Introduction

The Institute of Biomedical Science (IBMS) is the professional body for the UK's workforce of 22,000 Health and Care Professions Council (HCPC) registered biomedical scientists.

This workforce is employed largely, but not wholly, in UK pathology laboratories. IBMS members are the UK's expert scientific workforce in the safe and effective operation of pathology testing and form a key part of the government's testing programme for COVID-19 virus and antibodies. For this reason, our response for evidence to the Test and Trace hearing focuses primarily on the testing aspects of the COVID-19 response.

Key issues

1. Testing Strategy

Cases of COVID-19 were first confirmed in England at the end of January 2020. At this time contact tracing and outbreak management were led by Public Health England via health protection teams.

As the number of cases in the community rose, it became clear that the UK's limited testing capacity would be insufficient to meet demand. This lack of testing capacity was a key contributing factor to the government's decision to end the 'containment' phase and shift to the 'delay' phase. Testing capacity was targeted and reserved for patients in hospital.

A number of factors contributed to the limited testing capacity:

- public health laboratories were not geared up for mass testing
- initial classification of the virus as a category 3 pathogen further limited the number of laboratories that were able to undertake testing (this was addressed in early March to allow testing to be carried out in containment level 2 laboratories)
- the UK's diagnostic industry was not as well developed as that in other European countries and testing was further hampered by a shortage of testing materials and reagents.

As actions were taken to increase the existing laboratory capacity, IBMS President, Allan Wilson wrote to the Secretary of State for Health and Social Care (7 April) offering laboratory service-specific expert advice on scaling up the testing process, helping hospitals in their redeployment of staff to maximise testing capacity and providing quality assurance of the testing process in order to facilitate supporting frontline staff to be able to get back to work. As the NHS Test and Trace programme was launched a similar offer was made to Baroness Harding (13 May). Neither offer was taken up.

On 2 April, the government published its response to address the continuing capacity limitations by launching its five-pillar strategy which signalled the establishment of additional 'lighthouse laboratories' and to announce its ambitious target of reaching 100,000 tests per day.

The creation of this additional standalone capacity prompted the IBMS to raise concerns regarding the development of a parallel testing system and its impact on the utilisation of staff, equipment and consumables in both systems.

The announcement of the ambitious testing target, whilst commendable in its ambition to galvanise effort and deliver much needed testing capacity, became a distraction and diverted resource from testing effort to the achievement of an arbitrary political target. Pillar 2 laboratories were incentivised to stockpile consumables which could have been used more effectively by Pillar 1 laboratories.

Lessons learned

From the outset of the pandemic, the IBMS, along with other organisations, has been concerned about the lack of a clear and comprehensive testing strategy. Whilst the publication of the NHS Test and Trace business plan is welcomed, the IBMS recommends that it continues to be refreshed and updated to reflect the changing environment in which we live.

The IBMS also recommends that the government undertakes capacity/demand modelling for all stages of the NHS Test and Trace programme and works to ensure the security of the supply chain to avoid interruptions.

In relation to the NHS Test and Trace programme, the IBMS would caution against the announcement of further arbitrary political targets, with no evidence base, to avoid distraction and dilution of effort.

2. Capacity and demand

The establishment of the lighthouse laboratories increased the UK's testing capacity and was achieved at pace. However, the lack of integration and collaboration with laboratories providing Pillar 1 testing has created problems within the testing regime.

Pillar 1 and Pillar 2 laboratories have been working in parallel, not in collaboration. This has at times created unhealthy competition with laboratories competing for limited reagents and reducing the number of tests that could be carried out.

Testing capacity is only one element of an effective testing system. The events of recent weeks have shown that there is a mismatch between capacity and demand and this demand can reasonably be expected to increase significantly as we move in to winter.

Testing capacity is a projection based on reports from laboratories on how many tests they can carry out each day based on availability of resources. Available testing capacity is not the same as utilisation and testing capacity not used on any one day cannot be carried forward for future use. There needs to be robust modelling of demand versus daily capacity across all providers and clear communication with the public where demand outstrips supply.

The government has again set a challenging target, 500,00 tests per day by the end of October. This will need a further increase in capacity to meet ongoing demand, including informed predictions of demand, a road map as to how and where this capacity will be created and detailed plans for the delivery of all aspects of testing including sufficient testing and processing capacity and access to supplies and staff.

