## NHS ENGLAND'S CLOSING SUBMISSIONS FOR MODULE 4 OF THE COVID-19 INQUIRY

- 1. NHS England's oral submissions focussed upon what had gone well and *why*, an important part of the Inquiry's role in making factual findings and recommendations. We asked the Inquiry to particularly bear in mind 3 things: (i) how well did the system do against reasonable expectations in context; (ii) what has already been learned (drawing attention, in particular, to the new NHS England Vaccination Strategy published in December 2023 ("the Strategy")); and (iii) when considering any recommendations to consider the wider health ecosystem, and whether recommendations on deployment could be operationalised. <sup>1</sup>
- 2. These written submissions provide additional references to support the points made orally and address specific topics or points of challenge or disagreement or bring to the fore matters not addressed by us in hearings, covering (i) overarching points; (ii) vaccine deployment (the "Programme"); (iii) sponsorship of therapeutics and antivirals and means of distribution for treatment; and (iv) recommendations and work undertaken since the end of the Relevant Period.
- 3. In addition to the clear and cogent oral evidence on vaccination deployment from Dame Emily Lawson,<sup>2</sup> the Inquiry has substantial written statements from NHS England, setting out NHS England's responsibilities, evidence and reflections in this module.<sup>3</sup>
- 4. Those statements rightly recognise the very significant work and dedication of all those involved responding to the pandemic in the field of vaccines and therapeutics: from front line NHS clinicians and pharmacists, to volunteers, those employed within NHS England and other executive agencies, civil servants and politicians, the Army, and to specific roles such as Chief Medical, Nursing, Midwifery, Pharmaceutical Officers and their Deputies,<sup>4</sup> academics and so many more, including the very significant support from members of the public. To each person, we say thank you. We are also grateful to <u>all</u> those who have shared their personal experiences and perspectives in this module.

# **OVERARCHING POINTS**

- 5. The Inquiry has already had the benefit of significant NHS England evidence and submissions in M3: the position of the NHS prior to the pandemic, competing priorities including the very substantial pressures the system was under dealing with COVID-19 as a disease, and the impact on staff and on capacity. As with M3, the Inquiry is asked to bear in mind the balance between central direction and guidance, and continued local discretion and autonomy, the legal and structural framework of the healthcare system in England, in particular, the legal and regulatory framework in respect of vaccines and therapeutics.
- 6. The Inquiry has explored whether less importance was attached to therapeutics than vaccines, or if the latter was improperly prioritised over the former, with a number of

- witnesses disagreeing with this proposition. NHS England does not recognise that characterisation, being involved in both. Vaccines and therapeutics are different: as Professor Sir Chris Whitty explained, vaccines have "multiple hits on goal" and can deal with evolution of the virus to a much greater extent. Vaccines were necessarily deployed on a population level scale and were made available to every adult. They are preventative, rather than therapeutic, cheaper, easier to deploy and do not need to be taken as regularly. Plainly therapeutics were required but it is not a like for like comparison.
- 7. The response on both vaccines and therapeutics utilised and built upon existing NHS systems and ways of working. The NHS is an ecosystem of separate providers with a framework for securing the accountability of Trusts and community services including commissioning bodies such as local CCGs/ICBs. 5 As Dame Emily explained, vaccine deployment utilised the 7 RDCs (Regional Directors of Commissioning) to deploy the vaccine within their ICS (integrated care systems) and local health systems, working alongside local directors of public health.<sup>6</sup> Under the Health and Social Care Act 2022, ICSs have formed ICBs as legal entities with statutory powers and responsibilities including reducing health inequalities. This is relevant to any recommendations. As Professor Sir Chris Whitty recognised, the existence of the NHS played a critical role in therapeutics, which gave the UK several advantages: having a single provider of almost all medical services and a very central national research funding capacity provided a core function joined up across the system, the ability to set up trials extremely rapidly across the NHS, with much recruitment being done in hospitals and by GPs, and the strong tradition of clinicians taking part in clinical trials.
- 8. Any recommendations made in M4 will need to be consistent with and complementary to any M3 findings and recommendations, noting the reality of the operation of the healthcare system in England, necessarily within the funding allocated. For example, on data capture, requests in this module for more data collection must be considered against the concern in M3 that there were too many requests for additional data: each additional ask had to be justified, and 'adding fields' is not straightforward.
- 9. Because this was a pandemic, a very significant amount of resource was rightly put to addressing the impact of Covid-19, researching, obtaining and deploying vaccines and therapeutics at a speed not previously seen.
- 10. However, there were and are trade-offs, and as we submitted orally, no response can be perfect. As Professor Sir Chris Whitty noted, in the context of clinical trials: "there is a price to be paid because all the studies that were stopped were doing very important and useful things in other areas of medicine. So this [was] a trade off... we shouldn't pretend there wasn't a price". Regarding vaccines, Professor Whitty noted that the trade-off: "was

between perfection in terms of getting the exact people right and the speed and usability and simplicity of the system we were applying".9

## **VACCINES**

- 11. We welcome the Inquiry's provisional view that vaccines, including deployment, was an overwhelming success, and invite a finding to that effect. There were, understandably, challenges and NHS England recognises that notwithstanding the efforts to address accessibility, maximise convenience, and reduce barriers, there are those for whom the experience was unsatisfactory. However, issues of vaccine confidence, hesitancy, barriers to uptake were both anticipated and significant steps taken to address them, both before and after authorisation of the vaccine, adapting and improving the system as it was rolled out, and scaled up, across early 2021 and throughout the Relevant Period.
- 12. The "Programme" delivered because it was simple, enabling it to be deployed at speed nationwide. It built on and adapted existing NHS systems (local, regional and national) utilising existing delivery partners (e.g. GPs and pharmacies) but developing new vaccination pathways; building new systems when needed (such as the National Booking Service (NBS)). It brought in expertise, adapted and innovated. NHS England has sought to build on and retain the legacy created. Much was possible, because it was a pandemic, with significant political and public support which facilitated innovation, albeit with the dedication of significant financial and other resources.
- 13. Whilst it is vital to consider the perspectives of everyone, and recognising not every pathway worked for every person, each pathway worked for many people, and we submit multiple pathways was the right answer, with steps taken at every stage to reduce barriers, increase convenience, access and awareness. The Inquiry is invited to carefully consider whether alternative approaches were, in fact, possible to deliver at the time, whether they would have had unintended consequences or adversely impacted on another group or part of the Programme. NHS England accepts that not every person will have had the experience that was right for them, some will have had distances to travel, or accessibility issues, and from which lessons can, and we submit were, learned.
- 14. The Inquiry will of course look at the different approaches across the four nations. However, it is important to remember that they have different geographies, populations, legislation and healthcare systems. Any differences in approach should not be considered in isolation.
- 15. The Inquiry is invited to conclude that there was a robust system in place to address regulatory, safety, equality of access, inequalities, and barriers to access, through the contractual requirements, Standard Operating Procedures (SOPs) and assurance visits, with mechanisms for feedback utilised and amendments made where needed.<sup>10</sup>
- 16. We submit that, against reasonable expectations, considering the magnitude of the task:
  - a. There was significant and appropriate planning, consultation and engagement;

