ACSLM / MLSA JOINT SUBMISSION

Oireachtas Special Committee on COVID-19

19th June 2020

INTRODUCTION

The Medical Laboratory Scientists Association (MLSA) is the trade union representing medical scientists in Ireland. It has over 1,800 members in public and private hospital laboratories and non-hospital clinical diagnostic laboratories across the country. The Academy of Clinical Science and Laboratory Medicine is the professional body representing medical scientists in Ireland.

Medical scientists are highly educated and skilled scientists, with Level 8 degrees and specific multi-disciplinary clinical training to work in a clinical diagnostic laboratory setting. Over 70% of medical scientists have MSc degrees or other post-graduate qualifications including PhD, FRCPath and MBA. The profession is regulated by CORU, the regulatory body for Health and Social Care professions and registration with CORU will be a statutory requirement to practise as a medical scientist in clinical laboratories from 31st March 2021.

The medical scientist workforce has tremendous skill, expertise and experience in laboratory diagnostics, test development, assessment, adoption and whole-service rapid transformation for the benefit of the patient and indeed the population. They have demonstrated this by responding to the COVID-19 pandemic and providing new diagnostic services for a new virus expertly, rapidly and on a nationwide basis. Another added benefit of this high-quality testing for SARS-CoV-2 and associated biomarkers is good antimicrobial stewardship, through reduction in broad spectrum antimicrobial use thus reducing the potential for the pandemic to drive a further wave of antimicrobial resistance. This expertise shown with COVID-19 crosses all levels of the health service allowing patients to be stratified according to key laboratory parameters, leading to improved patient outcomes and ultimately increasing hospital capacity. Medical Scientists will also continue to play a key role in the surveillance of this virus.

KEY RECOMMENDATIONS

1. There is a need for more Medical Scientists in practice in Ireland, even more so now due to COVID-19 requirements (both diagnosis and ongoing patient care), the return to normal health service delivery and future healthcare development plans. Improving the career pathway, addressing pay anomalies and planning additional training places for Medical Scientists are urgently needed to address this.
2. We must use the current time to review and plan Irish laboratory services for COVID-19 screening requirements, a probable second wave of the pandemic and the return to other hospital activity. The HSE should engage urgently with Medical Scientists to maximise the contribution of the profession to better health outcomes for the population. Much of the profession's thoughts on the subject are contained in this document
3. There is an urgent need for progress on IT connectivity across the health service and to deliver the long-awaited single Laboratory Information System and Individual Health Identifier.

COVID-19 AND SARS-COV-2 TESTING IN IRELAND

Medical scientists in Irish hospital clinical laboratories have demonstrated their scientific and diagnostic skills and expertise by responding to the COVID-19 pandemic and providing new diagnostic services for a new virus expertly, rapidly and on a nationwide basis. Laboratory testing includes testing for the SARS-CoV-2 virus itself as well as a range of other analysis protocols required for the management of patients with COVID-19 infection. It should be noted that all of the resources that we had at our disposal were funnelled to these services, a situation that will not be sustainable under conditions of business as usual. As we look forward, we must ensure the sustainability of the COVID-19 diagnostic services for the next 18 months or more until the pandemic has run its course, in addition to all of the other laboratory services that are required as the routine health service is re-established and into the future.

1. Since the first positive COVID-19 case in February, medical scientists and Irish clinical laboratories have responded promptly by introducing SARS-CoV-2 testing in over forty sites.
2. This has required redesignation of laboratory spaces, introduction of new instrumentation that required extensive validation and verification, training of staff and considerable innovation when reagents and consumables were in short supply.
3. There has been excellent c-ooperation between laboratories and the National Clinical Programme for Pathology to deliver this analysis. This was augmented by co-operation with HSE procurement.
4. Dispersed nationwide testing has provided a service responsive to local need.
5. This was achieved while continuing to provide the existing internationally accredited diagnostic service to patients on a 24 hour / seven day a week basis. (Irish National Accreditation Board accreditation to ISO 15189)
6. The demand for many routine services was reduced during the crisis, which prevented the laboratory diagnostic service becoming overwhelmed and allowed laboratory resources to be diverted to support SARS-CoV-2 analysis and the other new analysis protocols required for COVID-19 patient management..
7. As the health service returns to normal activity in the new COVID-19 world, laboratories are understaffed and will struggle to handle the increased workload.
8. The Test/Track/ Trace strategy and rapid turnaround times will be key to ensuring containment of COVID-19 infection, as evidenced from other countries.
9. Public confidence in the testing process is crucial. Initial delays between sampling, testing and results to the patient did not inspire public confidence. Audit of each stage of the process is key to identifying gaps in these pathways.

