

Lessons learnt: the role of academia and industry in the UK's diagnostic testing response to COVID-19

Report of a virtual roundtable on 2 October 2020

The Academy of Medical Sciences

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Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows.

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Executive summary

Combined with other non-pharmaceutical interventions, such as physical distancing and regular hand washing, test, trace and isolation (TTI) strategies are likely to play an important role in limiting the spread of COVID-19 infection, including reducing the resurgence of infections in winter 2020/21.¹ Unlike some other countries, the UK was not equipped with the required national or regional capacity for diagnostic testing at the start of the COVID-19 pandemic in early 2020. This capability needed to be developed and expanded rapidly to cope with the rising number of infections, drawing on expertise and resources in academia and industry to complement services offered by public health and NHS laboratories. As the epidemic continues to spread in the UK, and as we approach winter, there is a need to optimise testing and maximise testing capacity, which can be supported through further engagement with industry and academia.

To explore the role of academia and industry in the UK's diagnostic testing response to COVID-19, the Academy of Medical Sciences convened a virtual roundtable on 2 October 2020. The meeting brought together key stakeholders from across the NHS, academia and industry to explore the challenges and enablers faced by academic and industrial laboratories in contributing effectively to the diagnostic testing response to COVID-19; consider lessons learnt from the initial upscaling of testing in spring 2020; and identify mechanisms that could be implemented for the UK to be better prepared in future. The following key messages emerged from the discussions at the meeting:

- **Fostering collaboration:** Collaboration across the NHS, academia and industry has supported the UK's testing response and the development of testing centres across the country, through the exchange of staff, equipment, reagents, knowledge and skills. Pre-existing mature relationships facilitated effective collaboration with a common purpose. Going forward, investment in existing relationships, and the development of new networks and alliances will help to strengthen the UK's testing capability. Attendees suggested that it would have been beneficial to establish a government-led cross-sectoral diagnostics taskforce in the very early stages of the pandemic. In future, partners from across the three sectors should be involved in the development of testing strategies, with greater transparency and timely communication of decisions to all stakeholders involved. This would provide clarity on the engagement opportunities for academia and industry and guide how they could most effectively contribute. The UK should also learn from the successful and less successful strategies that have been implemented overseas.
- **Nurturing innovation:** There is scope for the UK to explore more innovative ways of testing and to consider innovation more holistically, from pooling multiple samples for testing, the use of multiplex testing for several viruses and saliva testing, to improving the packaging of samples. Better defining the cases in which tests could be used will assist in the creation of more effective tests for specific unmet diagnostic needs e.g. mass testing in schools or large-scale events. Early engagement with the NHS and social care settings will help to ensure practical solutions are developed and embedded effectively. The regulatory agility catalysed by the COVID-19 pandemic was widely welcomed and should be maintained beyond the pandemic to help position the UK as a leader in advancing innovation and accelerating access to products and services to address unmet clinical need. Innovative mechanisms to enable a more proportionate laboratory accreditation process, which is required to deliver testing, should be considered to ensure that as many laboratories as possible with the capacity and capability are able to contribute to the national testing response.
- **Maximising resources:** The decision to create a centralised testing system with consolidated testing centres enabled a rapid and unprecedented increase in testing capacity, but provided challenges for diagnostic

¹ Academy of Medical Sciences (2020). *Preparing for a challenging winter 2020/21*. <https://acmedsci.ac.uk/file-download/51353957>

laboratories outside this process to engage and provide additional support. In future it will be important to consider how local and community-based diagnostics could complement the wider system to support the testing efforts, including exploring the value of local approaches for more localised decision-making and interventions in response to local outbreaks. As universities and other laboratories begin to reopen, skilled volunteers are resuming their usual positions, leaving a gap in the workforce required for the national testing response. There is a need for a sustainable workforce strategy, with an opportunity to engage recent university graduates and encourage greater permeability across the NHS, academia and industry to meet workforce requirements while enhancing expertise and building capacity. Acquiring sufficient, timely and long-term funding and contracts for diagnostic testing will also be key to providing the certainty needed for laboratories to secure the required resources and workforce to provide services going forward.

Looking ahead, participants emphasised the opportunity provided by the pandemic to position the UK as a leader in diagnostics in the long-term. This opportunity is consistent with the government's ambition to build a large-scale diagnostics industry in the UK as outlined in Pillar 5 of the strategy to scale up COVID-19 testing programmes.² Investing in the UK's diagnostic infrastructure, from discovery and development to evaluation and adoption, would ensure its future sustainability and could leverage further investment from the private sector into the UK diagnostics industry. It would also enable the rapid remobilisation of resources in the event of future epidemics, and allow for the advances in collaboration, innovation, regulatory agility, skills and infrastructure made throughout the COVID-19 pandemic to be repositioned to meet the UK's broader diagnostics demands for cancer, cardiovascular, and other disease areas. Such disease areas are likely to benefit from a precision medicine approach informed by appropriate prognostic and diagnostic tools.

Participants at the meeting, including representatives from academic and industry communities, expressed a desire to work with government and other partners across the life sciences sector to further develop the UK's testing strategy and sustainably build diagnostic capacity across the sectors.