- b. Each of the multiple pathways was important: GPs and pharmacies, new community settings and roving models to maximise convenience and reduce hesitancy;
- c. Centralised leadership and coordination was needed at the outset, with significant and increasing local and regional NHS, public health and local authority input, empowering trusted voices and local communities and bringing in expertise when required; and
- d. There was continual learning novel initiatives were trialled to encourage vaccine uptake with those considered successful being shared across the country.
- 17. Whilst there was significant planning across 2020, the extent to which plans could be meaningfully progressed, and any consultation on specifics, was necessarily dependent upon the authorisation of the vaccine, its characteristics and handling requirements. The approach was to deliver a system that was fair, simple and operationally excellent and could be built at speed. There needed to be <u>a system</u> that was operational which delivered against regulatory and safety requirements and the prioritisation of cohorts set by the JCVI, but which could be improved, adapted and developed. Simplicity was key, as was a system that was fair nationally.<sup>11</sup>
- 18. As Dame Emily explained, <sup>12</sup> there was a need to streamline meetings and consultation, build sustainable and proportionate governance structures, to allow something operationally effective to be built, at speed. The Inquiry may well conclude that the Programme sought appropriate input early from multiple stakeholders, with renewed efforts when the likely parameters were becoming clearer and on Dame Emily's appointment (November 2020).
- 19. NHS England recognises that there was a desire by many to be involved earlier or to a greater extent, and to be part of finding solutions for issues that would obviously arise. It was vital to ensure that there was a Day One offering, to stand up an effective Programme, utilising the existing NHS structures (which, at the outset, included the need to use NHS numbers), to build the NBS from scratch and deploy it when ready, and to develop sustainable complex supply chains. This, along with regulatory and safety requirements, the JCVI criteria, and the need for fairness, meant that approaches that some people legitimately wanted could not happen, or not as quickly as desired.
- 20. The Inquiry will also consider whether issues identified as 'concerns' at the time, or now, are in fact the impact of competing considerations and the need for <u>a decision</u> to be made, or the reality of changes made due to new or updated information, the system learning and implementing feedback or required changes. Not every issue can be addressed at the outset, there need to be priorities, with other changes following when possible.
- 21. For example, the decision made by JCVI to increase the dosage interval in December 2020, caused significant consternation and comment from GPs, the public and the media. It also had a very significant impact upon those delivering vaccines at that time and necessitated significant additional work in rebooking. Some disagreed with JCVI's decision. Once made,

- NHS England's role was to operationalise that. It did so, providing significant administrative support to mitigate the impact as much as possible, but could not mitigate it entirely. This was perceived by some as unwelcome central control. It is, perhaps, more an example of NHS England as the messenger delivering an operational solution to another's decision.<sup>13</sup>
- 22. As we set out orally, planning required the development of options: to provide a workable and scalable plan for vaccine deployment<sup>14</sup> which necessarily had to take account of this disease (Covid-19), and the assessment of who was most vulnerable (as set out in the JCVI criteria) which necessarily impacted upon what was prioritised (e.g. age, initially, care homes, healthcare staff, and subsequently those with Down's syndrome, learning disabilities, other carers in accordance with the cohorts), as well as the vaccine available (Pfizer initially with its handling requirements), the legal and regulatory framework and the need and ability to deliver a project at scale (including supply chain logistics).
- 23. Thus, the Programme prioritised decisions relevant to these factors. Decisions related to vaccinating children, for example, were necessarily not a priority until later.
- 24. Any future vaccination programme arising in a pandemic will likely be different: for example, in a pandemic where children require vaccination, there would need to be significantly earlier engagement to work with schools and elsewhere to facilitate vaccination of children. The benefit of having options and pathways, and the ability to pivot, enables standing up the right resources for the situation that the country is facing.
- 25. **Engagement and Consultation:** Both in planning for, and delivering the Programme, there was a very significant amount of work done to address convenience, confidence and complacency, through effective communications and engagement both prior to the appointment of Dame Emily in November 2020, and upon her appointment as SRO.<sup>15</sup> This includes work around underserved groups and the need for a targeted approach:
  - a. Autumn 2020: as part of Flu and Covid programme, there was significant engagement with voluntary, community, social enterprise and faith groups, with different Regions leading and developing tools, case studies and best practice communications and engagement materials around Covid: 16 The North West and London led on inequality of access and information, specifically in Black and ethnic minority communities, the South East on staff engagement, and the South West on secure settings, people experiencing homelessness and GRT communities. Devon ICS led on Learning Disability and Autism, working with national colleagues and the national carers forum.
  - b. NHS England also began to work with stakeholders including the British Islamic Medical Association<sup>17</sup> and NHS Black, Asian and Minority Ethnic Staff Network including testing accessibility of letter content about the Covid-19 vaccination.<sup>18</sup>
  - c. October 2020: NHS England regional teams were asked to provide operational plans and share their plans for developing Equality and Health Impact Assessments, engaging

- with local community groups, mitigating risks or negative impact of plans for individuals with protected characteristics, and a cohort breakdown including inclusion groups and those not registered with a GP. Regions identified groups including disabled people and inclusion health populations including people experiencing homeless and people from ethnic minority backgrounds as requiring targeted actions to support.<sup>19</sup>
- d. NHS England built on work already underway, described in M3, addressing "inclusion health" groups.<sup>20</sup> Such issues were regularly raised, discussed and actions taken at NHS England's Covid-19 National Incident Response Board (NIRB) as early as October 2020.<sup>21</sup>
- e. Dedicated leadership was put in place to lead on equalities through a National Steering Group set up in November 2020, headed by Dr Nikki Kanani, and national and local teams worked together to understand how they might better address the needs of underserved communities.<sup>22</sup>
- f. On 1 December 2020 the first BAME Health advisory group session took place to ensure partnership working with national organisations and systems to produce best practice guidance which was put before NIRB on 4 December 2020.<sup>23</sup>
- 26. This work complemented more general work on health inequalities, including work to restore health services inclusively.<sup>24</sup> Engagement continued throughout the Programme with a Vaccines Equalities Committee set up from January 2021 and the Vaccine Equalities Tool available from February 2021, although data was available earlier.
- 27. <u>As to local government</u>, Dame Emily met with the Local Government Association (LGA) on her first day and the National Vaccine Deployment Steering Group with Councils and the LRF was set up.<sup>25</sup> On 20 November, Dame Emily wrote<sup>26</sup> to all NHS Trusts and Foundation Trusts, ICSs, and Local Authorities, to set out the plan: what would be provided nationally, and what it was expected the NHS working with local government and others would deliver locally, followed by a communications and engagement plan on 30 November.<sup>27</sup>
- 28. There were weekly calls, and Eleanor Kelly was appointed as part of the leadership team from January 2021. With local government representatives on the Deployment Board, Equalities Advisory Board and Capacity Group, they were firmly embedded in decision-making.<sup>28</sup> The Inquiry may consider that this was the right time to ramp up engagement, as it became apparent that a vaccine would be available. There was, however, earlier partnership working with LGA, Royal Colleges and others as early as September 2020.
- 29. **Vaccination Pathways**: multiple pathways were considered, and planning took place for each of them. The Inquiry has the benefit of multiple planning documents.<sup>29</sup> Decisions and prioritisation on pathways was necessarily impacted by the Pfizer vaccine characteristics, supply constraints and the need to scale up a complex supply chain sustainably.<sup>30</sup> It was a

