UK COVID-19 INQUIRY

OPENING STATEMENT ON BEHALF OF THE UNITED KINGDOM HEALTH SECURITY AGENCY FOR MODULE 4

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1. Vaccines are a proven and critical tool in protecting public health. Vaccination ranks second only to clean water as the most effective intervention to prevent disease. Through vaccination, diseases that were previously common are now rare, and millions of people each year are protected from severe illness and death. Childhood vaccines alone prevent between 3.5 and 5 million deaths every year across the globe. The UK benefits from immunisation programmes which are among the most comprehensive in the world.

2. COVID-19 has been the most challenging pandemic for the UK in modern times and the most significant in global terms since HIV. Early access to safe and effective vaccines and drugs, together with steadily increasing hybrid immunity from vaccination and infection, reduced both transmission and severe disease for the majority of people, as well as the reliance on non-pharmaceutical interventions (NPIs).[1]

3. It is estimated that, globally, vaccines prevented 14.4 million deaths between December 2020 and December 2021[2], including over 100,000 deaths in the UK. The UK's COVID-19 vaccination programme also enabled the relaxation of other control measures, facilitating socio-economic recovery.

4. The United Kingdom Health Security Agency (UKHSA) has a broad remit which includes preparing for and responding to infectious diseases including pandemics. The government's expectation is that UKHSA will use its scientific and research expertise to anticipate and encourage advancements and innovations in vaccine technology. UKHSA does not seek in this opening statement to address every issue which will be explored in this module. Rather, mindful of the importance this Inquiry has rightly placed on looking

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[1] Technical Report on the COVID-19 Pandemic in the UK, foreword and Chapter 8 [INQ000177534].
[2] Watson OJ, Barnsley G, Toor J, Hogan AB, Winskill P, Ghani AC. '*Global impact of the first year of COVID-19 vaccination: a mathematical modelling study*'. Lancet Infect Dis. 2022;22(9):1293-302.

forward, we set out those capabilities which we see as key to vaccines and therapeutics being developed and utilised as a component of pandemic preparedness and say something about the work UKHSA is already carrying out in these areas.

Roles and Responsibilities

5. It is useful to begin with an outline of the different bodies, including UKHSA, that contribute to the development and delivery of a national vaccination programme.

6. The Joint Committee on Vaccination and Immunisation (JCVI) is an independent expert group and a statutory body. It advises health departments in the four UK nations on immunisations and their use in the prevention of infectious disease. The JCVI will advise for example on the effectiveness of different vaccines and on those most likely to benefit clinically, as well as the prioritisation of population groups.

7. The Medicines and Healthcare Products Regulatory Agency (MHRA) is the independent regulator of medicines, medical devices and blood components for transfusion in the UK. It is the lead agency for monitoring vaccine safety and for any regulatory response to safety signals. MHRA is responsible for providing vaccine safety information to JCVI so that the committee can consider any safety concerns against the expected benefits of vaccination.

8. Healthcare being a devolved responsibility, NHS England (NHSE) is responsible for commissioning the immunisation programme in England, which is then administered by healthcare providers across England. Coordination of the programme is undertaken mainly at regional level, working with local partners including primary care networks, integrated care systems and Directors of Public Health in local authorities. NHS England has responsibility for the overall performance of immunisation programmes, including measures to address inequalities. Because of its exceptional scale and scope, the COVID-19 programme drew on a much wider range of agencies and stakeholders than has been routine for other immunisation programmes. Many component activities within the COVID-19 programme were undertaken on a whole UK basis which is not routinely the case with national vaccine programmes.

9. UKHSA, as Public Health England (PHE) did previously, provides the secretariat for JCVI and ensures that the Committee has the available evidence when evaluating the benefits of vaccination against any potential risks both overall and within specific population groups. UKHSA also provides expert support to NHS England's programme implementation, ensuring that the deployment of an immunisation programme aligns with the rationale developed by JCVI, and delivers operational advice and a range of supporting materials (see paragraph 22 below). UKHSA publishes the Green Book which provides information for public health professionals on immunisation[3].