This report summarises the key points from the roundtable discussion. Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows. The Academy has developed a statement outlining actions to ensure that the capacity and capability in academia and industry are utilised to best effect to support the UK's future diagnostic testing response. The statement has been informed by the roundtable discussions detailed in this report.³

² Department of Health and Social Care (2020). *Coronavirus (COVID-19) Scaling up our testing programmes*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878121/coronavirus-covid-19-testing-strategy.pdf

³ Academy of Medical Sciences (2020). *Lessons learnt: the role of academia and industry in the UK's diagnostic testing response COVID-19 – a statement by the Academy of Medical Sciences*. <https://www.acmedsci.ac.uk/COVID-diagnostics-statement>

Introduction

Test, trace and isolation (TTI) strategies are a key part of the UK Governments' responses to the COVID-19 epidemic. TTI involves initial isolation and rapid testing of patients with symptoms consistent with SARS-CoV-2 infection, as well as tracing their contacts who are required to quarantine and advised to report their own symptoms. To be effective, this strategy relies on a robust system that is rapid, accurate, and encompasses a high proportion of symptomatic cases. The UK's COVID-19 testing routes are outlined in four pillars (see Box 1).⁴ Combined with other non-pharmaceutical interventions, such as physical distancing and regular hand washing, TTI requires strong public acceptability, and is likely to play an important role in limiting the spread of infection, including the resurgence of COVID-19 in winter 2020/21.⁵

Box 1: COVID-19 testing pillars

As described on the government website, tests in the UK are carried out through a number of different routes:

- Pillar 1 involves testing in Public Health England (PHE) labs and NHS hospitals of swabs from those with a clinical need, and health and care workers.
- Pillar 2 entails testing of swabs from the wider population, as set out in government guidance.
- Pillar 3 is serology testing to show if people have antibodies from having had COVID-19.
- Pillar 4 comprises blood and swab testing for national surveillance supported by PHE, the Office for National Statistics (ONS), and research, academic, and scientific partners to learn more about the prevalence and spread of the virus and for other testing research purposes, such as the accuracy and ease of use of home testing.

An additional pillar in the government's strategy to scale up COVID-19 testing programmes, Pillar 5, involves building the diagnostics national effort for mass testing at a new scale.

⁴ Department of Health and Social Care (2020). *COVID-19 testing data: methodology note*. <https://www.gov.uk/government/publications/coronavirus-covid-19-testing-data-methodology/covid-19-testing-data-methodology-note>

⁵ Academy of Medical Sciences (2020). *Preparing for a challenging winter 2020/21*. <https://acmedsci.ac.uk/file-download/51353957>

Unlike some other countries, the UK was not equipped with the required national or regional capacity for diagnostic testing at the start of the UK COVID-19 epidemic in early 2020. This capability needed to be developed and expanded rapidly to cope with the rising number of infections, drawing on expertise and resources in academia and industry. The creation of the UK Lighthouse Laboratories Network has shown that the scale-up of testing can be done at speed.⁶ As the epidemic continues to spread in the UK, particularly as we approach winter, there is a need to maximise testing capacity, which can be supported through further engagement with industry and academia.

The roundtable brought together stakeholders from across academia, industry, funders, the NHS and government (see Annex 2 for a full list of participants) to:

- Consider the barriers encountered by academic and industrial laboratories at the start of the UK COVID-19 epidemic, as well as the enablers where there was successful engagement.
- Reflect on lessons learnt from the UK's and other countries' diagnostic testing response to the first wave of COVID-19 infection in spring 2020.
- Propose strategies to enable more effective diagnostic testing capacity across academia, industry and the NHS in the UK for COVID-19 and other emerging infections.

This report summarises the key points from the roundtable discussion. Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Academy of Medical Sciences, or its Fellows. The Academy has developed a statement outlining actions to ensure that the capacity and capability in academia and industry are utilised to best effect to support the UK's future diagnostic testing response. The statement has been informed by the roundtable discussions detailed in this report.⁷

⁶ UK Lighthouse Laboratories Network. <https://www.lighthouselabs.org.uk/>

⁷ Academy of Medical Sciences (2020). *Lessons learnt: the role of academia and industry in the UK's diagnostic testing response COVID-19 – a statement by the Academy of Medical Sciences*. <https://www.acmedsci.ac.uk/COVID-diagnostics-statement>

Summary of discussion: challenges and enablers to engagement with the UK's COVID-19 diagnostic testing response

In a short period of time, the UK has responded rapidly to expand its diagnostic testing capacity in response to the COVID-19 pandemic. However, as the number of infections continues to rise, there is a need to further increase testing capacity in line with demand. The UK boasts strong academic and industry sectors, as well as a national health service, which when combined have the capability and capacity to support national testing efforts. Participants at the roundtable explored how the expertise, skills and capability in these sectors could be further utilised to maximise the UK's testing response. In particular, participants discussed how collaborations could be fostered, innovation nurtured, and resources maximised to support COVID-19 diagnostic testing.

Fostering collaboration

The UK's testing response has been rapidly developed in response to the COVID-19 pandemic. However, the diagnostic testing sector is largely fragmented, which posed challenges to mobilising a testing response at speed. Participants explored how collaboration across sectors, including academia, industry and the NHS, could be strengthened to best support testing efforts in future.

Relationship building

Participants highlighted that a key enabler for engagement in the COVID-19 testing strategy has been collaboration across the life sciences sector. This cross-sectoral collaboration has enabled the exchange of staff, equipment, reagents, knowledge and skills. Strong relationships between the 'triple helix' of the NHS, academia and industry have supported the development of testing centres across the country, including a number of those in the UK Lighthouse Laboratories Network (see Box 2). Attendees agreed that fostering these types of relationships more widely to leverage the totality of high-quality academic and industry capability, including that in small and medium enterprises (SMEs), could bolster the UK's testing efforts. For example, early stage research developed in academia can be combined with expertise from industry to commercialise and scale-up innovations.

Box 2: UK Lighthouse Laboratories Network⁸

The UK Lighthouse Laboratories Network was established at the beginning of the pandemic to rapidly increase COVID-19 testing capacity and support the national effort against the coronavirus pandemic. Originally, three Lighthouse Laboratories were set up in Milton Keynes, Alderley Park and Glasgow. The Network has since expanded to include laboratories in Antrim, Newport and Cambridge and smaller associated laboratories, including the University of Birmingham and London MedCity. The Network and its development has been supported by organisations across the life sciences sector, including the Department of Health and Social Care, the Scottish and Welsh Governments, the Life Sciences Hub Wales, the NHS, Public Health England, Medicines Discovery Catapult, UK Biocentre, BioAscent, the Universities of Glasgow, Cambridge and Dundee, Randox, PerkinElmer, GSK and AstraZeneca.