- significant exercise to set up each site; it required planning and assurance to ensure national coverage taking into account data around uptake.
- 30. As to GPs and Pharmacies: these were not initially considered as the main model for delivery of COVID vaccines. In August 2020, flu vaccine planning anticipated using business as usual models, and it was thought that COVID and Flu could not be delivered simultaneously. Plans therefore included fixed, mobile and roving vaccination models.<sup>31</sup>
- 31. However, by October 2020, local vaccination sites (LVS), including GPs and pharmacies were a key part of the plan.<sup>32</sup> Whilst wanting to use such sites to begin with, it was necessary to start with hospital hubs. Engagement took place and by <u>1 December</u>, a contract for GPs delivering vaccines was agreed, and vaccinations followed.<sup>33</sup>
- 32. That contract has an equalities and health inequalities statement and makes clear GPs may vaccinate unregistered patients and those without an NHS number. Paragraph 9.10 states that GPs should ensure all services are accessible, appropriate and sensitive to the needs of all patients and that, in relation to access, no patient should be excluded or experience particular difficulty due to a protected characteristic including disability.
- 33. By 2 December 2020, the Programme Board was already approving sites to start the following week and planning for future sites. The first GP led Primary Care Networks (PCNs) vaccinated on 15 December. By 17 December, GPs had started proactively making videos in multiple languages. NHS England worked in partnership with GPs to make videos, e.g. a Somali GP whose YouTube video was published on 27 December, talking about getting the vaccine. Throughout the pandemic, very many clinicians engaged with the public.<sup>34</sup>
- 34. Community pharmacies started vaccinating from 14 January 2021. Dr Ridge (CPhO) details consultation with pharmacies: proactive communication about rollout, the set-up of the Programme Pharmacy Short-Life Working Group in October/November 2020, <sup>35</sup> and discussions with Community Pharmacy England. Various letters were sent to the system to explain the position, manage expectations and encourage participation when feasible: <sup>36</sup>
  - 27 November 2020: indicating a limited number of sites for delivering high volumes;<sup>37</sup>
  - o Early December: legal framework, handling requirements and SOPs produced; 38
  - o 28 December: setting out principles and expectations for involvement; 39
  - 16 February 2021: permitting applications from pharmacies capable of 400 doses a
    week where 1,000 doses was not possible or it would assist priority patient cohorts,<sup>40</sup>
  - April 2021 encouragement in parts of the country where more LVS needed;<sup>41</sup>
  - 14 July 2021 notification enabling pharmacies to submit expressions of interest to deliver 100, 350 as well as 1000 vaccinations per week.<sup>42</sup>
  - Work to allow pharmacists to vaccinate outside pharmacies at "associated premises".

- 35. As with GPs, the contractual documentation has an equalities statement, cites the Equality Act, requires the service to be accessible, appropriate and sensitive to the needs of all service users with no eligible patient excluded due to any protected characteristic.<sup>44</sup>
- 36. As Dr Ridge sets out, the pharmacist profession is diverse. As part of the wider health inequalities work, the Inclusive Pharmacy Practice Programme was established (August 2020), and the Joint Plan published (March 2021) including a focus on promoting vaccine uptake in BAME communities. That plan continues today.<sup>45</sup> Dr Ridge and many other pharmacists played a significant role in encouraging uptake and addressing misinformation.
- 37. NHS England notes the concerns and viewpoints raised by the BMA (in the context of GPs) and the NPA (in the context of pharmacies) of the impacts upon their respective pathways. NHS England agrees with the BMA and the NPA that delivering Covid vaccines was a significant undertaking given the handling, workforce and safety requirements and that staff were already under significant pressure responding to Covid.
- 38. NHS England reiterates its view that <u>both</u> GPs and community pharmacies were a vital part of the ongoing delivery of vaccinations in England. They remain so today. NHS England does not agree that existing NHS resource was overlooked in favour of creation of temporary systems. Fight to develop multiple vaccination pathways such as mass centres, those within existing community sites and through mobile offerings to ensure wider access.
- 39. GPs and community pharmacies carried out vaccinations alongside their existing roles, which were of vital importance. Requests to pause other contractual requirements were considered and agreed where appropriate, but it was, and remains, important that GPs and pharmacists are able to undertake the other core parts of their role.
- 40. Each pathway has its advantages and disadvantages which will vary depending on the individual in question. For someone not registered with a GP, or those who rarely attend their GP, a GP is not the obvious option. For others, e.g. some who are disabled or clinically vulnerable, in regular contact with their GP, it may be the best option: individual invitations and existing awareness of vulnerabilities which may be easier to manage at their GP.
- 41. In different circumstances, it may be much easier to bring pharmacies on board much earlier, or to start with GPs. It may not. NHS England suggests that having multiple pathways going forward is important for flexibility, agility and the ability to adapt at pace.
- 42. <u>Care Homes</u> England utilised the existing structures of GP led PCNs (introduced by NHS England in 2019) once pack down provisions were approved, following a successful pilot from 16 December.<sup>47</sup> The majority of the then 10,809 adult care homes had less than 50 residents and could not be visited if there was an outbreak. Whilst delivery could not start on 8 December, it started as soon as possible. SOPs ensuring efficient, effective and safe deployment were developed based on real-time use of the vaccine, and it was right to

- prioritise care homes in accordance with the JCVI cohort. The Inquiry noted that in Scotland, an exemption could be found in the Medicines Act (Scotland) which allowed a work around to deliver vaccines to care homes earlier. That exemption was not available in England.<sup>48</sup>
- 43. Carers working at the time the GP visited would have been offered vaccination. It is recognised that those not working at that time would need to book elsewhere, such as through their GP or at a hospital hub, and efforts were made to support their attendance at those sites. As soon as the Programme was able to, it expanded sites which in turn increased the available options for carers in care homes.
- 44. The decision to prioritise care homes did impact on the number of doses delivered. This caused press speculation that the NHS were not capable of delivering, which led to a challenging environment. The Programme thought they were making the right trade-offs.<sup>49</sup> This highlights the limited viewpoint and knowledge of those outside the Programme who perceived a lack of success. Building public confidence longer term took time.
- 45. <u>Other Sites</u>: these sites needed the National Protocol, which was approved in December 2020,<sup>50</sup> setting out clear accountability and authorisation requirements.
- 46. The Covid Vaccines Delivery Plan was published on 8 January 2021,<sup>51</sup> the NBS launched on 9 January 2021, and 7 mass vaccination sites went live on 11 January 2021.

  Vaccinations took place in the first mosque from 21 January 2021, with many more sites following.<sup>52</sup>
- 47. Various concerns and questions have been raised regarding directions to those delivering vaccines in such sites (and more generally) around informed consent, IPC measures, accessibility and translation, amongst other issues.
- 48. It is important to note that <u>all</u> vaccination sites were required to comply with their contracts, set out in the specification documents and SOPs. Such requirements included maintaining IPC standards, ensuring staff training and compliance with regulatory requirements in the Green Book and Protocol, and ensuring sites were accessible.
- 49. In addition to the Operating Framework for Vaccination Centres, there was a Covid-19 LVS Deployment in Community Settings SOP (first issued 10 December 2020).<sup>53</sup> From the outset it made clear that vaccination sites should be accessible to all members of their community and take reasonable steps to improve access and reduce potential inequalities, and for translation and interpretation services available as required to support consent, mental capacity and clinical assessments. Amendments made requirements even clearer, e.g. version 4 (8 March 2021), made clear that no NHS number or GP registration was required (even for NHS staff), the importance of "close oversight of flow and compliance" of IPC measures, and a specific section specifically dealing with the Equalities Act.<sup>54</sup>
- 50. There were SOPs for clinical incidents and enquiries and setting up and manging the booking capacity.<sup>55</sup> Specifics for roving and mobile models were set out in the 5 March 2021

