence is compelling and supports the removal of several of the procedures as noted above."

- 363. On 15 March 2022 UKHSA published updated IPC guidance on behalf of the Four Nations Cell, amended to clarify the recommended use of PPE [Exhibit: SH3/346 – INQ000348433]. It confirmed that FFP3 masks were recommended when caring for patients with suspected and confirmed seasonal respiratory viruses including SARS-CoV-2 when carrying out AGPs and when caring for patients with a suspected or confirmed infection spread "predominantly" by the airborne route during the infectious period.
- 364. On 21 March 2022, UKHSA responded to the letter received by the CMO the previous month from royal colleges, professional bodies and trade unions flagging inconsistencies between the IPC guidance and public messaging [Exhibit: SH3/356 INQ000348456] [Exhibit: SH3/357 INQ000348458]. In the letter, UKHSA highlighted the clarifications added to the IPC guidance on 15 March 2022.
- 365. On 30 March 2022 UKHSA replied to NHSE/I on their review of the list of AGPs, email [Exhibit: SH3/358 INQ000348459] and response [Exhibit: SH3/359 INQ000348461]. UKHSA reiterated "we would hesitate before removing protective measures from staff (and surrounding patients such as patients who are ventilated on wards) as we feel that the conclusions of this evidence review support a precautionary approach for the use of respiratory protective equipment when providing close care to an infected or coughing patient, and that those patients would need to be isolated from other patients".
- 366. On 8 April 2022 UKHSA applied to NIHR for funding for the Sessional Use of Respiratory Protective Equipment (SURE) trial to develop the evidence base around different strategies of RPE. [Exhibit: SH3/360 – INQ000348462]. UKHSA proposed using an individual randomised controlled trial design, involving hospitals with clinical areas where sessional use of FFP3 respirators was not routine (outside of AGPs). Staff would be randomised (at the individual level) to either a) targeted use of FFP3 for direct patient care according to risk assessment, the current UK standard of care or b) sessional use of FFP3 whilst in any clinical area with patients with suspected or

confirmed respiratory infections. Additional collaborators with modelling and trials expertise were included in the SURE research team, including co-applicants from the Centre for Trials Research at the University of Cardiff, two Patient and Public Involvement (PPI) leads and a mathematical modeller from the University of Oxford. The outcome measure was narrowed to be COVID-19 related sickness absence rather than all respiratory sickness absence.

- 367. On 14 April 2022 the NHSE/I National Infection Prevention and Control Manual was published. [Exhibit: SH3/361 INQ000348463]. The manual, at the request of UKHSA staff, noted:
 - The distinction between the droplet/airborne route, through which COVID-19 is transmitted, is not always clearly defined
 - The decision to wear an FFP3 respirator should be based on a clinical risk assessment, including consideration of whether the task being performed is an AGP

The manual also contained the new, shortened list of AGPs:

- "awake bronchoscopy (including awake tracheal intubation)
- awake ear, nose, and throat (ENT) airway procedures that involve respiratory suctioning
- awake upper gastro-intestinal endoscopy
- dental procedures (using high speed or high frequency devices, for example ultrasonic scalers/high speed drills)
- induction of sputum
- respiratory tract suctioning
- surgery or post-mortem procedures (like high-speed cutting/drilling) likely to produce aerosol from the respiratory tract (upper or lower) or sinuses
- tracheostomy procedures (insertion or removal)."

368. On 27 May 2022, as part of the broader move to a business as usual approach, the UK wide COVID-19 IPC guidance was withdrawn. [Exhibit: SH3/362 – INQ000257936] The development of IPC guidance for healthcare settings reverted to

business as usual arrangements, including the newly adopted NHSE/I-led National Infection Prevention and Control Manual (NIPCM) in England. As well as continuing to provide science and evidence to support IPC guidance, UKHSA has a limited set of responsibilities for IPC in healthcare settings where these were not covered by the NIPCM, such as guidance on managing staff with a respiratory infection, and particular pathogen-specific IPC guidance including HCID guidance.

- 369. In June 2022 UKHSA was informed that its funding application to the NIHR for the SURE trial as detailed at paragraph 366 was unsuccessful, and consequently the study did not go ahead. UKHSA has, however, taken forward several related studies of policies and experiences relating to the use of face masks and RPE by healthcare, for example:
 - a. The SIREN study assessed staff infection rates by varying exposures. Key findings, captured in the paper exhibited here [Exhibit SH3/225 INQ000089714] and at paragraph 189, were fed back to NHSE leads;
 - b. 'Understanding healthcare workers' experiences of face mask and RPE use in healthcare settings: an interview study'. This study comprised a series of interviews with healthcare workers in order to understand their experiences of face mask and RPE use in healthcare settings, including factors associated with compliance and potential issues with wellbeing. Whilst healthcare workers (HCWs) are at high risk of contracting COVID-19, measures can be put in place to reduce the spread of COVID-19 and other respiratory infections in healthcare settings. These currently include the use of masks: fluid-resistant surgical masks and respiratory protective equipment. However, for mask policies to be effective, compliance with their use must be high. This study interviewed 12 HCWs from a variety of backgrounds to understand their experiences of mask use. We explored factors associated with compliance with mask use and potential impacts on HCW wellbeing. Overall, participants reported good understanding of the benefits of masks and high compliance levels with policy. However, factors that reduced their compliance with mask policy and impacted their ability to carry out their role were highlighted. These

included wearing masks for longer durations, policy being perceived as out of proportion with risk, communication challenges, and discomfort. This study highlights the importance of clear communication of guidance, particularly when it has changed, ensuring staff are familiar with up-to-date research on efficacy of masks, and ensuring guidance aligns with risk. Furthermore, this study highlights the importance of masks to be worn for an appropriate duration (based on risk)."This study is complete and is currently under review for publication in a peer reviewed journal [Exhibit: SH3/362a - INQ000398932];

- c. 'Developing an observational framework to assess mask use in healthcare workers'. In November 2022, funding was awarded for this project. The framework has now been created and will be further developed through two workshops comprising participants from the SIREN study. These workshops are being planned to take place in early 2024;
- d. 'Survey of local policy recommendations for face mask and respiratory protective equipment use in NHS hospitals in England'. [Exhibit: SH3/362b INQ000398931]. In February 2023, a survey of NHS Trusts in England was conducted to explore how guidance on the use of facemasks and respiratory protective equipment is adapted and applied at a local level by individual hospital Trusts. This study is complete, and a report is in draft. Further work is underway to explore incorporating this work into disease transmission modelling and future SIREN study analysis.
- 370. In June 2022 [Exhibit: SH3/363 INQ000257952] NHSE/I's review of the list of AGPs was published. It noted, "the review identified evidence which suggests that consideration should be given to removing some of the procedures currently included on the UK AGP list. However, the evidence assessed was subject to a number of limitations and uncertainties that should be considered before amending the UK AGP list." In response, the British Infection Association raised queries with an UKHSA contact about whether the list of AGPs published in the NIPCM remained the latest guidance. UKHSA responded to these queries individually. [Exhibit: SH3/364 INQ000348466].

371. In June 2022 UKHSA published a rapid review of airborne transmission.
 [Exhibit: SH3/365 – INQ000348467]. This set out UKHSA's understanding of transmission and epidemiology, stating that the review:

"found evidence suggesting that long distance airborne transmission of SARS-CoV-2 might occur in indoor settings such as restaurants, workplaces, and venues for choirs, and identified factors such as insufficient air replacement that probably contributed to transmission. These results strengthen the need for mitigation measures in indoor settings, particularly the use of adequate ventilation."

