

THE LABORATORY RESPONSE TO THE COVID-19 PANDEMIC

This document on the necessity for a local Public Health laboratory capability is submitted as a contribution to the consideration of the problems encountered in the Government's response to the Covid-19 pandemic as it affected England and the United Kingdom overall. The authors are a group of retired or part-retired Consultant and Clinical Academic Medical Microbiologists with a combined experience of more than 130 years tackling infections as Consultants and Senior Managers and Directors in the NHS, Public Health Laboratory Service (PHLS), Health Protection Agency (HPA), Public Health England (PHE) and the Department of Health.

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Summary

There is a need for the government to be advised by people who deliver public health microbiology to support the translation of scientific suggestions into action. The fragmented microbiology service has become more fragmented and progress in networking is still “in hand” 18 years after it was suggested at the dissolution of the Public Health Laboratory Service. There are no clear service standards for microbiology that might clinically underpin service delivery and modernity or inspection by those concerned not just with process but also outcomes. The quality assurance benefits of accreditation have been abandoned in favour of private sector Lighthouse laboratories with unknown quality assurance performance and a temporary volunteer workforce and equipment from outside the NHS. Each laboratory has a clinically qualified advisor. The public health microbiology service has recently been tendered in yet another politically driven reorganisation. Laboratory networks formed by “Pathology Modernisation” do not all have molecular virology capacity and do not match geographically to existing health protection teams which have also been side-lined by a commercial track and trace programme of dubious effectiveness. PHE, unlike the PHLS and HPA, is now an agency of the Department of Health and has no political independence enabling it to communicate publicly.

Educational changes mean that certified medical microbiologists can no longer be assumed to have adequate virology and molecular experience. The curriculum for microbiologists outside PHE includes no training secondments in epidemiology or control of communicable disease thus creating a restrictive public health silo for infection matters. Training programmes for clinical scientists in microbiology are in disarray. Nevertheless, the experience of the existing workforce should be properly used and we believe that the NHS in collaboration with academic centres, is the place where public health microbiology should be sited - in labs accredited for process and quality assurance performance, harnessing innovation and spinning this off into a new British diagnostics company as appropriate. The ever-changing nature of the microbial threats the NHS has dealt with in the last 30 years, and will continue to experience, means that the communicable -disease control mechanisms will always be in demand and should be integrated into the NHS. The future needs investment in scientists and modern open molecular equipment building on the existing nucleus of long practical experience and expertise, before existing hard-won NHS experience and academic international status is dissipated.

Background

As Covid-19 began to spread rapidly across Europe, the UK Government initially adopted the traditional method of case finding based on symptoms and travel history, testing using rt-PCR (reverse transcriptase Polymerase Chain Reaction) and isolation of cases. Their contacts were traced as far as possible, placed into quarantine for 14 days and similarly tested. Early in March, this approach was abandoned and testing was restricted to patients admitted to hospital in order to manage the clinical and organisational challenge facing the NHS. SAGE and the test selection, evaluation and procurement advisory group had no NHS clinical virology non-reference-laboratory representative. The papers released from SAGE and statements at news conferences by the Chief Medical Officer and the Chief Scientist have confirmed that the UK abandoned the test, isolate and contact trace approach to Covid-19 at such an early stage because of the inadequate capacity and capability of Public Health England (PHE) to deliver this World Health Organisation (WHO)- recognised and necessary approach to controlling the pandemic. Local services which could have identified recently arrived travellers from hot-spots had been disconnected from a centralised capability to test. Molecular finger printing of those early isolates of virus (not led by PHE) have shown that over thirteen hundred separate introductions

(<https://www.bbc.co.uk/news/health-52993734>) occurred supporting the contention that early decisive persistence with this track and trace action would have probably contained the disease. The targeted test and trace approach so successfully used in South Korea, Hong Kong, etc was replaced by a population wide “lockdown” to reduce person to person contact in the general community.

The Central Reference Laboratories (CRL) of PHE had rapidly developed an rt-PCR test for the virus based upon published genetic sequences. This local test, was not the same as a pan-European validated test in which the reference laboratory had participated (Corman *et al.* European Communicable Disease Bulletin 25(3) 2020 01). When the CRL test was compared with tests developed in two of PHE’s local laboratories it appeared to be relatively insensitive. Evaluation and scientific creativity amongst a network of centres of excellence is important rather than relying on a single centre. However, the evaluation and decision-making was slow, perhaps partly because 19 commercial systems were said to be available for different platforms by mid-March (<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf>). The time line of the English development is shown in Appendix 1. Prompt and efficient contact tracing and quarantine requires the fast deployment of a rapid test through a network of microbiology/virology laboratories covering the entire country that can be mobilised and coordinated rapidly. The Central Reference Laboratory is not designed to be a mass testing centre and has limited capacity; its fundamental role should have been to collect evaluation samples and rapidly and then continuously compare available tests and ensure roll-out of the most suitable as well as providing a quality control service for the laboratory network. Unfortunately, PHE had access to few laboratories under its own management into which it could deploy the testing. The historical evolution of the weakened situation of the current PHE Infection Service is explained in Appendix 2. For whatever reason, PHE and NHS England did not have arrangements in place with sufficient NHS and academic laboratories to successfully expand the testing capacity. NHS England on 16th March 2020 had specified roll out of up to 500 tests/day in total in the NHS including only 3 non-PHE laboratories (Newcastle, Leeds and Southampton) additional to 4 London laboratories already performing the test. (<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf>). The low target for daily testing suggests underestimation of the testing need and that non-PHE laboratories were not equipped with open PCR platforms with the easily attainable capacity of approximately 1500 tests/ thermal cycler/ day. At least some local PHE and many NHS laboratories never saturated their capability in the course of the first wave of the pandemic because of a change in testing policy. There was initially a shortage of reagents and equipment for PCR (Appendix 1). After some weeks the government implemented taking of samples and testing through the army and the commercial sector respectively. When this occurred is not evident in SAGE minutes (Appendix 1). These laboratories became known as the Lighthouse Laboratories. As rapidly constituted laboratories they did not have UKAS accreditation and their quality assurance programmes for tests were, and remain, uncertain. They were only equipped by requisitioning PCR platforms from academic departments together with staff from such departments This enabled a much-increased testing capacity but through a system totally separate from the NHS which, because general practice was not directly involved, meant that results did not automatically become part of the individual’s health record or be necessarily notified to one of the 21 dispersed PHE health protection teams (see Appendix 3), an essential linkage for advice for households and contact tracing. Consequent on the separation of initial testing from local NHS and PHE services, similar track and trace systems in the commercial sector replaced PHE’s health protection teams working with Directors of Public Health. It remains to be seen at the time of writing how successful this disjointed test and trace system is in controlling further spikes of infection. There is a possibility of further permanent change to not just testing for SARS CoV2 but the whole of

public health microbiology by the placing of a tender of an approximate value of £5bn for all such services in a new Microbiology Framework by PHE (<https://ted.europa.eu/udl?uri=TED:NOTICE:263375-2020:TEXT:EN:HTML>).

Future provision of a service fit for purpose

New infection problems in man and domestic animals continually emerge from the huge microbial world and we must be prepared to defend ourselves. In the last 25 years, 5 different significant viruses from animals have emerged causing varying levels of disease in humans (Nippah, Zika, SARS, MERS and SARS CoV2 (Covid-19)). The UK will thus be faced with this threat again in the near future. In the last 35 years, the NHS in England has dealt with national epidemic threats extending across healthcare and the community from Salmonella, Listeria, HIV, MRSA, Clostridium difficile, influenza shifts, and Gram-negative strains with multiple antibiotic resistance, evolving, as appropriate, from using 19th century culture methods to molecular testing. The NHS was supported in this until 2003 by the PHLS laboratory network across England and Wales and until 2013 by the much reduced HPA network. Covid-19 would have challenged any laboratory testing system, but PHE has been shown to be unfit for purpose in this respect and unable to lead capability and deploy new diagnostic tests rapidly to laboratories outside its control or manage extensive contact tracing. We believe the capability would be much stronger if the recommendations of two previous substantial CMO reports had been enacted in full rather than in part, although we believe the decision to transfer many Public Health Laboratories to the NHS exposed the country to risk. The detail is described and analysed in Appendix 3. Reform is much needed and should ensure that the country has an NHS and academic laboratory capability for public health to continue to deal with the present microbial challenge and be adequately equipped for the next one. We believe past capability and performance justifies the NHS hosting and being responsible for, the public health laboratory response to communicable disease. Further, this response is core to protecting the NHS from epidemic surges.

There are 119 accredited microbiology laboratories with hospital addresses or services in England (https://www.ukas.com/browse-accredited-organisations/?org_cat=850&parent=Medical%20Laboratories&type_id=7&cpage=1). This is a three-fold reduction on 18 years ago. They serve 769 hospitals (<https://www.interweavetextiles.com/how-many-hospitals-uk/>). Ninety of the laboratories in England and 14 in the devolved administrations are currently accredited for virology (See Appendix 3), Fewer than half are overseen by consultant scientific or medical virologists (See Appendix 3). Accreditation in laboratories is a fair measure of quality since it involves defined standards and external review. The accreditation process will need adjusting so network laboratories providing off-site services to other hospitals are themselves satisfactory in turnaround times and advisory services.

The DH Pathology Modernisation Programme through NHS Improvement is committed to creating hub and spoke arrangements by 2021 based on 29 pathology networks across the hospitals in England (<https://improvement.nhs.uk/resources/pathology-networks/>). Costing but not service delivery is well reported. Savings of £200m on a base cost of £2.2bn are anticipated by 2021 but it is not clear if there is any commitment to improving turnaround times in diagnosis of organisms causing infection or their susceptibility to antivirals or antibiotics, nor how savings will impact on microbiology capability and surge capacity. Nine of the 29 networks lack consultant virologists.