Each of the six Lighthouse Laboratories receives samples from the NHS front line and other testing sites, such as COVID-19 drive-through testing centres. A skilled workforce and infrastructure provided from across the scientific community, including from industry and academia, enables the Lighthouse Laboratories to collectively process close to 200,000 tests per day. At the meeting, the strong partnership between the 'triple helix' of academia, industry and the NHS was highlighted as key to the success of the development of the Glasgow Lighthouse Laboratories and provides an important example of how collaboration across these sectors has supported the rapid expansion of COVID-19 testing capability.

Some participants felt that the pandemic has been a catalyst for collaborative working with the UK's in vitro diagnostics (IVD) community (see Box 3), and noted that utilising existing networks would be beneficial to engaging industry. For example, trade bodies such as the British In Vitro Diagnostics Association (BIVDA)⁹, the BioIndustry Association (BIA)¹⁰ and other networks such as the Covid Testing Network could play a key role in facilitating collaborations between member organisations and other stakeholders involved in the UK's testing processes.

Communication

Participants recognised the need to respond rapidly in the early stages of the pandemic, with decisions over testing necessarily being made swiftly. However, many attendees agreed that the testing response would have benefited from greater communication of the decisions made and transparency of the underpinning rationale. Such clarity could have been beneficial to help academia and industry understand how to engage with the testing processes and guide how they could most effectively contribute. Participants noted that communication had gradually improved over time, including with new leaders of the testing response, which has enabled greater engagement from academia and industry.

Some industry representatives that were engaged in the testing process noted the good communication from government around their roles and requirements to develop testing capacity. Conversely, other participants attempting to get involved, particularly those from SMEs, felt there was less clarity on the roles, remits and responsibilities of the key organisations and

⁸ UK Lighthouse Laboratories Network. <https://www.lighthouselabs.org.uk/>

⁹ The British In Vitro Diagnostic Association (BIVDA). <https://www.bivda.org.uk/>

¹⁰ The BioIndustry Association (BIA). <https://www.bioindustry.org/>

individuals coordinating diagnostic testing. This lack of clarity meant that many academic and industry stakeholders looking to engage in the process found it challenging to reach the appropriate channels across government and the NHS to discuss potential involvement. In some instances, confusion over roles and remits led to offers of support to central government from academia and industry being redirected locally, only to not be pursued further.

Box 3: The role of the UK's In Vitro Diagnostics industry in supporting the COVID-19 testing strategy

At the meeting, the British In Vitro Diagnostics Association (BIVDA) relayed the enthusiasm and willingness of the UK's in vitro diagnostic (IVD) community to further contribute to the UK's COVID-19 testing strategy by conducting tests or designing, manufacturing and supplying high quality products for use in the NHS and other settings. BIVDA is the national industry association for the manufacturers and distributors of diagnostic testing products in the UK and currently represents more than 95% of the industry.¹¹

While the IVD community has the capability to further contribute to the UK's national testing response, BIVDA highlighted the challenges in communicating this capability, including the community's assets, with those initially leading the testing efforts. The community has also expressed the need for clarity relating to the roles and remits of organisations and individuals, as well as the process for test evaluation.

With enhanced communication and collaboration, BIVDA is confident that the IVD community can work with the government and other partners in academia, industry and the NHS to increase testing capacity through the supply of high quality diagnostics and further testing facilities.

Attendees suggested that it would have been beneficial to establish a formal government-led diagnostics taskforce in the very early stages of the pandemic in partnership with key stakeholders across the diagnostics sector. Such a taskforce would have been useful to support the development of the national testing strategy, allocating clearly defined roles and responsibilities of organisations and individuals, and communicating these widely. For example, the role and remit of Public Health England (PHE) as outlined at the meeting is described in Box 4, but this may have been poorly understood at the time. In addition, attendees noted the benefits of communicating with, and learning from, international comparator nations and the strategies that have been implemented overseas. Further detail on international comparisons can be found in the section on 'Nurturing Innovation'.

Participants noted that, going forward, there would be value in establishing a taskforce to inform future testing strategies. It would also be beneficial to assess the existing testing capacity and capability, particularly increasing the understanding and protection of supply chains for equipment, reagents and other consumables, which have so far experienced challenges with

¹¹ The British In Vitro Diagnostic Association (BIVDA). <https://www.bivda.org.uk/About-BIVDA>

procurement. The Royal College of Pathologists has published a strategy on coordinating NHS laboratories, which some participants had already considered when developing strategies locally.¹²

In addition, some participants noted that the need to rapidly expand the UK's testing response had challenged the fair and transparent competitive IVD market in the NHS and in the private sectors. The lack of transparency around the call for competition was felt by some to have resulted in a small number of suppliers being awarded contracts, while others with capacity and capability have been overlooked. Transparency in the calls for and the allocation of suppliers would enable the allocation of the most suitable products at the most suitable prices.

Box 4: The role of Public Health England (PHE) in the UK's COVID-19 response

PHE was the first responder when it came to testing capability in the COVID-19 pandemic, rapidly reshaping expertise and infrastructure to address the epidemic and utilising its high containment microbiology capability and expertise in virus culture, activation and assay development. The remit of PHE is broad, and in the context of infectious diseases includes: surveillance of known pathogens and horizon scanning of new hazards; pathogen outbreak detection and investigation; the integration of whole genome sequencing data with epidemiology for major pathogens; and development and provision of specialist pathogen expertise, guidance and policies aiming towards prevention and treatment. It is not, however, configured for mass testing on the scale required by the pandemic.