Guidance relating to rules for visiting patients in hospitals

- 372. In line with pre-existing risk-based approaches to IPC management, the Four Nations IPC guidance included high-level advice on visitor attendance and precautions (such as PPE to be worn by visitors), whilst referring readers to the main country-specific guidance for more information. In England, this was produced by NHSE/I, who can provide further information. [Exhibit: SH3/366 INQ000348468] [Exhibit: SH3/367 INQ000058539]
- 373. The Four Nations IPC Cell changed and adapted the limited advice on visitors within the IPC guidance as new evidence became available. Records and minutes pertaining to any relevant cell discussions would also be held within NHSE/I who provided the Secretariat for the Cell. An example of these discussions from the IPC Cell meeting of 21 April 2021 is exhibited confirming that PHE inputted into discussions around the visitor guidance [Exhibit: SH3/368 INQ000348470 and SH3/369 INQ000348472] [Exhibit: SH3/369 INQ000348472].
- 374. It should be noted that throughout the pandemic, PHE and UKHSA contributed to specific visitors' guidance for non-hospital settings, such as care homes, and prisons and places of detention, which UKHSA considers would be most relevant to future modules.

Guidance relating to testing the adequacy or suitability of PPE to protect the wearer

- 375. As production leads for the Four Nations IPC Cell guidance, NHSE was responsible for assessing the suitability of the guidance developed by the Cell, including its recommendations on PPE, for groups with different characteristics.
- 376. PHE and subsequently UKHSA conducted Public Sector Equality Duty (PSED) and Health Inequality Assessments (HIQAs) for guidance it owned. A list of PSEDs PHE and UKHSA completed for guidance was provided as an exhibit to UKHSA's Module 2 corporate statement [Exhibit: SH3/370 INQ000223614 including
 SH3/370A& INQ000223615 and INQ000223616
- 377. PHE and UKHSA considered the adequacy or suitability of PPE for groups with protected characteristics by completing a Health Inequalities assessment checklist for PPE guidance (which PHE and subsequently UKHSA led). The checklists included an assessment of the 'COVID-19: Considerations for acute personal protective equipment (PPE) shortages', from 18 June 2020 [Exhibit: SH3/371 INQ000348558] and PPE tables published on 2 April 2020, which also had a Public Sector Equality Duty (PSED) assessment [Exhibit: SH3/372 INQ000348559] [Exhibit: SH3/373 INQ000348560]. It should be noted that the date of April 2019 recorded on these two exhibits is incorrect and should read April 2020.
- 378. The PSED found that the development or implementation of the guidance did not lead to unlawful discrimination because of age, disability, gender reassignment. The HIQA flagged that:
 - a. Where a HCW has a disability or health condition that may make it difficult to comply with the guidance's PPE recommendations, and that a local risk assessment would need to be done to ascertain whether the HCW could work in frontline services;
 - b. Where HCW have facial hair for religious/cultural reasons, the effectiveness of facemasks and FFP3 respirators may be impeded. It noted this was mitigated by 149

publishing information on which types of facial hair are not suitable for effective use of facial mask, coinciding with the publication of the guidance within the IPC guidance published on 13 March 2020. This guidance (exhibited above) included a visual guide advising on safe use of FFP3s by those with facial hair;

c. In areas where there is a shortage of PPE supply it may be difficult to access sufficient PPE to comply with the guidance, and a lack of adequate PPE supply may result in HCWs being more exposed to infection with COVID-19. It noted this was by guidance on what to do if faced with PPE shortages, which was published on 17 April 2020.

The HIQA concluded that health inequalities issues within the remit of the PHE's guidance function had been addressed.

<u>Guidance relating to the use of PPE out-of-date or not marked with the CE standard in</u> <u>healthcare settings.</u>

379. From the start of the relevant period, 1 March 2020 to late March 2020, PHE maintained the existing PPE stockpile that had been purchased and maintained according to NERVTAG advice and Ministerial approval. Facial PPE that was out of date or had no expiry date and was not required for immediate use was subject to an accelerated aging and quality assurance testing regime that sampled stock from all batches and checked the product still met the relevant standard. The related test reports were used to inform NHS communications to the system. [Exhibit: SH3/374 – INQ000348561] [Exhibit: SH3/375 – INQ000348562] [Exhibit: SH3/376 – INQ000348563].

Guidance relating to the availability of testing for healthcare staff

380. DHSC had overview of the work of PHE and the NHS on testing. The NHS was responsible for the majority of testing capacity for hospital patients. Between 11 and 17 February 2020 PHE increased its diagnostic laboratory capacity from one to twelve

laboratories, which accelerated the country's testing capability. By 26 February 2020 there was testing capacity of more than 2,000 samples per day at PHE or PHE affiliated laboratories.

March-November 2020

- 381. On 1 March 2020 PHE circulated an internal discussion paper 'Laboratory testing capacity and prioritisation of testing' [Exhibit: SH3/377 INQ000223394] which outlined the development of what became the basis of the prioritisation of testing guidance as the UK was preparing to enter the next phase of the pandemic. It stated: "At present whilst in the containment phase, the majority of laboratory testing (>90%) is carried out for individuals in the community who are in self-isolation following a history of travel from a specified country or area. As an increase occurs in the testing of surveillance streams involving more severe cases or as we move to the next (pandemic) phase, existing laboratory capacity may not be sufficient and there may be a need to introduce prioritisation of testing."
- 382. On 8 March 2020 PHE detailed its advice on the proposed approach to testing in annex B of the submission sent to the Operational Incident team at DHSC for the Secretary of State for Health and Social Care titled 'Transitioning from Contain to Delay: advice in advance of COBR(M) on 9 March' [Exhibit: SH3/378 INQ000223503]. This document confirmed that clinical testing for the virus would transfer to NHS, supplemented with targeted testing by PHE for high-risk groups.
- 383. Rapidly rising case numbers leading up to the move from 'contain' to 'delay' on 12 March 2020 meant that testing of all suspected cases was not feasible due to testing capacity, as all individuals with symptoms were now assumed to be infectious and those who were not considered 'high risk' were no longer required to test. Careful consideration was given to how to prioritise testing across the population.
- 384. Together with the NHS and DCMOs, PHE developed a prioritisation of COVID-19 testing based on clinical and epidemiological need. The prioritisation groups were 151

reviewed and agreed by the DCMO, PHE Medical Director, PHE NIS Director, PHE Incident Director, NHSE Medical Director and NHSE Strategic Incident Director. The document dated 11 March 2020 [Exhibit: SH3/379 – INQ000087299] was agreed by DHSC, NHS and PHE as the priority testing order and shared with testing laboratories.

- Group 1 (test first): Patient requiring critical care for the management of pneumonia, acute respiratory distress syndrome (ARDS) or influenza-like illness (ILI), or an alternative indication of severe illness has been provided, for example severe pneumonia or ARDS;
- Group 2: All other patients requiring admission to hospital for management of pneumonia, ARDS or ILI;
- Group 3: Clusters of disease in residential or care settings e.g., long-term care facility, prisons, boarding schools;
- Group 4: Community patient meeting the case definition and not requiring admission to hospital – over 60 years or risk factors for severe disease (recognising that this is challenging); over 60s should be prioritised over other risk factors;
- Group 5: Community patient meeting the case definition and not requiring admission to hospital under 60 years and no risk factors for complication;

Group 6 (test last): Contacts of cases.

- 385. Following this, on 12 March 2020 at the Tripartite Senior Clinician's Group chaired by the CMO, the consensus view was that PHE should publish the top three priority groups on gov.uk to share with the health and care system. This was published on 14 March 2020 on GOV.UK and exhibited here. [Exhibit: SH3/380 -INQ000119553].
- 386. In late March 2020 PCR testing started to become available for NHS workers displaying symptoms of COVID-19. This allowed those with symptomatic infection but

without PCR confirmation of SARS-CoV-2 detection to return to work. Testing became available to other 'key workers' as testing capacity increased.

