Witness Name: Sir Paul Maxime Nurse OM CH FRS
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UK COVID-19 INQUIRY

WITNESS STATEMENT OF SIR PAUL MAXIME NURSE
ON BEHALF OF THE FRANCIS CRICK INSTITUTE

I, Paul Maxime Nurse, will say as follows: -

1. Role, function and responsibilities

1.1 Introduction to the Francis Crick Institute

1.1.0.1 Opened in 2015, the Francis Crick Institute ("the Crick") is the largest biomedical research institute under one roof in Europe. The Crick is a place for collaboration, innovation and exploration. We are prepared to take risks on unusual, pioneering research that answers fundamental questions about human health and disease, and with the help of our partners we aim to bridge the gap between research and application so that our discoveries can change lives for the better. We work with different types of organisations across the academic, clinical and industrial spheres to create a space for discovery without boundaries, and we support the translation of our discoveries into health benefits.

1.1.0.2 The Crick is an independent research institute located in the King's Cross Knowledge Quarter of London, and is a charitable company limited by shares. Uniquely in the UK, it has six founders: the three funders MRC, Cancer Research UK (CRUK) and Wellcome, and three university founders: UCL (University College London), Imperial College London and King's College London. No one shareholder owns a majority of the Crick, neither does a single funder provide a majority of the funding, giving the institute operational independence and the ability to take autonomous decisions. The Crick is ultimately governed by its Board of Trustees. A

Scientific Advisory Board, a group of internationally renowned experts, provides guidance to the Director, Crick senior management and the Board of Trustees.

1.1.1 Charitable objectives

1.1.1.1 The Crick's objectives, as set out in its articles of association, are to advance human health and education for the benefit of the public through all aspects of biomedical research and innovation by:

- Operating a centre for medical research and innovation;
- Carrying out and supporting research into any of the biosciences;
- Discovering and developing preventions, treatments and diagnostics for illness and disease; and
- Developing and training scientists and supporting biomedical research endeavours.

1.1.2 Strategic priorities

1.1.2.1 The Crick's Discovery Without Boundaries (DWB) strategy, agreed by the Board and founders in 2013, was further developed in 2021. It identifies five strategic priorities:

- Accelerate discovery through a culture of scientific excellence.
- Support the biomedical research endeavour across the UK and beyond.
- Drive benefits for human health.
- Engage and inspire with discovery science.
- Build capability for outstanding science support.

1.1.3 Overview

1.1.3.1 There are 112 active research groups at the Crick, led by 46 principal Crick faculty with rolling tenure, 49 early career group leaders with fixed term tenure, and 17 seconded lab heads from the founder universities. Our research rests on solid foundations: of the principal faculty, there are two Nobel laureates in physiology or medicine, over half are Fellows of the Royal Society and two-thirds are Fellows of the Academy of Medical Sciences. The Crick Director is Sir Paul Nurse OM CH FRS FMedSci, who will be succeeded by Professor Edith Heard FRS in September 2025.

1.1.3.2 In the funders' quinquennial review in 2021, the institute scored 10/10 overall and was awarded £1bn for the period 2022-2029 to consolidate and

enhance its already significant international standing. Crick scientists are notably successful in attracting external grant funding. Current awards comprise approximately £200m of funding from 90 separate funders, including 30 active Wellcome programmes and 30 active ERC programmes.

1.1.3.3 Scientifically, the Crick has a flat structure, with interdisciplinary interest groups rather than discipline-based departments, something that is very different to most other institutes and universities. New ideas come from scientists at all levels – programmes are not established top-down but initiated by the researchers the institute has recruited. The block grant we receive from our funders, coupled with our status as an independent institute, means we can choose to support ambitious, long term projects seeking to answer important research questions, but equally, we have the flexibility to quickly divert funding into new areas should the need arise.

1.1.3.4 Research advances often occur at the boundaries between disciplines, so the Crick is set up to encourage interdisciplinary interactions and to cover a wide range of research activities and techniques. The open design of the building and the lack of formal divisions encourage looser affiliations to form based on mutual interests, and facilitate sharing of techniques and methodologies between groups. Although the Crick's research is primarily biological and biomedical, it also undertakes research both of medical relevance and in the physical sciences that can inform biomedical issues. Scientists who are trained in the clinical and physical sciences work in the Crick, many employed or partially employed by the Crick Partner Universities in London. These partnerships are critical for the Crick, to promote interdisciplinarity and maintain its broad outlook.

1.1.3.5 Research, as well as being high quality, has to be innovative and ambitious. A major factor driving this at the Crick is the institute's policy of hiring through competitive open searches: the aim is to find the best in the world. Early career group leaders recruited through this process are completely independent and are employed by the Crick on a novel 12 year contract, with a review after six years. This means the research programme at the Crick is regularly renewed, maintaining an emphasis on work at or over the horizon, and preventing stagnation, a risk when turnover is limited, as in many research institutions. At steady state, the institute aims to have at least 60% early career faculty.

1.1.3.6 The Crick is mandated by its founders to conduct reviews of its research groups' science, and does so in a manner which aims to be rigorous, independent and fair. Reviews by visiting panels of international experts provide the Crick's senior scientific leadership with information to assess the quality, scientific merit, impact, cost-effectiveness and future direction of the research being carried out at the institute. The Science Management Committee considers the findings and decides whether the programme should be continued.

1.1.3.7 The Crick is committed to maintaining the highest standards of research integrity, promoting ethically responsible research conduct, and ensuring public trust in the research community. We actively support open science, and aim to make research outputs accessible and usable with minimal delay and with as few restrictions as possible, in order to promote scientific discourse, to translate research findings into application for health and societal benefit, and to foster public understanding of science.

1.1.3.8 Modern biomedical research requires highly complex and expensive infrastructure, and this is supplied at the Crick by the institute's 18 technical cores, known as Science Technology Platforms (STPs). This is financially effective and also means that individuals can use a wide variety of cutting-edge research techniques, supported by technical experts, to conduct ambitious experiments that are only possible in a very few places in the world. The STPs support UK science by acting as a hub for specialised training for visiting scientists, and are also available to external users where capacity permits.

1.1.3.9.Crick research is at the discovery end of the spectrum, but it is embedded in a culture promoting translation, where researchers are encouraged to explore training and opportunities within the research and innovation ecosystem. This is uniquely supported by the presence in the building of Cancer Research Horizons (CRH), the CRUK commercial partnerships team, LifeArc, which had its origins in the MRC, and by collaborations with a spectrum of companies, notably GSK, MSD, AZ and DeepMind. There is a pro-active IP and licencing strategy, and to date the researcher-led translation policy has resulted in 12 spin-outs and attracted over £1bn in investment.

1.1.3.10 Public engagement at the Crick is focused on provision of science teaching support for local schools, reaching some 20,000 school pupils each year,

with around 2,000 attending the 'in-house' science teaching laboratory for primary school children. A second initiative is the exhibition space, which demonstrates that the Crick is an open organisation – the institute's unique selling point is that its public engagement spaces are embedded in a community of researchers. As experts in their fields, the Crick's researchers also speak regularly to the media and opinion formers. Engagement with national and international policy makers and political leaders over both science for policy, and policy for science, is also a part of the Crick's mission, most recently exemplified by Crick Director Paul Nurse's independent review of the UK's research, development and innovation landscape, commissioned by the UK Government.

1.1.3.11 The Crick has a strong focus on creating a collaborative, inclusive and engaging culture that supports people to thrive. Crick staff come from nearly 80 countries, and all have access to a wide range of tailored training opportunities throughout their time at the institute. Equality, diversity and inclusion are actively promoted. We hold Athena SWAN bronze accreditation, with commendations for our commitment to gender equality, high activity levels and staff and student consultation. Our childcare support allowance scheme has been singled out as an example of good practice.

1.2 Overview of the Crick's involvement in the TTI system

1.2.1 Situated in central London, an epicentre of the UK COVID-19 pandemic, in March 2020 the Crick decided to repurpose its scientific and technical resources to support the immediate healthcare needs of the local hospital—University College London Hospitals National Health Service Foundation Trust (UCLH)—and care homes during the outbreak. Providing an end-to-end pipeline for clinical diagnostic testing of COVID-19, its aim was to increase testing capacity with a rapid turnaround of test results, to meet local demand and allow new surveillance programmes for healthcare workers to be implemented.

1.2.2 Key to finding a solution was the partnership created between the Crick, UCLH (a major source of clinical virology expertise) and Health Services Laboratories (HSL), a UK Accreditation Service (UKAS)-recognised clinical diagnostic laboratory. Through support from the Crick leadership and collaborative working across diverse areas of expertise, the Crick and its clinical partners were able to set up and run a clinically approved RT-PCR (Reverse Transcriptase Polymerase Chain Reaction) assay within

the space of the fortnight between 19th March and 1st April 2020. Together, these three organisations came together with scientists at the Institute of Cancer Research to form the Crick COVID-19 Consortium (CCC). The partnership allowed rapid implementation of robust end-to-end testing with test results available within 24 hours, and removed barriers to clinical translational research relevant to COVID-19.

1.2.3.The operation involved in excess of 150 Crick staff working in the influenza, TB and malaria groups and many other labs, the advanced sequencing and high throughput Crick Science Technology Platforms, pathology reporting, IT and computing, health and safety, and quality control and quality assurance. Crick scientists used their ingenuity and repurposed their existing skills and equipment to deliver a clinically validated assay at a time when there was a global shortage of RNA extraction kits, RT-PCR kits and numerous other materials vital to the pipeline.

1.2.4 By August 2020, >100,000 healthcare worker staff samples from NHS hospital sites across North London had been tested, protecting patients from pre-symptomatic or asymptomatic transmission from frontline healthcare workers. Care home residents and staff were also included in this testing effort. Figures compiled in April 2022, when the Consortium ceased work, showed that during its period of operation as a testing centre, the Crick COVID-19 Consortium completed 467,024 tests for the NHS, supporting 18 hospitals and 186 other locations including Care Homes, Mental Health Facilities, Crisis Centres, GPs and Medical Centres [PN/01 - INQ000587047; PN/02 - INQ000587058]. The pipeline enhanced clinical care across North London hospitals, allowing the creation of COVID-protected hubs for patient care. Subsequently, the Crick also set up a vaccination centre.