PHE has helped to expand the UK's testing capacity by assisting rollout in regional laboratories; increasing NHS capacity; and initiating a programme to evaluate some of the first commercial diagnostics to support industry. PHE and collaborating laboratories are now operating at between 50,000-70,000 tests per week. Winter planning is an ongoing challenge and PHE continues to pursue a suitable diagnosis pipeline (from the supply of kits to the result dissemination), and maintain in-house tests for backup use.

PHE has had to respond to the COVID-19 pandemic while also responding to other ongoing public health priorities, including other pathogenic outbreaks such as Legionella. PHE has played a crucial advocacy role, interacting with the Advisory Committee on Dangerous Pathogens and the Health and Safety Executive to enable the pathogen to be used outside of CL3 laboratories. This was critical in enabling the rapid scale up of diagnostics. PHE also engaged with Medicines and Healthcare products Regulatory Agency (MHRA) to assist in regulatory flexibility to help advance testing innovations.

¹² The Royal College of Pathologists (2020). *COVID-19 Testing: A National Strategy*. <https://www.rcpath.org/profession/on-the-agenda/covid-19-testing-a-national-strategy.html>

Opportunities for the future

At the meeting, participants highlighted the following future opportunities:

- Investing in existing relationships between academia, industry and the NHS, and developing further networks and alliances, will help to foster new relationships, create new collaborations and align incentives across the sectors, both in the near and longer-term.
- The governance and operation of any future testing strategies should reflect the level of urgency in crises and should be guided by a taskforce with cross-sectoral representation from across the testing community.
- Greater transparency and timely communication of decisions to all stakeholders involved would provide clarity on the engagement opportunities for academia and industry and guide how they could most effectively contribute.
- International communication and collaboration would enable learning from comparator nations on the successful and unsuccessful strategies that have been implemented overseas.

Nurturing innovation

The COVID-19 pandemic has brought with it requirements of national testing efforts at a scale and pace that are unprecedented. Diagnostic innovations will be key to support the COVID-19 testing processes in the UK, for example, by increasing the speed and decreasing the costs of tests. Participants discussed how effective innovations can be identified, developed and adopted to increase testing capability, capitalising on expertise across academia, industry and the NHS.

Test development

In developing new innovations, participants emphasised the need for better definition of the cases in which a test could be used (the use cases) to inform target product profiles and the design of effective tests for specific purposes. Potential use cases identified at the meeting included tests for disease diagnosis in symptomatic individuals; tests to reduce quarantine measures; mass testing in institutions such as schools and universities; testing at large-scale events such as sports stadia; and tests to determine immunity in vaccinated populations. Definition of use cases will require input from across sectors, particularly the NHS, which should be used as a stimulus for innovation by identifying areas of unmet diagnostic need on the frontline. Attendees noted that there is ongoing work to improve product profiles and that this should be communicated and coordinated across the sector. It was noted that the pillars present in the UK's national testing strategy (see Box 1) were not established based on use cases, and therefore working across these pillars will be beneficial when developing innovations. Attendees shared that Pillars 1 and 2 were beginning to work more closely together, which may support the design and implementation of new tests.

Many participants felt that there was also scope for the UK to explore more innovative ways of testing. For example, pooling multiple samples for testing and only retesting individual samples when there is positive result, the use of multiplex testing for several viruses, and saliva testing, are all being investigated. For serology testing, investigating the role of T-cells may provide further insight into immunity building and vaccination prospects. In addition, participants called for innovation to be considered in the round. For instance, some noted that the packaging used when collecting and transporting samples is a bottleneck for the testing process. This could be improved to limit the manual handling required to unpack samples prior to processing, while maintaining appropriate health safeguards for those involved in the logistics chain. Each of these innovations could speed up the testing process and increase capacity, while cutting the overall cost of testing. As such, sample pooling is already being implemented in some places in the UK, for example the regular and systematic testing of all university students in Cambridge. Some industry representatives noted that while they are currently pooling samples for private testing, they are unable to get approval for use beyond this. The potential of such innovations are being recognised by government, which is looking to implement changes in packaging and sample pooling.

Box 5: An international perspective on COVID-19 testing – India

In March 2020, private laboratories in India were asked to assist local government with COVID-19 testing. Logistical barriers in the accreditation process were overcome by moving to an entirely online system. Over six months, testing capacity in India increased from 10,000 tests to over 1 million tests conducted per day.

The Syngene laboratory in Bangalore, Karnataka is a private laboratory conducting around 1,500 tests a day for the local government as well as its own staff. Through a validated pooled testing procedure it has increased its testing capacity five-fold. Syngene provides tests with a 24 hour turnaround time to staff every two weeks and has implemented measures in zone-restricted working, social distancing, quarantining and contact tracing. Within two cycles of testing all staff members, a reduction in test positivity rates was observed in 50% of cohorts. Next steps for Syngene include introducing new testing methods to reduce turnaround time; comparing saliva and nasopharyngeal samples; and establishing ELISA-based serosurveillance.

In addition, some participants said that securing adequate test samples, including for validation, has proven challenging. Alternative methods for speeding up test validation are being explored, for example, using blinded markers and quality control samples for laboratories to conduct validation themselves, potentially decreasing the need for involvement from government bodies in the validation process. Participants also suggested that a national biobank of samples collected from a variety of clinical use cases with annotated clinical outcomes would be useful to enable more rapid development and evaluation of diagnostic methodologies.