- 387. By 12 April 2020 testing became accessible to staff across the NHS, and their household members, including individuals working in the NHS outside acute care, (mental health, primary care, community services). By the end of April 2020, the rapid increase in lab capacity enabled testing in healthcare settings of all non-elective inpatients at point of admission, the introduction of pre-admission testing of all elective patients, testing prior to discharge to a care home, as well as expanded testing for staff.
- 388. On 30 April 2020, following a proposal from DHSC to rollout regular screening to all care home staff and patients irrespective of symptoms, PHE contributed to a paper for NERVTAG setting out the implications of widespread testing and presenting options for the management of asymptomatic staff and patients who test positive. This paper and further information is provided at the 30 April 2020 entry in the Transmissions table in Section 2.
- 389. On 12 May 2020 PHE produced a paper for NERVTAG which looked at studies of asymptomatic healthcare worker testing in order to ascertain rates of COVID-19 in healthcare workers and patients. Exhibits shown in the Modes of Transmission table for the entry 12 May 2020 have further information, email. [Exhibit: SH3/381 INQ000348565 and B INQ000348576 and INQ000383857 and previously exhibited documents [Exhibit: SH3/128 INQ000120169], [Exhibit: SH3/101 INQ000348145 and C INQ000348146, INQ000348147, INQ000348150], [Exhibit: SH3/104 INQ000348151]. The paper [Exhibit: SH3/103 INQ000348150] noted "there is a lack of comprehensive data relating to asymptomatic COVID-19 infection in HCWs", and that "data thus far shows a wide range of asymptomatic infection rates (2% to 25%) in screened HCWs."
- 390. On 15 July 2020, in response to a commission from the SCG, PHE provided a paper to SPI-M which used modelling to evaluate alternative strategies for testing of

healthcare workers, as noted at paragraph 178 [Exhibit: SH3/211– INQ000348233]. On 30 September 2020 PHE provided an updated paper on HCW testing to SPI-M-O and on 8 October shared it with HOCI. [Exhibit: SH3/382 – INQ000348580], as exhibited in paragraph 180 [Exhibit: SH3/214 - INQ00087607].

- 391. On 31 August 2021 findings on the effectiveness of IPC interventions during the first wave of the pandemic and captured in the 9 August 2020 paper were presented to PHE and the HOCWG. The exhibit in paragraph 344 [Exhibit: SH3/333 INQ000339939] provides further information. The main findings were that the most effective interventions/changes for prevention of nosocomial infections in patients were testing/cohorting based on symptoms and increasing space between beds. In healthcare workers it was universal mask use.
- 392. By October 2020 point-of-care loop-meditated isothermal amplification (LAMP) tests were rolled out to 12 NHS trusts to tests staff and patients.
- 393. In November 2020 GP surgeries were able to order PCR tests, on an opt in basis, from the Testing programme via the GP Channel. These tests were available for symptomatic patients who presented with COVID-19 symptoms, as well as symptomatic GPs, practice staff and their symptomatic household members, to support general practice settings remaining operational. LFDs were added to the testing regime for Adult Social Care settings (including Hospices) in November 2020 alongside the existing PCR regime, with a phased rollout across lower risk setting types due to supply and logistics challenges.
- 394. Also in November 2020 the NHS published guidelines for the rollout of asymptomatic staff testing using LFDs. PHE has determined that the LFDs were valid and reliable. NHS Test and Trace purchased the tests supplied the tests to the NHS and received the results of the tests to include in daily epidemiological reporting. [Exhibit: SH3/383 INQ000348581]. This was aimed at all patient-facing staff, starting in 34 trusts, benefitting 250,000 staff, to later be expanded to cover all 1.3 million NHS staff, working in 209 NHS Trusts and Foundation Trusts throughout

England and covering four types of trust: Acute general and acute specialist trusts; Mental health, learning disability, and combined mental health and learning disability trusts; Community trusts and ambulance trusts.

December 2020 - June 2022

- 395. In January 2021 the rollout of regular COVID-19 asymptomatic testing was expanded to cover all 400,000 patient-facing primary care staff working in dentist surgeries, GP practices, optometry practices, and pharmacy practices. NHS Commissioned Independent Healthcare Providers received testing through the NHS Staff Testing Programme until April 2021 when they were moved to their own bespoke delivery channel.
- 396. From 9 April 2021 free LFDs were offered to everyone, inside or outside health and care settings in England (Universal Offer) to encourage twice weekly testing, even for those without symptoms. If a person tested with an LFD test at home, there was a requirement to register the result (positive or negative) on the government online portal or by calling 119. If positive, individuals were instructed to self-isolate and order a confirmatory PCR test online or by calling 119. Healthcare staff were able to access tests through the Universal Offer.
- 397. In January 2022, the requirement for a confirmatory PCR test following a positive LFD result was suspended. This change applied to all staff. From 11 January 2022, any staff member receiving a positive LFD result for COVID-19 was required to self-isolate immediately but was not required to take a confirmatory PCR test. This was because most people receiving a positive LFD result would have had COVID-19, due to its high prevalence at the time. LFDs were to be used by individuals who did not have COVID-19 symptoms; anyone who was symptomatic was expected to self-isolate, even if they received a negative LFD result, and obtain a PCR test as soon as practicable.[Exhibit: SH3/384 INQ000119761].

Guidance relating to utilising or maximising critical care capacity/availability of beds

398. PHE, and subsequently UKHSA, did not produce advice and guidance on any of these areas as this would have been the responsibility of NHSE. However, IPC advice and guidance would have had an operational impact on hospital capacity, for example bed spacing, but the interpretation and operational implementation would have been undertaken by NHSE.

<u>Guidance relating to the capability of the different sectors of the healthcare systems to scale up</u> or down to respond to areas of need

399. Section 2 paragraphs 117 provide information on syndromic surveillance systems routinely monitored by PHE, and subsequently UKHSA, including those monitoring daily NHS 111 calls, GP consultations in-hours and out-of-hours, emergency department attendances and ambulance dispatch calls. As part of the response to the pandemic, PHE supported NHS 111 lines including providing surge capacity, and introduced the 119 Contact Centre lines, as set out below.

Supporting NHS 111 lines

- 400. The NHS Helpline to support the COVID-19 pandemic went live on 3 February 2020. At that stage, public communications requested that all those returning from Wuhan to make contact with NHS 111.
- 401. On 7 February 2020 the Secretary of State for Health and Social Care asked for support from NHS Digital Transformation (NHSX) and other departments to explore how digital tools could support the COVID-19 response. The aim of the online service was to:
 - a. Provide a digital access point to reduce the burden on the NHS 111;
 - b. Give clear advice and guidance to the worried well;

c. Capture data for PHE surveillance.

As part of this, PHE provided advice on what data should be collected along with some answers to frequently asked questions for call handlers around the current case definition and guidance updated regularly throughout the pandemic [Exhibit: SH3/385 – INQ000348583] [Exhibit: SH3/386 – INQ000348584]. These lines were signed off by the Incident Director and checked by clinicians for accuracy.

- 402. PHE drafted a stepdown helpline service for those ringing NHS 111 to manage the surge in calls, email [Exhibit: SH3/387 INQ000348585 and SH3/387A INQ000348586] and email [Exhibit: SH3/388 INQ000348587 and SH3/388A INQ000348589]. This service was for callers seeking information and/or advice on COVID-19 and to allow NHS 111 to focus on assessing those who had symptoms of COVID-19 or additional clinical needs. The PHE service was available during working hours to relieve the pressure on NHS 111 and had an automatic filtering system at the front end that routed appropriate calls to PHE. For out of hours requests for those callers an automated route was provided to call back during working hours. 582,240 calls were handled by the PHE Helpline between February and June 2020. [Exhibit: SH3/389 INQ000339343]
- 403. The PHE call handlers, provided by Serco and Sitel, were not clinicians. Some were multilingual and could converse directly with callers in appropriate languages. Scripts and call algorithms were prepared to support call handlers by PHE. [Exhibit: SH3/390 INQ000348593]. These were updated and refined continuously as the pandemic progressed and policy changes were implemented.
- 404. From March 2020, as NHS service providers started developing and introducing COVID-19-specific clinical codes, PHE developed and launched "COVID-19-like" syndromic indicators in May 2020 for use in emergency departments, GP in-hours surgeries, the NHS 111 service and ambulance syndromic systems. These syndromic indicators did not monitor confirmed COVID-19 cases but monitored records of patients presenting to healthcare services with COVID-19 symptoms.