10. The removal of restrictions, the subsequent scaling up of testing and requirements for pre-hospital admission, discharge and transfer testing will require total turnaround time (from sampling to results delivery) within 24 hours. This will increase the pressure on routine and out of hours laboratory services.

11. This rapid turnaround time is achievable within the setting of hospital laboratories because they have complete electronic traceability of samples from receipt in the laboratory to reporting, well-established logistics for specimen transport and local IT connectivity.

12. Once reported on Laboratory Information Systems, results are available to both GPs and hospital clinicians.

13. In addition, the availability of surveillance scientists to follow up on those that have tested positive would ensure that all relevant details are passed without delay to the Public Health Officers for contact tracing.

14. Medical Scientists must be involved at all levels and central in the discussions on configuration of the service needed to diagnose and monitor this disease

15. Existing challenges in recruitment and retention have been escalated to the HSE for some time; with the additional pressures arising from COVID-19, efforts to address these challenges must be fast tracked.

16. Retention of our graduates requires offering an improved career path as envisioned in *New Horizons*, a joint paper by the MLSA and ACSLM presented to the Department of Health in 2016. A unified career structure for scientists, progressing to Consultant grade as in the UK, will provide a pathway for progression that will enable laboratories to build their workforce and their service to meet demand.

FULL RECOMMENDATIONS

1. Investment: future planning for COVID-19 requires investment in clinical laboratory services to ensure:

   1.1. An adequate supply of suitably skilled scientists to provide the required enhanced laboratory services in accredited hospital laboratories

   1.2. A unified scientific career structure for clinical diagnostic laboratories, including the opportunity to progress to consultant scientist grade, to enable adequate recruitment and retention of scientists.

   1.3. Guaranteed supplies of reagents for analysis and analytical platforms capable of providing rapid and batch analysis.

   1.4. Review of testing pathways to optimise and match with laboratory services and existing pathways. The sustainability of all other diagnostic laboratory services on a 24/7 basis must

be considered in any planning of the workflow demands of COVID-19-related diagnostic testing

1.5. Investment in IT connectivity solutions to fast track ordering of tests, return of results and support integrated patient care.

1.6. Prioritisation of the long-awaited single Laboratory Information System is key to the co-ordination of testing, integration of patient care and the streamlined collation of statistical and epidemiological information. Co-ordination of testing on a national basis has been hindered by the lack of an integrated national laboratory information system. Never has the need for an integrated IT system been more evident than during the current pandemic. SARS-CoV-2 test results were recorded on different systems throughout the country, making collation of data extremely difficult. COVID-19 patients presenting to hospital having been tested in the community needed to be tested again because clinicians in hospitals had no access to their results. GPs had no way of tracking samples through the testing system. MedLIS could have solved all these problems while presenting a platform to integrated care. In September 2015, the HSE signed a contract with Cerner, a multinational healthcare technology company, to replace the existing, stand-alone laboratory IT systems in Ireland with a fully integrated national system, known as MedLIS. After many delays, the system was due to go live in its first pilot site but this has now been further delayed by the COVID-19 crisis. Laboratory systems need to integrate between services to provide a full patient history. Laboratory results, if available to all relevant service users, would serve as a useful link between primary care and the acute hospital setting, both public and private. The Slaintecare report recognises the need to integrate care: the MedLIS project gives the opportunity to offer IT connectivity between all stakeholders within healthcare. Full roll-out of MedLIS nationwide must be an urgent priority

1.7. Introduction of an Individual Health Identifier (IHI) is key to eliminating duplication of testing, analysis and reporting.