1.2.5. Apart from the obvious medical and societal benefits of this initiative, there were also a number of publications and other outputs resulting from the Crick COVID-19 Consortium's work. Three are of particular note. First, Aitken et al (2020; PN/03 - INQ000587069) describes how the Crick repurposed itself to set up the rapid testing pipeline, and provides a link to freely available protocols and key documents for other labs seeking to emulate it. The paper is important in that it provides a template for the future, describing how excess testing capacity could be rapidly generated from a network of academic research laboratories in times of national emergency. Second, the evidence of healthcare worker infection presented in Houlihan et al (2020; PN/04 - INQ000587080) was a key part of efforts to change UK government policy on asymptomatic testing. In late March and early April, at the peak of the first wave of the

pandemic, samples from two hundred frontline staff at UCLH, tested at the Crick, showed that 44% had evidence of COVID-19 infection, more than twice the rate in the general population in London. Importantly, 38% of staff testing positive by PCR were asymptomatic, and for those that did develop symptoms, the average onset time was four days after a positive test. Of those testing negative by all methods, 13% tested positive within one month of follow-up. This evidence of high rates of infection, of which a significant proportion were asymptomatic, was among the data that eventually led the government to mandate regular testing for all healthcare staff, rather than continuing its previous policy of testing only those with symptoms. Finally, in a post-hoc analysis, Bailey et al (2023; PN/05 - INQ000587090) showed definitively that asymptomatic screening is an important addition to guidelines on workplace safety, and highlighted the importance of prioritising testing— including regular asymptomatic testing of key workers including NHS and care home staff—during the first phase of a pandemic response.

2. The Crick COVID-19 Consortium

2.1 Setting up the Crick COVID-19 Consortium pipeline

2.1.1 In March 2020, it became evident that SARS-CoV-2 had taken hold with frightening speed in the UK. Cases of Covid-19 surged mid-month, and on 17th March, six days before Prime Minister Boris Johnson announced a nationwide lockdown, Chief Scientific Advisor Sir Patrick Vallance warned that around 55,000 people in the UK were likely to have already been infected.

2.1.2 Many NHS staff were falling ill with COVID-like symptoms without any ability to access NHS COVID testing. Furthermore, there were concerns that many more were infected but pre-symptomatic or asymptomatic, with obvious risks to themselves and their colleagues and vulnerable patients. Crick Group Leaders Steve Gamblin, Sonia Gandhi and Charles Swanton met to plan how, at a time of new and unprecedented crisis, the Crick could support the NHS. Discussions turned to whether the Crick should set up a SARS-CoV-2 testing laboratory for local NHS healthcare workers.

2.1.3 At a time when the UK population had been told to stay at home, the idea that the Crick should stay open in this limited way, aimed at helping the response to the pandemic, met with initial opposition from some of the Crick's funders, who did not appreciate what we were trying to do, and were concerned that research money was

being spent on testing. Similar attitudes seemed to be replicated across the UK's universities and research institutions, so that other researchers wishing to set up similar testing operations were unable to proceed. The Crick, as an agile independent institution, was in the privileged position of being able to make its own policy on this matter, so with strong support from Crick senior management, the decision was taken that the Crick would repurpose its scientific and technical resources to support the immediate healthcare needs of its local hospital, University College London Hospitals National Health Service Foundation Trust (UCLH), as well as other local medical care environments during the outbreak. By providing an end-to-end pipeline for clinical diagnostic testing of COVID-19, the Crick would increase testing capacity to meet local demand and allow new surveillance programs for healthcare workers to be implemented. Given the extreme urgency of the situation, a two-week timeframe was set, so that testing would be operational by 1st April 2020.

2.1.4 To achieve this, the Crick partnered with Health Services Laboratories (HSL), a local UK Accreditation Service (UKAS)-recognised clinical diagnostic laboratory whose customers included UCLH and several other National Health Service (NHS) Trusts. All HSL services were compliant with HTA and MHRA regulatory requirements, where appropriate. HSL already had a clinically validated COVID-19 RT-PCR test against the SARS-CoV-2 nucleocapsid (N) gene and would be able to provide material and intellectual assistance to ensure that the Crick's RT-PCR pipeline was properly audited and validated. Together with UCLH, who supplied clinical virology expertise, and the Institute of Cancer Research, whose experience in bridging the gap between research diagnostics and the clinic was invaluable, the Crick and HSL formed the Crick COVID-19 Consortium (CCC). The skills of the four partners drove rapid implementation of robust end-to-end clinically accredited testing within two weeks. Crucially, it also allowed resources and expertise to be practically and rapidly mobilised to meet local healthcare needs.

2.1.5 Due to the need for rapid action, it was not possible to secure clinical laboratory accreditation for the Crick to an appropriate standard, namely International Organization for Standardization (ISO) 15189:2012, the equivalent College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) accreditation. Instead, the Crick ensured that the CCC test was evaluated, verified and performed for diagnostic use in an environment that was equivalent to ISO15189 standards.

2.1.6 The Crick worked with HSL to ensure that the RT-PCR test against SARS-CoV-2 was properly audited and validated. Samples were regularly exchanged with HSL, and the Crick tested an external panel of samples from the UK National External Quality Assessment Service (UK NEQAS) and confirmed that the results were in accordance with UK NEQAS. The Crick also did environmental surveillance of pipeline areas. Advice and oversight were also sought from registered professionals from existing nearby UKAS-accredited medical laboratories: HSL (UKAS 10204); Royal Marsden Hospital and North Thames Genomic Laboratory Hub (UKAS 9839); Great Ormond Street Hospital, North East Thames Regional Genetics Lab and North Thames Genomic Lab Hub (UKAS 7883); Institute of Neurology (UKAS 8045); and an approved UKAS inspector. CCC protocols were either written on demand or based on existing institutional protocols to ensure clinical grade testing at the Crick. Guidance from these professionals assisted the compiling of clinical diagnostic standard operating procedures (SOPs) for every stage of the pipeline, including implementing checklists and risk mitigation steps alongside the methods.

2.1.7 Additional SOPs were followed for sample storage, disposal of materials, batch certification of reagents and incident reporting. Appropriate risk assessments, training and competency assessment procedures were established and documented. Record sheets were created to document the receipt, batch acceptance testing, and start- and end-of-use dates for key reagents and consumables. An inventory of all key equipment was compiled that, where appropriate, included details of service and calibration records. Systems were established for the control of all key documents (version implementation, distribution and acknowledgement), audit trail (what samples were tested when, by whom, with what equipment and using which consumable or reagent batches), and a record of all incidents and issues (to facilitate appropriate investigation, rectification and recurrence prevention).

2.1.8 The CCC was set up to operate in an agile, flexible and innovative way. An RNA extraction method previously optimised for ancient nucleic acid work carried out at the Crick was repurposed for use in the testing pipeline; the Biological Resource Facility, with Crick group leader support, developed a SARS-CoV-2 sample reception and viral inactivation laboratory in an empty room in the basement in under a month; the health and safety team supervised and led a critical phase of the pipeline—the viral inactivation step—in the Category 3 facilities at the Crick; and management teams and IT and computing staff came together to work seven days a week to set up a booking and test barcoding hub, and to interface the Crick reporting system (LIMS) with that of

the NHS to deliver the 24-hour-turnaround reporting system. To note, the Crick's collaborator at the Institute for Cancer Research had been attempting to introduce barcode tracking into the genomic testing pipeline for NHS diagnostics for three years; the Crick managed it in three weeks, albeit driven by the urgency of the crisis.

2.1.9 The practical issues encountered during setup of the testing pipeline are summarised in the table below. The Crick had enthusiasm, commitment, skilled staff, excellent collaborators and appropriate equipment, but also had to work out how to rapidly fix the things it was lacking. This was only possible because of the quality and commitment of the people involved.

Issue:	Specific aspect	How specific issue was addressed
Regulatory	Accreditation	Formed partnership with HSL
	Establishing SOPs	Advice from HSL
	Legal Indemnity	Consulted the Crick legal and governance officer
	Training and competency assessment	Advice from HSL
	Environmental monitoring	Advice from external quality assessor
	Reagent batch acceptance	Adherence to batch certification SOPs
	Sample storage	Amended existing storage capabilities, created SOPs
	Equipment monitoring	Inventories created for all key equipment and monitored by internal quality assessor
	Waste management	Risk assessments written with advice from partner lab
	Safety	Measures implemented to reduce exposure to infections and chemicals/incident reporting monitored
Operational Management Structure	Workflow management	Discussed at daily operational meeting
	Interaction with partner lab	Met at daily operational meeting
	Interaction with sample providers	Met at daily operational meeting
	Staffing and rotas	Organised by Crick administrative staff
	Staff supervision	Organised by leads for each pipeline stage
	Planning and troubleshooting	Discussed at daily operations meeting
Supply chain	Robotic tips	Bulk orders from multiple suppliers by procurement team
	High throughput consumables	Bulk orders from multiple suppliers by procurement team
	PPE	Used available PPE in the institute with minimal procurement
	Swabs	Additional testing regimens considered
	RNA Extraction	Use of in-house buffers
	Beads for RNA purification	Beads optimised from two commercial suppliers
	RT-PCR kits	Sourced from BGI
	Viral inactivation reagents	Use of in-house buffer