405. From May 2020 a new national syndromic surveillance system was developed by PHE in collaboration with NHS England, NHS 111 and NHS Digital utilising NHS 111 online assessments. Initially, this reported "potential COVID-19" in NHS 111 online assessments but these were expanded to monitoring NHS 111 online assessments for reports of key symptoms such as anosmia in response to the changing symptomology of COVID-19 infections.

Set up of 119 Test Contact Centre

- 406. On 30 April 2020 DHSC worked with PHE to use PHE's infrastructure/routing with Teleperformance [Exhibit: SH3/391 INQ000348594] [Exhibit: SH3/392 INQ000348595], and a memorandum of understanding with South Central Ambulance Service, to set up the 119 Test Contact Centre. The Centre was set up to enable citizens without digital capabilities to access COVID-19 test booking services. It grew significantly in scale and scope, from 20 call handlers to 3000 by the end of 2020, providing support to the public and to organisations such as care homes and prisons regarding test kits, test bookings, registering of test kits and chasing test results. This reduced pressure on the NHS and enabled NHSTT to deliver population wide testing services for the country.
- 407. By 28 June 2022, the relevant period for this statement, the service had taken 13.5 million calls, averaging 31,000 calls per day. The highest number of calls the service received daily was 86,000: commercial arrangements with suppliers enabled rapid ramp up and ramp down of call handlers to receive calls. Following the Government's Living with Covid Strategy, published in February 2022, calls into the 119 Test service reduced significantly. Whilst resource levels have scaled back to meet reduced demand, the service remains operational.
- 408. When the service was initially introduced advisors for 119 only offered guidance related to information published on GOV.UK and NHS.UK. Over time the internal guidance for the service evolved to reflect changes on a weekly basis. An example of

the frequently asked questions (FAQs) is included from 14 July 2021 [Exhibit: SH3/393 – INQ000348597].

<u>Guidance relating to the decision to cancel and/or pause routine care or national screening</u> programmes

- 409. PHE was responsible for NHS screening programmes, such as routine breast and colon cancer screening, which were commissioned by NHSE/I, under a statutory delegation from the Secretary of State for Health and Social Care. PHE routinely provided the public health expertise required to NHSE for them to commission and oversee local NHS screening services and PHE professionals were placed in teams embedded in NHSE. Through its screening quality assurance services, PHE quality assured all NHS screening programmes in England to ensure these were operating within national standards and guidance.
- In March 2020 PHE supported NHSE/I in its decisions on pausing aspects of some national screening programmes [Exhibit: SH3/394 INQ000348598]. It also provided advice on the issue to the CMO and ministers [Exhibit: SH3/395 INQ000391318]
- 411. Based on PHE's assessment of clinical risk as detailed in the following exhibits, [Exhibit: SH3/396 – INQ000348600 and SH3/396A INQ000348602] [Exhibit: SH3/395 – INQ000391318] [Exhibit: SH3/394 – INQ000348598] anticipated pressures on the health system, and the Government's guidance that the public should stay at home as much as possible, senior clinical leaders from PHE, NHSE and DHSC recommended that invitations for some national NHS screening services were rescheduled and time-sensitive programmes, which could quickly result in significant clinical harm if delayed, including antenatal and newborn screening programmes and high-risk breast cancer screening, should be continued. This recommendation was supported by the NHSE/I national Incident Management Board and senior clinical leaders, including the CMO and NHS National Medical Director.

- 412. The approach was kept under review so that programmes could be reinstated as soon as practicable when NHS capacity and government social distancing guidance allowed. Freeing up resources through rescheduling invitations allowed for staff to be reassigned to more urgent clinical roles and tasks. This included, but was not limited to, GPs, radiologists, radiographers, endoscopists, CT technicians, pathologists, gynaecologists, ophthalmologist vascular surgeons and nurses.
- 413. NHSE/I led on proactive communications for the changes, supported by PHE, to reassure patients of the low clinical risk in the majority of cases and explain the steps they should take if they experience any symptoms. NHSE/I coordinated communications to NHS regional teams to ensure consistency in service delivery across England and issued programme-specific guidance to providers to support them in rescheduling invitations and answering questions from members of the public.
- 414. In October 2021, at the closure of PHE, PHE's responsibilities for screening moved to NHSE/I and OHID. [Exhibit SH3/397 INQ000348604].

Routine Vaccinations and Immunisations: Maintenance of the Childhood Immunisation <u>Programme</u>

- 415. From early March 2020, PHE began to receive reports of people being unable to receive routine immunisation because of GP practices introducing measures to prevent COVID-19. PHE was concerned that some staff who normally delivered immunisations, particularly those offering the BCG vaccine in maternity units, were being redeployed to support hospital care of COVID-19 patients.
- 416. In March 2020, PHE issued early advice in Vaccine Update [Exhibit: SH3/398 INQ000348605] (a regular bulletin that goes to around 67,000 frontline immunisation staff) to providers on the importance of continuing the offer for children and other vulnerable individuals. This included a message 'Keep calm and carry-on vaccinating' together with a clear call to action for the need to keep vaccinating all eligible groups as a priority.

- 417. Vaccine Update was published 12 times in 2020. In April 2020, PHE published a Vaccine Update special, "Maintaining immunisation services during the COVID19 pandemic to to support local administration of the routine programmes in order reduce the serious risk of vaccine-preventable disease" [Exhibit: SH3/399 INQ000348606].
- 418. PHE also rapidly developed a draft statement, endorsed by JCVI about prioritisation of vaccination. A statement from the JCVI was published in April 2020 [Exhibit: SH3/400 INQ000348607] and was accompanied by PHE practical guidance and the provision of FAQs on continuing to offer routine immunisations, including advice on infection control, how to interpret and manage fever after vaccination, and that commencing vaccination did not require completion of the postnatal check (which had been deferred).
- 419. NHSE sent national communications to providers in May and July 2020. [Exhibit: SH3/401 INQ000348608] [Exhibit: SH3/402 INQ000348609] [Exhibit: SH3/403 INQ000348610].
- 420. In November 2020 the guidance was incorporated into joint PHE/NICE advice [Exhibit: SH3/404 – INQ000348611] and this was supported by the Royal College of General Practitioners (RCGP) and the Royal College of Paediatrics and Child Health (RCPCH).
- 421. Public communications were issued in November 2020 by PHE reminding parents that the national COVID-19 restrictions should not stop children from receiving life-saving childhood vaccines. [Exhibit: SH3/405 INQ000348612].
- 422. PHE, and subsequently UKHSA, routinely monitored vaccination coverage of the routine immunisation programmes in childhood in England through the Cover Of Vaccinations Evaluated Rapidly (COVER) programme. Data was collected and collated quarterly and annually and measure coverage at age 12 months, 2 years and 5 years of age. More timely monitoring was provided during the pandemic by an early-assessment series coverage data in England from September 2020 to August 2021.

The series reviewed aggregated childhood vaccination counts (updated weekly from the electronic records of one supplier of IT services to general practices in England) as a means of assessing the impact of physical distancing measures on vaccination delivery. These data were not for the whole of England, nor did they reflect regional or local variations. The final report of that series is exhibited here: [Exhibit: SH3/406 – INQ000348613].