Test results identify which individuals have infection. Covid -19 is legally a notifiable infection and the person notified would be a Consultant in Communicable Disease Control serving in one of 21 local health protection teams of PHE (<https://www.gov.uk/guidance/contacts-phe-health-protection-teams> last accessed 18/6/2020). These teams are responsible for identifying outbreaks and contact tracing. Directors of Public Health also have contact

tracing teams in their local authorities of which there are 367 in England (<https://www.registers.service.gov.uk/registers/local-authority-eng>).

To respond to a future pandemic, and even epidemics far less catastrophic than Covid-19, a formally co-ordinated national network of microbiology and molecular virology laboratories is needed and this should include all NHS microbiology/virology networks and those academic departments with research interests in these fields. A similar informal network, the Clinical Virology Network, already has offered to fully employ its underutilised expertise in tests for SARS CoV2. This is not an attempt to recreate the centrally managed laboratory network of the PHLS, which would not be appropriate or feasible in the present NHS landscape. The expertise and innovative capacity of NHS and clinical academic laboratories across the country should be harnessed and could also repair the British diagnostics industrial capability, which in the last 30 years has become very restricted but remains critical for reliable national reagent supply and defence. A recent market survey (<https://www.marketwatch.com/press-release/ivd-infectious-diseases-market-size-and-growth-rate-2020-global-impact-of-covid-19-on-industry-share-explosive-factors-of-key-players-progress-status-and-recent-trends-forecast-to-2026-2020-06-19>) found no British company amongst 15 global players. Academic laboratories should all consider accreditation for diagnostic testing with appropriate quality assurance. This is currently the case for NHS and PHE laboratories but would be an additional requirement for some of the otherwise excellent academic laboratories whose main function is research but which have the skills, equipment and capability to contribute to the national need in times like this. Qualified biomedical and clinical scientists are required in their staffing and their diagnostic testing services should be overseen by medical and scientific Consultants and Honorary Consultants in Medical Microbiology with joint academic status and involvement. Such an approach would provide a service closely linked to all parts of the NHS and the results of the testing would inform both individual clinical care and the public health and epidemiological requirements for protecting the population during such emergencies. A review of the Central Reference function of PHE by an independent panel is needed to consider whether some dispersal to such academic and NHS centres of excellence within a network of evaluation centres would be advantageous (See Appendix 2). Optimal local microbiology and virology provision including expertise in response to epidemics, and national coordinated responses involving these and the reference facilities, wherever sited, are essential and are not a feature of any other branch of pathology.

The roll out to the NHS of innovative, fast turnaround molecular diagnostics for novel agents such as SARS CoV2 will need to be organised, sustained by training and experience, and include rapid evaluation response. Rapid deployment from sequences of emergent pathogens to testing in many laboratories with the same pre-validated test requires versatile thermal cyclers and liquid handling automation, and their associated base reagents, in all pathology networks; not just tests limited to manufacturer-based machines tailored and restricted solely to their own kits, which require time-consuming evaluation of the tailored kit in an emergent infection. National procurement expertise on behalf of all Pathology networks is needed to ensure the same assays can be rolled out from academic and reference centres throughout the service and secure best value for money. Such versatile capacity would be used under normal circumstances to support routine molecular tests but could be rapidly redeployed in the NHS in a major national epidemic (viral, bacterial, antibiotic-resistant, community or healthcare-acquired) and this should inform procurement as to configuration. Machine capacity to perform multiple different or one predominant test can easily be specified with many machines commonly capable of 1500 tests/day. New technology brings even greater capacity but linkage to health records and deduplication of repeat tests are the Achilles heels of over-centralisation and multiple machines may be preferable for resilience and to cater for standardised expansion.

The establishment of an executive coordinated network of networks building on both existing Clinical Virology and Pathology networks would require investment for the co-ordinating structure and initial outlay for equipment for extra capacity and flexibility to respond rapidly to a national need. The outlay is small compared with that already spent on commercial sector service provision. A budget for trained staffing and reagents is necessary. Maintaining public health outputs in former PHLS laboratories was damaged at the dissolution of the network by a lack of a small reserved central budget for work other than their local diagnostic service and preparedness was damaged by dispersal of capital funding to NHS trusts who used it elsewhere (Appendix 2). The experience of Covid-19 has shown how valuable the retention of a co-ordinated national network in some form could have been.

Our suggestions for future actions, based on the current experience and a review (below) of reports and strategy documents published over the last 30 years during which we were responsible for delivering clinical and public health microbiology services are shown in summary form in Table 1.

Acknowledgements: We thank Professor Deenan Pillay for advice especially on the time course of events shown in Appendix 1.

Table 1 Existing problems and suggested solutions

Problem	Suggested solution
Lack of critical mass of current PHE laboratory network	Add to network, but under NHS coordination not PHE management, widely distributed academic laboratories capable of reference function and also large existing laboratories with evaluation role
Weakness of national service workforce of clinical scientists and doctors with molecular training	Reinstate and rapidly reinforce clinical scientist and medical training in molecular techniques in all networks including PHE
Absence of HM Inspector of Microbiology, regional coordinators and lead public health microbiologists in microbiology laboratory networks to champion threats identified at frontline.	<p>Appoint these people.</p> <p>Give HM Inspector of Microbiology remit to organise coordination and network of networks, network relationship with academic institutions and national staffing changes. Give HM Inspector power to inspect healthcare and network laboratories, regulate national requirements, issue enforcement notices and financial penalties.</p> <p>Lead Public Health Microbiologists to take back management of regional Public Health Laboratories</p> <p>Each Pathology network to appoint an existing consultant to lead on public health microbiology and national priorities.</p>
Fragmentation of laboratory services and inequality in provision of molecular tests.	<p>All microbiology laboratories to be network associated within 1 year with commitment from trusts and local authorities (sexual health testing) to utilise the local network and fund it and its management. Bring sexual health and cervical papillomavirus PCR testing within local networks to also sustain molecular work.</p> <p>Central NHS procurement (after evaluation) to build capacity of versatile open-system* PCR equipment for all networks to ensure timely transferability of testing in emergency and adequate resilient capacity. Ensure molecular testing in admitting hospitals with turnaround within 4 hours (preferably 2).</p>
Accredited virology capacity staffed by specialist virology consultants with molecular expertise missing in many pathology networks	<p>Ensure each pathology network has certified scientific or medical consultant virologists to ensure improved resilience and capability.</p> <p>Arrange secondment of those with virological responsibilities (medical microbiology consultants and clinical scientists) to molecular-competent laboratories for molecular training and specialist certification. Temporarily, with appropriate sustaining, augment training</p>

	<p>numbers in virology with a view to consultant appointments and increase number of Band 8 scientists of consultant status with FRCPath. Augment front-line molecular testing as well as providing reference facilities, external quality assessment and accreditation for molecular services.</p> <p>Restore training in public health microbiology for medical, scientific and BMS staff.</p>
Development of new SOPs, tests and evaluation vested only in reference laboratories	<p>Network of networks charged with development of these with central PHE support. Evaluation re-organised using funded field-collected panels, and rapid field testing in designated evaluation centres or networks analogous to blinded multi-centre clinical therapeutic trials, with support from NIHR.</p> <p>Avoidance of closed system leasing and reagent deals without transparent competition on reagent costs. New tests from commercial sources independently pre-assessed but manufacturer-funded (as in National Blood Service) SOPs, reagents and open PCR equipment should permit national inter-laboratory transferability of assays**.</p>
British diagnostic companies not global players	<p>Ensure procurement of reagent and laboratory equipment with supplies for molecular testing favouring British companies. Co-develop marketable evaluated molecular assays using academic spin-off expertise to create innovative diagnostics with global sales potential. Permanently protect associated NHS supply interests.</p>
Communicable disease epidemiological data not easily visible for operational purposes to laboratories and CCGs	<p>Separate out for interrogation easily-usable open operational deduplicated anonymous data on communicable disease including syndromes, organisms and antimicrobial susceptibility. The English Surveillance Programme for Antimicrobial Utilisation and Resistance is an example in one area of microbial surveillance that works.</p> <p>Re-introduce an English Communicable Disease Surveillance Centre</p>
Health protection teams not coterminous with laboratories or local authorities and not integrated with other infection professionals such as hospital infection control teams.	<p>Bring health protection teams into the NHS Plan to strengthen with proximity and co-terminosity with pathology networks including clinical commissioning groups and local authorities served</p>

*The delay in commercial developments for closed systems is too great in an emergency such as a pandemic. Roll out capability in machinery needs to be pre-provided not just in PHE regional labs but in the NHS Virology labs which outnumber them to provide capability and resilience. A national network of microbiology networks would achieve national and emergency planning and operations. Whatever standing network committee is synthesised should develop emergency plans for testing evaluation and roll-out within approximately a 6-week period.

** For example, one of us (PH) as the regional microbiologist and director of the regional laboratory, transferred all faecal testing from Birmingham to Manchester so staff were freed up to provide 4 runs/day of flu PCR testing.

Appendix 1. Timeline of advice on testing to UK government from Scientific Advisory Group for Emergencies (SAGE) and actions.