10. UKHSA has continued with the role previously undertaken by PHE of monitoring and evaluating all routine immunisation programmes. This involves measuring coverage of vaccination in key population groups and the incidence and prevalence of the targeted infection. This then allows UKHSA to generate estimates of real-world protection from a vaccine and the overall impact of an immunisation programme.

Sustained Investment in Research and Development

11. Developing a vaccine responsive to a novel pathogen is inherently uncertain. The time between work starting in the UK on a COVID-19 vaccine and the launch of a vaccination programme was extraordinarily short. While that showed how fast a vaccine could be developed for a pandemic, it comes with a note of caution. It is quite possible that in another pandemic, securing production of a safe, effective vaccine may take considerably longer or that it may not be possible to produce an effective vaccine[4]. HIV, for example, is often cited as a virus for which, despite considerable research and investment, a vaccine remains elusive. Nonetheless continued research has seen the development and widespread use of antivirals against HIV, which has been transformative.

12. The extent to which the UK can develop pharmaceutical countermeasures for a future pandemic will always depend on the willingness of the Government of the day to routinely sustain investment in scientific research and development. The Oxford/AstraZeneca vaccine, important to the UK's early response and made available

[3] [INQ000496177_0012; INQ000496177_0017].
[4] Technical Report on the COVID-19 Pandemic in the UK, foreword and Chapter 8 [INQ000177534].

globally, was in part made possible through work funded to develop a vaccine against Middle East Respiratory Syndrome (MERS). That funding came from government research bodies and work was in progress several years before COVID-19 emerged.

13. Research and development (R&D) is a core function for UKHSA and the agency is a recognised Public Sector Research Establishment (PSRE). As the Inquiry is already aware from evidence given in previous modules, UKHSA has laboratories with specialist expertise at Porton Down and Colindale, which are recognised as centres of excellence in microbiology. UKHSA research into vaccines aims to strengthen pandemic and epidemic preparedness and response. UKHSA is not a research funding body. It bids for research funds and works with academia and industry to help ensure we have the vaccines we need. UKHSA uses its core funding and expertise to lead, promote and deliver R&D in a number of ways of which some relevant examples are given below.

14. UKHSA provides the secretariat for the UK's participation in the 100 Day Mission, a global initiative to better prepare the world for the next pandemic by driving the development of diagnostics, therapeutics, and vaccines so that they can be rapidly made available within the first 100 days of a future pandemic threat being identified. In addition, the Agency plays a leading role in co-ordinating industry, academia and the public sector in ongoing UK work to develop vaccines and therapeutics. It contributes directly itself in some significant areas, and has now established the UKHSA Diagnostics Accelerator, a specialist team charged with boosting the country's ability to diagnose and test for new and emerging infectious disease threats.

15. The capacity to sequence and analyse the genome of a pathogen is a vital element of the modern response to any infectious disease. Building on the agency's leading work in coordinating the genomics of SARs-CoV-2, UKHSA has published a pathogen genomic strategy which, over the next decade, will establish a single programme across the Agency, working with other bodies including the NHS, relevant government departments and academia. This programme will increase our understanding of the detailed characteristics of those pathogens that pose the greatest risk, their lineage and differentiation so that we can then explore further opportunities for supporting the discovery and development of new therapeutics and vaccines. Overall, it allows UKHSA to improve its capability to use genomics to detect new pathogens and threats, to track

the spread of infections and outbreaks and to better evaluate the effectiveness of mitigations.

16. UKHSA's scientific expertise and high-quality surveillance data informs and supports the prioritisation and development of new diagnostic technologies and vaccines and their evaluation. UKHSA has, since the pandemic, been commissioned by the Cabinet Office, as part of the implementation of the National Biological Security Strategy, to undertake an assessment of the potential for a specific UK-focused approach to identifying priority pathogen families. This work will inform policy decisions on research and development funding to protect health from biological risks.

17. UKHSA continues to support the development of new vaccine platforms and technology that successfully emerged through the pandemic, including through its current oversight of the UK's 10-year strategic partnership with Moderna.