- 423. In April and May 2020 PHE also worked with the LSHTM to undertake some attitudinal work with parents to understand concerns around attending for vaccination. Findings were published on 28 December 2020. [Exhibit: SH3/407 INQ000348614]. The majority of survey respondents (85.7%) considered it important for their children to receive routine vaccinations on schedule during the COVID-19 pandemic. In May-November 2020, PHE again worked with LSHTM to survey what GP practices in London were offering and findings were published in August 2021. [Exhibit: SH3/408 INQ000348615]. Sixty-eight per cent of London practices completed the survey and 97% reported having continued childhood immunization delivery.
- 424. From April 2020 the Immunisation Programmes Implementation Group (IPIG), which brings together partners from across the tripartite to oversee the implementation and delivery of all the individual immunisation programmes routinely considered recovery planning. By July 2020 NHSE were taking the lead updating IPIG on this work, with senior colleagues from PHE fully involved in supporting NHSE with expert clinical and public health advice and resources to enable effective operational implementation of recovery plans.
- 425. PHE developed an immunisations programme recovery options appraisal in May 2020. [Exhibit: SH3/409 INQ000348616]. Delivery of the school age immunisation programmes was impacted by the closure of schools and other physical distancing measures and school absences which then resulted in lower uptake of vaccines such as HPV. This was reviewed by the JCVI who advised that, due to the disruption caused by the pandemic, the priority for the delivery of the routine HPV immunisation programme should be for all eligible children to receive at least the first dose of

the HPV vaccine. The JCVI advice was made by the HPV sub-committee in May 2020, and endorsed by the main committee in June 2020 [**Exhibit: SH3/410** – **INQ000348617**]. This advice was provided to NHSE and provider School-age Immunisation Services to support the prioritisation of the recovery of this programme, and potentially mitigate the impact on population protection which is related to the timeliness of delivering the programme.

- 426. In addition to the routine quarterly COVER and other routine uptake surveillance reports, a Year 10 data collection for HPV was undertaken and reported on the national scale, to indicate coverage in that birth cohort compared to when it was measured when students were in Year 9. This was used to confirm whether local catch-up activities were effective in increasing coverage in those students who had missed vaccinations during the pandemic. Latest evidence suggests that these activities have been effective, as demonstrated in the exhibited report [Exhibit: SH3/411 INQ000348618].
- 427. A focus on recovery supported by data, clinical advice and publications provided by PHE and subsequently UKHSA, continued up to the end of 2022 and remains a priority in 2023.

<u>Guidance relating to the need for and, availability of, ventilators and the use of technology to</u> reduce face-to-face contact within healthcare settings

428. PHE, and subsequently UKHSA, did not produce advice and guidance specifically on these areas.

SECTION 4: Public Health Messaging

429. This section provides information relating to the public health messaging of "stay at home, protect the NHS, save lives" including the impact of this message in relation to patients delaying treatment, as well as providing some more general information in relation to public health messaging.

- 430. The 'stay at home and away from others' messaging, introduced on 23 March 2020 and supported by guidance, exhibited here [Exhibit: SH3/412 INQ000223510] set out three measures. They required people to stay at home, except for very limited purposes, closed certain businesses and venues and stopped all gatherings of more than two people in public in England.
- 431. The 'stay at home and away from others' messaging, along with the 'stay at home, protect the NHS and save lives' messaging were developed by the Cabinet Office. PHE did not develop the guidance and was not asked to consider, or provide advice on, whether the messaging would impact on whether people sought medical care. All communications handling for the emerging pandemic was led by the Secretary of State for Health and Social Care's team at the DHSC and, subsequently, the Cabinet Office. Events moved so quickly that consultation on everything would not have been realistic at that time.
- 432. More generally, PHE had developed a Publications Standard in January 2016 which covered both professional and public-facing materials. PHE routinely used this standard and 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. During the pandemic PHE provided a range of information on COVID-19 related issues, for example, regular surveillance data, the guidance detailed at Section 3 and for example, the in-depth review 'Disparities in the risk and outcomes of COVID-19', published in June 2020 and updated in August 2020. [Exhibit: SH3/413 INQ000101218], detailed at Section 5 of this statement.
- 433. Communications teams in PHE and subsequently UKHSA, had access to Government focus group research findings, polling and other insight data which looked at public health messaging. PHE's Behavioural Science Team (BST) contributed to some of this research, including the exhibited examples [Exhibit: SH3/414 -INQ000224000]. In addition, PHE's BST also provided access to open-access

published insights through its Behavioural Science Weekly Literature Reports [Exhibit: SH3/415 - INQ000224001]. This range of research and resources available from across government during the pandemic provided a picture of the high levels of awareness of public understanding of the public health messages and the public's compliance to the advice and guidance. UKHSA is unable to provide specific comment on whether people delayed seeking treatment as a result of the 'stay at home and away from others' messaging.

SECTION 5: Disparities in Risks and Outcomes for COVID-19

Disparities in Risks and Outcomes for COVID-19 report rationale and findings

- 434. As provided in the Module 1 statement Section 1 paragraphs 70 and 71, S1 c of the NHS Act 2006 (as amended by the Health and Social Care Act 2012) imposed a duty as to reducing health inequalities, stating that in exercising functions in relation to the health service, the Secretary of State (for Health and Social Care) 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 arm's length bodies sponsored by DHSC. The Health Inequalities functions worked across the whole agency while being overseen in the Directorate of Health Improvement. The Equality Act 2010, which applies to public bodies that carry out public functions, includes related but different legal duties.
- 435. On 1 December 2022, DHSC published a technical report on some of the scientific, public health and clinical aspects of the COVID-19 pandemic in the four nations of the UK. As noted in Chapter 2 of the Technical Report, [Exhibit: SH3/416–INQ000348619] evidence from previous pandemics indicated that it was important to understand differences in the risk of becoming infected, disease severity and outcomes between groups. Alongside this it was also important to understand the differential impact among population groups of interventions introduced to try and control disease spread.

- 436. On 4 June 2020, PHE published its report, "COVID-19 review of disparities in risks and outcomes" [Exhibit: SH3/417 INQ000399820]. It was available for participants to read at SAGE 40 on 4 June but was not considered or discussed at that meeting. PHE published an updated version of the report in August that year . [Exhibit: SH3/413 INQ000101218]
- 437. The report [Exhibit: SH3/413 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.
- 438. The report confirmed that the impact of COVID-19 replicated existing health inequalities and, in some cases, increased them. As set out in UKHSA's Corporate Statement for Module 1 at paragraphs 607-608, 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.
- 439. 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".

- 440. Following the report being published in June 2020 the Prime Minister and Secretary of State for Health and Social Care asked the Minister for Equalities with support from the Cabinet office Race Disparity Unit to lead cross government work to address the report's findings. Under the terms of reference for this work, the Minister for Equalities was tasked with submitting quarterly progress reports to the Prime Minister.
- 441. The rationale for this was set out in the final report on progress to address COVID-19 health inequalities published in December 2021 by the Equality Hub and Race Disparity Unit which included to "look at why COVID-19 was having a disproportionate impact on ethnic minority groups and to consider how the government response to this could be improved," adding that "at that time we knew that ethnic minorities were more likely to be infected and to die from COVID-19, but we did not know why." [Exhibit: SH3/418 - INQ000223703]

Findings attributed to practices within healthcare setting

442. Neither version of the PHE Disparities in the risks and outcome of COVID-19 report, [Exhibit: SH3/417 – INQ000399820] and [Exhibit: SH3/413 - INQ000101218] both exhibited above in paragraphs 436 and 437, stated that disparities in health outcomes could be attributed to practices within healthcare settings nor was the methodology underpinning the reports one which allowed any such statements to be drawn.

Advice on healthcare systems' operations to reduce the likelihood of unequal outcomes

443. In the August 2020 version of the report exhibited here [Exhibit: SH3/413 - INQ000101218] and above in paragraph 432, 436 and 437, PHE advised: "the results of this review need to be widely discussed and considered by all those involved in and concerned with the national and local response to COVID-19. However, it is already

clear that relevant guidance, certain aspects of recording and reporting of data, and key policies should be adapted to recognise and wherever possible mitigate or reduce the impact of COVID-19 on the population groups that are shown in this review to be more affected by the infection and its adverse outcomes. As the numbers of new COVID-19 cases decrease, monitoring the infection among those most at risk will become increasingly important. It seems likely that it will be difficult to control the spread of COVID-19 unless these inequalities can be addressed.