2. Planning and Integration for the Future of the COVID-19 Pandemic (Test/ Track/ Trace)

2.1. Medical Scientists understand and deliver workflows that provide efficient and rapid end to end testing. They are willing and able and should be involved in the commissioning of the pathway.

2.2. Use of local clinical laboratories is key to rapid turnaround of results.

2.3. Sampling centres should be linked to the laboratories performing the testing to ensure efficient turnaround times and reporting to Public Health, GPs and the person being tested.

3. Testing and Analysis Pathways Matched to Need

3.1. Public health and political decisions will dictate what screening services are to be provided for the general public and those engaging with the health service (e.g. pre op, scheduled

admissions etc). However, such policies must be informed by the potential testing capacity and prudent use of resources

3.2. There are different groups to be tested which, require different pathways based on the urgency/clinical need.

3.3. Symptomatic cases require rapid results.

3.4. Healthcare staff must be tested promptly if symptomatic or a close contact.

3.5. Testing must be responsive to emerging clusters.

3.6. All results must be reported within agreed time frames.

3.7. Testing laboratories require a combination of rapid and batch analysis capacity.

3.8. Existing pathways between primary care and local clinical laboratories should be used to capitalise on the existing logistics and IT connectivity.

3.9. The required timeframes and quality assurance standards dictate that analysis must be provided within the clinical laboratory testing network of accredited laboratories in the country and not outsourced.

3.10. Reporting frameworks must be streamlined and co-ordinated. At the beginning there was much duplication of reports required from different national bodies (e.g HPSC and HSE) There are now national reporting frameworks that could be used templates in the future to improve efficiencies.

4. Engagement with the MLSA and ACSLM

The MLSA and ACSLM are key stakeholders in clinical laboratory services and have a wealth of expertise in the field. Despite repeated requests, engagement and consultation with the organisations representing medical scientists nationwide has been inadequate to date and must improve. This is particularly disappointing given the willing contribution and efforts of our members to the COVID-19 response. As an example, SARS-CoV-2 testing has been outsourced without consultation with the MLSA, as required under the Public Service Stability Agreement.

CONCLUSION

The pandemic has demonstrated how much Ireland requires its highly educated and skilled medical scientists to be at the forefront of decisions about testing, quality assurance and training and to be able to respond rapidly when crises such as this occur. It has also clearly shown that investment is required in clinical laboratories to equip them for the demands arising from the ongoing pandemic and future service needs. Urgent investment in staffing, equipment and information technology is essential to safeguard existing services and to allow for future developments.

The government, Department of Health, HSE and NPHET have spoken throughout the pandemic of the importance of being led by science in all the measures that they take. At the same time, the Department and HSE have failed to adequately engage with the trade union and professional organisation representing the main cohort of scientific staff employed in the health service, whose output determines 70% of medical diagnoses.

As we emerge from the first wave of the COVID-19 pandemic, the MLSA and ACSLM seek investment in clinical laboratories and their workforce to provide for current and future service needs. This will require the creation of a single spine scientific career structure for all scientists in clinical diagnostic laboratories, as recommended by the 2001 Expert Group Report on Medical Technicians and Medical Technologist Grades. In addition, and in the interest of public safety, all scientists involved in clinical diagnostic testing should require state registration by CORU.

The single spine career structure should allow suitably qualified and experienced medical scientists to progress to consultant scientist grade, as is common in many health services worldwide, so that the Irish health service can benefit from the expertise and leadership of scientists that is essential for the future development of the service.