Strengthening partnerships between government, industry and academia

18. The Chair will hear evidence about the work of the Vaccine Task Force (the central component of which is now incorporated into UKHSA)[5]. Set up during the pandemic, the VTF contributed successfully to efforts to significantly reduce the usual timeline for the development and utilisation of vaccines. It benefited from the willingness of decision-makers responding to an emergency to rapidly commit significant resource based on imperfect information, and to take the risk that not every initiative would yield success. For both epidemiological and governance reasons these precise conditions are unlikely to pertain on a regular basis. Therefore, UKHSA seeks to develop and maintain systems which can be scaled up in the event of a future pandemic or epidemic together with the key technical skills which were available to the VTF during the pandemic.

19. The VTF demonstrated the benefit of establishing closer working between government (including policy expertise), industry, and academia. UKHSA is committed to supporting

[5] The VTF's Strategy and Analysis, Commercial and Project Management Office, Supply Management (including dose donations) and Supply Readiness functions were transferred to UKHSA. Its work to strengthen the UK's onshore vaccine development, manufacturing and supply capacity and capability were transferred to the Office of Life Sciences and its international work incorporated into DHSC's international directorate [INQ000492334_0060].

such close working through for example its 100 Day Mission workshops. Science is always an international endeavour and to be able to respond better to the next pandemic, the UK will want access to innovative products that can be swiftly developed, evaluated, licensed and delivered, as well as the opportunity to develop products itself. UKHSA's Vaccine Development and Evaluation Centre (VDEC) brings together the agency's lab-based capabilities and seeks to work with industry, academia and the MHRA to identify the most promising vaccine candidates, to support their development and to provide pre-clinical and clinical trial testing of vaccines.

Routine vaccination work in 'peacetime' provides a bedrock from which to scale in a pandemic

20. The COVID-19 programme benefited from the infrastructure already in place for the delivery of routine immunisation programmes. These are delivered predominantly at local level through those providing primary care. The system has proved highly effective. For example, the over-65 seasonal influenza programme is recognised for achieving an exceptionally high level of coverage by international comparison. The benefit of immunisation being implemented at local level, mainly through general practice, is that the high level of registration (particularly in the older population) and systematic use of information technology allows for the rapid identification of particular clinical risk groups. During the pandemic, this helped to ensure that the UK was able to effectively target and achieve high uptake in the groups at highest risk before vaccine supply was sufficient to offer the vaccine more broadly.

21. Like PHE before it, and drawing on its expertise in epidemiology, public health, health services and behavioural science, UKHSA supports the design of vaccine rollouts (both routine vaccination programmes and specific campaigns) and coordinates the procurement and supply of vaccines.

22. UK immunisation programmes are built on the principles of informed consent. Accurate information on both the benefits and the risks of any vaccination is critical, not only to ensure informed choice, but also to maintain strong levels of confidence in vaccination. UKHSA supports the process of consent by providing training and evidence-based resources for healthcare workers, as well as public-facing resources to support the consent process. These are produced in a variety of formats and languages and different

products are available for different age groups and risk groups. These materials use consistent information based on regularly updated, currently available evidence and independent expert opinions, such as those of the JCVI. These resources need to be maintained and updated for content, format and presentational style. Ensuring wide public and professional awareness of, and access to, such resources will further enhance the robustness of the current consent process.

23. Maintaining and improving the infrastructure for routine immunisation is fundamental to mitigating potential harm from a future pandemic because it provides a starting point for any scaling up of a vaccination programme. While mass vaccination centres may well be needed again, the existing infrastructure can be utilised in the initial stage of a pandemic vaccine rollout, while such centres are being set up, or to reach those who, for example, because of their medical conditions or age, are a priority for vaccination, and who may also be less able to travel to receive a vaccination. Being able to receive a vaccine in a familiar environment may also support confidence in vaccination for some individuals, which may be particularly important where the vaccine itself is novel.