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Date	Information	Link
10/01/20 Literature	First sequence published	https://virological.org/t/novel-2019-coronavirus-genome/319
22/01/20 SAGE 1 meeting	“The UK currently has good centralised diagnostic capacity for WN-CoV – and is days away from a specific test, which is scalable across the UK in weeks. The sensitivity of the test is currently unknown. There are conflicting reports of the sensitivity of diagnostic tests from upper respiratory tract sampling.”	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888767/S0369_Precautinary_SAGE_meeting_on_Wuhan_Coronavirus_WN-CoV_.pdf
28/01/20 SAGE 2 meeting	“Diagnostics: Specific test should be ready by the end of week, with capacity to run 400 to 500 tests per day. Guidance being rolled out to laboratories in the UK. Sensitivity of test unclear, particularly in early phases of illness or when symptoms are mild. Currently it would not be useful to test asymptomatic individuals, as a negative test result could not be interpreted with certainty.”	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888769/S0370_Second_SAGE_meeting_on_Wuhan_Coronavirus_.pdf
04/02/20 SAGE 4 meeting.	“Although the UK is building regional diagnostic capability within weeks, overall capacity is limited. Capacity cannot be substantially increased during this winter influenza season.” “ACTION: UK science coordination group for WN-CoV, which includes GCSA, CMO (NIHR), PHE, DfID, FCO and research funders, to consider whether the UK can accelerate diagnostic capability to include WN-CoV alongside regular influenza testing before the onset of the winter influenza season”	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888771/S0372_Fourth_SAGE_meeting_on_Wuhan_Coronavirus_WN-CoV_.pdf
10/02/20 Press release	Start of PHE rollout of rt-PCR tests from Colindale to 12 UK wide laboratories	https://www.gov.uk/government/news/phe-novel-coronavirus-diagnostic-test-rolled-out-across-uk
11/02/20 SAGE 6 meeting	“It is not possible for the UK to accelerate diagnostic capability to include Covid-19 alongside regular flu testing in time for the onset of winter flu season 2020-21. Validated serology for clinical use in the UK is around 4 to 6 weeks away. Singapore and Hong Kong are close to validated serological capability.”	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888774/S0374_Sixth_SAGE_meeting_on_Wuhan_Coronavirus_Covid-19_.pdf
18/02/20 SAGE 8 meeting	“Currently PHE can cope with five new cases a week (requiring isolation of 800 contacts). Modelling suggests this capacity could be increased to 50 new cases a week (8,000 contact isolations).” “Out of the 9 confirmed UK cases, 7 have had genetic sequencing. Samples taken from the respiratory tract appear to be most reliable for testing, with some positive detections in faeces.”	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888776/S0376_Eighth_SAGE_meeting_on_Wuhan_Coronavirus_.pdf

	<p>14. There has been no positive detection from blood or urine so far. This suggests that the transmission route may be faecal-oral alongside respiratory (e.g. coughing and sneezing) and contact. 15. Detection appears most straightforward shortly after disease onset when viral load is higher, with viral detection usually gone after 10-12 days.” “Serology testing will not be available for several weeks.”</p>	Covid-19 .pdf
<p>25/02/20 SAGE 10 meeting</p>	<p>“PHE continue to focus on contact tracing if cases are confirmed. PHE is sourcing commercial solutions for point of care testing in hospitals as a priority.”</p>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888777/S0378_Tenth_SAGE_meeting_on_Wuhan_Coronavirus_Covid-19_.pdf
<p>10/03/20 SAGE 14 meeting</p>	<p>“PHE has a serology test up and running for population-level analysis. Analysing greater volumes of samples is now the priority. A test for frontline diagnostics may come from the private sector.” ...”It was reported that all pneumonia cases in hospital are now due to be tested.” “ACTION: PHE and NHS to report at the next SAGE meeting (12 March) on:</p> <ul style="list-style-type: none"> * Whether currently available capacity for population-based serology for Covid-19 is being fully exploited * Plans for how PHE can move from 1,000 serology tests to 10,000 tests per week * Whether all intensive care pneumonia cases are being tested for Covid-19 (as per current policy) * Plans for consideration of commercial tests for frontline healthcare use 	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888782/S0382_Fourteenth_SAGE_meeting_on_Wuhan_Coronavirus_Covid-19_.pdf
<p>13/03/20 SAGE 15 meeting</p>	<p>"Community testing is ending today – which will increase the pace of testing (and delivery of results) for intensive care units, hospital admissions, targeted contact tracing for suspected clusters of cases and healthcare workers. This includes faster confirmation of negative results..... The current limiting factor on serology is availability of samples. This needs to be resolved as soon as possible... ACTION: PHE to urgently determine how it will ramp up to take 1,000 blood samples a week, taking advice from SAGE participants. PHE to contact Italian counterparts to request serology samples. If available, PHE to test these samples to ascertain symptomatic vs asymptomatic case ratio.”</p>	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888783/S0383_Fifteenth_SAGE_meeting_on_Wuhan_Coronavirus_Covid-19_.pdf
<p>16/03/20 NHS Letter and SOP</p>	<p>Letter on NHS Roll-out of molecular tests and Standard Operating Procedure</p>	https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/guidance-and-sop-covid-19-virus-testing-in-nhs-laboratories-v1.pdf

<p>16/03/20 SAGE 16 meeting</p>	<p>"SAGE highlighted the critical importance of scaling up antibody serology and diagnostic testing to managing the epidemic. A solution is urgently required, with a plan for implementation. Antibody testing is particularly vital to address the central unknown question of the ratio of asymptomatic to symptomatic cases. PHE explained how testing is being scaled up over the coming weeks to 10,000 per day – focused on intensive care units, hospital admissions and key workers. PHE is urgently assessing commercial self-test options, with accuracy a key criterion. ACTION: PHE to update SAGE on the efficacy and feasibility of rolling out a rapid home swab test for antigens, including the mechanism for collection (for next meeting). PHE to develop a proposal for ramping up antibody serology and diagnostic testing capacity, seeking input from DSTL and the National Laboratories Alliance."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888784/S0384_Sixteenth_SAGE_meeting_on_Wuhan_Coronavirus_Covid-19_.pdf</p>
<p>18/03/20 SAGE 17 meeting</p>	<p>. "NHS updated on a joint NHS-PHE plan for testing, including 25,000 PCR tests a day, an increase in viral antigen detection tests and increased serosurveillance, including a more widely available serological test. SAGE discussed how to ensure that key workers, particularly NHS staff, get full access to comprehensive testing and agreed the importance of ramping up testing as soon as possible."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888785/S0385_Seventeenth_SAGE_meeting_on_Covid-19_.pdf</p>
<p>20/03/20 D.Pillay(personal communication)</p>	<p>Deloitte commissioned to establish a commercial testing structure that became the Lighthouse laboratories</p>	
<p>23/03/20 SAGE 18 meeting</p>	<p>. "NHS testing is currently at around 5000/day, to be increased to 15000/day by mid-April. A platform in partnership with the private sector has been established to aim to increase capacity to 110,000 a day by mid-April. It is essential to have a clear rationale for prioritising testing for patients and health workers, and to coordinate testing supplies across the UK to ensure that reagent supply gets to the PHE screening effort. Data from serology will be discussed at the next SAGE. It is critical that it is used to understand the proportion of asymptomatic cases....ACTION: PHE to work with NHS to set out a national priority order for testing including UK-wide procurement and distribution of reagents to support testing capacity. PHE and Jeremy Farrar to present a proposal for UK-wide serological screening priorities and distribution of essential equipment."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888787/S0386_Eighteenth_SAGE_meeting_on_Covid-19_.pdf</p>
<p>26/03/20 SAGE 19 meeting</p>	<p>"Testing priorities are set by the CMO and these need to be used by all service providers."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888789/S0387_Nineteenth_SAGE_meeting_on_COVID-19_.pdf</p>

<p>31/03/20 SAGE 21 meeting</p>	<p>"The importance of testing was re-emphasised. It was agreed that SAGE will not consider operational questions, but rather clarify the scale and requirements from the testing programme - the scale of testing required to manage the next phase. ACTION: DHSC and PHE to define future UK testing requirements at an upcoming meeting including required scale and approaches i.e. serology and community testing, tracing and isolation) and public understanding / interpretation of testing.</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888791/S0389_Twenty-first_SAGE_meeting_on_COVID-19_.pdf</p>
<p>09/04/2 SAGE 24 meeting</p>	<p>"SAGE agrees that all available testing capacity should be used and noted the importance of anticipating future need, including as social interventions are lifted. NHS estimates that patient testing requires about 8000 tests per day and NHS staff testing requires a maximum of 6000 to 7000 tests per day. LSTMH has done an initial assessment of community testing volumes which can be further refined and will be reviewed at the next meeting. Any consideration of mass testing should consider impacts, if any, on clinical management - including whether testing can anticipate future demand on the NHS - and on enabling people to return to work. It would also need to consider the relationship between testing and contact tracing; how statistical sampling can inform testing volumes needed; testing in support of shielding the vulnerable; and behavioural consequences of mass testing (including whether more testing would encourage greater self-isolation)." "The serology working group has responsibility for the UK's overall approach, including research studies and testing capacity. Data is emerging internationally on antibody response. SAGE advises caution over interpreting the presence of antibodies as evidence of presence of neutralising antibodies. It is not known if antibodies confer resistance against disease and against carriage of the virus. Low levels of seroprevalence (c. 0.8% to 15%) are being reported internationally. SAGE advises there is no evidence globally that we can expect high levels of immunity to have been gained at this stage in the pandemic. Evidence on seropositivity needs to differentiate between positive for prior exposure to the virus versus positive for protection against reinfection. The only commercially viable assay offers low sensitivity - but useful information can be derived from it where testing is repeated. It suggests antibodies may fall away quite quickly over time. More sensitive assays are being developed but are not yet capable of high throughput. No rapid home tests are yet sufficiently reliable for "immunity passports". SAGE advised that planning for the use of serology (e.g. in care homes, understanding transmission within households) should be done in advance of deploying a reliable test. SAGE noted the importance of adopting consistent sera standards across the UK (and suggested NIBS take this on). SAGE also noted the importance of their being enough material (samples) to develop assays."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888794/S0392_Twenty-fourth_SAGE_meeting_on_COVID-19_.pdf</p>