Appendix : Issues Listed for Consideration by Oireachtas Special Committee

1. Daily/weekly capacity for clinical laboratories

As of June 1st there were over forty hospital laboratories providing seven day a week SARS-CoV-2 virus detection testing, many on a 24/7 basis. Testing capabilities of laboratories vary, ranging from rapid single test systems to large-scale batch analysers, providing from approximately 20 to up to 1,000 reports per day depending on the technology, workflow and staff resources.

By mid-June 2020, over 350,000 SARS-CoV-2 tests have been performed nationally and over 30% of those were conducted in the hospital laboratories, whose capacity has steadily increased since the start of the pandemic. Some 60,000 swabs have been outsourced to a commercial laboratory in Germany.

It is important to note that as winter approaches with its collection of normal respiratory viruses and flu, that differential diagnosis of respiratory symptoms will be required. The demand for laboratory testing for respiratory viruses will exceed previous years due to the presence of COVID-19 and the need for rapid isolation of cases. In addition, unless a combined test for SARS-CoV-2, influenza and other virus can be developed, the testing capacity of analysers will be compromised by the need for parallel testing for the other respiratory viruses.

2. Procurement and provision position

There has been a rapid national procurement of a variety of analytical products and systems during this emergency. This diversification has provided both a sustainable service and supply chain, which offer a range of turnaround times, balanced with the throughput of each analytical platform or instrument.

During this pandemic there has been outstanding cooperation between hospital laboratories and the National Clinical Pathology Programme (NCPP). Medical scientists understood the critical need to have robust and accurate testing algorithms in place at each site and used their existing networks to share scientific and analytical knowledge and reagents. They have shared expertise on test validation and supported each other through informal national networks. The establishment of weekly teleconference calls between Dr Mary Keogan, HSE National Clinical Lead for Pathology, and Microbiology Chief Medical Scientists involved in COVID-19 testing nationwide, has provided a forum where information can be pooled on testing methodologies, test validations and reagent supply and which provides a single source for procurement of test kits and reagents.

Rapid tests have a turnaround time of an hour. These are suitable for urgent or small numbers only. Batched tests that may take up to six hours can perform higher numbers, up to 92 samples per batch. For the main part there is a 24-hour turnaround time from receipt of samples for testing in the clinical laboratory.

Lesson learned: Monopolisation of the marketplace is not healthy. There needs to be a strategic approach to ensure that there is sufficient diversification across a range of platforms for this service so that the HSE is not dependent on a single supplier. However this provides logistical challenges for procurement.

Lesson learned: There is a need to strike a balance between innovation and quick adoption – there have been numerous different assays used. None have been introduced without rigorous evaluation of performance organised locally or through group verification of assays – pooling and sharing information very quickly from multiple laboratories.

Lesson learned: There was cooperation between the laboratories, the HSE and external companies in procurement of this equipment, there are new relationships and networks developed that can be built on in the future.

3. Scaling-up the testing following the removal of restrictions

Over the past three months Clinical Microbiology laboratories have gained huge experience and expertise in managing SARS-CoV-2 testing in a crisis setting where other laboratory activity was low. Moving forward as restrictions are eased and removed, the level of testing needs to be sustainable. It is important that the processes put in place in laboratories are realistic for the medium term

- Adequate staffing for safe and sufficient provision of the service
- A resilient supply of reagents including swabs.
- Analytical testing platforms that are suitable for the requirements of the service.
- The necessary IT links and interfaces to allow automated and timely reporting of results.

It is important that there is laboratory representation and engagement nationally where large-scale screening is planned. This is also necessary at community level to ensure sampling schedules are matched with laboratory capacity.

Testing is carried out for diagnosis, for screening and for gathering data to understand the spread or level of disease in a population. Any testing programme must be clear as to its purpose, and the tests chosen appropriate for that purpose. The scaling up of testing following removal of restrictions must be done on a sustainable level. Resilience of supply is needed. Widespread testing strategies must be based on the prevalence of the virus and the cost-effectiveness of the service.

As nursing homes are now trying to restore visitors, communication at a local level is required to ensure effective workflow planning by coordination of sampling with testing capacity. The rapid availability of results for these areas both staff and patients is vital and any planned monitoring of these patient and care setting cohorts needs to be managed in conjunction with the testing laboratory to spread planned testing over the week to ensure the best outcomes.