444. "PHE and UKHSA did not, and do not, advise NHSE on matters relating to its operations. Having said this, PHE and UKHSA have worked with NHSE in specific areas to reduce the likelihood of unequal outcomes between patients. For example, PHE contributed to research on vaccine hesitancy amongst particular groups facing health inequalities or with protected characteristics to improve vaccine uptake amongst those groups. [Exhibit: SH3/419 – INQ000348621]. PHE also provided advice on vaccination for priority groups such as the elderly and immunosuppressed. More information can be provided on these topics in UKHSAs corporate statements for Module 4.

SECTION 6 - Data/analysis of impact of COVID-19

445. This section provides an explanation of UKHSA's and PHE's approach to collecting and managing data on deaths caused by COVID-19 including those health care setting related, the method used to record and publish the data, the basis for a death being recorded as a COVID-19 death and how this evolved. In addition, an explanation of data on the impact of variants relating to the risk of hospital admissions and mortality is included.

Collecting, managing and publishing data on deaths

446. The collation and publication of COVID-19 mortality figures were carried out by multiple governmental organisations and arm's-length bodies. At the beginning of the

pandemic, NHSE provided data for the public reporting of COVID-19 deaths in England. During this time, PHE and the ONS also collected data on COVID-19 deaths.

- 447. During the period covered by this statement, two sources of data were used on individual deaths from COVID-19 in addition to estimates of excess mortality due to COVID-19 at a population level. The first individual deaths data source was death registrations where COVID-19 was included in the death certificate. This was published by ONS with a reporting lag, due to the time taken to register deaths. The second source of individual deaths data was based on the number of people who died following a positive SARS-CoV-2 test result, where PHE linked SARS-CoV-2 positive tests with deaths reported from a number of sources. The latter was intended as a more rapidly available data source not dependant on data from death certificates. The evolution of this measure is described further below.
- 448. The PHE mortality dataset was developed as management information, and specifically to support mathematical modelling by SPI-M-O, and this was provided to the PHE Joint Modelling Team for onward dissemination to relevant modelling teams represented on SPI-M-O. Some examples of SPI-M-O papers that demonstrate this data in their modelling are exhibited [Exhibit: SH3/420 - INQ000223534] [Exhibit: SH3/421 - INQ000223896].
- 449. In March 2020 Professor Neil Ferguson, who was then a member of SAGE, notified the CMO and Chief Scientific Adviser (CSA) of an inconsistency in deaths data between different sources, namely the PHE deaths dataset and the NHS dataset. [Exhibit: SH3/421a - INQ000223897]
- 450. PHE prepared a position paper and options appraisal, with potential options to further support national deaths reporting to ensure information on deaths was as accurate and comprehensive as possible [Exhibit: SH3/422- INQ000223898]. The document was presented to DHSC. The aim was to address publication figures derived using different methodologies. The preferred option was for PHE to provide a data flow intended to include deaths, both inside and outside of hospitals, which would

be available to be published seven days a week. On 21 April 2020 DHSC chaired a meeting that agreed that the publicly reported mortality figures should transition to the use of PHE's mortality data series. They noted that this would require ministerial agreement and engagement with the wider health family, ONS, Cabinet Office and the Prime Minister's Office [Exhibit: SH3/423 - INQ000223899].

- 451. The first publication of PHE mortality figures on the GOV.UK website was on 29 April 2020, for the week 16-22 April [**Exhibit: SH3/424 - INQ000223948**]. It initially used data from the following sources as detailed in the report on the ONS website published on 31 March 2020 and updated on 28 April 2020 [**Exhibit: SH3/425-INQ000223903**]:
 - a. deaths occurring in hospitals, notified to NHSE by NHS trusts;
 - b. deaths notified to PHE Health Protection Teams (HPT) in people with a confirmed COVID-19 test and recorded in an electronic reporting system;
 - c. information from the Demographic Batch Service (DBS) generated from NHS records and SGSS on individuals with a laboratory-confirmed COVID-19 test who died in the previous 24 hours.
- 452. Initially, at this acute phase of the pandemic response, the natural history of SARS-CoV-2 infection was not yet well-described. For this reason, no cut-off time was included in the definition of a COVID-19 death. This meant that at first, all deaths that occurred after a positive test were counted as a COVID-19 death.
- 453. Following a commission from the Secretary of State for Health and Social Care, in July 2020 PHE provided answers to a series of questions and a report detailing evidence for alternative definitions. These included potential time cut-offs at 28 and 60 days after a positive test result, for reporting the number of persons who died following a COVID-19 positive test in England. The report recommended moving to a 60 day cut-off as a trade off of sensitivity and specificity as linked to ONS death reporting [Exhibit: SH3/426 INQ000223904] and accompanying information [Exhibit:

SH3/427 - INQ000223905]. This report was sent to DHSC for approval for publication and approval from DHSC was awaited.

- 454. The routine data source for deaths information is death registration data collated by the Office for National Statistics. For COVID-19, this metric is the number of deaths where COVID-19 has been reported as a cause of death on the death certificate indicating clinical judgment has been used to determine if COVID-19 contributed towards a death. Due to delays in the registration of a death, this measure was not published in real time on a daily basis. PHE data was therefore used to meet the need for a real time measure of the number of deaths in persons with laboratory confirmed SARS-CoV-2 infection on a daily basis to rapidly inform the response to the pandemic in England.
- 455. Within the report PHE recommended using a 60-day measure that incorporated cause of death information to count the number of deaths following a COVID-19 positive test to provide a rapid proxy measure for the number of individuals who die from COVID-19. The rationale for this recommendation was that counting the number of people who die within 60 days of a positive COVID-19 test optimises the detection of deaths in a timely manner. This measure also counts deaths where COVID-19 has been reported as a cause of death on the death certificate, where clinical judgment has been used to determine that COVID-19 contributed towards the cause of death.
- 456. In this context, the measure's sensitivity refers to the extent to which the measure captures deaths that have actually died from COVID-19 (i.e.COVID-19 was a cause of death), and these deaths have not been left out of this measure using this definition. The specificity of the measure describes how well the measure captures deaths from COVID-19, i.e whether the people captured within the measure have actually died from the disease we are trying to measure (COVID-19).
- 457. Following this review the four CMOs recommended that the headline data series change to report the numbers of persons who died within 28 days of a positive test across the UK. This change was announced by DHSC on 12 August 2020 [Exhibit:

SH3/428 - INQ000223906]. This change reduced the reported number of persons who died following a positive test in England by 5,377, or 12.8% of the total at the time. In England, the numbers of persons who died up to 60 days after a positive test were also published as an additional metric from this point onwards. Deaths that occurred after 60 days were also added to this if COVID-19 appeared on the death certificate.

458. During this time the publication of the numbers of persons who died within 28 days of a positive test developed, and more detailed outputs were included in the UK COVID-19 Dashboard and the national flu and COVID-19 surveillance reports, where regular publication of those data continued throughout the period of interest covered by the Public Inquiry (up to 28 June 2022). Prior to the pandemic the routine flu surveillance report was published weekly during the influenza season (epidemiological weeks 40 to 20 of the subsequent year) and fortnightly during the summer period (epidemiological weeks 20 to 40), to which COVID-19 was added from 8 October 2020. Epidemiological weeks are a standard method for referring to time periods and used to report healthcare statistics and for comparison of data. Prior to this the national weekly summary of COVID-19 and Flu was published separately [**Exhibit: SH3/59 - INQ000120321**].