<p>16/04/20 SAGE 26 meeting</p>	<p>"SAGE agreed on the importance of getting an accurate estimate of Rand community prevalence over the next 2-3 weeks to inform decisions on lifting or modifying social distancing measures and to fill knowledge gaps. SAGE advised that sufficient testing capacity needs to be reserved for large-scale community testing. PHE confirmed it was unable to deliver a community testing programme. SAGE agreed that if PHE is unable to undertake the programme then this should be undertaken within an ONS-led household survey programme. SAGE also discussed testing for contact tracing. Even in scenarios featuring low incidence of infection, contact tracing would require testing capacity running into the hundreds of thousands per day (and commensurate quarantining of people)."ACTION: GCSA to send a letter to SoSDHSC regarding testing capacity and prioritisation, in relation establishing infection prevalence in population."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888798/S0394_Twenty-sixth_SAGE_meeting_on_Covid-19_.pdf</p>
<p>23/04/20 SAGE 28 meeting</p>	<p>"SAGE discussed indicative numbers required for viral testing. The NHS is asking Trusts to start testing every patient admitted to hospital from Monday onwards, rather than only testing symptomatic patients. Over the weekend 11 Trusts will be testing 500 asymptomatic staff to inform a strategy for routine staff testing. SAGE agreed the importance of understanding total testing capacity and what level of incidence it could cope with, as well as how far the epidemic needs to wane before the system can feasibly track and trace. Preliminary calculations suggest the level of incidence could fall to c. 4000 cases a day by May 4th, and to C.1000 cases a day by May 11th. These are to be reviewed by SPI-M, who should return, including confidence intervals. SAGE agreed that further discussions are needed to determine the incidence in care homes and agreed a suitable leader for those work is required. ACTION: CMO and NHS to provide viral testing volumes needed for hospital entrants and patients returning to social care settings by COP 23rd April as part of an overall paper on testing numbers."</p>	<p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/888801/S0397_Twenty-eighth_SAGE_meeting_on_Covid-19_.pdf</p>

Appendix 2. Historical context of Public Health Microbiology

From 1939 to 2003, a network of up to 52 laboratories across England and Wales was provided by the Public Health Laboratory Service (PHLS), set up originally as the Emergency PHLS to combat the threats of epidemics in a war-ravaged population. The laboratories provided public health microbiology testing for the local authorities in their area and for national programmes, investigations of, and responses to, outbreaks and epidemics. Infections covered included influenza, measles, mumps and rubella, food poisoning due to salmonella and campylobacter etc, meningitis, Legionnaires' Disease, tuberculosis and many more. The PHLS laboratories also provided the clinical microbiology service for the NHS hospitals in which they were based as well as the general practitioners in their area to ensure relevance to, and awareness of, current health problems and utilisation of core capacity and technology. In addition, many NHS laboratories cooperated and collaborated directly with the PHLS network. When an outbreak occurred or an epidemic was spreading, the PHLS co-ordinated the testing response across England and Wales through its laboratories working to standardised methods in common. Results were reported locally to District Health Authority Consultants in Communicable Disease Control (or under the successor Health Protection Agency, the health protection teams into which they had been incorporated) and collated nationally, from the 1980s, through the PHLS national Communicable Disease Surveillance Centre (CDSC), to provide the essential epidemiological data on which an effective public health response depends. Additionally, CDSC provided national expertise and field support, if required, in outbreaks. Reference laboratories also provided expertise and were often dispersed in the early days to small laboratories, many without an academic association and dependent on an individual with expertise. A dispersed system of reference laboratories continues to this day in Scotland, which never had a PHLS, but are mostly associated with academic centres.

In 2002, the then Chief Medical Officer published a strategy for Public Health (*Getting Ahead of the Curve*) which proposed the abolition of the PHLS and the creation of the Health Protection Agency (HPA) with a wider remit than infectious diseases and with much less emphasis on providing microbiology testing through a laboratory network. When the PHLS was duly abolished in 2003, only the central reference laboratories, CDSC, and a centre in each region were retained in the HPA. Public Health England subsumed the functions of the HPA and a number of other agencies under the Health and Social Care Act of 2012 – the Lansley NHS reorganisation – but even fewer laboratories were included, e.g., no laboratories in the North East, Trent, and London and the South East. This meant that some large populations were without a public health microbiology centre, although the Central Reference Services of PHE were a surrogate for London and the South East. Public health microbiology was now only a very small part in this non-NHS organisation and greater emphasis was placed on epidemiological modelling and prediction in a shrinking funding envelope. The former PHLS laboratories had been transferred to the management of their NHS Trusts and focused on the local clinical needs, meeting reduction targets for healthcare acquired infection and antibiotic prescription, and cost containment for their host. They usually lacked access to surge capacity, coherent linkage to large supporting regional laboratories and national exchange of information and experiences. Piecemeal Pathology Modernisation DH initiatives did not consider the need for a public health response or integration of services with those outside local pathology networks, e.g., Health Protection teams or *academia*.

As Inspector of Microbiology and Infection Control at the Department of Health from 2004 to 2010, one of us (BD) had a remit to ensure the continued contribution of NHS diagnostic laboratories to public health needs, but this became increasingly difficult and an aspiration more than an expectation. As now-retired clinical academics and NHS, PHLS, HPA and PHE consultant microbiologists we observe that with the 'modernisation' of Pathology services, of

which microbiology and virology laboratories are a part, laboratories were centralised in main hospitals, or even on non-hospital sites. Some were still managed by NHS Trusts but others by private laboratory companies and Trusts were only concerned to pay for the testing services they required for their own patients and those of local GPs – public health issues did not enter the frame. Seventeen years later, the failure of this approach has been cruelly exposed. The experience of Covid-19 shows that a large co-ordinated national network, used to working together, would have been of inestimable value.

APPENDIX 3. DESCRIPTION AND REVIEW OF RELEVANT GOVERNMENT REPORTS ON THE PROVISION OF PUBLIC HEALTH MICROBIOLOGY.

3.1 Introduction

The present CoVid-19 outbreak in the UK merits a discussion of central and local services for control of communicable disease. The current structure and organisation of public health services for communicable disease control have resulted from two major reports commissioned by Chief Medical Officers for England and published in 1988 (Acheson Report) and 2002 (getting Ahead of the Curve). Below we review these key documents and resultant policy, including changes to the public health laboratory provision, and our commentary discusses how the present position matches up to the judgements of the past.

3.2 Report of a committee of inquiry into the future development of the Public Health Function chaired by Sir Donald Acheson, Chief Medical Officer (HMSO ISBN 0 10 102892).

In January 1988 this report was presented to Parliament. The committee was set up in response to the 1984 outbreak of Salmonella at Stanley Royd Hospital in Wakefield and the 1985 outbreak of legionellosis at Stafford. Public inquiries into these had pointed to “a decline in available expertise in the investigation and control of communicable diseases”. Some would say a similar situation pertains today so the conclusions of this report are of particular importance.

Chapter 2 of the report considers the history of the public health function since the Royal Sanitary Commission of 1871. Control was initially vested in Medical Officers of Health which in 1948 were allowed to remain with local authorities and whose remit was confined to local authority affairs. The 1974 reorganisation of the NHS resulted in MOHs being re-designated as Medical Officers for Environmental Health and these officers retained responsibility for communicable disease investigation and control in the community. Following the further restructuring in 1982 with the abolition of Area Health Authorities and introduction of general management the change in management responsibility meant some structures lacked public health physician input.

Chapter 4 considers the role of public health within the NHS and local authorities. It reviews in detail the role of the Public Health Laboratory Service (PHLS). This had emerged from its wartime role into the NHS in 1946 and at the time of the report had 52 laboratories, with central reference functions and a headquarters in Colindale, North London. Whilst primarily having an epidemiological focus on limitation and investigation of outbreaks these laboratories had a major diagnostic component for the NHS which provided an overview of emergent and prevalent microbial threats. The Central Public Health Laboratory “gives specialised advice and assistance not only to PHLS laboratories and the Communicable Disease Surveillance Centre (CDSC) but to all NHS hospital laboratories. It supports and advises community physicians, local and central government and WHO. It will repeat standard tests when particular results need checking or do in depth investigations and typing of bacteria and viruses for epidemiological purposes”. The report acknowledges the role of local Public Health Laboratories. “Public Health microbiologists have essential local microbiological and epidemiological knowledge and maintain working relationships with relevant individuals in their area. The resources of the PHLS include the capacity to mount a national response mobilising its specialist reference laboratories and CDSC”. CDSC was formed in 1977 by amalgamation of former DHSS functions on coordination and control of outbreaks with the PHLS Epidemiology Research Laboratory and had the remits of national surveillance of communicable disease, advice and coordination of disease investigation and

control nationally, surveillance of immunisation programmes, epidemiological research in communicable disease, production of weekly communicable disease reports and teaching and training. "Evidence submitted to the inquiry demonstrated almost universal support for the PHLS and its epidemiological "nerve centre" the CDSC". This confirmed decisions reached (<https://api.parliament.uk/historic-hansard/lords/1985/jun/04/public-health-laboratory-service>) after a report to the NHS on the PHLS in 1985, one of a number of earlier reports.

Chapter 7 deals specifically with control of communicable disease and infection and co-option was used to form a subcommittee under Professor Alasdair Geddes to consider this issue and report. The report "is devoted to the organisational and administrative aspects of the subject. Evidence presented to the Inquiry makes it abundantly clear that the priority accorded to this branch of medicine both professionally and administratively has declined in recent years to a dangerously low level and we have seen it as our prime responsibility to make practical recommendations with a view to correcting this situation". It is noted that "In practice the main work of local authorities in the field of communicable disease and infection relates to the prevention and control of those notifiable diseases which are food or water borne." Further, the report states tellingly that "The microbes which give rise to communicable disease and infection do not work within statutory limits and responsibilities". The report recommended the abolition of the office of Medical Officer for Environmental Health and that "District Health Authorities should assign executive responsibility for necessary action on communicable disease and infection control to a named medical practitioner who will be called the District Control of Infection Officer (DCIO)." The report stresses that "it is important to recognise that there is a free flow in both directions of patients, visitors, staff *and microbes* between hospitals and the community outside." The DCIO will require support in contact tracing and administration within the district and specialist support from the region". The report states that "there is a need to provide specialist services in epidemiology at something approximating to the regional level geographically although not necessarily coterminous with NHS regions nor directly provided by Regional Health Authorities". The complex legal background at the time is reviewed. At the national level the inquiry stated "A national surveillance and control capability, flexible enough to be deployed promptly as and where required is absolutely indispensable for the control of communicable disease and infection". It recommended:

a)" more effective exchange of information between CDSC and its sources of data in particular Health Authorities, Family Practitioner Committees and PHLS area and regional laboratories. This should be a two-way exchange, including collection of data and dissemination of analysis".

b)" expanding the ability of CDSC to provide a service of field epidemiology on request by health and local authorities" with "staffing commensurate with need" and surveillance "analysed and reported to provide districts, regions and others with up-to-date information relevant to infection control".

c) a reserve power for the CMO "to authorise CDSC to assist in immediate investigation of an outbreak". The Inquiry report states "The speed of notification and its essentially local character which were its original *raison d'être* remain essential for those diseases where prompt follow-up action is required. It is a vital tool to enable contact tracing to get started." The report goes on to discuss changes to notification procedures and legislation.