- SOP.<sup>56</sup> Base sites were required to consider inequalities in vaccination uptake and skillsets such as languages when setting the workforce plan and "should have used the inequalities tool/s...and consulted with local communities to determine site location".
- 51. As Dame Emily explained, there was continual feedback. Regional leads led on ensuring contractual compliance by vaccination sites and would flag any issues via daily and weekly meetings with the central team, for consideration as to whether guidance, updates, etc were needed. Centres being safe and accessible were a critical part of delivery and, for example, mask wearing was expected to be upheld. Whilst acknowledging that individual accounts suggest that this was not universal, such issues should have been managed locally in the first instance. Issues around masking or CV/CEV feeling unsafe were not raised with her.<sup>57</sup>
- 52. **Ongoing engagement communications and inequalities work**: work continued throughout the Programme to continue to ensure high uptake.<sup>58</sup> This ranged from scaling up, increasing convenience to other interventions, and national messaging. It included communications from politicians in daily briefings, on the gov.uk website, through mainstream media, and NHS national systems.
- 53. These approaches worked for many but there needed to be a wide variety of communications. <sup>59</sup> Whilst new cohorts opened, continued encouragement of those who had not yet come forward, giving multiple opportunities and options, including sending additional invitations to ensure no one was missed. NHS England suggests it was more important to use multiple avenues even if there was overlap.
- 54. Whilst it was right to strongly encourage as many people as possible to have the vaccine given its significant benefits at a population level, vaccination is fundamentally an individual choice. NHS England agrees with Professor Larson of the need to address the drivers of hesitancy. Using data, NHS England sought to address hesitancy where it existed, and remove barriers to uptake both in terms of increasing convenience and increasing confidence. NHS England received feedback that some communities were concerned about being early adopters of a novel vaccine. Whilst it was important to address hesitancy and barriers to uptake, pushing too early may well have been counterproductive and had a negative impact upon confidence.
- 55. It is vital to note that groups are not homogenous, and there were multiple reasons why people did not come forward. Understanding the issues from data, and to target accordingly, rather than relying on assumptions or anecdote, was key. As more sites opened, more data was received, and combined with feedback from local systems, local communities could identify and suggest sites with their local knowledge. There was an increase in hyper-local initiatives once the Vaccine Equalities Tool with its intersectional approach was available.

  NHS England also secured financial support, such as the £4.2m funding.<sup>61</sup>

- 56. There are hundreds of examples of work undertaken, ongoing consultation and engagement set out in considerable detail in NHS England's written evidence and accompanying exhibits.<sup>62</sup> We invite the inquiry to carefully read and consider the many steps taken.
- 57. NHS England agrees that initiatives need to be evaluated. Data was shared throughout the pandemic, and published where possible, and there were some evaluations (e.g. the vaccine popups in May 2021 which were published). As the experts acknowledge, it is difficult to measure because tailored approaches were concurrent with other communications and the passage of time.<sup>63</sup> NHS England continues to work with academics to evaluate initiatives and welcomes the experts' acknowledgement that the Strategy builds on learning, engaging more closely with local communities, and places an emphasis on outreach and opportunistic delivery.<sup>64</sup>
- 58. <u>Data</u>: data insights played a central role in improving and adapting the Programme and increasing uptake. Data was reviewed daily and shared with local systems to facilitate decision-making. The Vaccine Equalities Tool enabled an intersectional approach to data, by age, deprivation and ethnicity and was instrumental in driving uptake and understanding where additional resources or local initiatives were required.
- 59. Having the right data was crucial in identifying those within cohorts to be vaccinated at the appropriate time and assessing the level of vaccination uptake by cohorts or population groups. Data is addressed in detail in the written evidence.<sup>65</sup>
- 60. Data was also challenging: NHS England acknowledges there were gaps, and took steps to and did address this. There was substantial engagement with clinicians, and NHS England leveraged existing relationships to improve data, and used the data it had.
- 61. As Dame Emily explained, 66 some issues were anticipated, and letters sent to the system e.g. in September 2020 to GPs asking them to review ethnicity data and ensure that it was captured and up-to-date. It was formally collected from January 2021 at the point of vaccination once the data system had been engineered to accept ethnicity data.
- 62. Dame Emily also referred to ongoing work to consider the definitions used when collecting ethnicity data.<sup>67</sup> Stephen Russell sets out the ongoing work of the Unified Information Standard for Protected Characteristics scoping project ("UISPC").<sup>68</sup>
- 63. There were a large number of unpaid unknown carers. A significant number were identified in NHS records, and NHS England used this data, but also obtained data from DWP to help complete the record. NHS England also worked with Carers UK to identify unpaid carers<sup>69</sup>. The Inquiry should reject any suggestion that operational considerations crept into Green Book definitions. As Dr Ramsey explained, the expansion of the definition of carer in the Green Book, to include those who were the sole or primary carer for an elderly or disabled person who is at increased risk of Covid-19, was at the NHS's request to ensure equity and consistency.<sup>70</sup> A specific SOP was introduced dealing with unpaid carers on 8 March 2021.<sup>71</sup>

- 64. Sharing data is not straightforward, given legal limitations, particularly given the data being discussed is sensitive personal information. Concerns have been raised that local government were not provided data early enough and that physical disability data was not collected at the point of vaccination and not shared with local government.
- 65. Available data was shared with local government from 15 January, once data could be generated at a level of aggregation to share in a safe and secure way.<sup>72</sup> On disability data, this was not collected, but it would plainly not have been right to share individual disability data with local government. Work is ongoing to address disability data.<sup>73</sup>
- 66. **Digital Exclusion:** The NBS launched on 9 January 2021 was a new resource to facilitate the population wide Programme. A SOP (7 January 2021) provided advice and guidance on setting up and managing booking capacity. Initially the NBS worked for a single vaccine type, but from mid-February could handle multiple vaccination types per site. NHS England recognises the wider issue around digital exclusion. However, it is important to note that the use of online systems has significant benefits to large parts of the population including in the ability to capture accurate data. The NBS is complimentary to other existing PCN and secondary care services where vaccinations were already being delivered; and the 119 number was available from the launch of the NBS.
- 67. The first national invitations sent out in January 2021 included a translated offer to 16 languages, with translation services and BSL interpreters available via 119. Additionally, NHS England encouraged those with a learning disability to call 119 or speak to their GP and worked with those running 119 to ensure staff responded appropriately.<sup>76</sup>
- 68. Today, using the digital system, NHS England can communicate according to people's preference in over 28 written languages, with accessible versions, via text, email and letter.
- 69. **NHS numbers**: the Inquiry has heard that the use of NHS numbers, not necessarily registration with GPs, was "pretty foundational", 77 for safety (to cross check against medical records), and the system was built around NHS systems. It was an existing dataset that, whilst not complete, covered a very large part of the population. It was a helpful starting point for identifying carers and matching DWP data to allow a cohort to be created. As Mary Ramsey noted, the need for a NHS number was not easy to correct, although NHS England led on addressing this, working with local NHS to work out the appropriate delivery model. 78
- 70. As Dame Emily explained, the need for a workaround was on the list of "tech issues" from early December, with a workaround clinically agreed by the end of January.
- 71. NHS England also encouraged people to register with a GP, with initiatives such as the GP Access Cards programme in February 2021. This had wider benefits: GPs were requested from mid-February 2021 to ensure that they were using the "Romani" data label to capture GRT ethnicity data.<sup>79</sup> Such approaches are also important in the longer term, and can create

- stronger (or new) relationships between the NHS and underserved groups, and offering additional checks at the same time (e.g. heart or dental checks).<sup>80</sup>
- 72. Local areas kept records of people in inclusion health populations to monitor uptake among people without an NHS number.<sup>81</sup>
- 73. Taking GRT as an example, there was engagement in October (South West) and November 2020 (Dorset) (as set out above), and resources started to be developed. To improve data, GPs were requested from mid-February 2021 to ensure that they were using the "Romani" data field where possible. The expectation was that local government and health systems would be aware of where many of the GRT communities were based and would seek to work with them. The specification and SOP made clear the importance of connecting with those not registered with GPs (including travelling communities).
- 74. Engagement took place at the Appleby Horse Fair, in both 2021 and 2022;<sup>82</sup> engagement online showed a wider reach of messages; and there were pop-ups on a boat along the River Avon for boating communities, and those initiatives were shared with local networks.<sup>83</sup>
- 75. Local NHS projects included developing a film in April 2021 featuring a Romany journalist and Romany boxer in partnership with First Community Health and Care backed by Surrey NHS to encourage GRT/Showmen communities to get their Covid-19 vaccine.<sup>84</sup>
- 76. On 8 July 2021, there was a national webinar for system partners to engage better with GRT and migrant workers and part of inclusion health initiatives.<sup>85</sup>
- 77. Looking forward, consideration is being given by DHSC to improving equality monitoring data including by adopting the 2021 census ethnic group categorisations including GRT.