Embedding innovation

To embed innovation effectively, attendees noted the importance of understanding the roles of the NHS, academia and industry, and the expectations they have of each other when developing innovation. In particular, attendees highlighted the need to align incentives across the sectors and utilise academic expertise in combination with industry's role in scaling-up to meet testing demands. Participants also stressed the importance of early engagement with the NHS and social care settings from the very outset to understand the adoption and implementation challenges they might face and to ensure that practical solutions are developed with these settings in mind.

The COVID-19 National Diagnostic Research and Evaluation Platform (CONDOR) was also highlighted for its role in evaluating new diagnostic tests in hospital and community care settings through the Medtech and IVD Co-operatives (MICs). This independent platform works to ensure the quality of innovations in testing and identify how they can be most valuable to the NHS. Capacity is, however, limited and therefore greater investment in this infrastructure could help to meet demand, especially given the high rate of innovation at the time of the meeting.

Regulatory agility

Participants indicated that there has been a positive shift in some regulatory mechanisms during the pandemic, for example

the expedited process for clinical investigations directly relating to COVID-19.¹³ Constructive conversations with the Medicines and Healthcare products Regulatory Agency (MHRA) and the new regulatory flexibilities were noted as being particularly beneficial to advancing innovations at speed. Attendees highlighted that the ability to maintain this regulatory agility beyond the pandemic will be vital to ensure the UK is a leader for advancing innovation. Participants also noted that the business cases required to bring innovation into the NHS have benefited from efficiencies during the pandemic, and encouraged the development of a common format to allow for more efficient business case formulation and approval in the future.

In addition, the initial requirements for handling of samples being tested for SARS-CoV-2 was containment level 3, which limited the number of laboratories able to provide testing. This has been downgraded in the interim so that tests for SARS-CoV-2 can be conducted in containment level 2 laboratories, enabling more testing and research to be able to take place. This move was positively received by many participants, with some adding that future incidents may benefit from strong links between industry and academia to allow companies access to containment laboratories for early diagnostic testing research and development.

Accreditation

The most notable regulatory challenge highlighted by attendees and experienced by industry, academia and NHS laboratories, has been the accreditation process required to deliver testing, such as polymerase chain reaction (PCR) testing for the SARS-CoV-2 virus. Although many academic and industry laboratory staff are highly trained in running PCR tests, laboratories still require a two-day in-person accreditation service from The United Kingdom Accreditation Service (UKAS). In addition, some already accredited laboratories have required further approval for the expansion of testing. The accreditation process, while important to ensure safety and reliability of tests and results, can be a lengthy and arduous process, historically taking up to 18 months. A fast-track COVID-19 assessment process is now available from UKAS; however, it is not yet clear how quickly laboratories may gain the correct level of accreditation. Participants highlighted the need for a more risk-proportionate approach to the accreditation process in times of crisis to ensure testing capacity can be rapidly scaled up.

The Francis Crick Institute has managed the challenges of the accreditation process temporarily by forming legal agreements with accredited laboratories to ensure quality standards (see Box 6). In other countries, such as India, accreditation has taken place online through a virtual audit process (see Box 5).

¹³ Medicines and Healthcare products Regulatory Agency (2020). *Guidance: Medical devices clinical investigations during the coronavirus (COVID-19) outbreak*. <https://www.gov.uk/guidance/medical-devices-clinical-investigations-during-the-coronavirus-covid-19-outbreak>

Box 6: The Francis Crick Institute

The Francis Crick Institute has worked alongside University College London Hospitals (UCLH) NHS Foundation Trust, the Institute of Cancer Research and Health Services Laboratories (HSL) to create the Crick COVID-19 Consortium.¹⁴ This consortium has supported the NHS with diagnostic testing by working with local partners and repurposing laboratories, all using in-house equipment and skills. A drive-through testing service was also established by the Institute, which is operated by UCLH and HSL. Up to 2,000 tests a day are now carried out at the Institute, with patients obtaining results within 24 hours.

The Crick was able to overcome the challenge of accreditation in the initial stages of this initiative by obtaining an extended accreditation of the laboratories at HSL, and ensuring all processes were closely coordinated. This enabled the Crick to play a key role in rapidly testing at a number of London NHS Trusts, allowing staff to safely deliver care, including non-COVID-19 routine care such operations for cancer patients.¹⁵

This model could be considered for other academic centres, where there is a valuable partner with existing accreditation. In parallel, achieving independent accreditation would further enable innovations and developments in diagnostic testing in academic institutes to be rapidly implemented. An accreditation process which ensures full and necessary due diligence in a quicker timeframe, given the current emergency, would facilitate this goal.

¹⁴ Aitken *et al.* (2020). *Author Correction: Scalable and robust SARS-CoV-2 testing in an academic center*. *Nat Biotechnol.* **38(8)**, 1000.

¹⁵ Houlihan *et al.* (2020). *Pandemic peak SARS-CoV-2 infection and seroconversion rates in London frontline health-care workers*. *Lancet.* **396(10246)**, e6-e7

Opportunities for the future

At the meeting, participants highlighted the following future opportunities:

- Better defining the use cases for tests to assist in the creation of better target product profiles for tests and therefore more effective tests for specific unmet purposes, for example, mass testing in schools or large-scale events.
- Early engagement with the NHS and social care settings to understand their innovation needs, as well as the adoption and implementation challenges, will help to ensure practical solutions are developed and embedded effectively.
- Maintaining the regulatory agility catalysed by the COVID-19 pandemic to position the UK as a leader in advancing innovation.
- Considering innovative mechanisms to enable a more proportionate accreditation process to ensure that laboratories with the capacity and capability are able to contribute to the national testing response.

Maximising resources

Academia and industry laboratories have the capacity and capability to provide support to the UK's COVID-19 testing response. However, the required infrastructure must be developed and maintained to enable this. Participants discussed some of these requirements, including connecting national and local efforts, workforce, funding and contracts and digital infrastructure.