Analytical and clinical validity	Assay validation	Advice from partner lab & external quality assessor
	Assay controls	Provided by partner lab and external panels
	Assay reproducibility	Establishing and following version-controlled SOPs
	Duplicate runs	Performed against N gene assay from partner lab
	Avoiding disruptions	Compartmentalise pipeline for diagnostics vs research
	Contamination	Geographic, personnel & equipment separation for pipeline
	Sample swaps	Incorporated sample tracking pipeline
Reporting pipeline	Accreditation of staff signing out clinical reports	Crick staff with clinical lab accreditation and partnership with local NHS labs
	Establishing thresholds	Liaising with partner lab
	Issuing reports	Custom made reporting web application
	Rapid &Standard Turnaround times (TAT)	Stratifying rapid TAT vs standard TAT and establishing workflows for each group
Sample tracking pipeline	LIMS - Internal	Incorporated the existing sample tracking, applications, pipelines and technical expertise. Custom made web platform dashboard for sample tracking and sample reporting
	External database	Partner lab proprietary system - Winpath
	External secure file transfer site	Provided by partner lab

2.2 Running the pipeline

2.2.1 Once operational, the pipeline was used to detect SARS-CoV-2 from combined nose–throat swabs and endotracheal secretions or bronchoalveolar lavage fluid in roughly 8 hours from sample arrival to reporting. Notably, it relied on a series of in-house buffers for viral inactivation and extraction of viral RNA, thereby reducing the dependency on commercial suppliers at times of global shortage. The CCC initially used a commercial RT-PCR assay from Shenzhen-headquartered BGI, but switched to Taqpath PCR in December 2020. RT-LAMP testing was evaluated later in the pandemic (Buck et al, 2021; PN/14 - INQ000587052), but even though it was quicker, the assay was ultimately not adopted for two main reasons: samples from a variety of settings were being analysed by our pipeline and had different requirements when it came to the need for absolute sensitive detection, and the demand for alternative testing strategies had diminished from an institutional perspective by the time governance and clinical validation had finally been established.

2.2.2 A notable strength of the CCC pipeline was that it allowed the testing of a wide variety of swabs that could be either dry or in any proprietary virus transport medium. These were taken at hospital sites and submitted to HSL for barcoding before being

transferred to the Crick. Clear instructions were given to those submitting samples [PN/06 - INQ000587091; PN/07 - INQ000587092], which were only identifiable by barcodes, preserving patient confidentiality. To ensure full traceability, incoming samples were barcode-scanned and proceeded immediately to viral inactivation, automated extraction of viral RNA, and RT-PCR to quantify SARS-CoV-2 RNA. Results were accessed through a custom-made online web portal that integrated with the national healthcare digital system, allowing the remote analysis of data by multiple trained reporters working from home. Once verified by the reporters, the results were released to HSL for onward communication to the source locations and NHS Test and Trace. Assurance of the pipeline was performed in collaboration with quality assessment provider Genomic Quality Assessment (GenQA; https://www.genqa.org/), following their checklist for non-accredited laboratories. The lab and CCC workflow were inspected by a qualified UKAS assessor against the GenQA guidelines to verify compliance to IS015189 equivalent standard.

2.2.3 To physically establish the CCC pipeline at the Crick, the institute repurposed 12 Category 3 tissue culture hoods for viral inactivation, three robotic platforms for RNA purification and six PCR machines, together with space to house these activities. The scanning equipment and tool tracker were already used with our LIMS system. Only a limited amount of extra protective equipment was procured for buffer preparation, and the pipeline could have been potentially scaled up further with minimal extra equipment. A rate-limiting step preventing the CCC pipeline from proceeding at full capacity was the global shortage of swabs.

2.2.4 The CCC pipeline is illustrated in Figure 1 below. The pipeline was operated by some 150 volunteers from the Crick scientific staff, who would otherwise have been furloughed. No additional funding was available, as this was being used for the large Lighthouse facilities. The volunteers worked in 10-hour staggered shifts, all in addition to their research activities. Competency training was conducted for staff to work on virus inactivation, RNA extraction, RT-PCR and result reporting. The specific reagents and requirements for each step of the entire pipeline—sample receipt, virus inactivation, RNA extraction, RT-PCR assay for the ORF1a gene, data quality assessment, online web reporting, barcode sample tracking—were made available on protocols.io and the Crick website [copies of the SOPs: PN/08 - INQ000587093]. Several amendments to the publicly available procedures were implemented to ensure the CCC test performed robustly at the Crick. Although the Crick performed viral inactivation in a Containment Level 3 suite with trained staff, a Containment Level 2 procedure was also provided with

our protocols for the use of other research laboratories lacking Containment Level 3 facilities.

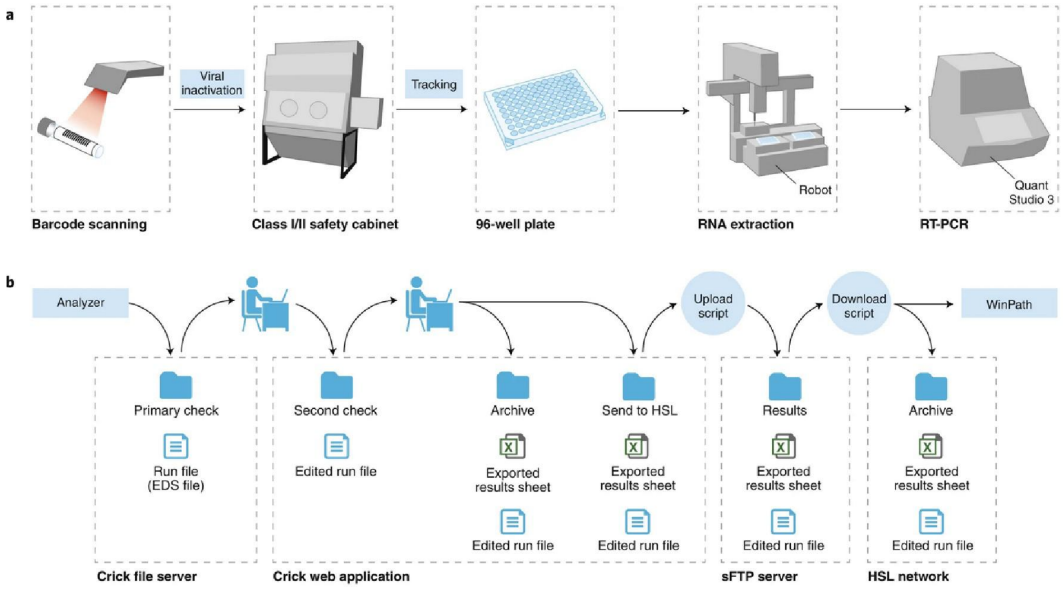

Figure 1 ***a****, Specimen barcodes were scanned at sample reception, before viral inactivation in a class I or II safety cabinet, processing through RNA extraction protocol and RT-PCR testing.* ***b****, CCC reporting pipeline. Test results were reported continuously through a custom-made remote web application, allowing remote clinical scientists and pathologists working outside the institute to authorise reports, in line with the established SOP. EDS, experiment document single; sFTP, secure file transfer protocol. Taken from Aitken, J et al. (2020). Scalable and resilient SARS-CoV-2 testing in an academic centre. The Francis Crick Institute. Figure 1 https://hdl.handle.net/10779/crick.12302819.v1*

2.2.5 The Crick's experience was useful to other institutions. Between 2020 and 2023, the SOPs page on the Crick website was accessed some 17,000 times, and in addition, we presented webinars on the pipeline, and provided information, assistance and advice on setting up a testing pipeline to over 40 other sites, including the MRC Unit in Gambia and The National Center for Biotechnology in Costa Rica. The *Nature Biotechnology* paper detailing how the centre and testing pipeline was set up (Aitken et al, 2020; PN/09 - INQ000587094) has been accessed over 14,000 times.

2.2.6 In response to potential shortages of supplies, demand was forecasted, reagents ordered in large batches, and in-house buffers were made from common reagents wherever possible—specifically for automated RNA extraction—circumventing dependence on scarce commercial reagents. The pipeline was automatable on widely available liquid-handling platforms, allowing its implementation in a large number of

biomedical laboratories with suitable robotic platforms that could be reprogrammed for this use. The reagents could also be used for manual RNA extraction where liquid-handling platforms were unavailable. The universal applicability of this approach would allow a resilient response to future critical events, even in countries where particular resources may be limited.

2.2.7 The speed and precision of the pipeline permitted the testing and reporting of 2,500–3,000 samples a day, adopted processes widely used by many research laboratories worldwide, and was free from dependence on supply-chain constraints other than swab availability. Between commencement of testing on 1st April 2020 to its cessation on 14th April 2022, the CCC reported on 664,085 samples, 467,024 of which were for the NHS (see table below and Figure 2). The remainder of the tests were for other research organisations and for Crick staff: it was recognised early on that the Crick needed to reopen for limited working, both for operation of the pipeline and for COVID-19-related research projects (see below), so comprehensive staff testing commenced in June 2020, to provide a safe working environment. This could have been duplicated elsewhere.