# **THERAPEUTICS**

- 78. No oral evidence was given by NHS England witnesses and NHS England relies upon the detailed written evidence on NHS England's involvement in therapeutics and antivirals. Our oral submissions noted the significant successes in therapeutics, which we invite the Inquiry to acknowledge. As with vaccines, the successes owed much to the strength of the NHS and its people, the use and adaptation of existing infrastructure, innovation and collaboration with partners and responding operationally, at pace and at scale.
- 79. Role of NHS England: The two most significant roles that NHS England played, as part of the wider effort to identify and deploy therapeutics against Covid in the UK, were through its leadership in forming and membership of RAPID C-19 (across its functions, but it led on developing clinical policy) and the deployment of therapeutics, including through CMDUs.
- 80. NHS England was responsible for deployment of therapeutics. Unlike vaccines, therapeutics were available to a more narrowly defined group and needed to be taken shortly after testing positive to be most effective. NHS England developed CMDUs, which allowed the community-based proactive deployment of nMABS and antivirals to those eligible, by matching health records suggesting an individual met the definition of priority groups. NHS

- England also had a significant role in managing the significant supply pressures placed on therapeutics during the pandemic.
- 81. NHS England did not have a formal role in the design of clinical trials run in the NHS but enabled their adoption at scale. As was acknowledged throughout evidence, these trials were extremely successful. Their outputs saved millions of lives worldwide. The ability to stand up and run these trials so quickly and effectively is a testament to the NHS.
- 82. RAPID C-19: NHS England, together with NICE, the MHRA, and other agencies, formed the RAPID C-19 group to facilitate cooperation between agencies and expedite ordinary processes. Although MHRA was involved in Rapid C19, providing advice on authorisation timetables for innovative commercial products, authorisation was *not* within Rapid C-19's remit. Its functions included monitoring all ongoing Covid-19 clinical trials worldwide to identify those promising enough to warrant appraisal for possible delivery in the UK; advising the CMO, recommending approval of particular therapeutics, where appropriate; and where approved by the CMO, preparing clinical policy to enable the deployment of that therapeutic by the NHS services across the UK.
- 83. By bringing together several groups that would ordinarily be involved at different stages of deploying therapeutics from clinical trials demonstrating clinical efficacy into the NHS, RAPID C-19 was able to create efficiencies in this process, best exemplified by dexamethasone being used for Covid-19 treatment across the NHS on the same day that clinical trial data was released. Rapid C-19 was not an additional bureaucratic roadblock on the way to therapeutics being used, it was a way of streamlining existing processes, or running them concurrently, enabling greater collaboration and information sharing between key agencies, to provide rapid access for patients. Other repurposed treatments were provided in a matter of days after publication of trial results, including hydrocortisone (1 day), tocilizumab and sarilumab (7 days). New treatments were able to be provided in a matter of weeks after market authorisation.<sup>86</sup>
- 84. NHS England's work on Rapid C-19 was primarily from members of the Specialised Commissioning team. Outside a pandemic, Specialised Commissioning has a network of over 40 Clinical Reference Groups, comprising experts in a particular area of medicine (e.g. vascular disease, HIV, or genomics). Clinical Reference Groups advise Specialised Commissioning on clinical policies in their respective areas of expertise, because that particular expertise is required. RAPID C-19 similarly received input from expert groups in its consideration of therapeutics, including the Prophylaxis Oversight Group and Expert Advisory Group. NHS England considers the ability to receive expert input into these technical areas of medicine when designing clinical policy at speed was a strength of its involvement with therapeutics.

- 85. Evusheld: Rapid C-19's involvement with Evusheld was during the second of the two periods considered in evidence. While it monitored progress of the drug from February 2021,<sup>87</sup> it produced its first advice to the CMO in December 2021, on receipt of data from the PROVENT trial. Evidence before the Inquiry has discussed the extent to which cost was considered in decisions around Evusheld. RAPID C-19 recommended approving Evusheld without consideration of cost. Significantly, RAPID C-19 recommended that Evusheld be progressed to patient access, subject only to MHRA approval (i.e., the drug meeting safety standards) and demonstrating effectiveness against the then-widespread Omicron variant.<sup>88</sup>
- 86. Following MHRA authorisation being granted on 17 March 2022,<sup>89</sup> a National Expert Group meeting was held on 26 April 2022 to begin preparing the clinical commissioning policy. This reflected the usual practice through RAPID C-19, in which NHS England convened an expert group to prepare clinical policy.
- 87. As the previous RAPID C-19 recommendation was to prepare clinical policy providing ongoing effectiveness against Omicron could be demonstrated, ongoing effectiveness was considered first. The meeting received written input from the Chair of DHSC's Prophylaxis Oversight Group, Professor Lalloo. His comments were that nMABS are particularly susceptible to mutations in the spike protein of the virus; the reduction in efficacy in vitro gave rise to a concern of creating new, resistant, variants; some testing indicated one of the two antibodies was compromised against the new variant; and that the Prophylaxis Oversight Group had concerns over some of the modelling assumptions.
- 88. The National Expert Group minutes record that published data from the PROVENT and STORM-CHASER trials was considered; that published data had demonstrated a more than 100-fold decrease in neutralisation against the new Omicron subvariant in in-vitro data; and that proceeding with only one effective antibody would effectively represent monoprophylaxis, which may have implications for resistance/escape variants. After lengthy discussion, all members bar one agreed with the conclusion that there was insufficient evidence at the time to progress a clinical policy.
- 89. The Expert Group's advice was echoed in RAPID C-19's 30 May 2022 advice to the CMO, ultimately recommending against progress towards patient access. RAPID C-19 noted it would continue to monitor for results from ongoing clinical trials. Further advice, dated 24 August 2022, reached a similar conclusion after considering further data.
- 90. Some evidence before the Inquiry has criticised aspects of the process of considering Evusheld. NHS England was not involved in all aspects of considering Evusheld. In respect of the processes it was involved in, NHS England submits the evidence shows a careful, measured, and evidence-led approach reliant on the advice of experts. RAPID C-19's conclusion, that there was insufficient evidence to show efficacy against new strains, is consistent with the conclusion of the thorough NICE assessment, which considered a large

- volume of material over many months, and that of the World Health Organisation in its 24 March 2023 guidance on prophylaxis.
- 91. Therapeutics Clinical Review Panel: NHS England did not have a role in this Panel, established by DHSC. Professor Palmer was chair of the Review Panel in addition to his NHS England roles and addresses this in his statement. The Panel oversaw the Covid-19 Neutralising Monoclonal Antibodies and Antivirals Access Independent Advisory Group.

