Witness Name:
Statement No.:
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Dated:

UK COVID-19 INQUIRY

WITNESS STATEMENT OF PROFESSOR KEITH GODFREY

I, Professor Keith Godfrey, will say as follows: -

1. My background is as Professor of Epidemiology and Human Development at the MRC Lifecourse Epidemiological Centre at the University of Southampton and Lead of the Nutrition, Lifestyle and Metabolism Theme of NIHR Southampton Biomedical Research Centre with expertise in epidemiology and molecular testing for research purposes. Alongside this I am a practicing medically qualified Honorary Consultant at University Hospital Southampton NHS Foundation Trust.

2. My involvement in the UK response to the COVID-19 was informed by having previously collaborated in a research capacity with the Hong Kong team that prevented that effectively lead the response to the 2002-2004 SARS outbreak. The work of that team was effective in limiting transmission of infection and preventing what could otherwise have been a global pandemic.

3. During the period pertaining to the Inquiry, my national roles included providing scientific advice to Government on the availability, use and effectiveness of a particular technology (reverse-transcription loop-mediated isothermal amplification (RT-LAMP)) testing for COVID-19 testing, particularly relating to the scope for mass scale RT-LAMP testing in particular settings using saliva samples. On the basis of our experiences in Southampton, I was asked to join the National COVID-19 Mass Testing Scientific Advisory Group, alongside roles on the Universities UK - Government COVID-19 Expert Advisory Panel, the Transmission of COVID-19 in School Children (ToCS) Oversight Group, the UKHSA and MHRA Oversight and

Steering Group, and as expert adviser Department for Education & Department for Health & Social Care national steering group for COVID testing for children with special educational needs and disabilities. Alongside my involvement in the above, I provided advice to international partners, such as senior New Zealand authorities.

4. Once set up, my view is that these advisory bodies operated effectively to mitigate the effects of the pandemic, with the UKHSA and MHRA Oversight and Steering Group being particularly effective in promoting consistency and coordination across the devolved nations.

5. I was not directly involved in the development or decision making relating to NHS Test and Trace, other than the development of the Southampton pilot and providing advice fed through the above advisory groups. The advice that I provided fed into decision making around the development of testing technologies, but I was not personally involved in these decisions, or those relating to tracing, isolation, modelling, public messaging, the use of symptom trackers, engagement with the private sector/non-government bodies or the centralisation of TTI. In the early stages of the pandemic I was part of a group of academics who publicly advocated for a decentralised approach [KG/1]. My personal view is that testing innovation was initially resisted by established NHS providers, who were slow to embrace the need for innovative approaches. Innovation did however eventually overcome the testing capacity challenges arising from global supply chain constraints, a paucity of skilled laboratory staff and the initially limited understanding of the biology of SARS-CoV-2.

Clinical and operational performance of the RT-LAMP test

6. The clinical and operational performance of the RT-LAMP test piloted in Southampton has been published as peer-reviewed scientific publications [KG/2, KG/3]. Use of the saliva RT-LAMP test within the Hampshire Safe and Certain Pilot Project and operation of the pilot has been documented in detail and made available through a peer-reviewed qualitative evaluation for Phase 1 [KG/4] and through a publicly available report for Phase 2 [KG/5]. These and other peer reviewed articles relevant to TTI were shared with UK government policy and decision makers and were embraced by senior government science advisers; in

my view barriers to their effective utilisation included the often limited scientific literacy among senior politicians, particularly in the early stages of the pandemic before effective sharing systems became established.