Category	**Test Source Centre**	**Total Tests**
NHS	Not specified - early tests, prior to site coding scheme	26426
NHS	Barnet	5691
NHS	Ealing	668
NHS	Marsden, Mortimer Market, CNWL NHS Trust, Care homes, RNOH.	277758
NHS	North Middlesex	12253
NHS	Northwick Park	4683
NHS	Royal Free	5613
NHS	UCLH	133932
Total		467024

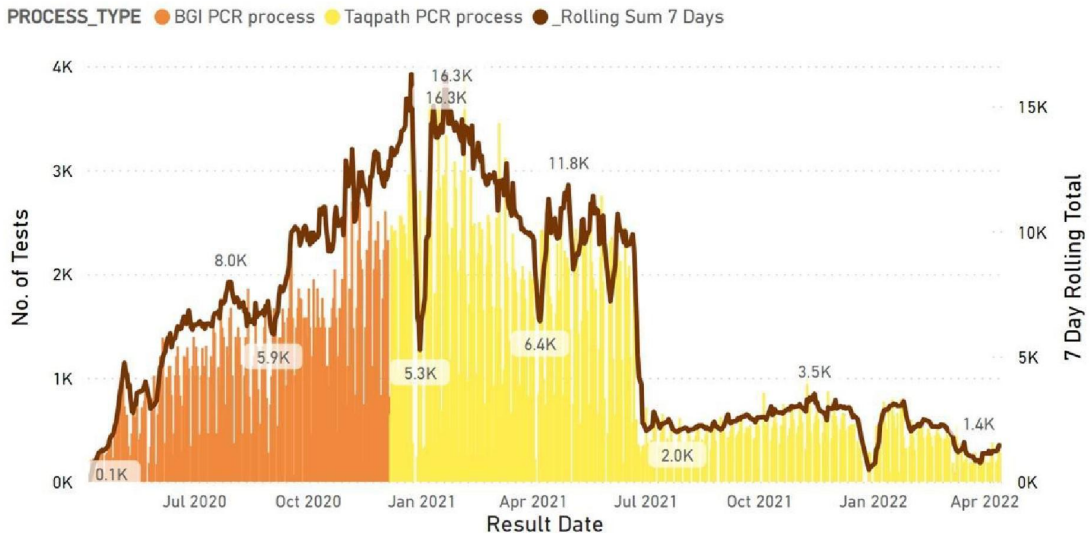

Figure 2 Numbers of tests conducted, April 2020 - April 2022

2.3 Impact

2.3.1 Local community outreach

2.3.1.1 There were many advantages to having a locally focused small-scale testing pipeline which could respond rapidly to local needs. Strong relationships were built between the people involved, allowing a responsiveness that was underpinned by the agreed processes but was not driven by them. Personal initiatives included a Crick staff member getting on his bicycle to pick up swabs from HSL and deliver them to a local GP surgery—a speed of reaction that meant the GP surgery could stay open—and the pipeline team locating and prioritising a swab belonging to a bereaved son so that he could attend his father's funeral in India. The CCC also prioritised testing of particularly vulnerable non-COVID patients such as those undergoing treatment for cancer, or awaiting surgery [PN/10 - INQ000587048]. Community relationships were cemented by activities such as our setting up of a drive-through hub with the British Library and UCLH, fruitful new collaborations with clinicians at UCLH and other local hospitals, and programmes to test the local homeless population, the residents and staff of local care homes, and staff and users of mental health units.

2.3.2 The Crick COVID Consortium's discovery and clinical research

2.3.2.1 Crossover between testing and research adds value to setting up testing pipelines in active research environments. Once the Crick began testing its staff, it

could reopen for limited working and begin to play to its strengths as a world-class research institute to tackle COVID-19 problems. Highlights of the fundamental research into COVID-19 performed at the Crick during this period are listed in PN/11 - INQ000587049: a document presented at the Crick's quinquennial review in 2021.

2.3.2.2 Research stimulated and supported by the existence of the testing pipeline also took place:

- The testing pipeline allowed the Crick to develop the infrastructure for a serology pipeline for testing immunity through neutralising antibodies. This platform, in conjunction with the SARS-CoV-2 positivity status from the PCR data, made possible the large body of research on immunity from COVID-19 that the Crick published. These outputs were fed directly to Government, and resulted in changes in policy around vaccine schedules.

- The CAPTURE study (led by Samra Turajlic; Clinical Study Identifier NCT03226886): a prospective, longitudinal study of cancer patients and healthcare workers, was established in response to the unique challenges of the SARS-CoV-2 pandemic for the care of cancer patients. The overarching aim was to establish an unbiased understanding of the susceptibility and morbidity of SARS-CoV-2/COVID-19 in cancer patients and the patterns of viral transmission in hospitals, and to inform clinical decision making and healthcare policy, especially the advice on self-shielding, safe delivery of cancer therapy and reduction of transmission.

- The Legacy study (led by Emma Wall; Clinical Study Identifier NCT04750356; Chief Investigators Sonia Gandhi and Charles Swanton) was designed to examine as many aspects as possible of coronavirus transmission and infection. The Crick is one of only a few places in the UK with Category 3 (enhanced) containment facilities to safely study highly infectious samples. The team uses a unique bank of over 400,000 coronavirus samples, gathered as part of the Crick testing pipeline. The research is ongoing and will help scientists and clinicians to understand the coronavirus and how it behaves in individuals—how the virus is transmitted

between people, how later stages of the disease develop and how the body's immune system attempts to control the virus.

A rapid response model was developed to ensure Legacy data were shared with policy makers in near real-time. These data were used to inform COVID-19 policy 2021-2024, including prolonging restriction measures to increase vaccination uptake in 2021, retention of Sotrovimab in NICE COVID-19 treatment guidelines in 2022 and efficacy of bivalent vaccination in winter 2022-23. More recently Legacy data have supported WHO strain selection for next-generation COVID-19 vaccines through TAG-COVAC. PCR testing data were shared with the UK's COVID enquiry and House of Commons investigation on pandemic preparedness to highlight the importance of early asymptomatic testing in healthcare workers (HCWs). Data from Legacy on immunity to Influenza H5N1 were shared with UKHSA and WHO for the purposes of H5N1 vaccine stockpiling [PN/12 - INQ000587050].

The Legacy study currently has an estimated 6,000 adults enrolled, including many Crick staff, under prospective follow-up, and includes recipients of all COVID vaccines licensed in the UK. The bank of samples and methodologies developed by the Legacy Study, COVID Surveillance Unit and Worldwide Influenza Centre are now also being used to study COVID immunology, long COVID, and the effectiveness of treatments like monoclonal antibodies against new variants. The data are also helping to evaluate the impact of COVID on immunocompromised people, including people with multiple sclerosis (MS), rheumatoid arthritis and dialysis patients. The Crick has developed and led 11 collaborative partnerships, using our data and platforms to provide comparative data on vaccine responses in immunocompromised patients with cancer and MS in the UK and healthy adults in Ghana and the West Indies. Most recently the work has been extended beyond SARS-CoV-2 to highly pathogenic and seasonal influenza.

2.3.3 Asymptomatic healthcare worker surveillance

2.3.3.1 In April 2020, shortly after the CCC pipeline became operational, a letter to *The Lancet* from Charles Swanton and collaborators made the case for screening

asymptomatic and symptomatic HCWs to prevent hospital transmission (Black et al, 2020; PN/13 - INQ000587051), but also to prevent unnecessary self-isolating of key staff. It drew on a number of previous studies, such as that into the *Diamond Princess* cruise ship, where it was clear asymptomatic transmission of SARS-CoV-2 had been instrumental in increasing the severity of outbreak.

2.3.3.2 This paper was soon backed up by one of the first collaborations in which the CCC was involved. The testing pipeline was used in the SAFER study, which investigated rates of COVID-19 infection in HCWs using RT-PCR together with serological analysis. SAFER showed that there were very high levels of asymptomatic infection in HCWs: 44% showed evidence of SARS-CoV-2 infection—more than double that of the London population. Strikingly, potential superspreaders were also identified: some staff were relatively asymptomatic but displayed unusually high virus levels. These data highlighted the urgent need to implement policies to better protect HCWs, and for regular asymptomatic HCW surveillance in hospital settings to protect both HCW staff and patients from hospital-borne transmission through a potential SARS-CoV-2 second wave [PN4 - INQ000000].

2.3.3.3 In a *post hoc* study published in 2023 [PN/05 - INQ000587090], the value of asymptomatic testing was further underlined: asymptomatic testing strategies had captured a considerable number of additional infections in HCWs, particularly in the early phase of the pandemic. In a hospital context, failure to pick up such asymptomatic infections could have life-threatening effects. The analysis also provided a unique insight into workplace exposure risk and screening strategies outside of hospital settings, as the Crick's enforced testing policy to support a safe workplace could be interrogated. Because of the testing regime, the institute was able to get back to 80% occupancy within a month of each lockdown ending, [PN/05 - INQ000587090; Supplementary figure 2], alone among other comparable research locations: for example, UCL only permitted 20% occupancy during these periods. Similar approaches could be used to protect and allow the operation of other nationally important facilities.

2.3.3.4 Taken together, this aspect of the CCC's work highlights the importance of prioritising testing—including regular asymptomatic testing—of key workers including NHS and care home staff during the first phase of any pandemic response. A report of how in the early days of the pandemic the CCC's attempts to

change Government policy on this were unsuccessful is presented in parts 3 and 4 of this document.

2.3.4 Wider contributions

2.3.4.1 Crick researchers were involved in a number of wider initiatives, two of which are of note:

- In April 2020, DHSC set up a crowdsourcing platform, #Testing methods2020, to review ideas for testing technologies. They established a reference group of senior experts, including Sonia Gandhi of the Crick. This committee became the DHSC Technologies Validation Group, which had the specific objective of reviewing PCR-based Point of Care devices and LAMP-based solutions for rapid technology deployment.

- Contribution to COG-UK: The COVID-19 Genomics UK (COG-UK) Consortium was created to freely share large-scale and rapid whole-genome virus sequencing data. Whole genome sequencing of SARS-CoV-2 from positive tests was performed at the Crick and many other sites, and uploaded to the COG-UK site. Virus genome data was combined with clinical and epidemiological information, and subsequent analyses enabled evaluation of novel treatments and non-pharmacological interventions on SARS-CoV-2 virus populations and spread and provided information on introductions versus community transmission and outbreaks. These data also allowed researchers to rapidly identify and evaluate emerging genetic changes and understand how they affected the ability of the virus to transmit from person to person and to cause severe forms of the disease.