3.3 Commentary on the Acheson Report

Overall, this report emphasizes a) a local basis for control of communicable disease with local resource to deal with local outbreaks, b) assimilation of information centrally to inform central decision and deployment of central staff, and c) satisfaction with the roles of CDSC and the then PHLS. The response to the review of MOH and then MOEH limitations was to incorporate the duties of MOEH and public health firmly in District Health authorities as Consultants in Communicable Disease Control almost exclusively as public health physicians but potentially including consultant microbiologists, and gives them wider responsibility than communicable diseases spread by food or water. This arrangement worked well until the Lansley reforms dissolved Primary Care Trusts, the successors of District Health Authorities when local Directors of Public Health were returned to local councils and Consultants in Communicable Disease Control were transferred separately to Public Health England and later aggregated into 21 local health protection teams (<https://www.gov.uk/guidance/contacts-phe-health-protection-teams> last accessed 18/6/2020). In PHE these and other services had their budgets reduced by 30% and it is not clear to what extent Consultants in Communicable Disease Control have manageable areas to supervise and adequate support.

The role of the Central Public Health Laboratory of the PHLS (later subsumed serially into the Health Protection Agency and Public Health England) notably does not include in its remit the need to develop new tests. Such capacity was vested in the local laboratories of the PHLS and NHS, and in academic departments of microbiology and the UK diagnostics industry.

The PHLS no longer exists.

Academic departments of Clinical Microbiology have been transformed and reduced with a reduced number of personnel scattered in Institutes, particularly of molecular medicine, and a low proportion are virologists.

The UK microbiology diagnostics industry has been reduced by takeovers and mergers such that the number of companies is far smaller than in 1988. A recent market survey (<https://www.marketwatch.com/press-release/ivd-infectious-diseases-market-size-and-growth-rate-2020-global-impact-of-covid-19-on-industry-share-explosive-factors-of-key-players-progress-status-and-recent-trends-forecast-to-2026-2020-06-19>) did not include any British company amongst 15 global players. A Department of International Trade report (<https://www.gov.uk/government/publications/infectious-diseases-develop-diagnostics-in-the-uk/infectious-diseases-develop-diagnostics-in-the-uk>) does not inspire confidence in recovery.

The importance of local microbiology laboratories of the PHLS in their local knowledge of microbes and people and their coordination role to form a national outbreak capacity was damaged when the local PHLS laboratories were largely transferred to NHS Hospital Trust management and cooperation of laboratories outside the residual network was abandoned when PHLS was replaced by HPA. The ability to mobilise national reference laboratories was maintained on transfer to HPA and PHE.

With the creation of PHE, the CDSC function for England was integrated into a broad surveillance function for all public health issues of which communicable diseases became only a small part. However, distinct communicable disease surveillance functions were maintained in Public Health Wales (<http://www.wales.nhs.uk/sites3/page.cfm?orgid=457&pid=25313>), in Northern Ireland (<https://www.publichealth.hscni.net/directorate-public-health/health-protection/surveillance-data>) and in Scotland (<https://www.hps.scot.nhs.uk/data/>). The Strategy document on

public health surveillance contains no reference to an operational communicable disease surveillance centre

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213339/Towards-a-Public-Health-Surveillance-Strategy.pdf). In respect of research the many voices of modellers in academic departments in England are not matched by an Epidemiology Research Laboratory within PHE and this has influenced the constitution of the SAGE committee. The loss of a government-independent, operationally effective, and research-capable national English CDSC, which the inquiry regarded as absolutely key, was, in our view, very undesirable.

Chapter 7 of the report was the foundation of the Consultants in Communicable Disease Control within the then District Health Authorities but District Control of Infection Officers as such were not created, largely because the emphasis on infection control in hospitals and hospital infection control committees took primacy. The support for a regional epidemiology structure is noteworthy in the field of communicable disease. These aspects of very local field epidemiology linked to and supported by CDSC have been aggregated into the health protection teams in 21 locations in England (<https://www.gov.uk/guidance/contacts-phe-health-protection-teams>) relating to 343 local councils (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/791684/List_of_councils_in_England_2019.pdf), 152 local authorities, and 135 Clinical Commissioning Groups (<https://www.nhscc.org/ccqs/>) and 134 Directors of Public Health, which generates a complex set of non-coterminous relationships.

3.4 PHLS Changes

In 1993 a new national Director of PHLS, Dr Diana Walford, was appointed, and was for the first time since 1939 not a consultant microbiologist but a consultant with extensive experience up to Deputy CMO level in the Civil Service. In 1995 changes were made to PHLS structure with laboratories aggregated into groups under a regional director with management responsibility for the group and accountable to the Director. Previously laboratory directors were individually and directly accountable to, and had access to, the Director of the Service. Regions were coterminous with NHS Regions.

These changes were not popular amongst NHS and many PHLS microbiologists generating feelings respectively of nervousness about competition and disenfranchisement in a network.

3.5 Getting ahead of the Curve – A strategy for combating infectious diseases (including other aspects of health protection). A Report by the Chief Medical Officer. 2002, Department of Health 26346 1p 5k Jan 02(WOO)

In January 2002 the then CMO, Sir Liam Donaldson, published *Getting Ahead of the Curve* a strategy for combatting infectious diseases (including other aspects of health protection). This report is very different from that of his predecessor Sir Donald Acheson. It lacked a list of contributors or consultees and contained mention of numerous historical outbreaks and national and international statistics. **Figure 2.40** of the document lists 21 infectious agents that had emerged between 1976 and 1999 of which 15 were viruses.

The action required to meet new and emerging infections is summarised as:

“ensuring that surveillance systems provide the comprehensive coverage necessary to detect new or unusual disease presentations or changes in the occurrence or profile of particular micro-organisms,

strengthening clinical reporting of unusual symptoms and disease presentations,

using surveillance data ...to anticipate outbreaks or epidemics so that preventative action can be taken before cases occur,

coordinating specialist laboratory facilities to enable micro-organisms to be assessed and profiled in a standardised way,

maintaining strong international links with agencies in other countries with responsibility for infectious disease surveillance and control policies,

establishing a national source of expertise in assessing the threat from new and emerging infections,

creating a mechanism to rapidly produce a specification for new control measures (e.g. drugs, vaccines) when new infectious disease problems emerge.”

Key priorities across the whole field of infections were assessed in **Chapter 3** as:

tuberculosis,
healthcare-acquired infection and antimicrobial resistance,
infectious diseases in children,
blood borne and sexually transmitted viruses,
chronic diseases,
new vaccines,
terrorism.

Chapter 5 proposed a modern system to combat the infectious disease and wider health protection threat. It starts with a requirement for world-class surveillance. Surveillance is not defined but we define it as information on incidence and prevalence for action. A number of areas where improvement could be made were specified:

Uniform recognition was needed that contributing to surveillance is integral to clinical care.., Illnesses possibly “caused by infection ... should be accurately diagnosed, a consistent approach should be taken to sampling for certain specific (but unspecified) infections,

Diagnostic microbiology laboratories should give equal emphasis to their public health protection role as to their clinical diagnostic role,

Clinical and laboratory reporting of infection should be linked and made mandatory,

Reporting must be made easier, for instance through greater use of compatible electronic information systems,

The surveillance of infectious diseases was to be linked to regional public health observatories,

Ways needed to be found to gather information on the occurrence of infection directly from the public

There would be greater alignment of national and European surveillance”.

The next section within **Chapter 5** dealt with **Organisation of Services**.

The Department of Health section is unexceptional with the primary duty of setting strategy and policy for the prevention, treatment and control of infectious diseases and the responsibility for taking charge when “national controls are required”.

The Local Authority section is similarly unexceptional.

The NHS section points out that the NHS “is responsible for local surveillance of infectious diseases and ensuring proper diagnostic and treatment facilities for people with infections....” Further it states that “A regional Director of Public Health will be present in every regional office of government ... and will be accountable for the protection of health (including infectious diseases.....) across the region; Additionally, “there will be an effective public health function at local level delivered to primary care trusts”.

The section on the Public Health Laboratory Service describes it as “organisationally complex, managed by a single executive body from the headquarters and essentially runs in three distinct but intertwined entities: the eight groups of laboratories...., the reference laboratories... providing specialist diagnosis, testing and advice, and outbreak investigation support and CDSC providing national and regional surveillance and operational support for management of outbreaks”.

It then discusses diagnostic and reference microbiology laboratories. It notes that clinical laboratories in England are mainly centred in hospitals with some local hospital microbiology services provided under contract by one of the PHLS laboratories and a very small number run by independent sector companies on a contractual basis. “Virus testing ... is undertaken mostly in the microbiology departments of larger teaching hospitals, Public Health Laboratories including some PHLS reference laboratories, and university Departments of Microbiology. Newer technology is allowing more virus testing to be carried out by local level laboratories. Further developments of molecular diagnostics combined with reduced numbers of virologists may reverse this trend.”