7. In brief, following our initial description of RT-LAMP for the rapid detection of SARS-CoV-2 in nasopharyngeal/oropharyngeal swab and saliva samples, myself and colleagues undertook a multisite clinical evaluation validating an improved sample preparation method for RT-LAMP. This included testing of RNA extracted from samples (RNA RT-LAMP) and directly on samples without RNA extraction (Direct RT-LAMP) as a faster and more scaleable technology. RNA RT-LAMP was performed on extracted RNA from 12,619 swabs and 12,521 saliva samples and Direct RT-LAMP on 559 swabs and 86,760 saliva samples from asymptomatic and symptomatic individuals across health care and community settings. For direct RT-LAMP, overall diagnostic sensitivity was 70.35% on swabs and 84.62% on saliva, with diagnostic specificity of 100% on swabs and 100% on saliva, compared with quantitative RT-PCR (RT-qPCR). Analyzing samples with RT-qPCR ORF1ab CT values of 25 or below (reflecting high viral loads and likely actively infectious cases), diagnostic sensitivity values were 100% for swabs, and 99.01% for saliva. For RNA RT-LAMP, overall diagnostic sensitivity and diagnostic specificity were 96.06% and 99.99% for swabs, and 80.65% and 99.99% for saliva, respectively. The findings demonstrate that RT-LAMP is applicable to a variety of use cases, including frequent, interval-based direct RT-LAMP of saliva from asymptomatic individuals who may otherwise be missed using symptomatic testing alone.

My personal perspectives on the advantages/disadvantages PCR/RT-LAMP testing

8. RT-LAMP saliva testing advantages (vs PCR testing):

- Automated testing shown to be feasible, using robotic systems, with faster turnaround times and less dependency on skilled laboratory staff
- Could be undertaken directly on saliva samples provided at home/workplaces by individuals, without a requirement for healthcare staff involvement
- Supply lines for equipment and consumables were less problematic than for PCR testing
- Sensitivity was high for samples where the individual was likely to be infectious

- Specificity was high, with a very low false positive rate that enabled decision making on the basis of results
- Results became negative when individuals were no longer infectious, while PCR continued to show positive results while individuals were in the post-infectious recovery phase
- Infected individuals had positive results in the important pre-symptomatic phase of infection, with salivary glands being a primary site of infection and aerosolised salivary droplets being the major mode of transmission
- As compared with self-administered lateral flow tests, the laboratory results could routinely be reported electronically to national contact tracing and monitoring systems.

9. RT-LAMP saliva testing disadvantages:

- Samples had to be processed in a quality assured facility (whereas lateral flow tests could be undertaken without this)
- In clinical settings PCR testing is often preferred, especially for patients who are beyond the initial stages of infection but who are experiencing consequences of that infection – PCR testing shows evidence of the recent infection, while RT-LAMP testing will likely have become negative.

Phases 1 and 2 of the Southampton COVID-19 Saliva Testing Programme

10. The Phase 1 Southampton COVID-19 Saliva Testing Programme assessed the feasibility of weekly community RT-LAMP testing for the SARS-CoV-2 virus using saliva samples collected at home within a partnership between Southampton City Council and the University of Southampton. Immediately on waking in the morning, the saliva samples were self-collected at home into specimen pots, which participants then dropped off at collection points for transfer to the testing laboratory. Direct RT-LAMP testing was undertaken using the OptiGene SARS-CoV-2 assay described above. Between June and October 2020, participants from two general practices in Southampton, staff and students at the University of Southampton and staff and pupils from one infant, one junior, one primary and one secondary school in the city were invited to participate in Phase 1 of the programme. The four schools had catchment areas in more deprived parts of the city, and the pupils were from diverse ethnic backgrounds. More than a quarter of

students at the University of Southampton come from outside the UK. Interactive engagement activities took place alongside the testing programme to maximise uptake of saliva testing, with extensive development and deployment of educational materials targeting different age groups of students and pupils in the schools, alongside work to engage university students.

11. A rapid qualitative evaluation explored the experiences of individuals and organisations who took part, of those individuals who declined to take part, and of those in the educational and healthcare organisations involved in the pilot testing who were responsible for roll-out. This included 77 interviews and 20 focus groups with 223 staff, students, pupils and household members from four schools, one university, and one community healthcare NHS Trust. Discussions revealed that high levels of communication, trust and convenience were necessary to ensure people's engagement with the programme. Participants felt reassured by and pride in taking part in the novel programme. They suggested modifications to reduce the programme's environmental impact and overcome cultural barriers to participation. The insights generated and informed the design and modification of the Southampton COVID-19 Saliva Testing Programme and the next phase of community-testing.

12. Key messages from the evaluation were that participants' and stakeholders' motivations, challenges and concerns need to be understood and these insights used to modify the programme in a continuous, real-time process to ensure and sustain engagement with testing over the extended period necessary. Community leaders and stakeholder organisations should be involved throughout programme development and implementation to optimise engagement.