- Evidence given by Crick researchers to Government committees is detailed below:

Date	**Output**	**Shared with**	**Impact**
May-June 2021	Post-vaccine antibody titres against Delta Pfizer vs AZ vaccines • Healthy adults • Kidney patients	NERVTAG, JCVI	Supported extension of restrictions to enable more people to get two vaccine doses

	• Cancer patients		
December 2021	Titres against Omicron in 2 vs 3 doses • Healthy adults • Kidney patients • Cancer patients	NERVTAG, JCVI	Supported extension of dose 3 vaccines to wider population
December 2021	Neutralising efficacy of Ronapreve (monoclonal antibody cocktail) and Sotrovimab against omicron	NICE	Supported withdrawal of Ronapreve from NICE guidelines
April 2022	Symptom data on non-hospitalised adults with Delta vs omicron infections	CMO, NHSE	Supported broadening of clinical definition of COVID-19 for isolation policy
June 2022	Neutralising efficacy of Sotrovimab against later omicron variants	CMO, NHSE, NICE	Supported other NHS clinical data leading to retention of Sotrovimab in COVID-19 treatment guidelines
March 2023	Early testing of HCW protects NHS staff and patients from SARS-CoV-2 variants	CMO, House of commons pandemic preparedness committee	Data to inform the HoC committees discussing and planning pandemic preparedness
December 2023/April 2024	Boosting of antibodies against JN.1 by either XBB.1.5 monovalent vaccine or Wu+BA.5 bivalent vaccine	WHO TAG-CO-VAC	Selection of JN.1 for the mRNA antigen for 2024 COVID-19 vaccine update
November 2024	Effect of JN.1 vaccine boosting against emerging sub-variants	WHO TAG-CO-VAC	Retention of JN.1 as the mRNA antigen for 2025 COVID-19 vaccines update
November 2024	Antibodies against Highly pathogenic avian influenza A (H5N1) in	NERVTAG JCVI	Support development/stockpiling of anti-H5 vaccines in

	sera of UK unexposed adults vaccinated with		the event of widespread human-human transmission

2.4 Recommendations for rapidly setting up a small-scale local testing pipeline

2.4.0.1 It is important to note that the Crick did not succeed in setting up the CCC testing pipeline because the institute possesses unique attributes; in fact, the pipeline was set up despite a number of obstacles that would have been easier to overcome in a research-active university with an attached medical school. The Crick does not have a partner medical school, and there were few staff who understood the complexities of interfacing with the NHS's electronic medical record systems, or the mechanics of setting up clinically certified assay protocols. We had the number of Category 3 hoods and PCR machines commensurate with an institute with just over 100 laboratories, but larger institutions with more equipment would have been able to do far more in terms of scaling up. Our advantages were speed and agility, and also the willingness of senior management to resist strong external pressures which were firstly, to conform to the Government decision to centralise testing into so-called "megalabs"—which were bound to take much longer to put in place for rapid turnaround of sample processing—and secondly, to withstand initial funder pressure to close the institute down.

2.4.0.2 The practical barriers we encountered during setup of the pipeline inform the recommendations we make below. Our experience demonstrates that by using a network of local testing facilities that can be quickly set up, the country would be better prepared in the event of a future pandemic.

2.4.1 Supply chain resilience—the need for reagents, equipment and skilled staff

- Given that a high proportion of the risk of a future pandemic lies with respiratory viruses, the reagents required, from sample collection through to nucleic acid preparation, are likely agnostic of the virus type. Further, the PCR kits for such viruses are likely only virus specific in terms of the required DNA primers. When the pandemic hit, the UK did not have a domestic manufacturer for many of the necessary reagents, leading to a lack of buffers and commercial PCR kits. **Recommendation: The UK should have a national stockpile of standardised reagents and/or resilient domestic manufacturing capacity.**

- Developing new assays for large-scale testing under the pressure of a pandemic is not easy. PCR, isothermal amplification and sequencing will be the front-line scalable tests in any near future pandemic as these techniques have proven and readily accessible reagents. Antibody-dependent tests (for ELISA and Flow tests) necessarily require the prior development of excellent antibody/affinity reagents. There are many different approaches to making these reagents so there would be the need for central coordination across a number of different streams of activity to avoid either unnecessary duplication of effort or leaving reasonable avenues unexplored. Newer assay technologies will also emerge.
  Recommendation: there should be a clear roadmap for the development of new assays in the early stages of a pandemic (bearing in mind there is likely to be restricted access to control standards and consumables), or a scheme for continual pre-evaluation of emerging technologies as scalable and fast testing platforms.

- Unlike reagents, it is impractical to store stocks of equipment; if equipment is not routinely used and updated, it will be unlikely to work when needed and will quickly become obsolete. This can be dealt with, as universities and other government-funded labs around the country hold substantial amounts of the necessary equipment, which could be rapidly redeployed. Any future planning should include knowledge of the reagents and machines approved for testing purposes; from our experience this list should be as wide as possible, to make use of the majority of the current infrastructure available in research institutions at short notice.
  Recommendation: Government should maintain an up-to-date register of the nation's network of research and clinical laboratories where large amounts of equipment are housed and relevant expertise is available, for rapid repurposing in the event of a pandemic.

- For a network of smaller laboratories to be efficiently deployed for testing in the initial stage of a pandemic, there must be coordination of effort: for example, there are a limited number of labs with the Category 3 facilities needed for virus inactivation in the UK, but the sites where reagents could be made and other parts of a pipeline could be run are far greater.
  Recommendation: There should be coordination of production of reagents and testing across the nation's network of research and clinical laboratories.

- Staff whose skills lend themselves to all aspects of pipeline delivery will be needed in the future. For example, the increased use of robotics requires a larger cohort of trained staff across academia and industry.
  Recommendation: An up-to-date register of staff training across all aspects of testing should be maintained.

- The heaviest workforce cost in any testing centre is sample processing and creating the input for automation platforms (from sample delivery to the centre, to processing from tubes to plates). In another pandemic with a much higher rate of incapacity or death, this workforce dependency could limit the total testing throughput. From a sample handling point of view, a standard approach to swab (type/length/breakpoint), tubes and viral transport buffer is also important.
  Recommendation: There should be prior planning for sample collection standardisation in a readily automatable format.

2.4.2 Data

2.4.2.1 While many of the scientific and clinical issues with implementing testing at the Crick were solved in a matter of weeks, the lack of standardisation of approach across the NHS remained a barrier to scale throughout the pandemic. From a digital standpoint this breaks down into the following problems:

- Lack of standardisation: IT implementation is the responsibility of the thousands of different bodies that comprise the NHS in England, and they have used different technologies, often implemented independently of one another. As such, when they need to act as a 'system', very basic tasks, such as the exchange of a summary patient record to associate with a test, becomes extremely complex. This also holds true for third parties trying to interact with the system at scale, whether those parties are commercial or public.
  Recommendation: Urgent action is required to develop common 'platforms' for patient care and data management, procured, managed and integrated system-wide, not at individual trust/body level.

- Lack of a consolidated patient record: the NHS Test and Trace system was constructed out of necessity, as a stand-alone silo of data, with minimal linkage back to any primary care system. This meant that it was impossible to properly federate testing to many different providers, and it was also difficult to integrate those test

results back into views of data visible to clinicians or NHS management teams. This is due in part to the fragmentation of patient data across the numerous different bodies mentioned above: there is no standard patient record to which to append new data, nor the digital infrastructure to facilitate that exchange of information with different parties.

Recommendation: Patient data has to be consolidated across platforms into a single patient record, which can be presented via Application Programmable Interfaces (APIs) to allow for key patient data to be shared with, and updated by, approved non-NHS organisations.

- Lack of digital capability within the NHS: as the Crick attempted to interact with various provider bodies within London, it was very apparent that they had restricted in-house digital skills. Typically, solutions would have to be created by the Crick and HSL teams to work around the inability of NHS trusts to deliver even trivial technical tasks, like writing scripts to move data between servers. When working with smaller providers and care homes, there was frequently zero digital infrastructure or people with these skills.

  Recommendation: NHS must invest in technology professionals and skills development system-wide, and dramatically reduce reliance on external contractors and restrictive managed service arrangements.

Overall data recommendation: the NHS must 'join the dots' between the many digital policy initiatives and create a single, coherent technology architecture and strategy to deliver all transformation use cases, including pandemic readiness.

2.4.3. Clinical testing

2.4.3.1 The Crick had no experience of the many issues surrounding the development of a clinically validated RT-PCR test for an infectious pathogenic virus: safe viral inactivation, RNA extraction, the buffers required; the thresholds for reading out positive and negatives, why sensitivity matters, and what PCR machines were appropriate, to name but a few. As well as being able to meet the mechanical requirements of running assays, non-clinical testing labs need to address the following:

- Equipment and processes need to be evaluated rapidly to ensure that they meet necessary standards. This is non-trivial; laboratory discovery science has different deliverables than clinical testing. During the pandemic the Crick was very fortunate in its partners and was able to achieve adequate verification. A more general approach to this would be important if more widespread use of distributed laboratories was envisaged. For small scale labs, it is difficult to access control material for the QC and standardisation of testing pipelines.

- Delivery of testing results is dependent on existing data portals and notification systems and assessment of PCR results by clinically qualified staff with specific domain expertise. The Crick was again very fortunate in that its partners were able to cover these aspects, but for wider rollout, a scalable solution is required. **Recommendation: A pre-pandemic plan should include a list of favoured or approved sites for quick mobilisation, to help prioritise distribution of limited test material, potentially scarce consumable resources, and rapid integration into the reporting system.**

2.4.4 For easy access, the recommendations in this section, which are specific to the practicalities of setting up a small local testing pipeline, also appear in the final list; this latter also covers wider issues and recommendations and can be found at the end of the submission.

3. Barriers to effective testing for SARS-CoV-2

3.1 Introduction

3.1.1 The Government, and the scientists advising Government, faced very difficult problems with the SARS-COV-2 pandemic, coping with constantly changing circumstances and significant numbers of deaths, particularly among the most vulnerable in society. These difficulties were due to a lack of pandemic preparedness reflecting failures of several administrations. This was a major barrier to rapidly setting up effective testing. However, in addition, political leadership and competence were insufficient to deal with a crisis of this magnitude, which resulted in further barriers. Too much attention was given to one-liner slogans like 'following the science' and non-existent successes being claimed, such as 100,000 tests completed when many were actually only in the post. In addition, there was a reluctance to take full responsibility for what was happening, shifting that to others. The Government mostly

turned to private commercial solutions rather than in addition exploring effective public initiatives, a strategy which separated politicians from the key delivery of outcomes. These failures in leadership led increasingly to a lack of public trust. To use another Second World War analogy, 'there were no Churchills'.