The report states that “Variation exists in the contribution of laboratories to the investigation of incidents of infectious diseases. There is a need to bring consistency to the delivery of the public health functions of laboratories and standardise on current good practises”.

There is a description of reference laboratory functions. Of note they are said to: “undertake testing of rare or unusual infections”, “carry out research and development, including kit evaluation, assessment of new technology, recognition of pathogenicity and virulence factors and development of diagnostics”. The report states: “There are multiple lines of accountability for reference and specialist microbiology provision. Better co-ordination and improved support for surveillance and epidemiology could be achieved by a single point of management.” It also comments that “the PHLS Reference Laboratories organise national and international quality assessment schemes for food, water and clinical microbiology, which includes 220 NHS laboratories as well as the 46 public health laboratories in England and Wales”.

Standardisation of testing is considered in **Chapter 5** which comments that:

- a) “most, but not all reference microbiology laboratories work to a common service specification and are accredited”
- b) “clinical microbiology laboratories are usually managed within NHS pathology services, with little managerial separation at the local operational level. The consultant microbiologist provides clinical oversight and advice and as the infection control doctor advice, and support to infection control staff”

- c) “the Pathology Modernisation Programme set up in 1998 by the Department of Health, is encouraging rationalisation of NHS pathology services. The vision is of services serving larger populations rather than individual hospitals. The reason for this change of emphasis are better use of scarce human resources, development of subspecialty diagnostics, efficient use of expensive sophisticated equipment, introduction of new technologies and the development of information technology. The Pathology Modernisation Programme will facilitate improvement in standardisation of testing”
- d) “much clinical microbiology is labour intensive and part of the work can be carried out at a centre away from the hospital site but emergency analyses are time critical. These need rapid turnaround times. Such issues are being examined in the Pathology Modernisation Programme.”
- e) 53% of NHS microbiology laboratories are accredited. “All PHLS. laboratories providing clinical microbiology services are CPA (Clinical Pathology Accreditation) accredited.... Of the independent sector 34% have CPA accreditation and 65% are registered”.
- f) “Laboratory methods differ... The PHLS has a system of Standard Operating Procedures for use within its own laboratories, in order to provide a greater uniformity of approach. These include detailed specifications and guidance notes. They have been made available to other laboratories, although there is no requirement for them to be used”

The report then identifies opportunities for improvements in primary diagnostic microbiology:

- g) “Improvements in quality assurance schemes,
- h) adoption of standard operating procedures,
- i) formation of a comprehensive network of accredited laboratories,
- j) improved and integrated clinical and laboratory reporting of test results and infection locally and nationally through IT developments”,
- k) establishment of a co-ordinated system for evaluation and managed introduction of new technology,
- l) further integration of testing between disciplines within pathology”

A section on legislation concludes that no reform was ever made to the 1984 Act after the 1988 Inquiry and there is a need to review legislation on infectious disease surveillance, prevention, control and investigation with a view to modernising it (5.82).

Microbiology and Virology Workforce is also reviewed in **Chapter 5** which states...” Typically, consultant medical microbiologists are the source of knowledge and advice on all matters related to the diagnosis, treatment and control of infection in a locality served by the hospital microbiology laboratory”

No information is given on the number of consultant medical microbiologists but it is stated that “There are 44 consultant medical virologists in the UK and a dozen clinical scientists who carry out some clinical work as part of their duties”. Further “The distribution of consultant clinical virologists today reflects past patterns of investment and current difficulties in filling posts, rather than current clinical need. The result is a specialty group, most of whose practitioners are carrying very large clinical workloads, maldistributed geographically, and with a significant proportion of consultants practising in isolation”. “In most district general hospitals provision of virology advice falls largely to consultant medical microbiologists, few of whom have received specialist training in this area, and amongst whom there is considerable demand for updates in both clinical and laboratory aspects of diagnostic virology”.

The sections on consultants in communicable disease control (CCDC) - medical posts with training in infectious disease control in public health set up after the Acheson review, usually in health authority departments of public health - note that in many cases these posts have a strategic role with operational matters lead by specialist nurses. The CCDC role in defined populations includes health protection that is multi-agency, exercise of proper officer powers for local authorities under the Public Health (Control of Diseases) act 1984 and its accompanying 1986 regulations, dealing with imported infections relating to ports and airports, investigation and management of communicable disease incidents and outbreaks (and also non-infectious environmental hazards), advice to commissioning services and development, co-ordination and monitoring of immunisation programmes, and coordination of health protection aspects of NHS emergency plans for local populations. .

Chapter 5 also includes a section on **research, development and innovation**.

This includes developing and evaluating effective diagnostic tests, discovery of new infectious agents, vaccines and treatments, The report comments that automation may “aid rationalisation of testing between disciplines in pathology such as serum samples for clinical chemistry and microbiology “ but notes there is “no mechanism for evaluation and national managed introduction of new technology”. It also notes that “a number of issues need careful consideration if the benefits of near-patient testing are to be fully realised” viz “ensuring that information on types of a micro-organism circulating in the population is not compromised, formulating and disseminating guidance on performing and reading the tests, and establishing effective quality control schemes.”

Chapter 6 proposed **ten key actions** amongst which are: a) “giving every microbiology laboratory a public health as well as a clinical diagnostic role and rationalising the management arrangements for such laboratories”; b) “being prepared to anticipate, respond swiftly and consistently to outbreaks and epidemics”; c) “being much better prepared to recognise and take action to control new infectious diseases threats....”; d) “creating a unified system of health protection from national to local level adding other aspects to infectious disease control”.

Amongst some 16 acid tests of a health protection service equipped for the future that the report gives are: a) an outbreak of unknown illness; b) the appearance of a previously unrecognised pathogen in the national blood supply; c) uncontrolled serious infection contracted in hospitals; d) a serious imported infection affecting a number of hospitals; e) the next influenza pandemic.

The report then makes proposals under the headings given in Table 2.

Table 2. Headings for proposed changes in *Getting Ahead of the Curve* and our mapped proposals

1. *A new agency for infection control and health protection
2. *A new mechanism to identify and assess the threat from new and emerging infectious diseases
3. *A strengthened system of infectious disease and health protection surveillance.
4. *Intensified action to reassert control over serious infectious disease problems – tuberculosis, healthcare-associated infection, antimicrobial resistance, blood-borne and sexually transmitted viruses
5. *Rationalisation and standards of microbiology laboratory standards
6. A programme of new vaccine development to create opportunities to eradicate particular infectious diseases
7. Strengthened integrated approach to infection in childhood

8. *Clear and comprehensive contingency plans to reduce the impact of any future terrorist attack
9. *A new capacity to provide the public with information about infectious diseases and the risks associated with them
10. Enhance programmes of professional education and training in infectious disease prevention, control, and treatment
11. *A research and innovation programme
12. Modernising Public Health Law.

*Priorities mapped to our current concerns

These proposals do not refer specifically to earlier items in the report. Details of action under these headings are.

1. The new Health Protection Agency (HPA) subsumes PHLS, the Centre for Applied Microbiology and Research, Porton Down, The National Radiological Protection Board (NRPB), The National Focus for Chemical Incidents, partners with the National Institute of Biological Standards and Control. The Communicable Disease Surveillance Centre and NRPB remain distinct entities within the HPA. The main functions of the HPA include “to work with the NHS and local authorities to provide health protection and an infectious disease control service” and “to commission microbiology laboratories to provide specialist public health or reference functions” .”Rigid geographical boundaries, expertise locked into single organisations, a surge capacity in emergencies, poor connections between national expertise and local service needs are the serious disadvantages of the present system which will be addressed by the new proposals.” Pandemic preparedness is not specifically mentioned in these functions.

2.”A new national panel is proposed which would regularly review any new or emerging infectious diseases reported in this country or from elsewhere in the world.....It will assess the potential threat to this country and advise on any protection or control measures that should be initiated to reduce the potential threat to the population’s health.”

5. “Rationalisation and standards of microbiology laboratory services. It is proposed that the present fragmented system of microbiology laboratories which are under differing management arrangements be simplified with a clear categorisation of laboratories into those providing routine diagnostic microbiology work and those providing public health, specialist or reference functions. This will mean that the number of local PHLS laboratories doing a major part of their work for NHS diagnostic purposes will reduce. However, it is essential that major diagnostic laboratories are not decoupled from the public health laboratory function. A good public health laboratory function relies on specimens taken for diagnosis of patients with infection. Similarly, the cadre of microbiologists undertaking specialist microbiology work for public health purposes must also have involvement and experience of routine clinical microbiology. All clinical microbiology laboratories will be required to operate to common reference standards and standard operating procedures. All microbiology laboratories will be required to make mandatory reports of infection for surveillance purposes, to contribute to outbreak investigations and to recognise their public health as well as clinical responsibilities. Regional directors of public health will oversee the commissioning of the public health component of microbiology services within each region. An Inspector of Microbiology post will be established to ensure that laboratories meet their public health requirements which are essential to protecting the health of the public in England.

8. “Clear and comprehensive contingency plans to reduce the impact of any future terrorist attack.....It is proposed that plans for responding to a terrorist attack should continue to be

strengthened particularly through: enhanced new surveillance and training of key personnel to identify new disease of unusual patterns, developing rapid diagnostic techniques, identifying newly emergent pathogens, ensuring adequate specialist diagnostic and management support, promoting research into antiviral drugs and vaccines, continuous horizon scanning , scenario planning, risk assessment and research, creating innovations in countermeasures.”

10.” Enhanced programme of professional education and training in infectious diseases, prevention, control and treatment. It is proposed that there is a review of the content of infectious diseases and health protection in the current education programmes with a view to strengthening it through NHS workforce and education confederations and educational providers. The control and prevention of infectious diseases is a responsibility of all healthcare professionals – not just the specialists.”

There is no mention in this document of surge capacity requirement in laboratories in a pandemic.

