THE UK COVID-19 INQUIRY

MODULE 4 CLOSING STATEMENT ON BEHALF OF THE UK HEALTH SECURITY AGENCY

Introduction

1. The UK Health Security Agency ("UKHSA") is an executive agency of the Department for Health and Social Care ("DHSC") and carries out certain statutory functions on behalf of the Secretary of State for Health and Social Care. Fully operational from 1 October 2021, UKHSA's role is to protect the public from infectious diseases as well as external hazards including chemical, nuclear and environmental threats. It now brings together expertise from predecessor organisations including Public Health England ("PHE"), NHS Test & Trace ("NHSTT"), the Joint Biosecurity Centre ("JBC") and the Vaccine Task Force ("VTF").[1]

2. Module 4 has focused on the development of COVID-19 vaccines and therapeutics and the implementation of the vaccine rollout programme across the four nations. UKHSA has provided two corporate witness statements[2] in this Module which include explanation of PHE/UKHSA's role in relation to the COVID-19 vaccination programme. This closing statement addresses the following topics relevant to vaccines and pandemic preparedness:

   (a) Addressing inequalities in vaccine uptake.
   (b) How to improve access to safety information.
   (c) The importance of data to preparing for a future pandemic.
   (d) The suggestion of a national vaccines agency.

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[1] Further detail on the organisation of UKHSA is set out in earlier corporate statements. See 3rd Witness Statement of ("WS") Professor Dame Jenny Harries at §§26 to 33 [INQ000251906_007-009] and the 1st WS Professor Susan Hopkins at §§40-50 [INQ000410867_0114-0016].

[2] 1st WS Dr Mary Ramsay [INQ000496177]; 7th WS Professor Dame Jenny Harries [INQ000492334]; 8th WS Professor Dame Jenny Harries [INQ000474715].

Addressing inequalities in vaccine uptake

3. The COVID-19 pandemic predictably replicated, and in some cases exacerbated, existing health inequalities.[3] For disease control and elimination strategies to be as effective as possible, it is essential that vaccine uptake coverage is not only high overall, but high within communities or groups who are underserved by the healthcare system or are otherwise less likely to access it. Two core points must not be ignored. First, the reasons why inequalities in access arise are multifactorial and often complex and longstanding.[4] Second, vaccination is a medical intervention delivered at specific points in time and low vaccination uptake in underserved communities often reflects a broader picture of inequalities and should not be seen or addressed in isolation.

4. Dr Mary Ramsay, Director of Public Health Programmes at UKHSA, explained that the question of why inequalities in vaccine uptake arise is "*an issue for all time*" which requires "*sustainable solutions … to ensure [communities] are getting access to vaccination and to other healthcare interventions and other prevention measures.*"[5] There is, or should be, consensus that tackling inequalities in vaccine uptake requires a concerted, long-term commitment of time and resources from multiple organisations working together to lay the foundation for an effective response in a pandemic.[6]

5. Building and keeping trust over the long-term is paramount to addressing barriers to vaccine uptake in less confident communities. Addressing health inequalities to achieve more equitable health outcomes has been central to UKHSA's work from its inception and remains so[7], and the Agency has an important but defined role to play in addressing barriers to vaccine uptake and building trust.

6. An important aspect of that role is the provision of information in an accessible form. In supporting routine immunisation programmes, UKHSA, as PHE did before, publishes resources and guidance intended to be culturally competent, sensitively focused and available in different languages and media. This was and is often prepared with

[3] PHE briefing note 10/01/2021 [INQ000477083]; Expert Report of Kasstan-Dabush & Chantler, §§212 and 230 [INQ000474623_0067; INQ000474623_0072].
[4] Expert Report of Kasstan-Dabush & Chantler, §238ff [INQ000474623_0074]; PHE Immunisation Inequalities Strategy, February 2021 [INQ000101216_0011]. Professor Heidi Larson 16/01/2025 [Day3/152/21-153/17]; Dr Tracey Chantler 28/01/2025 [Day10/198/8-199/7].
[5] Dr Mary Ramsay 21/01/2025 [Day6/119/7-12].
[6] 1st WS Dr Mary Ramsay, §8.17 [INQ000496177_0040].
[7] UKHSA First Remit Letter of 13/07/2021 [INQ000090310_004]; UKHSA Strategic Plan 2023-2026 [INQ000235221_0013].

contributions from others (including external clinicians, academics, NHS England, and the voluntary and community sector).[8]

7. Equally important is the support that UKHSA (and PHE before it) provides to the development, implementation, surveillance, and evaluation of immunisation programmes.[9] This work is vital to ensuring vaccine safety and securing public confidence. PHE/UKHSA provides data, evidence and analysis to inform the work of others and its expertise in this area is recognised.[10] During the pandemic, PHE/UKHSA utilised that expertise both to monitor the effectiveness of the COVID-19 vaccine programme[11] and to provide technical advice and information on those factors which could deter vaccine uptake.[12]

8. Alongside its work on the COVID-19 programme, PHE continued with the National Immunisation Programme, which provides protection to 19 diseases across the population.[13] In February 2021, PHE published the health equity audit of the National Immunisation Programme and its Immunisation Inequalities Strategy, work on which had begun before the pandemic.[14] That analysis examined in detail inequalities in vaccination. Looking forward, building on its strategic plan, UKHSA has published a Health Equity for Health Security Strategy which sets out a commitment to providing national, regional and local partners with the data, evidence and advice needed to understand and address health protection outcomes.[15] The Agency is in the process of updating the Immunisation Inequalities Strategy and accompanying health equity audit to provide a more granular analysis of the current evidence base on immunisation

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[8] See for example PHE Paper "COVID-19 vaccination in Inclusion Health Populations" dated 20/01/2021 [INQ000477084_0001]. Contributors included the Independent Anti-Slavery Commissioner and FFT.