13. The Southampton COVID-19 Testing Programme Phase 2 Study conducted saliva testing successfully in educational settings between September 14th and October 31st 2020. Staff, students/pupils and contractors at four schools (an infant, junior, primary and secondary) and at the University of Southampton were included. The contract was initiated on August 3rd 2020, though planning had started before that date. Phase 2 drew heavily on the systems and procedures used in Phase 1, with most of the multi-disciplinary team involved in Phase 1 continuing into Phase 2,

with extra expertise, particularly in relation to schools, being added. It established the feasibility, acceptability and utility of saliva testing in schools and the University. Key factors in its success were:

- Continuity of expertise and the learnings from Phase 1
- Highly motived, creative and engaged team members
- Early establishment of governance, programme management and workstreams
- Strong engagement from the leaders of the schools, the university and local government
- Well-developed laboratory, IT, enquiries and case contacting systems
- Good liaison between all partners
- Excellent communications and engagement materials
- Bespoke educational materials developed to meet the needs of teachers in the classroom
- Timely feedback from participants, leading to rapid and iterative modifications.

14. A significant step in Phase 2 was the development of the legal framework to enable mass transfer of personal details from the schools to the NHS systems, so that registrations could be conducted for each school with the option for staff or parents to opt-out. Asking parents to register their children individually would have reduced participation and increased inequalities in access to testing. The legal frameworks adopted were shared with the government Department for Education and developed as the basis of the legal framework for other testing programmes. External contractors (e.g. cleaning services) at the schools opted-in to the system by contacting the enquiries team at Southampton City Council Customer Services. Testing in two schools started on September 21st with the remaining two schools starting on September 28th. In total, 7,549 tests were conducted by staff and pupils in the four schools before the half term week.

15. Some 2,284 school staff, contractors and students were registered for the programme and of these 2,043 (89.5%) in the four schools submitted at least one sample during the testing period. Engagement of the schools, both pupils and staff, was high, and the schools warmly welcomed the testing programme. During the testing period, only three pupils tested positive and no staff or contractors. During the pilot, with regular testing and high participation rates, there was no evidence

of any within school transmission of infection whatsoever. Inconclusive results, which were due to insufficient or occasionally a leaked sample occurred in 57 of the 6,162 tests in pupils (0.9%).

16. Within the University, a different approach was used in that students were asked to register themselves, thus an opt-in approach rather than opt-out. University staff and contractors were not invited but were asked to register for testing if they fitted certain risk criteria, and this was a self-selection process; testing capacity was limited so eligibility focused on those most exposed to others. Testing of university students started on September 14th; though uptake was slow initially as most students had not arrived in Southampton by then. University staff started testing on October 5th. In total, 19,458 tests were conducted by University staff and students by October 31st. In time for the last week of testing, 12,353 students had registered for the programme and so were eligible to have done at least one test within Phase 2. Of these, 77.9% provided at least one sample. This compares with 18,823 students registered at the University of Southampton, but not all of these would have been in Southampton as they were studying online elsewhere, or were on placements. Some 1,593 staff and contractors registered and 18.5% provided at least one sample. Positive tests occurred for 56 students but none for staff. During the time period covered by the programme, test positivity rates increased exponentially in Southampton and in almost all other universities, but such a rise was not seen in the University of Southampton population in spite of continuation of some face-to-face teaching; the regular testing programme was felt likely to have contributed to this suppression of transmission. Inconclusive results, usually due to inadequate saliva sample were not common, occurring in 29 of 28,572 tests (0.1%).

17. The Animal and Plant Health Agency laboratory conducted all the testing, as in Phase 1. The methods for the Direct-LAMP testing were refined further and a full protocol has been produced and is provided in the published programme report as an Appendix to section 2e of the [KG/5] report. The number of tests per day that could be conducted was limited to a maximum of 2,000, so modelling and monitoring the numbers was a necessary part of this Phase. The 2,000 limit was never breached. The percentage of results that were reported to participants within

24 hours of receipt in the laboratory was 97%, and 95% were reported within 12 hours.