Two additional related documents were also created at this time. **Health protection A consultation document on creating a health protection agency (27933 1P 12k June 02** and **Action to strengthen the microbiology function in the prevention and control of infectious diseases produced by the Health Protection Agency Implementation Team.** These, as subsidiary documents, are not examined in detail here but some excerpts are of relevance.

In the first document, it is stated that the Government expects the changes to be neutral in terms of overall public expenditure and that changes in legislation needed will be through a Regulatory Reform Order. The HPA would not be an executive agency avoiding accreting functions to central government. The HPA would work with NHS Care Improvement where standards of infection control are deficient in hospitals, primary care or other health service premises. The HPA under service level agreements with regional directors of public health would identify and put in place, the extra capacity (“surge capacity”) needed to tackle outbreaks of disease. Welsh arrangements were somewhat different incorporating clinical microbiology into the National Public Health Service. The English government believed “that a unified agency would be able to provide more effective services for health protection than can be achieved under the current more fragmented arrangements”.

In the second document Primary Care Trusts (PCTs) and NHS Trusts are charged “to ensure that all laboratories provide help and support to those responsible for the management and control of incidents of infection whether they occur within NHS Trusts, PCTs or in the wider community. Throughout this document the Modernisation of Pathology Services recommendation that pathology networks are set up serving populations equivalent to Strategic Health Authorities is referred to. A lead consultant microbiologist with a significant sessional commitment to public health is posited in each network and a regional public health microbiology coordinator as well. A clinical need for more molecular testing at local level is identified. A template document for local service level agreement with NHS laboratories in NHS Trusts, PCTs , and the Regional Director of Public Health is provided and states that all laboratories should work towards being part of a microbiology network, in order to contribute promptly to the provision of surge capacity when microbiological services come under public health pressure e.g., during large outbreaks, where extra testing capacity is needed, when other local laboratories unable to provide services etc.

3.6 Commentary on Getting Ahead of the Curve

The document points out that the commonest microbial causes of emerging new infections are viruses but this is not addressed elsewhere in the document. Actions necessary to deal with emerging infections indicate that slow transmission is envisaged and only include

assessments not operational process to create surge capacity in the NHS and clinical microbiology and virology laboratories in particular. Pandemic transmission is always rapid with modern travel and surge capacity takes time to create. Key priorities did include terrorism where historical precedent suggests microbial threats are with unfamiliar and emergent organisms but this is not stated These and new organisms require consideration not only under health protection but also under national defence capability.

The need for improvement in a consistent approach to sampling in infection is recognised but the necessity for diagnosis of the causative agents of common syndromes such as pneumonia and the need for strengthening active surveillance and contact tracing is not specified.

Improvement in use of electronic communication in mandatory reporting has occurred – indeed all laboratory reports, not just of mandatorily reportable organisms, were collated in at least one former NHS region and used to inform epidemiological studies of antibiotic resistance prevalence by HPA (Ironmonger D et al 2013 AmWeb a novel interactive web tool for antimicrobial resistance surveillance applicable to both community and hospital patients J Antimicrob. Chemother. 68:2406-24) . This could be applied to virus detection.

The responsibility of the NHS for diagnosing and treating infection is vested in Primary Care Trusts and regional Directors of Public Health. Neither now exists.

The report describes the PHLS as organisationally complex but the parts relate directly to the microbiological diagnosis, investigation, and surveillance of infectious diseases, missing only the control function in the community. Other authorities with a microbiological component, with the exception of the Centre of Applied Microbiology & Research, later subsumed into the Health Protection Agency, have a more circumscribed role.

The report gives a figure of 330 microbiology laboratories in England in 2002. Of these, the 46 local PHLS laboratories were accredited by Clinical Pathology Accreditation (CPA) and 53% of the NHS laboratories (say 150) suggesting 196 accredited local laboratories. The current figure is not known but is certainly much reduced following modernisation of pathology and mergers between services and trusts. The UK Accreditation Service, which subsumed CPA, lists 119 accredited microbiology laboratories with hospital addresses or services in England (https://www.ukas.com/browse-accredited-organisations/?org_cat=850&parent=Medical%20Laboratories&type_id=7&cpage=1). A considerable number are now run by private companies and the proportion of these not accredited is not known despite the very low accreditation rate of the very small numbers present in 2003. Scotland, Wales and Northern Ireland laboratories that are accredited amount to 12, 5, and 5. The workforce reduction associated with these changes is unknown. The number of laboratories accredited specifically for virology in 2002 is not known but the consultant and scientific workforce is given as 56. Currently UKAS has accredited 104 laboratories in the UK for virology of which 90 are in England, 9 in Scotland, 3 in Wales, 2 in Northern Ireland. Of the virology laboratories in England, 2 were National Blood Service and 1 PHE Virus reference, and 14 clearly private companies (https://www.ukas.com/browse-accredited-organisations/?org_cat=854&parent=Medical%20Laboratories&type_id=7); 23 were former PHLS laboratories. The consultant manpower in virology laboratories (other than reference functions in PHE and excluding less specialised consultants in medical microbiology) in England is 59, in Scotland 7, in Wales 4 and in Northern Ireland 2 (<http://www.clinicalvirology.org/>). Thus, although there are considerable numbers of NHS Virology laboratories these seem not to have all had significantly strengthened consultancy since 2003. Because medical virology requires reporting in a timely fashion for infection control and use of antivirals, local rather than central provision of service is required so in laboratories and hospitals served only by consultant medical microbiologists they must currently provide the service. Nowhere in this 2003 strategy paper is the risk of reduction in,

or centralisation of, microbiology laboratories or the need to strengthen virology consultancy by modernisation, considered. Indeed, NHS microbiology services and those related in pathology, have never been reviewed for their service performance, integrity, resilience, turnaround time or planning and resourcing.

Health protection staffing in their teams by PHE is opaque. Medical staff are not named and the proportion of medical, nursing and other staff and their training and continuing medical education is not in the public domain (<https://www.gov.uk/guidance/contacts-phe-health-protection-teams>). There is no system for accreditation of health protection teams or hospital infection control teams and this is desirable. There are European performance indicators for infection control programmes in nursing homes (Cookson, B et al. Development and assessment of national performance indicators for infection prevention and control and antimicrobial stewardship in European long-term care facilities. *J Hosp. Infection*, 2013;85:45-53.) but no explicit accreditation process for ensuring they are in place.

Accreditation in laboratories is a fair measure of quality since it involves defined standards and external review, although the inspection process is not as clinically incisive in its communication with managers as its predecessor. Notably the Lighthouse Laboratories as new laboratories remote from health service customers are unaccredited and their adherence to quality standards unknown.

The importance of new developments and molecular tests in virology and their potential is emphasised although the authors of the strategy seem to anticipate this will be provided at a regional level rather than the radical siting at the door of local hospital admission facilities where they can provide a response within 2 to 4 hours, as described in Marseilles to drive treatment and containment isolation (Cohen-Bacrie S et al Revolutionizing clinical microbiology laboratory organization in hospitals *PLoS ONE* 6(7)e22403 2011; Drancourt M et al. The Point of care laboratory in *Clinical Microbiology Reviews* 2016; 29:429-447). The implementation document notes the clinical need for more molecular testing at the local level. The present situation with availability of molecular testing in the NHS is a classic case of the UK developing a new technology (PCR) and failing to take it into routine use (NHS) so resilience is available.

The role of reference laboratories is augmented in this report compared with the 1988 inquiry by the addition of development of diagnostics. With the disappearance of many academic departments of clinical microbiology, this may be prudent but should not be exclusive.

The UK National External Quality Assessment Scheme for Microbiology is still organised nationally and operated as a service by PHE from its reference laboratory site (<http://www.uknegasmicro.org.uk/images/pdf/DOC.0427.pdf>).

The role of local and University-linked laboratories in technical development, evaluation, and cooperation with industrial development is ignored as is the role of local microbiology consultants in determining repertoire within the intellectual constraints of standardisation. A pluralistic intellectual, advisory and management function in microbiology is more important than management segregation into clinical and public health microbiology.

The report touches on the Pathology Modernisation Programme and its declared positive purposes within rationalisation. Now NHS Improvement is committed to creating hub and spoke arrangements by 2021 based on 29 pathology networks across England (<https://improvement.nhs.uk/resources/pathology-networks/>). Costing but not service delivery is well reported. Savings of £200m on a base cost of £2.2bn are anticipated by 2021 in the 105 hospitals in England. However, the proposed developments contain no information or specification by pathology sub-specialty or by clinical need. Comparison with data from the

Clinical Virology Network (<http://www.clinicalvirology.org/>) suggests that 9 networks (Midlands and East 1, 6 and 8; South 1,2,4,and 8; and North 8) lack a consultant virologist or consultant clinical scientist in virology although some have consultant microbiologists providing virology services. Some pathology networks have 3 or more virology centres. Some of the networks have only a single virologist. This situation needs rectifying by additional secondment experience and certification in virology of medical and scientific microbiology consultants or planned temporary additions to the virology and molecular training programmes of the Royal College of Pathologists with creation of new consultant posts in these networks. Not all pathology networks have obvious academic partners and the possibility of two service partners for appropriate existing academic centres needs exploration.

Public Health needs are not recognised in pathology networks which is unfortunate given the potential opportunity to cohere communicable disease control and its laboratory network which provides its immediate alerts and laboratory surveillance database.

Standardisation of operating procedures matches well a factory concept of pathology and UK Standard Operating Procedures (SOPS) were based on PHLS SOPs. These national SOPs have been updated but without a national network it is inevitable that more diversity is in place and this is necessary for the subject to advance in the absence of evaluation centres in peripheral networks. Nevertheless, some professional standardisation of repertoire and standards of performance available within pathology networks, for the service of general practitioners within clinical commissioning groups and hospitals served, is necessary, overdue, and requires national oversight and frequent strategic and tactical revision so it is responsive and ensures adequate quality including turnaround time.