Connecting national and local efforts

The UK's diagnostics sector is largely fragmented and therefore can pose challenges to developing a national testing strategy for COVID-19. The decision to create a centralised testing system with multiple sampling sites and fewer consolidated testing centres across the UK enabled the rapid setup of UK Lighthouse Laboratories and other testing centres. This system increased testing capacity significantly in record time and in partnership with some industry partners, who worked as collaborators rather than competitors (see Box 2). As described previously, the Lighthouse Laboratory Network is constantly evolving to bring in new collaborators, for example the testing facility in Cambridge, which was initially set up locally to test frontline NHS staff and care homes (see Box 7).

Box 7: Cambridge COVID-19 Testing Facility

Collaboration between the University of Cambridge, AstraZeneca and GSK has resulted in the formation of the Cambridge COVID-19 testing facility on the Cambridge Biomedical Campus, with capacity for tens of thousands of tests per day. Now a highly automated high-throughput testing centre, it was initially set up independently from the UK Lighthouse Laboratories Network in 6 weeks and utilised the local skilled workforce in Cambridge with agreement from funders to allow postdoctoral researchers to volunteer to work in the centre. The testing facility uses alternative chemical reagents to those used in other UK Lighthouse Laboratories to avoid potential disruption to supply chains. The centre now works as an integral part of Pillar 2, having transitioned to a paid staffing model with staff being employed by Charles River Laboratories. In addition to delivering testing capacity, the centre is innovating to create simplified testing methodologies and to investigate new testing strategies including sample pooling.

Participants felt that it is important to consider the testing response as one system, with the desire to work collaboratively and engage extra capacity at local levels. Some attendees indicated that the more centralised approach to testing initially prevented a number of laboratories from contributing to the diagnostic testing response, limiting potential capacity at a time of unprecedented need. Some highlighted that a less centralised approach may allow for more localised decision making and interventions in response to local outbreaks, and could also help to mitigate the impacts of other external factors, such as adverse weather conditions, on the logistics of transporting samples. Many areas have provided successful local testing initiatives, for example the Norwich Research Park and Earlham Institute (see Box 8). In future it will be important to consider how local and community-based diagnostics could complement the wider system to support the testing efforts.

Box 8: Norwich Research Park

A local collaboration between the Norwich Research Park Partners has seen The Earlham Institute and the University of East Anglia (UEA) support the Norfolk and Norwich University Hospital to scale up COVID testing capacity, leading to a seven-fold increase in test processing. To facilitate the rapid scale-up, an automated testing pipeline operating extended hours, seven days a week, was developed using equipment and laboratories loaned from the Earlham Institute, Quadram Institute and UEA.

A volunteer programme across the park was also coordinated by the Earlham Institute, to recruit the required skilled workforce, resulting in over 200 microbiologists coming forward, of which 35 were seconded to NHS laboratories to process tests. Critically, reagents were sourced outside of the NHS supply chain to avoid procurement issues. These laboratories are now seen as satellite laboratories for the NHS following auditing and validation by NHS diagnostic teams.

This collaboration led to the Norwich Testing Initiative pilot, established to identify pre-symptomatic and asymptomatic carriers, and provide a template for campus-based testing programmes. The pilot saw over 3,000 samples analysed and has proven the effectiveness of local swabbing and testing. The Earlham Institute is now supporting UEA to test students and staff, and trialling new testing processes to increase capacity and minimise costs.

Workforce

Attendees expressed their gratitude for the testing workforce, noting their dedication and diligence across the UK. With no sign of the testing workload easing, and the negative media attention impacting morale, there is a risk of burnout for the workforce, and a strong requirement to build resilience. Many participants praised the university sector in particular for providing immense support for the testing process through the provision of postdoctoral and PhD students, much of which had been on a voluntary basis. As universities and other laboratories begin to reopen, skilled volunteers are returning to their day-jobs, leaving a gap in the workforce required for the national testing response. Attendees shared that the government had written to universities requesting their further support in providing experienced staff in the coming months.

Participants highlighted the need for a sustainable workforce strategy, and the opportunity to engage recent graduates from universities in need of employment. Participants discussed the different job roles within testing laboratories. These require various levels of skills and expertise, from unpacking samples, which doesn't require a life sciences background, to laboratory technicians and laboratory managers, for which a life sciences background and varying levels of experience would be essential. Participants noted how these positions provided much needed opportunities for a range of graduates (from the life sciences and beyond), which would be particularly welcome in the challenging job market as a result of the pandemic. Some attendees were keen to offer their support, for example by sharing job opportunities with university students and alumni. To facilitate this, clear role descriptions outlining the job requirements and expectations are needed, as well as targeted advertising to graduates and others across the UK.

Some participants noted further enablers for workforce transitioning, for example, secondment opportunities could play a role in attracting more experienced managerial staff to the testing process. In addition, the apprenticeship levy could help to bring placement year students into the testing strategy, and contractual arrangements whereby volunteers would have protected jobs to return to following the pandemic could also be considered. Participants also highlighted that a greater number of trained clinical scientists was required across the NHS, industry and academia in the immediate and longer-term

and that permeability across the sectors would be particularly beneficial to the workforce, supporting scientists with their career paths and progression (see Box 9).

Box 9: King's collaboration to increase Pillar 1 and Pillar 2 testing capacity

An NHS-academia-industry collaboration between Guy's and St Thomas' and King's College Hospital NHS Foundation Trusts, King's College London and Viapath led to the establishment of a Pillar 1 laboratory delivering coronavirus testing for healthcare workers, local care homes, and those with a clinical need within the participating hospitals.