  NHS England's Clinical Policy team had a supporting role with the Advisory Group.
- 92. The Review Panel was responsible for identifying those at highest risk from Covid-19 and who would receive most benefit from therapeutic drugs if they became infected. 93 It made recommendations to the CMO as to who should receive priority access based on risk faced.
- 93. <u>CMDUs</u> were the principal mechanism by which therapeutics were rapidly delivered in the community to those in the priority groups identified by the Therapeutics Clinical Review Panel. Therapeutics faced different challenges to vaccines in terms of their delivery. As discussed in evidence, <sup>94</sup> therapeutics are at their most effective if delivered shortly after infection. CMDUs were a mechanism for quickly and proactively delivering therapeutics to those who needed them. As noted by Lord Bethell, the usual approach to providing medicines is that a person falls ill, becomes symptomatic, decides to consult a GP or other healthcare provider, and may then receive access to a therapeutic. <sup>95</sup> CMDUs were a mechanism for providing therapeutics proactively.
- 94. NHS England worked with UKHSA (responsible for providing access to testing) and NHS Digital (which was able to identify those whose health records suggested they may belong to one of the priority groups identified by the Therapeutics Clinical Review Panel). Aligning these two systems meant CMDUs were alerted when a possibly-eligible patient had tested positive, and they in turn were able to contact patients to assess whether they did meet the eligibility criteria for treatment (in terms of the cohorts identified by the Therapeutics Clinical Review Panel, and having recently tested positive for Covid-19 and still being symptomatic); and whether they were otherwise suitable to receive the therapeutic (including assessment of health history and other medication).
- 95. NHS England was also able to contact the majority of people who were at higher risk from Covid-19, in order to advise them in advance of their possible eligibility for access to therapeutics, and what to do to in the event of developing symptoms.<sup>97</sup>
- 96. CMDUs were rolled out from 16 December 2021, less than two weeks after the first supply of oral antivirals arrived in the UK and by June 2023 had provided almost 115,000 community-based treatments to Covid-positive patients from the highest risk cohorts.<sup>98</sup>
- 97. CMDUs were a radical change to the delivery of therapeutics. By proactively providing the medicines, NHS England was able to overcome some of the hurdles associated with the use of therapeutics that are most effective when used early on in treatment, 99 while still

- maintaining proper stewardship of the therapeutics, complying with MHRA requirements around monitoring, and ensuring appropriate and safe use by patients. However, NHS England recognises that there were challenges, undertaking significant work to improve data, facilitate access for more patients and reduce health inequality.
- 98. <u>Medicines Supply</u>: NHS England had a role in monitoring and helping to maintain medicine supply, which was not specific to Covid-19 therapeutics, though of course supply constraints often followed the discovery of therapeutics relevant to treating Covid-19.
- 99. DHSC maintained overall responsibility for medicines supply. NHS England assisted by developing tools to monitor and forecast medicines supply issues, and where possible worked to resolve them. This included instigating new data sharing arrangements and proactive discussions with suppliers. Forecasting demand allowed NHS England to act pre-emptively in engaging wholesalers and manufacturers ahead of a supply issue, as well as working with pharmacy teams and ICU clinicians to manage supply in the NHS and to identify alternatives where needed.
- 100. Maintaining medicines supply through the disrupted supply chains and demand peaks that typified the pandemic was a significant achievement. A proactive approach to medicines supply management seems an inevitable requirement for a future pandemic.
- 101. <u>Lessons Learned:</u> In the event of a future pandemic, it is likely that a structure like RAPID C-19 would be useful in monitoring clinical research trials and facilitating access to therapeutics where those trials were positive. Professor Palmer advised the CMO that RAPID C-19 could be re-established promptly in a future pandemic.<sup>101</sup>
- 102. Aspects of the CMDU approach during the pandemic, using data to proactively contact patients and offer them medicines, have been retained. In a future emergency, a similar approach to proactive and rapid deployment of therapeutics, while maintaining necessary medicines safeguards, may be appropriate.
- 103. Some evidence has also considered whether there were too many committees or advisory structures relating to therapeutics, and explored whether there may have been benefit in rationalisation of some structures in future. The question of rationalising the therapeutics response generally goes beyond NHS England's role. In respect of its own involvement, NHS England does not consider there was an excessive proliferation of groups or processes. Input from relevant expert advisory groups was an essential element of being able to respond rapidly to the pandemic challenges. Decisions on deployment of a new therapeutic were made directly by the CMO following clinical advice drawn together by clinical consensus coordinated by RAPID C-19. NHS England did not put in place any intervening governance steps, nor did any other body (DHSC, MHRA, or NICE).

## RECOMMENDATIONS GENERALLY

- 104. On recommendations generally, we ask the Inquiry to consider them against the wider health ecosystem and existing structures and legal frameworks in place.
- 105. During evidence, the Inquiry explored the question of whether it should recommend a national vaccines agency, or other roles or new bodies. We share UKHSA's concerns in their oral closing submissions that whilst superficially attractive, there are obvious questions which are not easy to answer. There is a need to have systems in place capable of addressing multiple different threats, capable of being scaled up and being made even more timely in their response: i.e. what do we need to have ready now (and the implications including cost of doing so) versus knowing how to build when it is needed.
- 106. As we address below, much work has been done since the end of the Relevant Period and we endorse the need for the Inquiry to assess whether any recommendations or any reset would undermine the progress made or set pandemic preparedness back.<sup>102</sup>
- 107. The Inquiry has also asked questions about the role of Government versus the private sector. There is also the role played by the NHS, which is not one organisation but an ecosystem of entities, each with their own distinct role and function. NHS England is an executive non-departmental body, with a degree of autonomy from the Secretary of State. Both vaccines and therapeutics worked because of the NHS and NHS England.
- Dame Emily Lawson became the SRO, and, as Nadim Zahawi (former Minister for Vaccine Deployment) said, she was very experienced and certainly capable of managing the rollout of the vaccine within the NHS. Whilst her private sector experience was no doubt invaluable; the fact is that she was and had been an employee of NHS England for 3 years. She was plainly the best person to lead the Programme in November 2020. Where expertise was more limited, it was brought in: in particular on the supply chain from the Armed Forces and from industry, through Steve Gibb. So too, when necessary, management consultants were engaged. However, there are competing considerations. We invite the Inquiry to avoid directive recommendations that may not be right for the situation that presents itself. One reason the Programme worked so well was because Dame Emily was empowered to lead her team and deliver, in turn empowering others with the assistance of the mission statement to enable decisions to be made at the right level, by the right people.
- 109. We repeat the request that the Inquiry ask whether recommendations on deployment can be operationalised.<sup>104</sup> There needs to be a response in place which is as resilient as possible, but also flexible and agile to adapt to uncertainties, to bolster, and it cannot be perfect.
- 110. **On data**, the Inquiry has acknowledged that health data is extremely complex and requires careful public engagement. We endorse UKHSA's oral submissions that the use of data raises important legal and ethical questions, and, particularly, in the context of vaccine hesitancy, trust is central to combatting low uptake. Any recommendations on data must