[9] 1st WS Dr Mary Ramsay, §3.2 [INQ000496177_0012].

[10] See for example 1st WS Dame Emily Lawson, §§304-307 [INQ000492335_0090-0091]; Professor Sir Jonathan Van-Tam 20/01/2025 [Day5/153/17-20].

[11] 1st WS Dr Mary Ramsay, section 6 [INQ000496177_0027]; PHE COVID-19 vaccine surveillance strategy published 11/01/2021 [INQ000477132]; 6th WS Professor Sir Christopher Whitty, §6.22 [INQ000474401_0026]; Professor Sir Jonathan Van-Tam 20/01/2025 [Day5/176/19].

[12] See for example, Briefing note from PHE's Behavioural Science and Insights Unit (BSIU) "Barriers and facilitators to COVID-19 vaccination uptake", dated 16/09/2021 [INQ000477091]; BSIU's summaries of vaccine uptake in various communities, 2021 [INQ000477100]; "COVID-19 Vaccine and Health Inequalities: considerations for prioritisation and implementation"; PHE paper dated 02/11/2020 [INQ000477079]; PHE paper, "COVID-19 vaccination in Inclusion Health Populations", dated 20/01/2021 [INQ000477084].

[13] PHE Immunisation Inequalities Strategy, February 2021 [INQ000101216_0006].

[14] 1st WS Dr Mary Ramsay, §§8.5-8.7 [INQ000496177_0038]; PHE Immunisation Inequalities Strategy, February 2021 [INQ000101216]; PHE National Immunisation Programme: Health Equity Audit [INQ000477141].

[15] UKHSA Health Equity for Health Security Strategy 2023-2026 **INQ000533618**

inequalities. UKHSA is also convening a UK wide "4 Nations Forum" to review vaccination uptake.

9. Ensuring the availability of accurate information and monitoring the effectiveness of an immunisation programme are critical to building trust. In its opening statement, UKHSA highlighted the importance of routine vaccination work as a platform from which to scale in a pandemic.[16] It is a point of learning that having those with operational experience of routine immunisation programmes involved from the outset in the rollout of a pandemic vaccine can only be beneficial.[17] Dr Ben Kasstan-Dabush and Dr Tracey Chantler observe in their report, a "*robust approach to routine vaccine programme delivery is a prerequisite to effective vaccine roll-out as part of pandemic preparedness"* and the "*allocation of sufficient resources to routine immunisation delivery is needed to maintain routes of vaccine delivery and communication between health providers and marginalised communities."*[18] It is important looking forward that there be a commitment to ensuring that all aspects of routine immunisation programmes are resourced properly.

10. As Dr Ramsay explained[19], during the pandemic, PHE/UKHSA worked not only with cross-government partners but with charities to ensure the vaccination programme was accessible to those identified as inclusion health groups. That built on work undertaken with local partners such as Directors of Public Health in local authorities[20] and included, for example, workshops and evaluations with groups such as the Gypsy, Roma, and Traveller communities.[21]

11. This experience emphasised the importance of preserving and developing a local network of public health professionals. UKHSA continues to maintain long-established relationships[22] with public health experts in the NHS and with Directors of Public Health. Following the establishment of UKHSA, the management of the public health immunisation teams embedded in the NHS and hitherto overseen by PHE was transferred to NHS England. UKHSA currently maintains links with that expert network. The upcoming delegation of commissioning responsibility to local Integrated Care

[16] UKHSA Opening statement for Module 4 [INQ000474800_0006].
[17] Expert Report of Kasstan-Dabush & Chantler, § 22 [INQ000474623_0013]. 1st WS Stephen Russell, §147-149 [INQ000474228_0034-35].
[18] Expert Report of Kasstan-Dabush & Chantler, §§ 370 and 370b [INQ000474623_0105].
[19] Dr Mary Ramsay 21/01/2025 [Day6/116/13-24].
[20] 1st WS Dr Mary Ramsay, section 7; §8.8 [INQ000496177_0032; INQ000496177_0038].
[21] Dr Mary Ramsay 21/01/2025 [Day6/116/13-24]; 1st WS Dr Mary Ramsay, §8.30 [INQ000496177_0043].
[22] PHE National Immunisation Programme: Health Equity Audit [INQ000477141_0015].

Boards brings a risk of diminution of public health teams with expertise at a local level. It is vital that expert teams remain resourced and operating as part of a network, able to access national specialist capability and to share learning and intelligence.

12. Effective local networks counteract a one-size-fits-all approach to addressing barriers to vaccine uptake. They make it easier to identify trusted individuals who can be important allies in reducing gaps in routine uptake and hesitancy.[23] Accordingly, there should be a local to national public health focus, building on work led by Directors of Public Health, and emphasising the importance of those working at the local level who are likely to be more attuned to the specific needs of communities in their area and can build trust over the longer term in partnership with those communities.[24] Engagement with communities should not be transactional (or seen as such).

13. In summary, promoting a whole system approach directed to enabling those in underserved or marginalised communities to better access high quality primary care and other services in peacetime is likely to have the beneficial effect of increasing vaccination uptake. Were this Inquiry to highlight the importance of a holistic approach to tackling health inequalities at a local level – with community services offering sustained engagement through trusted workers – then that would be of real value to embedding continuity of care – and trust – in the longer term.

Enhancing access to safety information

14. Throughout the COVID-19 pandemic, PHE, and then UKHSA, published resources both for healthcare workers (including in adult social care) and for the public providing information as to the risks and benefits of vaccination. These resources were updated regularly. UKHSA's disclosure to the Inquiry in this Module includes examples of the material which PHE/UKHSA published over the course of the pandemic. By way of illustration, it includes a leaflet titled "*COVID-19 vaccination: Guide for healthcare workers*" first published in December 2020, which went through 20 updates. The iterations of this resource provided information on for example pregnancy and the scheduling of a second dose (with similar information available to those in social care).