18. Sophisticated IT systems were developed to manage the registrations, label printing, linking participants to their results, storing results and communicating them to participants. Results were made available to the GP-led Case Contacting Team (CCT) through the Oracle Application Express (APEX) system and to feed into the participants' GP records. The CCT reminded those testing positive to inform their school or the University. Positive results were sent to NHS Test and Trace.

19. Southampton City Council's Customer Service Team, who were already established, were equipped to deal with enquiries also had to have access to certain information, though they did not see actual test results. These systems were highly developed through Phases 1 and 2 and were being rolled out in other parts of the country where testing was being undertaken.

20. A steering group comprising senior representatives from each of the partners was formed – this included the University, Southampton City Council, the University Hospital Southampton and the Southampton City Clinical Commissioning Group. The steering group provided strategic guidance for the programme, while the operational activities were directed by a programme management group that met every weekday. The members of this multi-disciplinary team were highly committed and motivated to make the testing scheme work. Expertise required included: project management, business analysis, logistics, procurement, law, communications, engagement, education, finance, university and school organisation, public health, clinical, epidemiology, statistics, laboratory procedures, handling enquiries and evaluation. Work stream groups were established for key elements of the programme as in Phase 1. They met frequently, sometimes daily, to keep the work on schedule and to iron out difficulties rapidly when they arose.

21. Successful engagement of participants was key to the success of the programme. Schools were highly motivated and all schools worked extremely hard to engage

their staff and pupils. Highly successful education and engagement materials for both primary and secondary school students were designed and delivered in the schools by our LifeLab scientific literacy team and material was translated into seven languages to assist parents. This was accompanied by continuing professional development for the school staff. All these aspects were highly valued by students and staff, and undoubtedly contributed to the success of the programme. Based on our insights into science for health literacy to reduce COVID-19 transmission through engagement with testing and other measures, the University received funding from Department of Health and Social Care (DHSC) to develop educational materials for national application focused on young people's decision-making and resilience to support themselves and their communities.

22. Engagement with university staff and students was by email, text, social media and university websites. It was noted that it was hardest to engage the older secondary school pupils and the university students. Participant experiences were captured and revealed a variety of reasons why some people did not engage in the programme or only took part occasionally. These are described in detail in sections 2d and 3d of the report [AB/5].

23. Building on the work of the Enquiries Team in Phase 1, Southampton City Council Customer Services took on the enquiries function for Phase 2. They were open seven days a week, but the hours of opening were tailored to demand through the programme. They had received 1,095 calls and 694 webchats by October 31st 2020.

24. As in Phase 1, Southampton Primary Care Ltd (SPCL, the local GP federation) provided the GP-led Case Contacting Team. They contacted those who tested positive and those with inconclusive results. They assessed isolation, public health, clinical presentation and social support issues, and advised or signposted accordingly. A core Case Contacting Team (CCT) was also established comprising public health consultants, public health academics and public health specialty registrars. This team provided operational management of the SPCL Case Contacting Team, and provided public health oversight and input to all aspects of the programme.

25. The programme was warmly embraced by Southampton City Council as a contribution to the efforts to contain the pandemic. Dr Debbie Chase, Director of Public Health commented as follows:

"As Director of Public Health for Southampton, I am very proud to support the Southampton saliva testing pilot programme. This ambitious and innovative testing programme is offering us a more frequent, easier to undertake tests to better protect our residents. In the second Phase of this pilot, we are assessing provision of testing in some of our schools and at the University of Southampton. To date, experience of testing has been very positive and has provided reassurance to students, staff and their families. It has offered an opportunity for our educational settings to continue to provide a high quality educational experience for our children and young people whilst enabling extra vigilance in managing the risk of COVID-19 through the regular testing approach. I look forward to reviewing the results of this second Phase and the potential for the third Phase of this programme."

26. Under Phase 3 of the programme, testing continued in the four schools and the University, with 51,022 tests completed as of 14th November 2020. All positive tests were confirmed by E gene PCR and no false positives were recorded. E gene PCT CT values for the positive samples ranged from 17.4 to 34.0, similar to the range of CT values seen in cell culture positive samples in published reports. Governance subsequently moved to University Hospital Southampton NHS Foundation Trust, with roll out of robotic methods to automate testing with a capability of processing more than 10,000 samples daily.