3.1.2 There were also barriers as a consequence of the scientific, or perhaps more precisely the logistical, advice with respect to testing, particularly with the exclusive emphasis on the Lighthouse laboratories, the large-scale testing facilities. This strategy was inflexible, lacking in imaginative and innovative thinking, and there was a reluctance to consider other approaches even when new evidence and options emerged. The large commercial Lighthouse labs were not a bad idea, but what *was* bad was a policy that suppressed other approaches. It was glaringly obvious that setting up the large labs would not only take time, but would be very complex given the often long distances involved in getting samples to the labs and the information quickly back to individuals. This meant the Lighthouse labs were of little use during the first pandemic wave: with a slow turnaround time of around seven days, test results came too late for effective isolation of infected individuals, something particularly important in healthcare environments. Because of the lack of capacity, the testing of asymptomatic healthcare workers also could not be delivered and was not implemented for months, with consequences for vulnerable individuals.

3.1.3 Why were these obvious problems ignored and no attention given to setting up local solutions based on existing facilities which could have been more rapidly put in place? It is difficult to be sure, but the large advisory committees involved may have led to consensual decisions which were too conservative, resulting in insufficient attention being given to unusual solutions. Perhaps there were also some dogmatic or even arrogant behaviours from some, that meant status quo conventional decisions could not be easily challenged. What is evident is that the overall approach was inflexible and deaf to offers of advice and help more widely from across the scientific community. What follows below is a more detailed account of these issues and barriers.

3.2 First emergence of SARS-CoV-2 in the UK

3.2.1 From the first reported case of SARS-CoV-2 infection in the UK, researchers at the Crick gathered information on relevant research happening within the building, answered calls for equipment loans and scientific volunteers, and began to design the Crick Covid Consortium testing pipeline in support of the NHS. Summaries of the Crick's capabilities were shared with Public Health England and senior civil servants, and staff were primed to refocus their time and research capacity on testing and SARS-CoV-2.

3.2.2 On March 10, 2020, the Crick Director Paul Nurse wrote to the Chief Medical and Scientific Officers [PN/15 - INQ000587053] summarising relevant Crick research and offering any support that might be helpful, including trained scientific volunteers to aid diagnostic efforts and use of the Crick's containment laboratory facilities. This was followed by an email from the Crick's Medical Director Peter Ratcliffe [PN/16 - INQ000587054] to the Chief Medical Officer, offering specific help to scale up testing capacity. On March 19, Paul Nurse wrote to Special Advisor to the Prime Minister William Warr [PN17 - INQ000587055], offering to quickly hand over significant resource to assist with diagnostic testing, but received no response.

3.3 The value of small-scale targeted healthcare worker testing

3.3.1 Clinicians and scientists around the world were aware of the risk of nosocomial asymptomatic transmission without routine testing of healthcare workers. The Crick made strenuous efforts to highlight the value of rapidly established, local small-scale testing with a quick turnaround to the Government, stressing that the reason for setting up the pipeline in partnership with NHS hospitals was to protect patients and focus on areas where the virus was mostly likely to spread. On April 1, Paul Nurse wrote to Chris Wormald, Permanent Secretary in the Department of Health [PN/18 - INQ000587056], referencing earlier attempts to engage with Downing Street and detailing progress with the Crick PCR pipeline. At this time, there was also the first contact from Director of COVID testing supplies Sam Roberts [PN/19 - INQ000587057], who asked about use of consumables in the pipeline and was interested in extending the Crick model. On April 8, Paul Nurse gave evidence to the Science and Technology Select Committee. He highlighted the value of small labs complementing the work of larger facilities that can take a while to get running and the critical need to test NHS staff because of the dangers to patients.

3.3.2 A letter from Crick leaders was immediately sent to Secretary of State Matt Hancock [PN/20 - INQ000587060] summarising the evidence provided to the Select

Committee and reiterating the risks of not systematically testing healthcare workers. No policy action was taken, nor was there any response from the Secretary of State, despite the letter coming from two Nobel Laureates in Physiology or Medicine. An anodyne response eventually came three months later from a civil servant [PN/21 - INQ000587061].

3.3.3 The Crick's testing efforts attracted a lot of media attention [PN/22 - INQ000587062] with small labs being described as having the 'Dunkirk' spirit, emphasising the 'little boats' as well as the 'big ships'. At this time, scientists gave interviews [for example, see PN/23 - INQ000587063] with messaging consistent with that being sent to Government, in the hope that this might encourage policy action to protect clinical settings and wider engagement with scientists. A letter was also submitted to *The Lancet* [PN/13 - INQ000587051] to engage the clinical community.

3.4 Lighthouse laboratories and mass testing

3.4.1 In April 2020, the Government's testing strategy was launched, linked to the opening of the first Lighthouse testing laboratory. At this time, Matt Hancock set the target of running 100,000 tests a day by the end of April. This large-scale 'big ships' approach was prioritised and the 'little boats' approach ignored, despite the suggestions of Crick scientists and others [PN/24 - INQ000587064]: the Government strategy was to support only Lighthouse labs, and not smaller agile local testing hubs as well. It is still unclear, and should be investigated, who proposed this approach, who approved it, and why no consideration was given to more local small scale efforts which could have been put in place more rapidly. The large laboratories were subject to criticism throughout 2020 due to IT errors, incorrect results and slow turnaround times [for examples, see PN/25 - INQ000587065 and PN/26 - INQ000587066].

3.4.2 On April 30, the day of the 100,000 test target, Paul Nurse was invited to appear on BBC Question Time [PN/27 - INQ000587xxx] alongside Secretary of State for Transport Grant Shapps. Paul again highlighted the failure to recognise the value of small labs in improving testing capacity and strategically testing healthcare workers. Shapps noted the progress towards this target, stating that 80,000 tests had been processed the day before; in fact the records [PN/28 - INQ000587067] indicate it was under 67,000. Shapps also said that 100,000 tests took place on April 30 [for example, see PN/29 - INQ000587068]. Astonishingly, this number had been artificially inflated with retests and merely posting out testing kits [for example, see PN/30 -

INQ000587070 and PN/31 - INQ000587071]. Paul was so flabbergasted by this that he was left speechless on the programme. Of course, such statements undermine the public's trust in Government which is counter-productive in a crisis.

3.4.3 Shapps went on to state that testing had been expanded to asymptomatic healthcare workers 'so people can just take a test if they are just concerned'. This was not correct: routine asymptomatic testing [PN/32 - INQ000587072] did not come into place until months later in November 2020. It appears PR statements were favoured over reality.

3.5 Expansion of Crick testing and continued call for asymptomatic testing of healthcare workers

3.5.1 As UK testing capacity increased, the Crick continued with efforts to share testing protocols and help with the national testing efforts. The Crick COVID Consortium paper 'Scalable and robust SARS-CoV-2 testing in an academic centre' [PN/03 - INQ000587069] was published in *Nature Biotechnology*, and in meetings with representatives of the Department of Health [PN/33 - INQ000587073] Crick scientists engaged with national testing issues, making recommendations for targeted improvements including updating national guidelines to include asymptomatic testing of healthcare workers and providing guidance for testing at a local level. These updates, offers and recommendations were also shared [PN/34 - INQ000587074] with Parliamentary Under-Secretary of State for Innovation at the Department of Health and Social Care, Lord Bethell, but no further action was taken by the department.

3.5.2 By summer 2020, having seen no proactive movement on the issue, Crick researchers increased public efforts to call for systematic testing of healthcare workers to protect clinical settings. On June 22, following evidence from the Crick, the Leaders of the Health and Science Select Committees, Jeremy Hunt and Greg Clarke, sent a letter to Matt Hancock stressing the importance of asymptomatic testing and noting his previous lack of response to Crick correspondence. On June 24, Paul Nurse was interviewed on ITV's Peston [PN/35 - INQ000587076], and Principal Group Leader Charles Swanton was interviewed for a BBC Panorama documentary on testing failures [PN/36 - INQ000587xxx], where he outlined the dangers of asymptomatic spreading of COVID-19 in healthcare settings.

3.5.3 On July 10, the Crick released data published in *The Lancet* [PN/04 - INQ000587080] showing high levels of asymptomatic infections during the peak of the pandemic in London and highlighting the importance of routinely screening healthcare staff for the virus to protect frontline workers and their patients. This was reported in the media [PN/37 - INQ000587077] and shared with Lord Bethell [PN/38 - INQ000587078]. Similar letters were sent to Leader of the Opposition Keir Starmer and Parliamentary Under-Secretary (BEIS) Amanda Solloway, with a separate letter to Matt Hancock [PN/39 - INQ000587079] ahead of the data being made public.

3.5.4 On July 21, Paul Nurse was invited to give evidence to the Health and Social Care Select Committee as part of the investigation into management of the coronavirus outbreak. Here he outlined missed opportunities to mobilise local testing capacity and also presented the evidence on known asymptomatic spread in hospitals. At this same oral hearing, Chief Medical Officer Chris Whitty said (candidly) the decision not to test asymptomatic healthcare workers was due to a lack of capacity in the mass-testing system. This recognition of a lack of capacity further highlights the damage following the large lab approach adopted by Government as the only testing strategy; had the Government facilitated and encouraged small targeted testing facilities around the country, this would likely not have been an issue.