[23] Expert report of Professor Heidi Larson, §197 [INQ000474705_70].
[24] See for example, Dr Mary Ramsay 21/01/2025 [Day6/117/20-118/2].

15. As to public-facing resources, these included, for example, leaflets explaining why there was a need to wait for a vaccination and what to expect after a vaccination as well as guides on vaccination for those with a weakened immune system, and "*a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding*".[25]

16. Considerable effort was made to provide accurate and consistent information in as accessible a manner as possible and through different media. Resources were provided in 28 different languages as well as British Sign Language and Braille. They were delivered in a variety of formats tailored for different audiences including large print, Easy Read HTML, audio and video. Information was published through social media, on the gov.uk website, through the NHS and on PHE's YouTube channel.[26] PHE worked with NHS England, stakeholders and community representatives to ensure information reached specific groups. Examples include working with Doctors of the World to send a letter to those in asylum accommodation[27] and working with trusted elders and community leaders. The latter included developing videos using community members to build trust.[28]

17. The intent behind this work was to ensure that those receiving a COVID-19 vaccine were able to make an informed choice and to promote vaccine confidence. This objective was made possible because of the established expertise within PHE in producing public-facing resources and providing guidance and analysis of the enablers and barriers for under-vaccinated communities in the context of routine immunisation programmes. This expertise had been gained over years of delivering such programmes[29] (UKHSA's disclosure includes examples of the resources deployed for routine immunisations).

18. PHE/UKHSA appreciated that a lack of reliable information was a barrier to vaccine uptake.[30] It has been suggested that there were gaps in the information available to the public for example, relating to the time it took for vaccines to become effective. In fact, such information was available at the material time. For example, leaflets were published

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[25] See also 1st WS Dr Mary Ramsay, §§4.9-4.10 [INQ000496177_0017].
[26] 1st WS Dr Mary Ramsay, §§8.10-8.15 [INQ000496177_0039-40]; 1st WS Dame Emily Lawson, §305 [INQ000492335_00091].
[27] WS MPCAG, §243 [INQ000474407_0044].
[28] 1st WS Dr Mary Ramsay, §8.16 [INQ000496177_0040].
[29] Dr Mary Ramsay 21/01/2025 [Day6/90/7-15].
[30] See for example, Briefing note from PHE's BSIU titled "Barriers and facilitators to COVID-19 vaccination uptake", dated 16/09/2021 [INQ000477091_004].

on “COVID-19 vaccination and blood clotting”[31], “Why do I have to wait”[32] and “What to expect after your COVID-19 vaccination”.[33]

19. The COVID-19 pandemic was an instance where vaccination was aimed at the whole of the UK population not, for example, at those of a particular age. A vast majority of the population wanted to be vaccinated.[34] The effect was that the public, in significant numbers and some perhaps for the first time, sought out information about vaccines. They did so in an age when inaccurate information about a vaccine's effectiveness or safety is easily spread. The public was, through the internet and social media, confronted by what Professor Heidi Larson called *“the explosive spread of mis-and disinformation”*.[35]

20. This has been described as an “*infodemic*”[36] – an abundance of both accurate and inaccurate information with no clear line between the two categories but rather the space for conspiracy theories to flourish. The risks of an infodemic include an erosion of trust in those responsible for and involved in a vaccination programme. The damage impacts all immunisation programmes.

21. The characteristics of an infodemic are complex and more work is needed to understand how government can better challenge mis- and disinformation. There is some research which indicates that an escalating epidemic will lead people to progressively pay more attention to a reliable source.[37] The experience of the first pandemic to arrive in a digital age prompts the question as to how to make it easier for the UK public to access accurate information.

22. UKHSA endorses the proposal, explained by Dr Ramsay[38], that establishing a central trusted digital resource for immunisation, such as a dedicated website accessible to both the public and healthcare professionals, could play an important role in countering

[31] Webpage: “COVID-19 vaccination and blood clotting” **INQ000574417** and associated leaflets dated 07/04/2021 **INQ000574400** and 07/05/2021 **INQ000574403**
[32] Webpage: "Why you have to wait for your COVID-19 vaccine” **INQ000574394**; and material, dated 07/12/2020 **INQ000574425**
[33] Webpage: “What to expect after your COVID-19 vaccination” **INQ000574424**, and associated leaflets dated 07/04/2021 **INQ000574401**, 11/06/2021 **INQ000574404**, and 16/09/2021 **INQ000574408**.
[34] 4th WS Lord Vallance of Balham, §79 [INQ000474482_0031].
[35] Professor Heidi Larson16/01/2025 [Day3/154/3-155/14].
[36] 2nd WS Professor Wei Shen Lim, §126 [INQ000471988_0033].
[37] “Assessing the risks of ‘infodemics’ in response to COVID-19 epidemics” Riccardo Galloti et al, published 29/10/20, Nature Human Behaviour [INQ000516488].
[38] Dr Mary Ramsay 21/01/2025 [Day6/97/21-98/9].

misinformation. Such a resource, if set up in peacetime and with a population now more aware of vaccines than before, could – in a very practical way – enhance public awareness of safety signals, facilitate informed consent, and sustain vaccine confidence. At present, government directives regarding the use of the gov.uk site mean that UKHSA could not easily set up such a digital resource. In any event, it must be a multi-agency project to achieve maximal effect. That would allow it to host additional information for example about entitlements such as the right to speak to a healthcare practitioner about vaccination and to register with a GP if an individual is without a permanent address.