459. By November 2021 it was apparent that some people were being re-infected more than once with COVID-19 and that definitions of cases and deaths did not reflect this. On 15 November 2021 a submission was sent to the Secretary of State for Health and Social Care regarding proposed changes to counting COVID-19 cases to include reinfections of individuals who have already been recorded with a positive episode of COVID -19. [Exhibit: SH3/429 – INQ000348622] This change meant that UKHSA reported episodes of infection in its COVID-19 surveillance from 31 January 2022. A note outlining this change is exhibited here. [Exhibit SH3/430 – INQ000348623].

Severe illness and mortality risk

460. UKHSA has performed several assessments of the severity of SARS-CoV-2 infection as new variants emerged during the pandemic, specifically including the risk

of mortality and hospital admission. As discussed at paragraphs 146 onwards, the outcomes of these analyses were presented in Variant Technical Briefings [**Exhibit: SH3/431 - INQ000223917**] and published in peer reviewed articles. In summary, after accounting for factors such as sex, age group, deprivation, ethnicity (and after January 2021, vaccination status) these analyses determined in relation to mortality and hospital admissions that:

- a. During the 2020/21 winter, Alpha variant cases were associated with an increased risk of hospital admission compared with previously circulating variants [Exhibit: SH3/432 INQ000348624]; [Exhibit: SH3/433 INQ000348625];
- b. Later in 2021, we observed higher hospital admission or emergency care attendance risk for patients with COVID-19 infected with the Delta variant compared with the Alpha variant.[Exhibit: SH3/M434 – INQ000348626];
- c. Between June and November 2021, results indicated that the risk of hospital admission for the Delta variant sub-lineage AY.4.2 was similar compared to cases with other Delta sub-lineages [Exhibit: SH3/435 INQ000348627]; [Exhibit: SH3/436 INQ000348628]; [Exhibit: SH3/437 INQ000262572];
- d. The risk of hospital attendance and admission assessed during the 2021/22 Winter was lower for the Omicron variant compared to the Delta variant. Among Omicron sub-lineages, BA.2 was associated with a lower hospital admission risk compared to the BA.1 but there was no significant difference in hospital admission risk between BA.2 and later sub-lineages BA.4 and BA.5 [Exhibit: SH3/438 INQ000348629].
- 461. In relation to the overall mortality rate of the disease, as of 1 March 2020, the PHE SitRep reported that there had been 2,870 deaths among 79,824 COVID-19 patients in mainland China and 109 reported deaths among 7,174 cases reported in the rest of the world. There were no deaths reported in England in the PHE SitRep by that date [Exhibit: SH3/190 INQ000348216]]. The first death of a person with COVID-19 in England was on the 2 March 2020 and was reported on the 3 March

2020. As of the week ending 24 June 2022, there had been 166,593 deaths registered where COVID-19 was mentioned as one of the causes on the death certificate.

COVID-19 deaths in healthcare settings

- 462. UKHSA collates information on individuals who died following COVID-19 infection from multiple sources - ONS, NHSE, HPTs, and DBS tracing of COVID-19 testing data. These data are provided to UKHSA for use in the 28-day metric mentioned at paragraph 461.
- 463. NHSE specifically collate data on people who died in hospital settings, where an individual died within 28 days of a COVID-19 positive test [Exhibit: SH3/440 INQ000348631].
- 464. Data on those whose death is attributed to COVID-19 to some degree on their certificate, rather than having died within 28 days of a positive COVID-19 test, are collated by the ONS [Exhibit: SH3/441 INQ000348632]. These data are obtained through death registration information and includes information on the cause of death and setting of death (including deaths in hospitals). ONS counts COVID-19 deaths where there is any mention of COVID-19 (ICD10 U071 and U072) on the death registration.

Hospital acquired COVID-19 infection

465. UKHSA holds individual patient-level data on dates of hospital stays as well as SARS-CoV-2 test dates, enabling assessment of whether the infection was likely to be hospital associated. These data could be linked to mortality data from the PHE National Incident Coordination Centre EpiCell. These data are derived from the sources listed at paragraph 451.

- 466. On 19 April 2020 PHE presented to Scientific Pandemic Influenza Group on Modelling, Operational sub-group (SPI-M-O) a modelling paper on quantification of nosocomial transmission and the role of HCW [Exhibit: SH3/198 - INQ000120648]. This paper provided an overview of the modelling work undertaken, in four studies, so far on nosocomial COVID as well as proposed future work and data needs. Preliminary findings from: i) "Quantification of nosocomial transmission" indicated that COVID-19 admissions and putative nosocomial cases of COVID-19 in the previous week were both associated with increased rates of putative nosocomial acquisition of COVID-19; ii)"Consideration of vulnerable/at risk patients" suggested that, under the assumption that infected patients are tested within 2 days of becoming symptomatic, it is likely that higher proportions of nosocomial infections are related primarily to transmission; iii) "The role of HCW" estimated 27% of all infected patients acquired their infection while in hospital, and an average of 16% of nosocomial infections were due to transmission from infected HCWs, with the remainder due to direct and indirect patient to patient transmission and iv) "Impact of IPC and testing strategies" showed that fortnightly testing of HCW decreased HCW to patient transmission events by approximately 20%, while increasing the proportion of the total HCW workforce absent from around 0.5% absence with COVID-19 at any one time to <2%. This paper only considered whether cases were hospital acquired and did not look at mortality.
- 467. A later paper, submitted to SPI-M-O on 23 June 2021, did look at COVID-19 length of stay (LoS) and mortality [**Exhibit SH3/442 INQ000348633**]. The paper provided a descriptive analyses of Secondary Uses Service (SUS) data to the end of April 2021. It looked at length of stay (LoS) and (crude) mortality over time, by age and whether hospital associated. The main findings in this paper are: the median length of stay over time is correlated with overall case numbers, and generally there are proportionally more hospital associated cases; hospital associated cases had longer stays than community associated; the median length of stay by age is generally stable over time, and the overall length of stay distributions by age and hospital/community association show very little change in the most recent weeks; Mortality rate appears to reflect number of COVID admission; and there is a clear distinction between mortality rate in hospital onset and community onset cases in the second wave.

Death of staff in healthcare settings (including doctors, nurses and healthcare workers)

- 468. Primary data collection related to the death of staff in healthcare settings was collected by ONS and NHSE. ONS held death registration data including the current or previous occupation of the deceased as reported by the informant. NHSE, through its own COVID-19 deaths reporting system (COVID-19 Patient Notification System) gathered information on whether the deceased persons were employed by the NHS. These organisations owned these datasets and collected these data according to their own definitions and therefore would be best placed to advise definitively on their interpretation. Through the course of COVID-19 response work PHE, and later UKHSA, did receive the same data from these two organisations and attempted to undertake secondary descriptive analysis. However, this was not completed due to competing demands on our epidemiology function and limited resources and the publications delivered by ONS, the organisation with overarching responsibility for mortality statistics.
- 469. In 2020 PHE explored whether it could provide analysis of HCWs who were infected and could have died from COVID-19; they attempted to link the list of registered medical doctors to other COVID-19 data assets. However, PHE could not make an assessment on whether these doctors were working or where they were working and could not assess where their infection could have been contracted and therefore terminated the work. An internal draft report of this work is exhibited; due to the challenges of relating these cases to where the individual worked rather than where they resided and even whether they were working in patient facing roles this was not progressed [Exhibit: SH3/443 INQ000348634]. No lists of other healthcare workers or nurses were available. The ONS have published data on deaths by occupation. [Exhibit: SH3/444 INQ000348635].
- 470. PHE's, and later UKHSA's, epidemiology function did not collect detailed occupational exposure information for persons with COVID-19 who were HCWs, and

therefore could not determine whether these could be attributed to contracting the infection through work in a healthcare setting.