The cross-sectoral collaboration was key to the rapid testing response and encouraged staff permeability across sectors, as well as diagnostic innovation, leading to three PhD positions and numerous academic publications, including a piece on how COVID-19 helped dissolve the professional and organisational boundaries across the translational research pathway.^{16, 17} The adoption of new technologies, automation of data entry and surge capacity offered by academic laboratories based in King's College London further supported the expansion of testing capacity at pace. The need to evaluate different assays while maintaining fast daily processing times for clinical care, procurement of consumables, and uncertainty on the expected testing approach in the initial stages of the pandemic posed challenges that the collaboration worked to address. Building on its combined experience, the collaboration is now focussing on increasing capacity to cope with the anticipated additional need this winter while setting up a new Pillar 2 testing facility for the wider population.¹⁸

Funding and contracts

The government has invested significant sums of money into infrastructure for COVID-19 diagnostic testing since the beginning of the pandemic. Where funding has been secured, it has enabled the rapid development and implementation of innovation. The DnaNudge platform is a good example of this (see Box 10). However, some attendees indicated that acquiring sufficient, timely and long-term funding for diagnostic testing has been challenging. This has impacted on the ability of laboratories to scale up testing processes, due to the up-front fees needed to secure resources and workforce for a set period of time. In addition, participants indicated that agreeing contracts in a timely fashion has been challenging. This has contributed to financial uncertainty and limited the ability to expand testing processes. Challenges experienced with the reimbursement of funds can be particularly problematic, leading to cash-flow problems that may be less easily absorbed by smaller industry or academic laboratories. Attendees at the meeting heard that the issue regarding contracts is being considered by government; participants agreed that this would provide much needed certainty for laboratories to continue their services going forward.

¹⁶ Edgeworth & Malim (2020). *Translational research in the time of COVID: dissolving boundaries*. PLoS Pathog, **16(9)**, e1008898.

¹⁷ Viapath (2020). *COVID-19: Resourcing and the June Almeida Laboratory*. <http://www.viapath.co.uk/covid19/workforce/expansion2>

¹⁸ King's Health Partners (2020). *King's Health Partners and Testing Alliance offer new COVID-19 test capacity*. <https://www.kingshealthpartners.org/latest/3040-kings-health-partners-and-testing-alliance-offer-143500-covid19-tests-weekly>

Box 10: DnaNudge

The DnaNudge COVID-19 test, produced by an Imperial startup using innovation developed at Imperial College London, has repurposed existing technology to create a portable PCR test delivering results in 90 minutes.¹⁹ Collaboration between the startup, Imperial College London and several NHS hospitals enabled the performance of this point-of-care test to be further understood in clinical settings. The collaboration had pre-existing funding in a related area of diagnostics supported by the NIHR, and benefitted from strong pre-existing relationships between the partners.²⁰ Since determining efficacy and sensitivity of the test, there has been government investment of £161 million for scale up and roll out of 5.8 million tests in health and social care settings.

Digital infrastructure

Participants agreed that strong digital infrastructure underpinning the testing response is vital to its success and expansion. The limitations of the NHS's digital infrastructure posed initial challenges for some testing sites due to the difficulties in sharing data related to COVID-19 testing with NHS and social care settings. Some attendees noted that the pandemic had precipitated much-needed improvements in IT systems that have been contemplated for many years. As a result, digital infrastructure has progressed significantly, with particular success in connecting pathology laboratories in the NHS and wider public health laboratories. Attendees noted that an understanding of the direction of travel for digital infrastructure would be useful to guide future investment of resources, particularly for industry. Participants were therefore keen to ensure that any future testing strategy features digital infrastructure as a key component and includes input from IT specialists.

Opportunities for the future

- Going forward, it will be important to consider the testing response as one system, with central government laboratories working collaboratively with and engaging extra capacity at local levels.
- The dissemination of job opportunities with clear role definitions to recent graduates from all universities should be explored to meet workforce requirements.
- Better permeability across the sectors will support the immediate diagnostic testing staffing needs while enhancing expertise and collaborations across sectors in the longer-term.

¹⁹ Gibani et al. (2020). *Assessing a novel, lab-free, point-of-care test for SARS-CoV-2 (CovidNudge): a diagnostic accuracy study*. *Lancet Microbe*.

²⁰ Gurralla et al. (2016). *Novel pH sensing semiconductor for point-of-care detection of HIV-1 viremia*. *Scientific Reports*. **6**, 36000.

- Reassurance around contracts and longer-term funding to help with the resourcing and staffing commitments made by laboratories is needed.
- TTI strategies are underpinned by IT and digital capability which must be invested in and maintained to ensure it is fit for purpose.

Looking ahead: the UK as a leader in diagnostic testing

At the time of the meeting, the pandemic showed no signs of slowing in the UK, and attendees noted that testing capacity would need to be expanded to cope with increasing demands over the winter.²¹ Participants agreed that going forward, there are opportunities to engage industry and academia in future COVID-19 testing processes to assist with this capacity building and to assess and respond to unmet diagnostic needs.

Participants emphasised that COVID-19 presented the UK with an opportunity to position itself as a leader in diagnostics throughout and beyond the pandemic; an opportunity which is consistent with the government's ambition to build a large-scale diagnostics industry in the UK, as outlined in Pillar 5 of the strategy to scale up COVID-19 testing programmes.²² This would require funding to incentivise and advance the diagnostic sector and ensure its future sustainability, which will be vital in preparations for any resurgence of COVID-19 or other future disease pandemics. For a sector which, prior to the COVID-19 pandemic, had historically received little government funding, such investment could also send a positive signal to leverage further investment from the private sector into the UK diagnostics industry.