23. Of course, recognising that "*consent is a process, not a one-off event*",[39] this digital resource would complement rather than replace the use of written materials and face-to-face conversations with healthcare practitioners, which should remain an integral resource, particularly for those experiencing digital exclusion.[40]

24. Professor Stephen Evans expressed the view that "*a new approach is needed to Patient Information Leaflets, with categories of information – what one needs to know and when – available online using a structure that is appropriate to the user's needs at different stages of their taking a medicine*".[41] He cited a study which "*found that nearly 20% never read the PIL and … 56.0% never sought more information about possible side effects of medicines*".[42]

25. Providing a Patient Information Leaflet ("PIL") is a statutory requirement placed on the manufacturer of a medicine. In the case of vaccination, the PIL would usually be given to a patient at the point of vaccination.[43] There is no requirement that it be available in more than one language or in different formats. UKHSA is not responsible for the PIL and is not the vaccinating agency (i.e., the body responsible for putting the drug into the patient's arm). However, UKHSA already produces leaflets to be provided at different stages in the vaccination pathway (in advance of the appointment or after vaccination), which are available in a range of formats (both digital and printed) and in different languages (including accessible versions) and include a link to the Coronavirus Yellow Card reporting site. UKHSA's provision of such additional information helps reduce

[39] Dr Mary Ramsay 21/01/2025 [Day6/93/7-8].
[40] Dr Mary Ramsay 21/01/2025 [Day6/93/2-6; Day6/98/9-16].
[41] Expert Report of Professor Stephen Evans at §§6.63 and 7.7 [INQ000474707_0073; INQ000474707_0076]; Professor Stephen Evans 22/01/2025 [Day7/77/8-78/1].
[42] Expert Report of Professor Stephen Evans at §2.48 [INQ000474707_0022].
[43] Dame June Raine 22/01/2025 [Day7/142/20-143/2].

inequalities in the vaccination process. The Agency supports Professor Evans' recommendation in relation to the PIL. The additional material offered by UKHSA, along with a restructured version of the PIL as proposed by Professor Evans, could be hosted together on the digital resource proposed above.

The importance of data to pandemic preparation

26. Consideration of inequalities in vaccine uptake and how patients can be better informed about the risks and benefits of vaccination leads to the question of building a more resilient data infrastructure. Improving the safe collation and sharing of data across the health and care system will offer significant opportunity to improve health outcomes.

27. Preserving and developing the UK's capabilities in relation to how data is used and shared in the future both at a national and international level could prove to be one of the most critical elements of pandemic preparedness. The issue is one in which UKHSA has a strong interest. It cuts across the Modules in this Inquiry and UKHSA has addressed it in previous closing statements.[44]

28. As previously explained, UKHSA is a service, scientific and research organisation focused on health protection. Much of its work therefore involves the analysis of data. UKHSA relies on data to identify the emergence of health threats and to inform guidance, recommendations as to interventions, and its science.

29. UKHSA strives to be a driver for data improvement. It published its first data strategy in September 2023[45] and has strengthened the ability to access health data across secure systems to enable sharing with international, national, and local partners. It has created scalable and adaptable data platforms (such as the UKHSA data dashboard which provides the public with health data and the Enterprise Data and Analytics Platform which will allow access to real-time data). UKHSA is increasingly including disaggregation by ethnicity and other protected characteristics in its routine surveillance reports to ensure it can work with its partners to identify and address the drivers of health inequalities and monitor progress towards more equitable outcomes.[46] The analysis

[44] The Inquiry is invited to review UKHSA's Module 2 Closing Statement §§9-12 [INQ000399527_004] and Module 3 Closing Statement, §§81-87 [INQ000553307_0027-0030].
[45] UKHSA data strategy, 11/09/2023 [INQ000528385].
[46] UKHSA's Health Equity for Health Security Strategy 2023-2026 [**INQ000533618**_0012].

produced by UKHSA (and PHE) has proved valuable to others including the experts in this Module.[47]

30. Lord Vallance of Balham, the former Government Chief Scientific Adviser, observed that the practices governing data sharing in the NHS at the start of the COVID-19 pandemic were *"weak and unclear"*.[48] The Chief Medical Officer ("CMO"), Professor Sir Chris Whitty expressed concern that the increased sharing of data across the NHS seen during the pandemic was no longer taking place.[49] UKHSA agrees with Lord Vallance that government must maintain and develop data capabilities.[50] The centralised nature of the NHS is an advantage and UKHSA, with its interest in obtaining robust data, is committed to working with others to put in place resilient arrangements for the rapid sharing of data which could then be scaled up in the initial stages of a pandemic.

31. Since trust is central to combatting low vaccine confidence and promoting vaccine uptake, the data systems developed in peacetime must be sufficiently secure and transparent to maintain public trust. Consideration must be given to the possibility that relaxing restrictions on data sharing during an emergency could undermine public trust. The risk is not only an increase in vaccine hesitancy and/or reduction in vaccine uptake but also a wider impact on the public being willing to access information about other treatments, or the treatments themselves or even relevant social support.

32. The benefits of sharing data are inevitably contingent on the quality of the underlying data to be shared.[51] Recommendations for enhanced data collection are complicated by individual reluctance to report personal details.[52] The difficulties of maintaining data sets for certain populations groups, and which can arise for different and overlapping reasons, can be illustrated by two examples both of which reiterate the centrality of trust. The first was the concern that information provided to healthcare bodies might reach the Home Office deterred migrant uptake of the vaccine,[53] which Dr Ramsay explained was *"not a new phenomenon"*.[54] The second is the 2022 Mpox outbreak presented a further