The number of excess patient deaths within healthcare settings during the relevant period

- 471. Neither PHE nor UKHSA produced analysis on excess patient deaths within healthcare settings. More generally, PHE, and subsequently OHID, produced excess mortality reports from all causes from July 2020 to improve understanding of the impact of COVID-19 on the wider population [Exhibit: SH3/445 INQ000348636].
- 472. PHE also contributed to a publication on the 17 August 2022, related to the impact of vaccination on hospital outcomes. [Exhibit: SH3/446 INQ000348637]. The publication provides estimates of the fatality risk of those hospitalised between March 2020 and September 2021. The publication provided estimation of trends in mortality by month of admission and vaccination status among those hospitalised with COVID-19 in England between March 2020 to September 2021, controlling for demographic factors and hospital load.
- 473. Among 259,727 hospitalised COVID-19 cases, 51,948 (20.0%) experienced mortality in hospital. Hospitalised fatality risk ranged from 40.3% (95% confidence interval 39.4–41.3%) in March 2020 to 8.1% (7.2–9.0%) in June 2021. Older individuals and those with multiple co-morbidities were more likely to die or else experienced longer stays prior to discharge. Compared to unvaccinated people, the hazard of hospitalised mortality was 0.71 (0.67–0.77) with a first vaccine dose, and 0.56 (0.52–0.61) with a second vaccine dose. Compared to hospital load at 0–20% of the busiest week, the hazard of hospitalised mortality during periods of peak load (90–100%), was 1.23 (1.12–1.34).

Changes in COVID-19 deaths in healthcare settings

474. UKHSA does not hold specific analysis on how figures changed in healthcare settings during the relevant period. Primary data was collected by ONS and NHSE, and therefore they may be best placed to provide relevant information.

SECTION 7: Lessons learned

Internal or external reviews, lessons learned exercises PHE/UKHSA.

- 475. UKHSA and its predecessor organisations have undertaken a series of lessons identification work that includes workshops, surveys, internal audits and debriefs. From the outset of the COVID-19 response in 2020, PHE, NHSTT and subsequently UKHSA initiated a multi-modality programme of lessons identification activity.
- 476. The initial lessons learned exercises were carried out by the PHE incident response cells, commencing in April 2020. The lessons identification work was actively continued on a rolling basis by the various cells, which were recorded and tracked to support response interventions.
- 477. The PHE ERD exercises team was tasked to develop and deliver a number of COVID-19 exercises during the pandemic, which in the main were to explore and agree key processes especially with the formation of NHSTT and JBC (the Exercise Sirius series). The team was also commissioned by DHSC to run two health ministerial level exercises (the Ex Gemini-series) and upon the formation of UKHSA, the team ran a series of confirmatory exercises (Ex Atlas) exhibited here [Exhibit: SH3/447 INQ000348638] examples are exhibited at [Exhibit: SH3/447a INQ000273915, Exhibit: SH3/447b INQ000319850, Exhibit: SH3/447c INQ000319851 and Exhibit: SH3/447d INQ000319853], and [Exhibit: SH3/448 INQ000348661]. The ERD team's remit extended only to identifying lessons from the respective exercise and not to following up and addressing actions, which was the responsibility of the exercise sponsor.

478. A repository of 23 lessons identified that fall within the outlined scope of Module
3 is exhibited here [Exhibit: SH3/449 – INQ000348662].

<u>A summary of the conclusions and recommendations of reviews, lessons learned exercises, or</u> <u>reports, and implementation of any recommendations.</u>

- 479. UKHSA has committed to being a learning organisation with a focus 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. Recommendations from internal reviews are helping to inform UKHSA's capability and capacity planning for future health threats.
- 480. The Centre for Pandemic Preparedness (CPP) based at UKHSA is working with partners in Government to understand evaluations of COVID-19 policies and lessons exercises. These lessons are being used to inform the key topics of interest that make up our Pandemic Preparedness Portfolio. CPP will work with programme leads to highlight important actions needed as part of delivery, or to mark for further policy development in these areas, including further analysis of long-term recommendations focused on the capabilities and capacities we need to optimise our preparedness. Examples of some of the lessons emerging in different capability workstreams include:
 - a. Surveillance the need for multidisciplinary, collaborative working and a range of data sets needed upfront within surveillance to ensure high resolution analysis and risk assessment;
 - b. Diagnostics the importance of defining strategy and planning to surge diagnostic capacity, including prioritisation as we scale and securing the resilience of our supply chain;

- c. Research and Development and advice ensuring research and evidence underpins policy and practice through rapid processes, early dissemination of initial results, preprints (non-peer-reviewed articles) and observational studies;
- d. Medicines establishing the right investment, infrastructure and relationships with the market for development of broad- spectrum antivirals which would allow us to mount an immediate response to a future novel pathogen. DHSC are the organizational lead for this area with UKHSA supporting with expert input and providing the commercial and logistical support for countermeasures recommended;
- e. Communications & guidance setting up the communication structures for regular, consistent engagement with a range of partners and networks.

Information on lessons learned in respect of vaccines and therapeutics will be provided as part of the response to Module 4.

- 481. On 30 March 2022 UKHSA held a workshop with local health protection system partners at which it was agreed to work jointly to establish and deliver a light touch programme to enhance the resilience and scalability of national and local health protection systems, named 'The Future of the Local Health Protection System (FHPS).' The FHPS programme has a vision to enhance the current health protection system to ensure it is locally delivered, regionally enabled, and nationally supported.
- 482. Driving this work is the FHPS Co-Design Group, co-chaired by UKHSA and the Association of Directors of Public Health UK, which brings together strategic system partners to facilitate the design, development, and delivery of improvements to the health protection system. The five high-level outcomes for the FHPS are:
 - a. Clarity around roles, responsibilities, duties & powers and boundaries;
 - b. Consensus around distributed & adaptive system leadership for health protection;

- c. Awareness of key areas of contention, overlap, ambiguity or gaps;
- d. Shared input into system design decisions;
- e. Prioritisation of areas for capacity & capability building while responding to competing pressures.
- 483. Since its establishment it has signed off the three documents, set out below, which have been shared with some external stakeholders, but have not been published and are not government policy:
 - a. 'Statement of Intent' [Exhibit: SH3/450 INQ000348663];
 - b. High-Level Behaviours and Outcomes Document [Exhibit: SH3/451 INQ000348664];
 - c. Co-Design Group Workplan [Exhibit: SH3/452 INQ000348665].
- 484. A debrief and review of lessons identified from the Four Nations IPC Cell was commissioned by NHSE, led by an independent reviewer from DHSC. The reviewer collated feedback from former members of the NHSE-chaired Four Nations IPC Cell, which included distilled comments from UKHSA, and presented findings in a report finalised in May 2023 [Exhibit: SH3/453– INQ000339322] on which further comments were provided by UKHSA. NHSE will be able to provide further information on this review.
- 485. UKHSA used the review to reflect internally on the IPC cell. The lesson learned approach focused on both the content of the report and individual experience not detailed within the report. This culminated in the actions detailed in the exhibited paper [Exhibit: SH3/454– INQ000348667], which provides a basis for further discussions as part of ongoing work to develop the IPC function within UKHSA. The main takeaway was to establish agreement and robust governance structures between DHSC, NHSE and UKHSA to ensure:

- a. Decision making authority, clarity of roles and responsibilities, approval process and escalation pertaining to non-consensus
- b. Guidance ownership, relevant transfer and responsibility for publication is clarified and agreed
- c. SME opinion is enhanced through the development of a clinical reference body of specialist advisors
- d. Investment and development of a specialist national IPC team building resilient capacity for future pandemic response.
- 486. Learning from the experience of health-related guidance during the pandemic, UKHSA considers it important that there are agreements in place for the appropriate organisation to lead the development and production of relevant public health related guidance. There is a formal agreement in development between DHSC, UKHSA and NHSE to facilitate the collaboration and decision making governance when agreeing leadership, ownership, and publication of guidance. UKHSA has also acknowledged the need for a centralised guidance team and has developed a Guidance team in UKHSA.
- 487. The lessons identification work and subsequent implementation is an ongoing process, and the organisation is continuing to look for, and identify, lessons from teams across the organisation.

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.

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	Personal Data
Signed:	

Dated: 31 January 2024