Lessons learned

The IBMS has, and continues to, call for an operational alignment of all laboratory providers whether they support Pillar 1 or 2 in order to maximise available capacity and utilisation.

The IBMS recommends that the government undertakes capacity/demand modelling for all stages of the NHS Test and Trace programme to avoid potential mismatch.

It is likely that demand will outstrip capacity over the winter period and the IBMS recommends that a clear strategy on prioritisation of testing is available and communicated in advance of the event occurring.

3. Resources

The rapid increase in testing capacity brought about by the establishment of the lighthouse laboratories relied on unregulated, volunteer staff, mainly from academia, as well as 'borrowed' or donated equipment, again from universities and commercial companies. This arrangement has been put under pressure on a number of fronts. As with the volunteer staff, universities are now asking for the return of their loaned equipment and this will impact on the testing capacity available.

Staffing

The mobilisation of staff from academia and other sectors to staff the lighthouse laboratories was necessary. However, the nuances of running a mass testing diagnostic laboratory and the expertise required is very different from those required in a research laboratory. Additionally, the tests being undertaken are not always easy to set up and then to interpret.

Whilst calling for greater alignment between Pillar 1 and Pillar 2 laboratories, both in terms of staffing and processes, the IBMS has promoted the importance of all laboratories having appropriately qualified/skilled staff to undertake the testing. Also, for adequate supervision by HCPC registered scientists in order to assure the quality of the testing and the result –the wrong test result is worse than no result at all. There should be opportunities to second senior operational staff from UKAS (United Kingdom Accreditation Service) accredited laboratories into lighthouse laboratories and vice versa to share and accelerate learning for the benefit of those being tested.

As was to be expected with the start of the new academic term, 'volunteer' staff are now returning to their universities and, therefore, potentially reducing staffing capacity to deliver testing. On 3rd September the Prime Minister wrote to universities asking for their assistance in scaling up capacity for winter and for them to support the requirement for over 400 staff for lighthouse laboratories and the NHS Test and Trace team by sending back staff who had previously volunteered.

As increases in capacity are likely to be needed over winter and beyond, and within both Pillar 1 and 2 laboratories, it is vital that there is an integrated staffing plan to meet this need. The pool of available laboratory staff is limited and integration of staffing resource is vital to ensure that one testing stream does not destabilise the other through 'poaching' of staff.

Testing platforms

As has been previously noted, the UK diagnostic industry was starting from a low baseline at the beginning of the pandemic. This resulted in limited availability of instruments and shortages of consumables to support the testing regime.

The government has supported the testing regime through the purchase of analysers, and this is to be welcomed. However, it should be noted that funding needs to extend beyond the initial equipment purchase to cover the cost of reagents, maintenance of the equipment, staff to operate and integration with clinical IT systems. Reliance on a single provider of analysers and consumables should be avoided as it builds in further risk to the resilience of the testing system.

While a single supplier solution may support consistency in user familiarity and comparability of test results, the risks of security of the supply chain outweigh these benefits. The IBMS, therefore, supports a multiplicity of testing platforms to improve the resilience of the supply chain and advocates for the involvement of HCPC registered scientists, who understand the differences in analyser performance and limitations, ease of use and outputs, as an integral component of the testing regime.

Lessons learned

The IBMS recommends close alignment between all providers of the testing function within the NHS Test and Trace programme and for the active involvement of registered scientists, and other professionals, as the required additional capacity is created.

Laboratory staff, both qualified and unqualified, are a key resource in delivering the NHS Test and Trace programme and should be identified as such. A human resource plan needs to be developed across all providers of the testing element of the NHS Test and Trace programme to ensure that staffing demands can be planned for and met that deliver a consistent service standard.

The IBMS also recommends the use of multiple platforms to carry out testing to minimise the risk associated with the supply chain and maximise resilience.

The associated additional costs of capital equipment purchases need to be identified and supported centrally.