[47] Expert Report of Kasstan-Dabush & Chantler [INQ000474623_0152].
[48] 4th WS Lord Vallance of Balham, §23 [INQ000474482_0011].
[49] Professor Sir Christopher Whitty 20/01/2025 [Day5/49/3-52/14].
[50] 4th WS Lord Vallance of Balham, §149d [INQ000474482_0056].
[51] See for example Expert Report of Kasstan-Dabush & Chantler, §228a [INQ000474623_0072].
[52] Expert Report of Professor Heidi Larson, §28 [INQ000474705_0014]; Professor Heidi Larson 16/01/2025 [Day3/131/2-132/8].
[53] WS MPCAG, §291 [INQ000474407_0052]; Dame Emily Lawson 27/01/2025 [Day9/182/9-183/24].
[54] Dr Mary Ramsay 21/01/2025 [Day6/113/19-114/4]; Briefing note from PHE's BSIU titled "Barriers and facilitators to COVID-19 vaccination uptake", dated 16/09/2021 [INQ000477091_0017].

example of the complexities of data collection, as the legal requirement that certain data fields be reported once Mpox became a notifiable disease, clashed with a *"well-established principle of being able to get testing and treatment at sexual health clinics anonymously"*.[55]

33. As has been articulated during this Module, and for a combination of reasons including those discussed herein, there remains a lack of robust national data in relation to certain groups, for example, undocumented migrants[56] and Gypsy, Roma and Traveller communities.[57] Further, membership of certain inclusion health groups are not often recorded in routine healthcare records with the result that these records cannot be used to identify such groups.[58] This highlights two wider points. First, information sourced from local networks ("*soft intelligence"* as Dr Ramsay called it) should not be overlooked, because to do so risks worsening the exclusion of individuals and communities that already struggle to access healthcare services.[59] Second, improvements in the sharing of health data should be mirrored by similar moves in other parts of the public sector, particularly local government, who may hold information on those who may for example be experiencing social isolation.

A National Vaccines Agency

34. Counsel to the Inquiry explored the concept of a "*national vaccines agency*" with some witnesses. The genesis for this idea was a paper produced in December 2020[60] by Dame Catherine Bingham, chair of the Vaccine Task Force ("VTF") from May to December 2020, and Dr Clive Dix, deputy chair and then interim chair of the VTF from May 2020 to April 2021 and submitted to what was then the Department for Business, Energy and Industrial Strategy ("BEIS").[61] Nick Elliott, Director General of the VTF from May to December 2020 does not discuss this document.[62] His successor, Madelaine

[55] UKHSA data strategy, 11/09/2023 [INQ000528385].
[56] See for example, Dr Mary Ramsay 21/01/2025 [Day6/114/5-17].
[57] PHE National Immunisation Programme: Health Equity Audit [INQ000477141_0026].
[58] 1st WS Dr Mary Ramsay, §7.3 [INQ000496177_0032].
[59] Dr Mary Ramsay 21/01/2025 [Day6/82/6-Day6/82/7].
[60] Document produced by Dame Catherine Bingham and Dr Clive Dix titled VTF Recommendations [INQ000330659_001].
[61] 7th WS Professor Dame Jenny Harries [INQ000492334_0017]; WS Dame Catherine Bingham [INQ000474406_004; INQ000474406_0057]; WS Dr Clive Dix [INQ000474423_0009].
[62] WS Nick Elliott CM MBE [INQ000474250_0001].

McTernan, appears not to have been aware of it.[63] Similarly, Sir Richard Sykes, appointed Chair of the VTF in June 2021[64] makes no reference to the paper.

35. The suggestion, now four years old, was for a new "*executive agency*" with a remit that would "*include vaccine scale-up and manufacturing, including of supply chain readiness, tech transfer & stockpiling, oversight of the UK's clinical development capability including immunological profiling and human challenge models as well as attracting and supporting the development of innovative new vaccines. It would also monitor and relay current threat assessment of novel diseases to industrial partners, working in partnership with cross-government functions on horizon-scanning and intelligence*.' It would have an '*independent, industrially experienced chairman and board…to bring together the work of the various strands of vaccine activities that will define the UK as a global leader in vaccine development and manufacturing*". [65] That remit suggests an agency operating in much the same way that the VTF could do during the pandemic. As canvassed with Dame Kate, the VTF was able to sit "*slightly outside government*", have "*very strong external input*" and "*the independence and the authority to be able to report directly to the Prime Minister*"[66].

36. The VTF was created in unique circumstances. It was stood up at a time when virtually all other work stopped for COVID-19 and had a sole mission – to secure an effective vaccine for a single pathogen. Rightly, during an emergency of this scale, the risk appetite of elected decision-makers widens radically. To the country's good fortune, the VTF benefited from the political will to take necessary risks and to invest at speed in multiple vaccine candidates but with no guarantee that a successful vaccine would emerge. As Lord Vallance observed had the VTF not achieved its central objective it would "*have been lambasted as a huge waste of public money*".[67]

37. Those witnesses asked about a national vaccine agency pointed to UKHSA fulfilling the role[68]. As Professor Harries clarified, UKHSA absorbed a component of the VTF – which

[63] WS Madelaine McTernan [INQ000474380_0014].
[64] WS Sir Richard Sykes [INQ000499054_005].
[65]Document produced by Dame Catherine Bingham and Dr Clive Dix "VTF Recommendations" [INQ000330659_001-002].
[66]Dame Catherine Bingham 21/01/2025 [Day6/64/16-24].
[67]4th WS Lord Vallance of Balham, §108 [INQ000474482_0043].
[68]Rt Hon Matt Hancock MP 16/01/2025 [Day 3/103/12-106/3]; Alexandra Jones 20/01/2025 [Day5/32/16-33/20].

initially became the Covid Vaccines Unit ("CVU"). [69] It is now the Vaccines and Countermeasures Delivery unit ("VCD") within UKHSA Commercial Group, with a focus on all pathogens and countermeasures. It is not appropriate however to see the CVU or the VCD as a rebadged VTF. Peacetime asks different questions of operational agencies who, like UKHSA, have a remit that covers pandemic preparedness:

(a) Are the processes and mechanisms in place capable of addressing multiple different known and unknown threats?
(b) Are they capable of being scaled up and of being made even more timely in their response?
(c) Can they through sophisticated surveillance and evaluation identify pathogens and trends in disease that could have an adverse impact on the health, wellbeing and economic resilience of the UK population?
(d) Can they be utilised not only to anticipate and manage risks but also to contribute to economic growth and life science development more broadly?
(e) Can a system doing all this in peacetime turn swiftly and seamlessly to an active operational node within an emergency system and working between government, academia and industry?