Over-centralisation may preclude the turnaround time required for proper allocation of patients to appropriate locations in healthcare in Covid-19 and other epidemics such as influenza. Rapid turnaround times (less than 4 hours) are essential to prevent entirely predictable serious healthcare acquisition in hospitals and care-homes by admission or discharge to inappropriate locations. The 2002 specifications for improvement in clinical microbiology service have been partly met but there is no agreed planning and funding stream for the NHS-wide introduction of new technology, or not in transparent form. Particular issues such as the surveillance reporting of infections identified in clinical chemistry laboratories where they have subsumed serology testing from microbiology laboratories has not been systematically audited nationally either as absolute numbers or on a population served basis. This sharing is advocated by the report and indeed now extends to the use of papillomavirus PCR in former cervical cytology screening departments. Formal Notification, a legal requirement, remains a responsibility of clinicians but parallel laboratory reporting of HIV and hepatitis serology critically determines the amount of under-notification and in practice is more reliable since it can be driven automatically in laboratory information systems by Boolean logic.

Similarly, the low sensitivity of near patient testing for microbial antigens which are still widely advocated by industry is not recognised by the report. In chlamydia testing these methods are substantially inferior to nucleic acid amplification tests (polymerase chain reactions - PCR) (Kluytmans et al. Evaluation of Clearview and Magic-Lite tests, polymerase chain reaction and cell culture for the diagnosis of *Chlamydia trachomatis* in urogenital infections. J Clin Microbiol 1993; 31:3204-10). Similarly, in *C. trachomatis* and *N. gonorrhoeae* testing amplified immunological (EIA) and bacterial culture methods were clearly shown to be inferior to PCR methods (Van Dyck et al. Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by enzyme immunoassay, culture and three nucleic acid amplification tests. J Clin Microbiol 2001; 39:1751-6). Nucleic acid probe methods that are not amplified are also inferior (Young DC et al. Comparison of Abbott LCx *Chlamydia trachomatis* assay with Gen-Probe PACE2 and culture. Infectious Disease in Obstetrics and

Gynecology 2000; 8:112-5.). A similar pattern is emerging in SARS2-CoV detection but Appendix 1 suggests SAGE members were not generally aware of these limitations, or indeed of the limitations of serology, reflecting their lack of virology testing experience in clinical practise. False negative results are a serious impediment to infection control and contact tracing with all infections but near-patient PCR testing technology for viruses is not available in the UK. Improvements in rapid access to PCR testing, although it requires trained staff and care, is still urgently needed in many parts of the NHS at both local and sub regional network level. Local NHS-contracted specimen collection and transport systems from general practice and hospitals avoid patient inconvenience and social exclusion from testing. Local NHS IT reporting systems with preloaded identifiable local general practices and practitioners transfer reports around the NHS within the day and often much faster without intervention of centralised data exchange in the NHS and transfer to local authorities or health protection units in preference to the patient's GP as seems to be the case with Covid-19 reporting from Lighthouse laboratories. The delays and deficiencies of collection, transport and reporting in over-centralised systems are strategically ignored by many with no experience of pathology services.

Experience as well as science, should properly guide infection diagnosis and control in epidemics. Not all the 10 key actions and 16 acid tests of the 2002 proposals have been made in 2020, a catastrophic failure partly due to inadequate operational specification. Critically, the actions proposed in the Getting Ahead of the Curve report are apparently partly decoupled from the antecedent part of the report and this may have led to completion of necessary actions being overlooked.

The reduction of centres of infection expertise including academic departments of medical microbiology and virology has reduced the plurality of intellectual contribution to practical innovations in management and diagnosis of infection as has the reduction in public health microbiology laboratories. Some university interfaces have been lost and universities vary widely in their support for medical microbiological research. More expertise has been locked into single organisations, surge capacity has been lost in the routine NHS, there is less interaction within the NHS, connections have been lost between national expertise and local needs and more rigid geographical boundaries have been introduced – the precise antithesis of the remedies this report proposed to introduce.

Strengthening laboratory capacity in other cities outside those currently included in the PHE network permits a closer integration with major distributed academic medical microbiology centres. The limited microbiology research budget (approximately £10 million) following the creation of PHE was put into specific joint academic/PHE research centres across 6 or so topics identified by PHE. No centre for new viral diseases was created. Only one or two Universities were included, decreasing intellectual diversity. Simultaneously joint medical training, lectureships and PhD programmes in public health microbiology (Manchester, Cambridge & Birmingham Universities) were abolished, support for 2 chairs that had been joint PHLS or HPA and Academic appointments was removed, and all of the Clinical Scientist training posts supported by PHE were removed as cost cutting exercises. This added to the previous removal of medical trainees from the PHLS's successors has removed the essential academic, medical and scientific support for public health and national microbiology compounding this by the consequent destruction of the focus to support clinical diagnostics with research and innovation.

4. CONCLUSION FROM THE REVIEW OF PREVIOUS REPORTS AND STRATEGY DOCUMENTS AND THE CURRENT ORGANISATIONAL STRUCTURES

The national panel, SAGE, that addresses new infectious diseases has no NHS experts in virology or microbiology with appropriate expertise in delivering large scale diagnostic microbiology/virology testing services and is dominated by model observers and prophets, and behavioural modification experts. Government specifically precluded SAGE from operational considerations of testing (Appendix 1). There is a need for the government to be advised by people who deliver public health microbiology to support the translation of scientific suggestions into action. At the moment experience does not obviously guide the science and it is not surprising that the basic infection control process used in Covid-19 predates the introduction of scientific testing and advocates population control measures on movement initially described in 1665 for bubonic plague in Eyam, Derbyshire as a village-wide rather than individual household measure. Clinical diagnosis (confirmed nowadays by testing) and contact tracing, a Victorian innovation introduced by Dr John Snow in a common-source outbreak of cholera, was abandoned early in the UK as an infection control measure for the multicentric introductions of Covid-19 in this pandemic, with a rush to a numerical target for tests without consideration by DHSC of its use. This contrasts with the background of the restriction of the Guangzhou SARS outbreak (the first ever in 2003) to 400 people by a rapid integrated local public health response despite the causative virus not having yet been identified and no PCR diagnostic test being available (Zhao Z et al Description and clinical treatment of an early outbreak of SARS in Guangzhou PR China 2003 J Med Micro 2003; 52:715-20). The subsequent spread of SARS in Hong Kong, Beijing and Toronto illustrates the importance of early comprehensive alertness and intervention.

The fragmented microbiology service has become more fragmented and progress in networking is still a work very much in progress 18 years after *Getting Ahead of the Curve* and has no clear service standards for microbiology that might clinically underpin service delivery and modernity. The proposed organisational oversight of the microbiology service has dissolved in politically driven reorganisation. The failure of PHE to match NHS terms and conditions of service for Biomedical Scientists has driven morale down and will affect recruitment. Laboratory networks do not directly match geographically to health protection teams and virology services show vestiges of superceded regional structures and are not adequate in all the laboratory networks.

The contingency plans for terrorism might resemble those required for a newly recognised microorganism with epidemic potential. There can be little confidence that emergency preparedness from December 2019 onwards was adequately planned in operational biosecurity terms and existing measures in human and animal health therefore require major review.

Educational changes have been made for consultant microbiologists by the Royal College of Pathologists. Instead of five years of experience in laboratories, this now comprises two years general medical training including attainment of Membership of the Royal College of Physicians, two years combined infection training including 2 months of experience in a clinical virology laboratory and 4 months in a medical microbiology laboratory with 18 months in clinical care of the infected patient, and two years of higher specialty training either in clinical virology (for virologist specialist training) or medical microbiology (for medical microbiologist specialist training). At qualification there is less direct experience of laboratory techniques and more experience of clinical work. Certified medical microbiologists can no longer be assumed to have adequate virology experience. Laboratory technique experience is particularly needed with the increasing reliance on molecular methodologies which these individuals have had little opportunity to understand and deploy in anything other than highly

structured settings. PHE unlike the PHLS and the HPA, no longer trains in medical microbiology either medical or clinical scientist staff and has cut key trainer and training posts. The curriculum for microbiologists outside PHE includes no training secondments in epidemiology or control of communicable disease thus creating a restrictive silo in infection matters.

PHE, unlike the PHLS and HPA, is now an agency of the Department of Health and has no political independence enabling it to communicate publicly. Its involvement with NHS Improvement is obscure if present at all. There is no evidence from the NHS programme in pathology that surge capacity is present in NHS microbiology laboratories and this deficiency is supported by the government decision that only co-option of the commercial sector and universities without experience of diagnostic testing could provide the surge capacity to deal with the diagnostics deemed necessary in the Covid-19 pandemic. NHS improvement has made progress in procurement but the details of whether savings are matched by an increase in versatility of equipment for open PCR to meet emergent infections and development down-time of commercial diagnostics, and whether turnaround times, surveillance reporting and clinical service delivery from the laboratories are improved is absent.

The regional public health microbiology coordinator or regional microbiologists no longer work in microbiology laboratories where they could liaise with lead consultant microbiologists for the laboratory services across the multiple networks or indeed where they could lead services. The lead consultant microbiologist for public health in microbiology networks apparently does not now exist thus calling into doubt speciality oversight of the NHS Improvement programme in Pathology.

For all these reasons we consider the dissolution of the local network of the PHLS in 2003 in response to the "Getting Ahead of the Curve" strategy was unjustified and unwise for the reasons given and the implementation of the vision it contains for a public-health supportive NHS microbiology service has not been realised even over an 18-year period. PHE has failed to engage adequately with the NHS or repair any defects in service and relationships transposed from the HPA. For this reason, we consider that PHE is now unfit for purpose in the organisation of communicable disease control and interface with clinical microbiology. Furthermore, Pathology networks are not necessarily fit for purpose to cope with national epidemics affecting hospital capacity and infection control in communities and healthcare. A new future is needed and inquiry into the acceptability of new proposals.