Inequalities

27. Consideration of groups disproportionately impacted by COVID-19 was a prime driving force behind the development of the Southampton pilot, seeking to mitigate the effects of the pandemic on minoritised groups, on the education of children and young people, and those with preexisting health conditions or special educational needs and disabilities. My work in this area included the development and dissemination within schools of videos in multiple languages, co-produced with children, and the generation of augmented alternative communication materials

appropriate for children with special educational needs. Saliva testing provided a valuable means of testing children with severe disabilities, many of whom struggled with traditional naso-pharyngeal swab collection. Such measures should be prioritised at the earliest stages of any future pandemic.

Personal perspectives on test, trace, isolate system readiness as at 1 January 2020

28. I had no personal knowledge of the systems in place as of this date. My subsequent involvement made it clear to me that effective systems were not in place for any of testing, tracing or isolation. Between January and March 2020 I was not involved in COVID-19 decision making, so am not able to comment on prioritisation of TTI.

Personal perspectives on lessons in planning for the event of a future pandemic

29. In the event of a future pandemic, my personal perspectives include:

- Early government and arms-length organisation engagement with the wider national and international academic and public health community to better inform decision making in relation to testing, tracing and isolation; in the COVID-19 pandemic engagement with this community was delayed and initially ad hoc, dependent on the academic and public health community "reaching in" to provide advice, with limited "reaching out" by Public Health England and policymakers.
- Ensure that there is a strong infrastructure within the national life sciences infrastructure that can respond to national emergencies without reliance on global supply chains for testing hardware and consumables.
- Retain the memory on the lessons learnt from the COVID-19 pandemic in relation to the legal and digital infrastructure for mass testing.
- Focus on rapid turnaround tests that can be undertaken at scale, that become positive during any presymptomatic but still infectious phase and that become negative when individuals are no longer infectious but may nonetheless excrete viral remnants.

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 in its truth.

Signed: Personal Data

Dated: 30th April 2025

AB/1. Peto J, Alwan NA, Godfrey KM, Burgess RA, Hunter DJ, Riboli E, Romer P; 27 signatories. Universal weekly testing as the UK COVID-19 lockdown exit strategy. Lancet. 2020 May 2;395(10234):1420-1421. doi: 10.1016/S0140-6736(20)30936-3. Epub 2020 Apr 21. PMID: 32325027

AB/2. Howson ELA, Kidd SP, Armson B, et al, Godfrey KM, Fowler VL. Preliminary optimisation of a simplified sample preparation method to permit direct detection of SARS-CoV-2 within saliva samples using reverse-transcription loop-mediated isothermal amplification (RT-LAMP). J Virol Methods. 2021 Mar;289:114048. doi: 10.1016/j.jviromet.2020.114048. Epub 2020 Dec 20. PMID: 33358911

AB/3. Kidd SP, Burns D, Armson B, et al, Hill SL, Godfrey KM, Fowler VL. Reverse-Transcription Loop-Mediated Isothermal Amplification Has High Accuracy for Detecting Severe Acute Respiratory Syndrome Coronavirus 2 in Saliva and Nasopharyngeal/Oropharyngeal Swabs from Asymptomatic and Symptomatic Individuals. J Mol Diagn. 2022 Apr;24(4):320-336. doi: 10.1016/j.jmoldx.2021.12.007. Epub 2022 Feb 2. PMID: 35121140; PMCID: PMC8806713.

AB/4. Watson D, Baralle NL, Alagil J, et al, Godfrey K, Barker M. How do we engage people in testing for COVID-19? A rapid qualitative evaluation of a testing programme in schools, GP surgeries and a university. BMC Public Health. 2022 Feb 14;22(1):305. doi: 10.1186/s12889-022-12657-4. PMID: 35164728; PMCID: PMC8842975.

AB/5. Godfrey K, Southampton COVID-19 Testing Pilot Programme. Evaluation of the expanded Southampton pilot study (Phase 2) for use of saliva-based lamp testing in asymptomatic populations: Final report, 16th November 2020 Southampton. University of Southampton 120pp. Epub 30 Dec 2020. doi:10.5258/SOTON/P0045https://eprints.soton.ac.uk/445622/