Investing in the UK's diagnostic infrastructure from discovery and development, to evaluation and adoption, could enable the rapid remobilisation of resources in the event of future epidemics. It would also allow for the advances in collaboration, innovation, regulatory agility, skills and infrastructure made throughout the COVID-19 pandemic to be repositioned to meet the UK's broader diagnostics demands for cancer, cardiovascular, and other disease areas. Taking full advantage of precision medicine for these major health challenges is reliant on better diagnostic and prognostic tools that can facilitate risk stratification, including point of care testing. By repurposing diagnostic testing capacity during periods when the UK is not facing an epidemic, it would enable the rapid remobilisation of resources should a future resurgence or pandemic occur.

Participants at the meeting, including representatives from academic and industry communities, expressed a desire to work with government and other partners across the life sciences sector to further develop the UK's testing strategy and sustainably build diagnostic capacity across the sectors.

²¹ Academy of Medical Sciences (2020). Preparing for a challenging winter 2020/21 <https://acmedsci.ac.uk/file-download/51353957>

²² Department of Health and Social Care (2020). *Coronavirus (COVID-19) Scaling up our testing programmes*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/878121/coronavirus-covid-19-testing-strategy.pdf

Annex 1: Agenda

09.30 – 9.35	Welcome and introduction <i>Chair: Professor Sir John Tooke FMedSci, Executive Chair, Academic Health Solutions</i>
9.35 – 10.05	Perspectives from across the sector <i>Scheduled speakers:</i> <ul style="list-style-type: none"> • Professor Jo Martin, Royal College of Pathologists • Professor Neil Woodford, Public Health England • Professor Jonathan Edgeworth, King's College London • Dr Sonia Gandhi, The Francis Crick Institute • Helen Dent, BIVDA • Professor Dame Anna Dominiczak DBE FMedSci, Department of Health and Social Care and University of Glasgow
10.05 – 10.20	Q&A and discussion An opportunity for participants to reflect on the perspectives from across the sector and ask questions.
10.20 – 10.45	Discussion of barriers and enablers to engaging in the testing process This session will focus on exploring the main barriers and enablers experienced by academia and industry to engage in the testing strategy. <ul style="list-style-type: none"> • Are there any additional barriers and enablers beyond those described in the background document? • Are there any additional UK or international exemplars that we should be aware of?
10.45 – 10.50	Break
10.50 – 11.20	Lessons learnt from the UK's initial approach to COVID-19 testing Reflecting on the challenges and enablers, this session will provide an opportunity for participants to discuss the learnings from the initial response to COVID-19 testing. Issues to discuss include: <ul style="list-style-type: none"> • How could the barriers to testing be mitigated in future? • What were the key enablers and how can these be implemented across the UK?
11.20 – 11.55	Strategies to enable more effective diagnostic testing capacity Attendees are asked to propose strategies to enable engagement of academia and industry in testing processes to enhance the UK's diagnostic testing capacity in future. Issues to discuss include: <ul style="list-style-type: none"> • What are the roles of academia and industry in building the UK's diagnostic testing capacity? • How can academia and industry partner with the NHS to ensure effective adoption and implementation of testing innovations in healthcare settings? • What can be put in place now? What should be considered in the longer term? • What is required to build sustainability in the UK's approach to testing for COVID-19 and other emerging infections? • Who should have oversight of any future strategies and initiatives?
11.55 – 12.00	Summary of key points raised and next steps <i>Chair: Professor Sir John Tooke FMedSci</i>
12.00	Close of meeting

Annex 2: Attendee List

Professor Grahame Cooke, Professor of Infectious Diseases, Imperial College London
Simon Denegri OBE, Executive Director, Academy of Medical Sciences
Helen Dent, Chief Operating Officer, BIVDA
John de Pury, Assistant Director of Policy, Universities UK
Professor Dame Anna Dominiczak DBE FRSE FMedSci, Director of Laboratories, COVID-19 National Testing Programme, Department of Health and Social Care and Regius Professor of Medicine, Vice Principal and Head of the College of Medical, Veterinary and Life Sciences, University of Glasgow
Professor Jonathan Edgeworth, Director of the Centre for Clinical Infection and Diagnostics Research, King's College London / Guy's and St Thomas's Hospital
Professor Sir Mike Ferguson CBE FRS FMedSci, Regius Professor of Life Sciences, University of Dundee
Dr Sonia Gandhi, Group leader, Neurodegeneration Biology Laboratory, The Francis Crick Institute
Dr Jane Gate, Executive Director, Association for Innovation, Research and Technology Organisations
Professor David Heymann CBE FMedSci, Professor of Infectious Diseases Epidemiology, London School of Hygiene and Tropical Medicine
James Hynard (observer), Private Secretary and Deputy Head of the Office to the Chief Medical Officer, Department of Health and Social Care
Professor Jo Martin, President, Royal College of Pathologists
Dr Joanne Mason, R&D Director, Yourgene
Kiran Mazumdar-Shaw, Chair, Biocon
Professor Sharon Peacock CBE FMedSci, Director of COVID-19 Genomics UK Consortium, University of Cambridge
Dr Tim Peakman OBE, Chief Operating Officer, University of Leeds
Dr Jonathan Pearce, Interim Director, Covid-19 Response, Medical Research Council
Tim Perkin, Co-Founder, Covid Testing Network
Professor Deenan Pillay, Professor of Virology, University College London
Dr Steve Rees, Vice-President Discovery Biology, AstraZeneca
Professor John Simpson, Professor of Respiratory Medicine, Newcastle University
Professor Sir John Tooke FMedSci (Chair), Executive Chair, Academic Health Solutions
Professor Neil Woodford, Deputy Director NIS Laboratories, Public Health England
Dr Peter Wrighton-Smith, CEO, Oxford Immunotec

Secretariat

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Dr Claire Cope, Head of Policy, Academy of Medical Sciences
Claire Bithell, Head of Communications, Academy of Medical Sciences
Thomas Langford, Policy Intern, Academy of Medical Sciences
George Philips, Policy Officer, Academy of Medical Sciences
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