3.6 Emergence of vaccines

3.6.1 Problems communicating with Government continued into 2021 and the vaccine rollout, where Crick scientists again had to resort to media interviews to effectively highlight wasted vaccination capacity. Building on the existing partnership with UCLH, the Crick worked with the NHS trust to deliver a large-scale COVID-19 vaccination centre at the institute with capacity to vaccinate up to 1,000 people a day [PN/40 - INQ000587082]. People over the age of 80, at-risk individuals in priority groups and frontline healthcare staff were the first to be vaccinated at the centre as part of the NHS vaccination programme. However centre staff quickly reported that the Crick was vaccinating people well under capacity, vaccinators were left waiting for patients and the centre was closing at weekends. With no policy response, Paul Nurse wrote an op-ed in the Times [PN/41 - INQ000587083] and was interviewed on BBC Radio 4 Today, calling for agile local approaches to patient management rather than waiting for national level decisions on which groups could be vaccinated. As a result of the Today programme interview, a phone call was received from NHS England threatening to close the vaccination centre. This was extraordinary: the response to the identification of a

pipeline problem resulted in a threat to close the centre, *reducing* vaccination capacity. This issue mirrors the problems with the inflexible testing strategy.

3.7 Communications barriers

3.7.0.1 The common barriers to an effective pandemic response identified here are inflexible national strategies and poor communications. The issues were covered widely in the media and discussed in Parliament throughout the pandemic, but there was little proactive change. Outlined below are examples of interviews where Paul Nurse highlighted poor government communications and lack of accountability.

3.7.0.2 In the Observer [PN/42 - INQ000587084], he argued that it is important to evolve the relationship between politicians and scientists. 'Science is crucial to developing sound public policy to manage the pandemic, but it is important to recognise that at this stage scientific knowledge of the virus is still tentative. Scientists can only give the best advice available at the time, but some of that advice will turn out to be incorrect. It is only through sustained quality research that clarity will emerge and advice will become increasingly reliable and that will take time.'

3.7.0.3 In the Guardian [PN/43 - INQ000587085] he criticised Government for the 'shroud of secrecy' drawn over major decisions in the coronavirus crisis and urged ministers to be more open about the reasons behind their policies.

3.7.0.4 Writing with Lord Saatchi in the Telegraph [PN/44 - INQ000587086] he called for clear accountability and clarity about the governance arrangements and the demarcation of advisory versus decision-making roles. 'The public want to know who is in charge. There are too many organisations, too many cooks in the kitchen.'

3.7.0.5 Paul Nurse expanded on these and other problems with pandemic communication in his appearance on 21st July 2020 before the House of Lords Science and Technology Committee. What follows below is an edited, abridged version of his evidence.

3.7.1 Communicating science to the public

3.7.1.1 Our educational system does not foster understanding that scientific knowledge is not chiselled in granite. That is probably true of Newton's laws of physics (at least in certain circumstances), but it is not true for a lot of research, especially when you are doing research at the frontiers of science and especially when you are dealing with an outbreak such as a pandemic. The science involved is tentative and uncertain; it changes and evolves. If we have a citizenship who are taught that science is written in stone, when we encounter a scientific problem like the pandemic, it looks to them that scientists are dithering around rather than pushing knowledge forward. We need a more sophisticated understanding of the nature of science so that we communicate properly to the public. Increasingly, our society will get technocratic and dependent on science—across the board, not just in a pandemic—and we need a more sophisticated response. Politicians should be more aware of this.

3.7.1.2 There is a particular problem relating to pandemics: they are a situation where the scientific knowledge is definitely uncertain, and is evolving and changing. This makes it a difficult challenge for communication professionals, who are generally trained to deal with communicating certainties in the form of memorable one-liners, which on the whole do not work well with complex science of this sort. Uncertainties will arise. There are limitations of data and analysis and the interpretation of the data, and differences in scientific consensus and conclusions. Advisers need to be clear in giving advice about what is known, what is partially known, what is unknown and what is unknowable. These are complicated things that we need to disentangle, and this needs to be explained by experts to policymakers and then to the public. We just have to handle that complexity. Unfortunately, we often are forced to take binary decisions based on a range of different opinions. We have to learn how to communicate that, and we have not managed to do so.

3.7.1.3 For communication and public engagement to be effective, there must be public trust. We rely on the public behaving in particular ways, but they have to have trust in the system, in the political leadership and in their scientific advisers. That means that we all have to earn that trust and we have to maintain it. We need honesty and transparency, along with humility; it is no good being arrogant or, as in the case of the alleged 100,000 tests, attempting to hide a problem.

3.7.1.4 There is another complicated point when it comes to communication and engagement: when something is uncertain and the knowledge is not clear, scientists deal with that by challenging each other to debate and discuss. Normally that occurs in a professional environment, but during the pandemic it had to play out in the public arena. That meant that scientists were seen to disagree with each other, but there was little understanding that that was all part of the process of trying to find the best way forward.

3.7.1.5 In all this uncertainty, it is difficult for politicians to come to clear decisions. In such situations, it is important to have clarity in the governance. Who was making the decisions? Who was giving the advice? That is both a scientific advice issue and a political issue. On the science side, although SAGE eventually had open discussions, many of the decisions that were critical, such as how and where we should test, were being made behind closed doors. An example is the decision to have only big Lighthouse labs. We do not know where that decision was made or how much it would cost, and no alternatives were looked at. We need transparency in decision-making and governance to inform communication and public engagement.

3.7.2 Communications between scientists

3.7.2.1 One of the great 21st century advances in sharing scientific knowledge is our ability to quickly publish scientific research online, in the form of non-peer-reviewed preprints. In normal times, this works well as a way of encouraging scientific discourse and informing colleagues of important research as early as possible. Pandemics of course are not normal times, and the lack of peer review for preprints meant that unverified, fallacious opinions were put into the public domain and cited to promote dangerous theories about the pandemic, most notably by antivaxxers.

3.7.2.2 Reputable preprint servers such as medRxiv and bioRxiv do have stringent criteria to screen out the most egregious examples of the genre, but the critical point is that while we should continue to encourage preprints, we have to combine that with immediate commentary on the information that is being given—preferably from government scientists or another trusted source such as the Royal Society and other learned academies—who have the scientific authority to be able to say when things matter and when things do not. To go back to the point about

anti-vaxxers, they produced a lot of misinformation masquerading as scientific fact, so much so that our task in encouraging vaccine uptake was not only about meeting demand, but in having the vaccines accepted by the public, some of whom were extremely sceptical about the benefits versus the dangers.

3.7.2.3 Our recommendations as to how these communications problems might be overcome appear in the last section of this submission.

3. 8 Summary of the major barriers to effective SARS-CoV-2 testing

3.8.1 Barriers to the practical setting up of testing pipelines (mostly covered in Section 2 and related to Recommendations 1-13 in Section 4)

1. There was no national stockpile of the reagents and consumables immediately required for testing pipelines. which could be located in local testing facilities. There was also insufficient relevant manufacturing capacity in the UK.

2. There was no national register of pandemic relevant testing and research capacity, infrastructure or expertise. There was limited 'thinking outside the box' capacity, as well as little interdisciplinary engagement with logistics and the social sciences.

3. There was no comprehensive register of infection 'hot-spots' such as hospitals, care-homes, and vulnerable individuals, and how these could be rapidly connected to testing facilities, including repurposed ones such as the Crick.

4. There was a lack of standardisation of sample collection procedures across the UK which could rapidly be put in place, because there was no national stockpile of reagents and consumables.

5. NHS data management systems were poor and divergent across the UK, resulting in weak standardisation and a lack of coherence.

3.8.2 Barriers to effective political and institutional operations needed to set up testing pipelines (related to Recommendations 14-19 in Section 4)

1. Government and other agencies setting up the UK testing capability were too conservative and unimaginative, and resisted alternative suggestions as to what should be done.

2. Political leadership and capability were too poor for a crisis of this magnitude. This resulted in inadequate decision making, a lack of clarity in decision making, and weak accountability.

3. Decisions appear to have been driven in part by dogma, such as considering only commercial solutions and not how already available and operational public institutions could also be mobilised. These alternative solutions may well have been cheaper options as well as being more effective in some situations.

4. Communications from the Government to the public were sometimes poor. There was too much emphasis on 'one-liners' and public statements driven by PR considerations. The public were not always treated seriously enough in these communications, which could damage public trust.

5. There were few authoritative voices pushing back on unreliable evidence and opinion in the public sphere. This allowed incorrect and sometimes dangerous statements to spread quickly, damaging management of the pandemic.

4. Lessons learned and the legacy of Covid-19

4.1 Overview of the lessons learned

4.1.1 Governmental structures usually have a tendency to move slowly and to follow established procedures; precipitate action in normal circumstances is rarely the correct option. This applies as much to healthcare as to any other aspect of government. However in a time of crisis such as the pandemic there is a need for more rapid and imaginative decision making, which requires a shift in thinking and operational decision making. The decisions made by successive UK governments during 'normal times' to eliminate waste and duplication in the NHS by centralising services, including in pathology [PN/45 - INQ000587088], may have led to a 'centralisation mindset', which as

a consequence hampered the setup of testing in the COVID-19 pandemic. This prioritisation of centralisation was further compounded by the mothballing of mechanisms previously in place for pandemic preparedness.

4.1.2 The way TTI was handled initially when it became clear that increased testing capacity was difficult to put in place, was to centralise testing into the big Lighthouse labs. That was not a bad idea, but what was *not* wise was to think that it could be accomplished in a few weeks, which was logistically impossible. Unfortunately the big labs helped very little with the first phase of the pandemic.

4.1.3 The Crick's decision to set up a testing pipeline outwith the existing system in order to support the local healthcare staff and vulnerable patients probably did not attract attention due to its novelty given a 'centralisation mindset'. We told Government—formally, but also informally many times through our network of contacts and the media—about how the pipeline was helping, and also that we had valuable data regarding the importance of asymptomatic testing of healthcare workers, but the possibility of rapid changes to national testing policy foundered, partly because of the 'mindset' and also because it was unclear who was leading the test and trace policy. There appeared to be a lack of coherence between DHSC, Public Health England and the NHS. None of these bodies appeared predisposed to consider our testing pipeline as a model to alleviate the strain on the existing testing capacity.

4.1.4 We believe that our model for repurposing academic research laboratories as testing centres in times of national emergency should be fully evaluated nationally in any planning for a future pandemic. The reasons are set out below, and our recommendations for how this might be achieved appear at the end of this section.