38. Since it became operational in October 2021, and as the demands of responding to the COVID-19 pandemic eased, UKHSA has sought to build a system capable of answering these questions effectively and embedding that system for the future.

39. To do so requires that the capabilities identified in UKHSA's opening statement are nurtured and developed. These were: sustained research and development; strengthening partnerships between government, industry, and academia; the benefit of routine vaccination work; and the importance of surveillance and monitoring. These capabilities reflect work undertaken for many years before the pandemic and which were a critical resource for the VTF.[70] As Dame Kate observed: "*You can't build stuff de novo in a pandemic but you can increase what's already there*".[71] A successful vaccine strategy depends not only on funding research to find vaccine candidates (mRNA vaccines were originally conceived as cancer vaccines)[72] but also on having

[69] 7th WS Professor Dame Jenny Harries [INQ000492334_0061]; Professor Dame Jenny Harries 20/01/2025 [Day 5/193/4-6].
[70] 1st WS Dr Mary Ramsay, §4.14-4.22 [INQ000496177_0019-0021]; 7th WS Professor Dame Jenny Harries, §2.9, §5.2, §5.25 [INQ000492334_0006; INQ000492334_0023; INQ000492334_0025].
[71] Dame Catherine Bingham 21/01/2025 [Day6/29/20 – 30/12].
[72] 1st WS Dr Mary Ramsay [INQ000496177_0065].

effective systems in place to deliver the vaccine to the patient's arm, to provide necessary information to the public and to surveil and evaluate the effectiveness of the vaccine (particularly if variants emerge). With these capabilities and the future in mind, UKHSA for example:

(a) Has made improving health outcomes through vaccination a strategic priority and one which is not limited to pandemic preparedness.[73]

(b) Operates with both an executive committee and an advisory board with an external chair.[74] The membership of the board is publicly available and includes external expertise from the commercial sector, the military, local government as well as the healthcare sector.

(c) Building on arrangements which evolved during the pandemic, UKHSA continues to work with the devolved administrations and their public health agencies including discussing means of working effectively together including to future pandemic preparedness.[75]

(d) Successfully competes for and receives funding to undertake research in collaboration with academia and industry partners. That allows UKHSA to undertake its own innovative research (including with a commercial element) and to maintain the reputation of scientific work. A pertinent example of the funding received by UKHSA is that provided by the Coalition of Pandemic Preparedness Innovations ("CEPI") to develop a laboratory assay for mpox – a first step to developing a vaccine.[76] CEPI is a partnership between public, private, philanthropic, and civil organisations, launched in 2017, to develop vaccines against future epidemics. Dr Dix considered that a national vaccines agency would need, as UKHSA has done, to establish links with CEPI.[77]

(e) Has built a new global surveillance system and is developing a UK priority pathogen tool aligned to and working with the World Health Organisation ("WHO").[78] UKHSA works with DHSC and other government departments to fulfil the UK Government's responsibility for the UK's compliance and support to relevant international agreements. The Agency is the focal point for reporting notifiable diseases under the International Health Regulations and works with

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[73] UKHSA Strategic Plan 2023-2026 [INQ000235221_0028-0031]; 1st WS Dr Mary Ramsay [INQ000496177_067].
[74] 1st WS Professor Susan Hopkins at §§46-50 [INQ000410867_0115].
[75] 3rd WS of Professor Dame Jenny Harries at §§160-161 [INQ000251906_0040].
[76] Webpage: CEPI, UK MHRA, and UK Health Security Agency to advance key tools for Monkeypox vaccine research | CEPI **INQ000574415**
[77] Dr Clive Dix 30/01/2025 [Day 12/95/7-10].
[78] Professor Dame Jenny Harries 20/01/2025 [Day5/216/22 – 217/13].

WHO both on a global and regional level. [79] On behalf of WHO, UKHSA is a Collaborative Open Research Consortia ("CORC") working on a family of priority pathogens. Dr Dix envisaged this type of relationship with the WHO for a national vaccines agency.[80] UKHSA's involvement with the 100 Day Mission is another example of the agency operating as part of a global initiative.[81]

(f) Is continuing to develop ongoing relationships with industry. UKHSA's published commercial strategy recognises that "*commercial expertise is just as important as our scientific, clinical and other capabilities in protecting the health of our nation.*" That strategy seeks to make UKHSA a partner of choice not only with industry but also with universities, research organisations and social enterprises. It aims to develop UKHSA's commercial capability, including by recruiting, retaining and developing the expert commercial staff.[82] The UKHSA commercial pipeline provides a forward look at potential commercial activity within UKHSA.[83]

(g) Launched the Vaccine Development and Evaluation Centre ("VDEC") in August 2023 with a remit to support the identification of the most promising vaccine candidates and to provide pre-clinical and clinical trial testing of vaccines. VDEC built "*on the existing clinical immunology capabilities at UKHSA Porton Down and will help to maintain this critical capability beyond March 2024 when VTF support for these facilities ended with the potential to secure further funding through additional work with industry and academia.*" [84]

40. It has been suggested that the decision to cancel contracts with Valneva and Novavax, two of the portfolio of seven vaccines to which the VTF secured access[85], undermined relations with the pharmaceutical and bioscience industry[86]. Others including[87] Professor Van-Tam[88] are not of that view. The decision to cancel the Valneva contract was taken in September 2021 and was a ministerial one. It followed a submission from the VTF