Surveillance of the real-world effectiveness of the programme, and the presence of a robust system for safety monitoring, are vital to both inform future policy, and to sustain public and professional confidence in the programme

24. All pharmaceutical products are associated with side effects, including vaccines. In normal practice, the prescriber makes an individual judgement on whether the benefits of any product outweigh those potential risks. In mass vaccination campaigns, these benefits work at a population level, and JCVI, the National Institute for Health and Care Excellence (NICE) and certain specialist professional groups will make these overall assessments for groups of the population, based on different levels of risk from the disease due to age or underlying medical conditions. This is then balanced against the overall risk of any adverse effects for the group, based on MHRA assessments, and with specific consideration of any individual factors that need to be taken account of during the assessment process.

25. The effective delivery of a vaccine programme requires multi-agency collaboration. Working with NHSE, MHRA and academic partners, PHE, and now UKHSA, has a long-established record of delivering the surveillance, monitoring and evaluation of routine

vaccination programmes. The work in this area has often led the way for other countries. The UK was the first country to report protection from MenC and MenB vaccines (meningococcal vaccines) and has used similar approaches for a range of vaccines, such as seasonal influenza vaccines.

26. This expertise brings wider benefits. First, as with the COVID-19 programme, it can inform the design and planning of a mass vaccination campaign. The COVID-19 programme was designed from the outset to ensure that surveillance systems were in place for the long-term monitoring of the programme and to help maintain the public and healthcare professionals' confidence in COVID-19 vaccination. The JCVI is therefore able to flex policy advice knowing that any impact will be detected rapidly and appropriate adjustments implemented. For example, JCVI was able to advise a longer interval between the first and second doses of COVID-19 vaccines in the early part of the programme, when death rates from SARs-CoV-2 infections were high. This meant that scarce vaccine supply was used to protect more people more rapidly.

27. Second, PHE and now UKHSA, has over many years surveyed the public's understanding of, and attitudes towards, vaccination. This work has been reinforced by activity across the public health system, for example in academia and by local public health teams. From this, when the pandemic struck, it was known that the UK public had a strong level of confidence in vaccination. Continuing to retain this confidence through local and national engagement, by studying and listening to people's concerns and by the generation of high-quality evidence on risks and benefits, is a pre-requisite to any successful future rollout. Analysis of surveillance data informs the production of accurate information, vital in an age when inaccurate information about a vaccine's effectiveness or safety can be so easily spread. Analysis allows for consideration of the factors that influence confidence in particular vaccines (the decline in uptake in the MMR vaccine being an example). Vaccine hesitancy and vaccine confidence are complex issues, the course of which can be multifactorial and emerge over time.

28. Third, UKHSA's surveillance and analysis functions support decisions as to which vaccines should be deployed and to what schedule. Tackling the challenge of health inequality is central to UKHSA's approach. Surveillance and analysis contribute to the health system's work in developing tailored outreach services and understanding the

reasons why specific population groups may not be receiving immunisation and therefore remain at higher risk.

29. It is recognised that there are many population groups underserved across the broader healthcare system and therefore at risk for a wide range of poor health outcomes. These groups may be easy to predict in advance, for example those who are digitally excluded, those who are homeless, and travelling populations. Such predictions can facilitate development of tailored services early in a pandemic, but more effective mitigation is likely to come from constant and sustained efforts to ensure that these groups are better able to access high quality primary care services in peacetime. Models deployed during the COVID vaccination programme, such as outreach vaccination, can also be used to offer other healthcare interventions, and by adding in processes such as GP registration, to help embed continuity of care in the longer term.

Conclusion

30. Care must be taken not to prepare for the last pandemic but, as best as possible, to prevent future occurrences and to prepare the response for the next. Utilising its scientific and operational expertise, UKHSA has an important contribution to make to future pandemic prevention and response preparedness. The Agency recognises that in this post COVID-19 environment, risk appetites and funding priorities will rightly change. Quite properly it is for elected decision makers to decide where future efforts should be focused and to what extent such efforts should be resourced. The factors discussed above however, when taken as a whole, underscore the importance of maintaining appropriate baseline capabilities to allow for faster scaling in a time of emergency.

UKHSA

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