- recognise that the effective sharing of data depends on the underlying data, which is complicated by individual's reluctance to give personal information, or to trust Government or the NHS, including GPs, or pharmacists. Whilst data in national systems is important, it is not easy to simply 'add a field' to a database or share data between systems. Information sourced from local networks is also vital and helps to reduce the exclusion of those who do not access or have difficulty accessing healthcare services.
- 111. Work is already underway, and the Inquiry will need to consider steps taken to date. The Sudlow review, to which the Inquiry has referred, was commissioned by NHS England amongst others. Work is ongoing to deliver a single patient record and an engagement campaign to let people have their say on using data is underway.<sup>105</sup>
- 112. **On other work**, as addressed orally, NHS England published the current vaccination strategy in December 2023,<sup>106</sup> which is addressed briefly in Stephen Russell's statement, and we welcome the recognition from the experts that the Strategy builds on lessons learned.<sup>107</sup>
- 113. The Inquiry is requested to consider the whole Strategy. To develop the Strategy there was wide engagement with ICSs, GPs and community pharmacy, NHS trusts, professional bodies, charities, private sector organisations, clinicians, local authorities, directors of public health, UKHSA and the public via a citizen survey. The work on Covid vaccination allowed NHS England to be transformative in its approach, engaging with communities in a way that had never done before. It demonstrated the value of giving local systems the ability to build effective, flexible, integrated, local delivery networks for vaccination in collaboration with a range of local partners using their local population health intelligence.
- 114. The Strategy brings the Covid vaccination operating model alongside more longstanding vaccination and screening programmes to help ensure what the NHS learnt from the Programme can be shared across other vaccinations where appropriate and ensure the Covid programme itself is as effective and sustainable as possible going forward. It sets out a clear mission with three clear priority areas to increase uptake and coverage of vaccination; improving access inconvenient local places; enabling targeted outreach to support underserved populations, and a more joined up prevention and vaccination offer. It builds on the learning and innovations from the pandemic, retaining new systems such as the NBS, roving vaccination models and other effective outreach approaches, and extending them to other vaccine programmes including flu and RSV.
- 115. The Strategy sets out that a core vaccination service is needed, with some level of national consistency in terms of locations with local tailoring to ensure it is designed to be as accessible as possible. The Strategy also described how some communities will nevertheless not be well served by a core offer and need supplementary, bespoke outreach services, designed to meet specific needs. Outreach services may in many cases be

required to actually administer vaccinations. In many cases however the main value is in reaching directly into communities that have low confidence in health services, or in vaccination specifically, to build that confidence and address concerns that are specific to that community. This groundwork often needs to happen before any vaccination delivery can take place, and may be best delivered through local community, voluntary or faith groups. The Strategy suggests that ICBs are best placed to identify those who require these bespoke or targeted approaches. These populations will often align with Core20PLUS populations and ICBs should be responsible for planning outreach in partnership with local government, screening and immunisation teams, local community groups and the voluntary sector.

- 116. Local systems will be provided with national digital tools that help them identify those who are unvaccinated or who need a catch-up offer.
- 117. The Strategy document welcomes feedback on how to implement the proposals and those engaged with Module 4 are encouraged to participate and provide feedback.
- 118. There is evidence that the steps taken are working in the recent national MMR campaign, the largest coverage increases for MMR1 and MMR2 were consistently seen in people from African, Arab, other black, and white Gypsy and Irish Traveller ethnic groups.
- 119. The first mpox outbreak in 2022 demonstrated that regions and ICBs were able to build on the commissioning and communications arrangements developed during the Programme to rapidly stand up the mpox vaccination programme. Together with the Covid digital and data infrastructure, the use of which is now being extended to other vaccination programmes, this supports an 'always on' approach to system resilience.
- 120. On evaluations, the Inquiry will note that a central part of the Strategy includes the ability to evaluate the steps taken, and the strategy includes a draft vaccinations outcomes framework to facilitate evaluation at Annex A. 108 NHS England is also working with UKHSA to evaluate the effectiveness of different outreach approaches. When working at speed, the decision was taken to try all reasonable available options with a view to reducing barriers and widening access. To wait for formal evaluation structures to be in place would have delayed the important work. However, it would be wrong to say that there was no evaluation.
- 121. If the Inquiry would benefit from additional evidence on the Strategy, we are happy to assist.

#### Conclusion

122. We look forward to the Inquiry's findings and recommendations on this module.

- <sup>5</sup> CCG= Clinical Commissioning Group; ICB = Integrated Care Boards.
- <sup>6</sup> First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraphs 46 and 247.
- <sup>7</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 596.
- <sup>8</sup> Evidence of Professor Sir Chris Whitty, [5/73/8-5/74/21].
- <sup>9</sup> Evidence of Professor Sir Chris Whitty, [5/12/98-100/11].
- <sup>10</sup> First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraphs 181-182.
- <sup>11</sup> First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraph 43. Also discussed in Evidence of Professor Sir Chris Whitty [5/98/16-99/14] and Professor Jenny Harries [5/200/4-7 and 5/201/21-202/19].
- <sup>12</sup> First Witness Statement of Dame Emily Lawson [**INQ000492335**] at paragraphs 50 to 60 and evidence of Dame Emily Lawson [**9/144/2**].
- <sup>13</sup> Sixth Witness Statement of Professor Sir Chris Whitty [**INQ00047440**1], at paragraph 6.69, and evidence of Professor Sir Chris Whitty [**5/88/1-91/6**].
- <sup>14</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 76.
- <sup>15</sup> First Witness Statement of Stephen Russell [**INQ000474228**] at paragraphs 81-99; First Witness Statement of Dame Emily Lawson [**INQ000492335**] at paragraphs 26(f), 29(f) and (h), 46, 57, 62, 148, 162 to 171, 176, 177, 218 to 224, and 230.
- <sup>16</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 424-425
- <sup>17</sup> Evidence of Dame Emily Lawson [9/186/11-22] (The Inquiry heard from Dr Salman Waqar, with whom the engagement took place).
- <sup>18</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 425.
- <sup>19</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 426.
- <sup>20</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 473.
- <sup>21</sup> First Witness Statement of Stephen Russell [**INQ000474228**] at paragraph 516 addressing consideration of Black, Asian and minority ethnic communities at the National Incident Response Board ("NIRB"): 5 October 2020, 18 November 2020, 30 November 2020 and 4 December 2020. The latter paper is at [**INQ000421368**].
- <sup>22</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 427.
- <sup>23</sup> [INQ000421368] and First Witness Statement of Stephen Russell [INQ000474228] at paragraph 429.
- <sup>24</sup> [INQ000414404] Paper by Ian Dodge (National Director for Primary Care, Community Services and Strategy) and Ben Jupp (Director of Strategy), titled Health Inequalities Urgent Actions programme update, presented to NIRB on 30 November 2020.
- <sup>25</sup> First Witness Statement of Dame Emily Lawson [**INQ000492335**] at paragraph 311; [**INQ000474430**] at paragraph 36.
- <sup>26</sup> [INQ000414403] and First Witness Statement of Stephen Russell [INQ000474228] at paragraph 427.
- <sup>27</sup> [INQ000414405].
- <sup>28</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 443.
- <sup>29</sup> See for example First Witness Statement of Dame Emily Lawson [**INQ000492335**] at paragraphs 26, 61, 76, 77, 79. See also discussion of planning phase in Evidence of Dame Emily Lawson [**9/140/19-144/21**].
- <sup>30</sup> Evidence of Dr Kasstan-Dabush and Dr Chantler [10/173/16-174-21].
- <sup>31</sup> [**INQ000414393**] whole document but particularly see p.8 assumption.
- <sup>32</sup> [INQ000421396]; [INQ000414396]; [INQ000474589] at paragraph 78.
- <sup>33</sup> [INQ000329490], see specifically /6; /17; /26.
- <sup>34</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 230 and 540.
- <sup>35</sup> First Witness Statement of Dr Keith Ridge [**INQ000474510**] at paragraph 25 this became the Pharmacy Standards Group; on communications see paragraphs 29, 32, and 45 to 53.
- <sup>36</sup> First Witness Statement of Dr Keith Ridge [INQ000474510] at paragraphs 43 to 53; First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 256 to 261; Evidence Nadim Zahawi [9/107/21-9/108/24].
- 37 [INQ000502242].
- <sup>38</sup>First Witness Statement of Dr Keith Ridge [**INQ000474510**] at paragraph 47; [**INQ000492092**]; [**INQ000329404**].