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[79] UKHSA Strategic Plan 2023-2026 [INQ000235221_0028/0033/0035/0049].
[80] Dr Clive Dix 30/01/2025 [Day12/95/7].
[81] 1st WS Dr Mary Ramsay, §13.19 [INQ000496177_0069].
[82] UKHSA Commercial Strategy [INQ000421934_004; INQ000421934_018 – 027]
[83] Webpage: UKHSA Commercial and Partnerships - GOV.UK [**INQ000574433**]; Webpage: UKHSA commercial pipeline as at 7 March 2024 [**INQ000574435**].
[84] 7th WS Professor Dame Jenny Harries [INQ000492334_031]; 1st WS Dr Mary Ramsay INQ000496177_068].
[85] 7th WS Professor Dame Jenny Harries [INQ000492334_0025].
[86] WS Dame Catherine Bingham [INQ000474406_0061-062]; WS Dr Clive Dix [INQ000474423_0012 - 0013].
[87] WS Sir Richard Sykes [INQ000499054_0015 – 0017]; WS Madeleine McTernan [INQ000474380_0023].
[88] 3rd WS Professor Sir Jonathan Van-Tam [INQ000474404_0075].

supported by the Treasury.[89] The decision to cancel the Novavax contract and to seek recovery of $112.5M of public money was made in January 2023 and so is outside the relevant period for Module 4. The Inquiry has confirmed to UKHSA that it does not consider the issue of the cancellation of the Novavax contract to fall within the scope of Module 4. It has however been the subject of evidence and core participant submission. Given that such evidence and submission have been permitted, it is important to make clear that the proposition that Professor Harries made the decision to recover monies under the Novavax contract is factually incorrect. The decision to recover what was on any view a significant amount of public money was not taken by the VTF or UKHSA. As the Inquiry is aware, there is a mechanism by which such decisions are taken. Here, and as it should be, this was a ministerial decision informed by a submission from the VTF. The submission itself illustrates the need to be aware of conflicts of interest. Ensuring the efficient use of public monies is plainly important. Once the responsible minister had taken the decision, Professor Harries was involved in taking any necessary operational steps.

41. The experience of UKHSA is that the pharmaceutical and bioscience industry remains very willing to engage constructively with the UK Government. There can be many reasons why a company decides whether to invest in the UK or not. Global economic factors play a part. As Professor Van-Tam noted, the UK is "*a very small market in the eyes of vaccine manufacturers now*".[90] The country punches above its weight because its strong science and research base remains attractive to industry.

42. UKHSA's engagement with industry seeks to develop three categories of relationship. First, strategic partnerships where government, UKHSA and a private company can collaborate across a range of scientific, innovation and policy priorities. Second, relationships with suppliers of goods and services to UKHSA and, third, relationships with organisations whose development needs to be supported. The Moderna Strategic Partnership, for which UKHSA is the senior responsible owner, is an obvious example of the continued interest of the industry. This ten-year partnership will see the opening of a new mRNA production unit (the Moderna Innovation and Technology Centre or MTIC) by autumn 2025 with capacity to produce up to 250 million doses of respiratory vaccine.[91] Moderna has committed to investing over £1 billion in mRNA research and

[89] 8th WS Professor Dame Jenny Harries [INQ000474715_0002]; Email re submission, dated 09/09/21 [INQ000514012]; Submission to the Secretary of State, dated 09/09/21[INQ000514013].
[90] Professor Sir Jonathan Van-Tam 20/01/2025 [Day5/166/5 - 7].
[91] Darius Hughes 27/01/2025 [Day9/26/20-28/24].

development in the UK. So far, Moderna has launched 15 clinical trials (including on season influenza, norovirus and cancer therapy). The relationship between UKHSA and Moderna, as Professor Harries explained, goes beyond vaccines and has included tabletop exercises.[92]

43. UKHSA is working with the bioscience industry to accelerate developments of new capabilities to improve public health and to support growth in the life sciences sector. An example is the consortium which will bring together experts in UKHSA, AstraZeneca and Imperial College London to research and evaluate mucosal vaccines and understand their benefit for public health.[93] UKHSA also ensures the timely supply of vaccines for routine immunisation programmes and to respond to future health threat. UKHSA's relationship with CSL Seqirus has seen an advance purchase agreement for influenza vaccines.[94]

44. Dr Dix described VDEC as "*a small little lab when we started the VTF*".[95] VDEC was launched in August 2023. Unlike the VTF which had significant financial resource to pass on to other organisations, UKHSA's remit does not allow it to fund and invest directly in external research as a means of incentivising or supporting industry or academia. UKHSA must do so by different means. As well as being operational in its own right, VDEC is one such route. It enables and supports the work of industry and academia by bringing together all the functions needed to develop, evaluate, and support the licensure of vaccines and therapeutics (despite the name VDEC also undertakes work in relation to therapeutics). VDEC has established a number of partnerships with industry.[96]

45. VDEC provides high quality, cutting-edge science.[97] It has access to high containment bio-secure laboratory capabilities (biosafety level ("BSL"). 2, 3 and 4) which are the most extensive of their kind in the UK. There are over 200 scientists running over 100 projects per year, including many that are with external partners. UKHSA scientists publish peer-reviewed research papers, and their work is recognised as world-leading. VDEC therefore can support industry to de-risk vaccine development.[98,99] It assists industry to