Future arrangements

In recognition of the likely need to flex future capacity, both in terms of equipment and staffing, as further waves are encountered, the IBMS has proposed a model for future delivery of COVID-19 testing. In this model testing resource should be concentrated on a limited number of mass testing molecular laboratory sites within existing NHS pathology networks across the UK with sufficient capacity to expand quickly in the event of further outbreaks of this or future pandemics. This model would have inbuilt expansion options by utilising capacity in other NHS pathology networks with more limited molecular testing capacity.

This renewed focus on NHS diagnostic and clinical laboratory services would maximise the capacity and expertise of the UK pathology community and hold in reserve a strengthened and more formal partnership arrangement with the lighthouse laboratories with registered, expert biomedical and clinical scientists embedded in the new centres to ensure the quality of standards and procedures in a model similar to the 'Nightingale' hospitals for COVID-19 patients.

This model also has the benefit of allowing staff, who are not required in molecular virology during periods of low demand, to be cross trained in other pathology disciplines and deployed to

these areas to deal with backlog activity. This would mirror the cross training of scientists that has taken place to create additional capacity in virology.

4. Operational aspects

Key to the success of the testing programme is the speed with which results are produced and made available to those who need to know in order to make clinically informed decisions. The international standard is for all tests to be turned around within 24 hours. In recent weeks there has been significant deterioration in the turnaround times in the Pillar 2 stream of the programme with reported performance figures showing that the percentage of 24- hour test turnaround has dropped by half.

Turnaround time targets and performance against these targets needs to equitable, well defined and clear across all testing streams. This would allow for accurate comparison, early identification of 'hot spots' and targeted support at both national and local levels.

Linked to turnaround times is the provision of the test result to those who need to know and who can take appropriate action. When the lighthouse laboratories were first established there were concerns that result data from Pillar 2 tests were not getting into all the relevant patient health records fast enough and, in some cases, were not being entered into the patient record at all. Additionally, local authorities complained that they have not been provided with the data either in sufficient detail or sufficiently quickly enough to support a local response. Whilst these data issues are reported to have been resolved, future provision of laboratory testing must include integration with existing clinical systems as part of the service specification.

Lessons learned

In order to make informed decisions, turnaround performance data for all the testing streams needs to be measured and reported on, regularly and frequently, in a consistent way against clearly defined and agreed targets. Underperformance should be acknowledged, the root cause established, and supportive measures implemented.

There should be clearly defined data sets and turnaround times for recording and making test result information available to those who need to know.

5. NHS COVID-19 app

The launch of digital technology across the four home nations in support of identifying people at risk of contracting COVID-19 and then protecting them is to be welcomed. However, the use of different apps across the UK and the inability of the apps to 'talk' to each other, given the ease of movement within the UK, is a significant shortcoming.

The initial problem with the app adopted for use in England, whereby those whose results were produced by Pillar 1 laboratories could not have their result registered within the app, has been resolved. However, although England and Wales adopted the same app, this problem was resolved before launch in Wales.

Lessons learned

There is a need for greater alignment of approach across the home nations to accelerate learning, avoid confusion and to promote confidence to the general public.

6. New technologies

In early August 2020, the UK government announced two new rapid SARS-CoV-2 tests capable of delivering results in 90 minutes, and there are many media headlines heralding rapid testing and its ability to be a "game changer" in the COVID-19 testing programme.

However, these rapid tests are not the silver bullets in the coronavirus response, they are only one part of the armoury. The most important aspect of laboratory medicine is the diagnostic testing pathway which includes the end to end process consisting of:

- correctly identifying those who need testing
- obtaining appropriate samples from the correct patient
- producing results in a timely manner
- making the results available to the clinical decision maker
- interpreting the results and taking the appropriate action.

The goal of all high-quality medical laboratory services can be summarised as; ensuring the right test, for the right patient, at the right time, and giving the 'right' result to inform the right response.

Access to rapid testing in the UK will support individuals and communities and complement the national COVID-19 testing strategy for PCR testing across NHS and lighthouse laboratories, but will not be the solution to matching testing capacity with demand which has been the challenge faced throughout the pandemic.

Rapid testing

Rapid testing is defined as an analytical test performed for a patient by a healthcare professional with a short delivery time to results (less than 4 hours). Rapid testing may be carried out as a point of care/near patient test. Due to the complex nature of the testing process, it is more likely that this rapid testing is carried out in a laboratory setting and supervised by HCPC registered biomedical or clinical scientists. The current priorities for rapid testing are to enable the acute management of patients and clinical services where only the use of rapid testing will facilitate better patient care.