4.2 The value of small-scale, agile testing hubs

4.2.1 Speed:

4.2.1.1 At the start of any viral pandemic, rapidly suppressing the spread of infection by identifying and isolating those carrying the virus is crucial. Key workers, both symptomatic and asymptomatic, should be the focus of early testing; this is especially important for healthcare workers in order to guard against nosocomial transmission, a known risk factor in a pandemic. It is important to note that this testing capacity should only be aimed at outpatients since accreditation for inpatient testing is an insurmountable barrier for academic research laboratories.

4.2.1.2 Although the DHSC acknowledged the need for this in Pillar 1 of their strategy to scale up testing [PN/46 - INQ000587089] there appeared to be a failure to understand why the utmost speed was important; this document was not published until April 4th 2020. Further, the assertion in this document that the Government was 'working with the best minds in science, industry and logistics across the world to scale up our testing capacity' may overstate the case, as laid out in Section 3 of this submission: there was a failure to embrace the breadth of scientific expertise in the UK.

4.2.1.3 Had the Government used the UK's world class academic research sector by encouraging a mixed economy whereby universities and research institutes got testing hubs up and running with the speed that the Crick proved was possible, testing asymptomatic and symptomatic key workers in the first wave of the pandemic ought to have been possible. Conceivably, lives could have been saved.

4.2.2 Capacity

4.2.2.1 After a slow start, the large, centralised Lighthouse labs were eventually effective in TTI, but expectations that such complex centres would come on-line quickly should have been recognised from the start as being unrealistic. Until they were fit for purpose, a network of smaller hubs such as that being run in the Crick could have at the very least protected the most vulnerable. Our work with local hospitals was important within London and had it been replicated around the country the approach would have played an important role nationally.

4.2.2.2 There was significant capacity in our public universities and medical schools, all of which had been shut down because of the pandemic: a capacity of machinery and expertise that could have supported and serviced not only the needs of local hospitals and healthcare workers but also local outbreaks with a more rapid turnaround than Lighthouse labs.

4.2.2.3 In Section 3 of this submission, we referenced the debacle over the Government's claim they were testing 100,000 samples a day at the end of April 2020. We suggest that had they used the existing research ecosystem, that objective could have been achieved. These labs, both public and private, had the

capacity, a ready-trained cohort of staff, and the correct equipment. They were desperate to help, but they were ignored.

4.2.3 Local integration and demand-led flexibility

4.2.3.1 By nature of its close contact with the local healthcare community, from primary caregivers right through to large NHS Trusts, those operating the Crick's testing pipeline could act rapidly and flexibly in response to local needs. Further, if things went wrong—the IT failed, or samples went missing for example—problem solving was relatively simple; all the people involved knew each other, and could just pick up the phone and work out a fix. Interactions with local clinicians, leading to new collaborations and important research outputs, were also generated by the institute's involvement in testing. If replicated across the country, this model for integration of a research lab into its local healthcare environment would give a flexibility and humanity to the testing process that is conspicuously lacking in a mass testing approach. And as set out above, the rapidity with which such a pipeline could be set up mean that hotspots of immediate need in the healthcare system and other essential services could be catered for in the very earliest stages of any future pandemic.

4.2.4 Feedback into pandemic-related research

4.2.4.1 An unexpected consequence of setting up the testing pipeline was the significant body of COVID-related research that the Crick produced and continues to produce. As detailed in Section 2 of this submission, the samples taken during testing have been valuable in research into evolution of variants, and have also led to important work on the immune responses to SARS-CoV-2, and on the development and efficacy of vaccines, among many other outputs. Further, because the institute could do in-house testing, researchers could quickly come back to work in a COVID-safe environment once lockdowns were lifted, meaning that other COVID-related projects, for example influential studies on the SARS-CoV-2 spike protein, could be pursued.

4.2.5 Early asymptomatic testing with a rapid turnaround

4.2.5.1 Throughout this submission, we have emphasised the extreme importance of implementing rapid turnaround testing of asymptomatic as well as symptomatic healthcare workers (HCW) in the earliest stages of a pandemic. This did not happen, and one of the key messages for the future is that it has to be embedded

in any planning for pandemic preparedness. Such testing should be extended to other key workers dealing with vulnerable groups, and also to the vulnerable groups themselves, including patients, care home residents, and those with healthcare and disability needs being supported in the community. If so, a top priority in any future pandemic should be the need to ascertain if the agent is transmitted from asymptomatic individuals.

4.3 Summary of a way forward

4.3.1 We propose a straightforward plan for initial testing that should be put in place in preparation for any future pandemic. Firstly, 'hot-spots' for infection should be identified, that is places around the UK such as hospitals, care-homes, and other healthcare institutions which require special care because they contain vulnerable patients and individuals as well as their carers, who could spread an infection. In 'normal times' there will be accredited testing pipelines in place supporting these places, which should operate with common standardisation operational and IT procedures.

4.3.2 If a pandemic should occur then that part of the pipeline will already be in place but what is missing is the increased capacity to test. That could be rapidly provided by local biomedical research laboratories, usually found in university and medical schools but also other public and commercial research facilities. Plans should be in place to rapidly repurpose their activities to undertake testing, making use of pre-existing equipment and skilled laboratory personnel, and connect the increased testing to the front part of the pipeline already in place. The Crick has shown that is completely practical, and if appropriate preparation has occurred, this could be put in place even more rapidly than was the case with the Crick. Protection of other local critical workplaces could also be provided should the capacity be big enough.

4.3.3 This is a simple solution, building on pre-existing facilities and using individuals already trained and locally available. Nothing or very little has to be moth-balled, just repurposing what is already there, following already established plans and preparations.

4.4 Recommendations

4.4.1 Setting up a small-scale local testing pipeline

4.4.1.1 Supply chain resilience

1. The UK should have a national stockpile of standardised reagents and/or resilient domestic manufacturing capacity.

2. There should be a clear roadmap for the development of new assays in the early stages of a pandemic (bearing in mind there is likely to be restricted access to control standards and consumables), or a scheme for continual pre-evaluation of emerging technologies as scalable and fast testing platforms.

3. Government should maintain an up-to-date register of the nation's network of research and clinical laboratories, where large amounts of equipment are housed and relevant expertise is available, for rapid repurposing in the event of a pandemic.

4. There should be coordination of production of reagents and testing across the nation's network of research and clinical laboratories.

5. An up-to-date register of staff training across all aspects of testing should be maintained.

6. There should be prior planning for sample collection standardisation in a readily automatable format.

4.4.1.2 Data

7. Urgent action is required to develop common 'platforms' for patient care and data management, procured, managed and integrated system-wide, not at individual trust/body level.

8. Patient data has to be consolidated across platforms into a single patient record, which can be presented via Application Programmable Interfaces (APIs) to allow for key patient data to be shared with, and updated by, approved non-NHS organisations.
9. NHS must invest in technology professionals and skills development system-wide, and dramatically reduce reliance on external contractors and restrictive managed service arrangements.

10. The NHS must 'join the dots' between the many digital policy initiatives and create a single, coherent technology architecture and strategy to deliver all transformation use cases, including pandemic readiness.

4.4.1.3 Clinical testing

11. A pre-pandemic plan should include a list of favoured or approved sites for quick mobilisation, to help prioritise distribution of limited test material, potentially scarce consumable resources, and rapid integration into the reporting system.

4.4.2 Setting up a national network of small-scale testing pipelines

12. A national register of potential hotspots requiring rapid, early asymptomatic and symptomatic testing should be compiled; the register should include hospitals, care homes, and all services caring for medically vulnerable individuals, as well as other essential services.

13. A UK-wide network of not-for-profit prospective 'Dunkirk labs' to serve these testing hotspots in the early stages of a pandemic should be evaluated as part of any pandemic preparedness plan. In the interests of pooling expertise, partnerships between public and private sector labs should be considered.

14. To alleviate worries regarding financing, Government, the research councils and funders should automatically allow research grant funding to be repurposed in the service of a national emergency such as a pandemic and extend both funding and time limits on the original project to compensate.

15. A quasi-independent body similar to the vaccine taskforce and advised by relevant, capable, and multidisciplinary scientists should administer this network to enable scientifically-driven rapid decision-making and necessary changes of direction.

4.4.3 Communication

16. Pandemic preparedness should include establishment of a clear command structure in Government and the NHS, so that all decisions made are accountable.

17. Government communication should as far as practically possible be transparent. Healthcare decisions should genuinely be driven by science, not dogma.

18. A programme to educate the public in how science navigates the unknown should be instituted, to enable better understanding of science-based decision making.

19. A body of scientific experts should undertake review of all preprints pertaining to a pandemic, and a system of universal rapid validation should be established.

LIST OF ACRONYMS USED IN WITNESS STATEMENT

CCC	Crick Covid-19 Consortium
COG-UK	Covid-19 Genomics UK Consortium
CMO	Chief Medical Officer
CRH	Cancer Research Horizons
CRUK	Cancer Research UK
DHSC	Department of Health and Social Care
ERC	European Research Council
HCW	Healthcare Workers
HSL	Health Service Laboratories
HTA	Human Tissue Authority
JCVI	Joint Committee on Vaccination and Immunisation
MHRA	UK Medicines and Healthcare products Regulatory Agency
MRC	Medical Research Council
NERVTAG	New and Emerging Respiratory Virus Threats Advisory Group
NHSE	NHS England
NICE	National Institute for Health and Care Excellence
SAGE	Scientific Advisory Group for Emergencies
SOP	Standard Operating Procedures
STP	(Crick's) Scientific Technology Platforms
TAG-COVAC	Technical Advisory Group on COVIS-19 Vaccine Composition
TTI	Test, Trace, Isolate
UKAS	UK Accreditation Service
UCL	University College London
UCLH	University College Hospitals NHS Foundation Trust
UKHSA	UK Health Security Agency
WHO	World Health Organisation

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 9 April 2025