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[92] Professor Dame Jenny Harries 20/01/2025 [Day5/219/8-220/12].
[93] UKHSA Science: Securing Health and Prosperity 2024 Review [INQ000563069].
[94] Professor Dame Jenny Harries 20/01/2025 [Day5/220/15-22].
[95] Dr Clive Dix 30/01/2025 [Day12/96/10-20].
[96] Professor Dame Jenny Harries 20/01/2025 [Day5/215/19-218/23].
[97] Vaccine Development and Evaluation Centre (VDEC) factsheet **INQ000574442**
[98] Webpage: UKHSA's Vaccine Development and Evaluation Centre ("VDEC") – "What we offer" section **INQ000574434**.
[99] Webpage: UKHSA's VDEC – "Partnerships and Projects" section **INQ000574434**

identify those vaccine candidates which are most likely to be effective. The collaboration provided by VDEC puts industry in a better position to identify products which will achieve licensing and go to market. UKHSA's disclosure in this Module includes publicly available information about the work done by VDEC including for example developing an organ- on-a chip model.[100]

46. The Inquiry will note that only 30% of VDEC's funding comes from core government funds. The unit must attract external funding. In its first year VDEC received £8.8 million in research and commercial income[101].

47. Against the background of the progress since October 2021, a suggestion to now establish a national vaccines agency raises critical questions which were canvassed during UKHSA's oral closing statement[102]. These include asking how such a body would manage conflicts of interest if its external input was short-term secondment from industry bearing in mind that relationships with industry, if poorly managed, can contribute to vaccine hesitancy. Further, given there are no discreet boundaries in clinical and scientific work, would the creation of an agency with a single focus (as the VTF had[103]) lead to the duplication of resources in other agencies with consequent costs. Dr Dix's view seemed to be that UKHSA had too wide a remit. However, that ignores the need to take an anticipatory approach to future health threats. For example, UKHSA carries out work on climate change and health security as well as entomology and vector borne diseases. This brings obvious opportunities for future vaccine development.

48. This brings matters back to the vexed question of funding. The VTF was expensive. Its initial funding was over £5 billion.[104] It did not work alone but drew upon the existing system. Using the analogy of the Ministry of Defence (which has a published defence spend of £53.9 billion), Dr Dix suggested that such a new vaccines agency need not be "*hugely expensive*".[105] By contrast, Professor Van-Tam's view was that "*vaccine pandemic preparedness is not free. It is very expensive.*"[106] How much funding would a new agency with the remit envisaged by Dame Kate and Dr Dix need to avoid being left to "*wither on the vine*"?[107]

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[100] Professor Dame Jenny Harries 20/01/2025 [Day5/217/18].
[101] UKHSA Science: Securing Health and Prosperity 2024 Review [INQ000563069_0010].
[102] UKHSA oral closing statement 30/01/2025 [Day12/120/7-130/7].
[103] Dr Clive Dix 30/01/2025 [Day 12/91/15 – 92/2].
[104] Catherine Little 17/01/2025 [Day4/149/5-11].
[105] Dr Clive Dix 30/01/2025 [Day12/97/20-98/19].
[106] Professor Sir Jonathan Van-Tam 20/01/2025 [Day5/154/24-155/3].
[107] Rt Hon Matt Hancock MP 16/01/2025 [Day3/104/4-20].

49. The reality is that how much can be spent on pandemic preparedness in peacetime is a difficult decision for elected decision makers having regard to competing priorities. As it has to, UKHSA currently operates to provide *all* of its services, including non-infectious disease science and response and global surveillance within 3% of its original pandemic budget, a figure, as has been pointed out before, akin to that allocated to a moderate district hospital.[108] The Agency bids for research funding and, as with VDEC, seeks to generate commercial income.

50. Stepping back from the detail, the key question which emerges is whether a proposal to now establish a national vaccines agency would have the opposite effect to that intended by those who support the proposition i.e., would such a reset actually set pandemic preparedness back? This question was not canvassed with for example, the CMO, Professor Harries, Dame June Raine, Chief Executive of MHRA, or Lord Vallance, now Minister for State for Science, Research, and Innovation. It is an important question and one, which on balance, falls to be answered in the positive.

51. While the themes outlined in UKHSA's opening statement may be more prosaic, UKHSA contends that the main focus should be on embedding them. Thus:

    (a) Sustaining research and development and strengthening the relationship with industry and academia will allow better opportunity for the UK to expand its portfolio of vaccine candidates and to develop onshore manufacture of non-mRNA vaccines.[109] It will make it easier to identify those experts, in government, industry and academia who may need to be called upon in an emergency.
    (b) Lord Vallance is right to point to the need to recruit those with industry experience and more STEM graduates into the Civil Service and the aim for of 50% of Fast Stream entrants to have a STEM degree is welcome.[110] Placing such recruits in a policy role would ensure scientific advice and the views of industry are understood and appreciated.
    (c) There needs to be a commitment to ensuring all aspects of routine immunisation programmes are resourced to provide a positive baseline for future pandemics and continue to build public trust. The benefit of local networks should not be ignored.

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[108] Professor Dame Jenny Harries 20/01/2025 [Day5/216/4-6].
[109] Alexandra Jones 20/01/2025 [Day5/22/6-23/7].
[110] 4th WS Lord Vallance of Balham, §149e [INQ000474482_0056].

(d) Developing the infrastructure for the secure collation and sharing of data must continue to allow for better monitoring and evaluation of vaccine coverage, hesitancy, and update. It must be done in a transparent manner with due regard for public concerns to avoid undermining public trust.

(e) Government should consider establishing a single digital resource (bringing together information from UKHSA, NHS England, MHRA and others) which can become a trusted point of information on the risks and benefits of vaccination.

Conclusions

52. Vaccines are critical to health protection now and in the future. A lesson from the COVID-19 pandemic was that the UK must seek to be in the best place to ensure that all aspects of vaccination from initial research to onshore manufacture, procurement and the licensed vaccine reaching a patient are achievable. UKHSA trusts that the issues considered in its oral opening statement, oral closing statement and this written closing statement will be of assistance to the Inquiry in making effective operational recommendations.

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