Rapid testing devices are available to healthcare providers on a limited scale and have been unable and are unlikely to meet testing demand in this setting. It is therefore vital that rapid tests are only used where there is no other clinically acceptable alternative.

Speed of reporting is countered with the compromise of limited test processing capacity and is dependent upon the platform used. Capacity can be as low as 9 tests or as high as 138 test per day on a 24-hour operating schedule. This is compounded by a number of systems only being able to process samples one at a time. Results often need to be manually linked to the patient health record as these platforms do not generally allow electronic transmission of data to patient files. This may also present challenges with the reporting of results to the NHS and appropriate public health bodies.

The absence of economies of scale means that decentralised rapid testing can be prohibitively expensive (reports of £140 per test for reagents only), especially when compared to large scale

laboratory testing (typically £20 per test for reagents). Rapid testing is also labour intensive and, combined with the cost of consumables, makes it the most expensive modality of testing.

Medical laboratory high throughput RT-PCR testing
This is the most widespread form of testing nationally, where swab samples are processed using automated or semi-automated instruments. This is also an area where constant innovation is improving the testing pathway. For example, a study is underway to validate tests that use a saliva sample rather than a nose/throat swab.

PCR testing is carried out in accredited NHS laboratories, usually hospital based, or other laboratories and should be overseen by a team of competent HCPC registered biomedical scientists and/or clinical scientists.

It is typically the preferred test, due to its sensitivity (ability to detect weak positives), for patients before elective operations and invasive procedures. It is suitable for large scale testing over a clinically acceptable timeframe. Results are typically delivered within 15-24 hours back to the hospital or the requesting clinician.

Centralised mass testing
Mass testing provides testing for screening purposes in the wider population. Swabs are collected at sampling centres from symptomatic and asymptomatic individuals. Samples are then processed on a large scale in a laboratory setting which enables thousands of tests to be processed each day. Results for these samples are expected to be reported within 24 hours. Due to the scale of the testing operations any failures in the system can cause a delay to thousands of sample results being available in a timely manner.

Lessons learned
Despite the wide publicity that 'rapid testing' has received in the press it is only a small part of the national response to fighting COVID-19. There will need to be an integrated use of all three forms of testing outlined above.

Rapid testing should only be utilised when results are clinically required quicker than can be provided by a traditional laboratory-based system. This is due to a lack of testing capacity, limited availability of platforms and reagents, significant expense of testing and the limitations of the tests (i.e. risk of incorrect results). It is paramount for patient safety that these tests are only used in the clinical scenarios approved by the manufacturer together with local validation. It must not be assumed that these systems are appropriate for testing in all patient cohorts.

IBMS recommendations

Testing for COVID-19 remains crucial for the control of the virus through identifying possible close contacts of those who test positive and in turn asking those close contacts to isolate, the spread of the disease can be contained. This approach is key in the absence of approved vaccines.

To support the NHS Test and Trace system and the government's COVID-19 response the IBMS recommends the following:

- The government invests in the diagnostics industry in the same way that it has invested and incentivised the pharmaceutical industry to build a UK based diagnostic manufacturing base that can supply laboratories in the UK in the event of a future pandemic.
- The government publishes, and regularly updates, a clear and comprehensive testing strategy that identifies clinical priorities.
- The testing response utilises multiple platforms to minimise the risk associated with the interruption of supply chains and maximise resilience of testing.
- There is greater integration of Pillar 1 and Pillar 2 laboratories to allow current, and future, mass testing laboratories to be run as a single system to maximise both capacity and utilisation.
- An integrated workforce plan is developed for Pillar 1 and 2 laboratories including cross training of staff to prepare for future pandemics and to secure a sustainable experienced and appropriately qualified workforce to support the testing effort.
- Experienced members of the pathology community are involved in key decision-making groups to inform strategy development, facilitate improved decision-making and improve operational deployment of testing to benefit patients and public.
- An agreed set of national performance standards are published, regularly and frequently, for all testing streams to monitor performance, diagnose problems and speedily resolve any performance issues.