<sup>&</sup>lt;sup>1</sup> Evidence of Emily Lawson, [9/199/4].

<sup>&</sup>lt;sup>2</sup> First Witness Statement of Dame Emily Lawson [INQ000492335].

<sup>&</sup>lt;sup>3</sup> In addition to the above: First Witness Statement of Stephen Russell [INQ000474228]; Second Witness Statement of Stephen Russell [INQ000474662]; First Witness Statement of Gareth Arthur [INQ000474328]; First Witness Statement of Professor James Palmer [INQ000474312]; and First Witness Statement of Dr Keith Ridge [INQ000474510].

<sup>&</sup>lt;sup>4</sup> The Chief Nursing, Midwifery and Pharmaceutical Officers, and their deputies, are all within / employed by / report to NHS England.

<sup>39</sup> [INQ000329409]. <sup>40</sup> [INQ000319588] Letter from Dame Emily Lawson, Ed Waller, and Dr Keith Ridge. <sup>41</sup> [INQ000502247]. <sup>42</sup> [INQ000329512]. <sup>43</sup> First Witness Statement of Dr Keith Ridge [INQ000474510] at paragraph 57. 44 [INQ000486275]. <sup>45</sup> First Witness Statement of Dr Keith Ridge [INQ000474510] at paragraph 59; [INQ000498138]. <sup>46</sup> First Witness Statement of Dr Keith Ridge [INQ000474510] at paragraph 80. See also paragraphs 74-79. <sup>47</sup> First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraph 104. <sup>48</sup> [10/15/22-16/16] <sup>49</sup> First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraphs 138-140. <sup>50</sup> [INQ000486279] (version as at 20 November 2021). Dame Emily oral evidence [9/155/23]. It was supported by visual diagrams on accountability and delegation. [INQ000329410] dated 31 December 2020. <sup>51</sup> First Witness Statement of Stephen Russell [INQ000474228] paragraph 262-266; [INQ000329425]. <sup>52</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 262 to 266. <sup>53</sup> [INQ000329393] Version 2, 18 December 2020 (which also shows Version 1 content); [INQ000329413] Version 3, 4 January 2021; [INQ000329429] 14 January 2021; [INQ000329465] Version 3.3, 8 March 2021; [INQ000329481] Version 3.4 26 March 2021, and [INQ000329546], Version 4, 8 October 2021. Each version shows the changes from the previous version in vellow highlighting. <sup>54</sup> [INQ000329465] 8 March 2021 SOP. <sup>55</sup> [INQ000329492]. <sup>56</sup> [INQ000329500], particularly /4-6. <sup>57</sup> Evidence of Dame Emily Lawson [9/202/19-9/205/4]. <sup>58</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 105 to 134. <sup>59</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 370 to 403 and First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraphs 218 to 239. 60 Professor Heidi Larson Report [INQ000474705] page 11, paragraph 19; Larson Evidence: [3/136/17 -3/138/24]. <sup>61</sup> First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraph 171. 62 First Witness Statement of Stephen Russell [INQ000474228] Part 5, paragraphs 329-603 and First Witness Statement of Dame Emily Lawson [INQ000492335] at paragraphs 161-213. <sup>63</sup> Expert report Kasstan-Dabush and Chantler [INQ000474623] paragraph 285. <sup>64</sup> Expert report Kasstan-Dabush and Chantler [INQ000474623] paragraph 112. 65 First Witness Statement of Stephen Russell [INQ000474228] including at paragraphs 331 to 369; Second Witness Statement of Stephen Russell [INQ000474662] at paragraphs 9 to 14; First Witness Statement of Dame Emily Lawson [INQ000492335] including at paragraphs 110 to 130, 178, and 210-212. 66 Evidence of Dame Emily Lawson [9/166/7 - 9/169/21]. <sup>67</sup> Evidence of Dame Emily Lawson [9/191/4]. <sup>68</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 505. <sup>69</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 194. <sup>70</sup> Evidence of Dame Emily Lawson [6/99/14- 6/103/7]. <sup>71</sup> [INQ000329462] Vaccine Deployment Programme: JCVI priority cohort 6. <sup>72</sup> Second Witness Statement of Stephen Russell [INQ000474662] at paragraphs 9 to 14. <sup>73</sup> Fifth Witness Statement of Professor Sir Stephen Powis [INQ000474664] paragraphs 14 to 21. <sup>74</sup> [**INQ000329424**] version 1, 7 January 2021, updated at [**INQ000329492**] version 2, 14 May 2021. 75 [INQ000329424]. <sup>76</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 564. <sup>77</sup> Evidence of Dame Emily Lawson [10/181/17]. <sup>78</sup> Evidence of Mary Ramsey [6/106/5-109/2]. <sup>79</sup> [INQ000414497] which followed a communication to the system by NHS England launching GP 'Access Cards' registration campaign. <sup>80</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 174 and 335. <sup>81</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraph 344. 82 First Witness Statement of Stephen Russell [INQ000474228] at paragraph 511. <sup>83</sup> First Witness Statement of Stephen Russell [INQ000474228] at paragraphs 392 and 511. 84 [INQ000414481] and First Witness Statement of Stephen Russell [INQ000474228] at paragraph 512. The video has had 7,400 views and featured Les Stevens who died of Covid in the first wave, and the National Chaplain to Gypsies and Travellers, Father Dan Mason, and NHS Nurse Lisa Gavin, addressing misinformation and fertility concerns. 85 First Witness Statement of Stephen Russell [INQ000474228] at paragraph 510.

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86 [INQ000474611/46 and /47].

87 [INQ000474611/49] (Table 7).

- <sup>88</sup> First Witness Statement of Professor James Palmer [**INQ000474312**] at paragraph 43(a);
- [INQ000479901].
- 89 [INQ000474337] at paragraph 277.
- <sup>90</sup> [INQ000502396/6].
- <sup>91</sup> First Witness Statement of Professor James Palmer [INQ000474312] at paragraph 33 to 38.
- <sup>92</sup> First Witness Statement of Gareth Arthur [INQ000474328] at paragraph 156.
- <sup>93</sup> First Witness Statement of Professor James Palmer, [INQ000474312], from paragraph 33.
- 94 Discussed in evidence of Lord Bethell, [11/49/24].
- 95 Evidence of Lord Bethell [11/51/6].
- <sup>96</sup> First Witness Statement of Gareth Arthur [INQ000474328] at paragraphs 161, 163, and 168-169.
- 97 First Witness Statement of Gareth Arthur [INQ000474328] at paragraph 169.
- 98 First Witness Statement of Gareth Arthur [INQ000474328] at paragraph 163.
- 99 Discussed in evidence of Lord Bethell, [11/49/24].
- <sup>100</sup> First Witness Statement of Gareth Arthur [INQ000474328] at paragraph 188.
- <sup>101</sup> First Witness Statement of Professor James Palmer [INQ000474312] at paragraph 60.
- <sup>102</sup> [12/125/18-129/23].
- <sup>103</sup> Second Witness Statement of Stephen Russell [INQ000474662] at paragraphs 15 to 21.
- <sup>104</sup> Evidence of Dame Emily Lawson, [9/199/4].
- <sup>105</sup> Evidence of Dame Emily Lawson [9/169/22-172/20] regarding Sudlow Report [INQ000474861].
- <sup>106</sup> NHS England Vaccination Strategy, published December 2023.
- <sup>107</sup> First Witness Statement of Stephen Russell [**INQ000474228**] paragraphs 632 to 638, and Dr Kasstan-Dabush and Dr Chantler Report [**INQ000474623**] at paragraph 112.
- <sup>108</sup> Evidence of Dr Kasstan-Dabush and Dr Chantler [10/153/19].