Decisions about who is tested are public health and political ones but must be informed by testing capacity and opportunity costs.

4. Investigation of capacity of outcomes of different testing pathways

There is a need for different patient work-streams - one for the emergency/unexpected events such as emergency surgery or referral to another hospital site and the other for the planned events such as elective surgeries, Caesarean Sections, Endoscopy etc. Additionally, pathways need to be considered for both the admission and discharge of patients.

Models and systems for the identification of urgent samples and the rapid turnaround of results already exist in our hospital laboratories where certain areas such as ED, ICU, Theatre, Oncology are prioritised. SARS-CoV-2 testing will need to be included into these pre-existing pathways.

Personnel responsible for community screening should have a defined pathway for fast-track testing if required; the introduction of an Individual Health Identifier would ensure speedy tracing and reduce duplication.

5. Provision of swabs and other consumables

The HSE has done a huge amount of work in procuring a large range of supplies to allow testing. People have been seconded to do this work alone. The procurement system put in place needs to be regularised and augmented by medical scientists to allow them to provide the necessary expertise. What is required is a dedicated team to look at the range of tests available and what can be done to ensure a continuously reliable supply.

The procurement department benefitted from expert medical scientist advice during the pandemic and could be broadened going forward. As we diversify the testing platforms, procurement must be aware that certain platforms have very specific swab requirements. Procurement of swabs must match the platform requirements.

6. Sampling centres

There is now an opportunity, when screening levels are low, to review the processes in place in sampling centres to ensure that their practices are in line with laboratory requirements for all samples. Over the past three months there has been good communication at local level to ensure that requests meet laboratory minimum acceptance criteria. Medical Scientists are best placed to advise on the quality requirements necessary to safeguard a high quality result which, include the importance of correct sampling technique, correct sample type and sample labelling.

It is worth noting that robust systems are in place for all other Primary Care samples sent from General Practice and that this pathway should be considered for samples ordered by the GP. In the majority of cases automatic electronic reporting occurs once the report has been authorised and systems for phone communication with GP's exist with efficient turnaround times.

Medical Scientists would normally engage with users of our service with respect to correct samples and their identifiers as this affects the quality of our resulting. Quality of sample is reflected in the quality of our result. The quality of the sample is critical to the performance of the test (right sample at the right time with the right test). We need to ensure that those taking the samples continue to be trained to do so. We would advise against the practice of asking patients to take their own samples, or using a postal service for self-testing for SARS-CoV-2.

Currently no standardised labelling systems for samples has been put in place, however, we can help and advise on this to align with existing systems. A standardised labelling system with barcodes, which can be read by the Laboratory Information Systems in all testing laboratories would be a distinct advantage. The barcode should capture the required dataset for tracing.

Some unintentional misinformation regarding testing delays in the early days of the pandemic, appeared in both print and broadcasting media reports. Clinicians, HSE representatives and media commentators often referred to delays in testing when they meant delays in sampling which were then referred for testing: this undermined public confidence in the testing process. While there were some delays in performing tests in hospital laboratories at some stages of the pandemic, this was mainly due to reagent supply issues that were quickly overcome. In most instances the reported delays appear to have been in taking the specimens or in batching the community specimens for transporting to the Enfer laboratory via the NVRL.

In more recent times, the terminology on the testing process has been expanded to measure the entire multistep process from the time it is determined that a test is required on an individual through to the completion of contact tracing for individuals who test positive. This clarification of the terminology is welcome, and the process can be further defined to identify and audit at what part of the multi-step process a delay may occur.

Could the GP service replace large sampling centres?

Clinical Laboratories perform millions of tests every year and more than 99% get reported back to their correct destinations successfully.

A more sustainable model on an ongoing basis would be to use these normal channels, where the sample comes from e.g. GP surgeries and Primary Care Centres and the results are reported in a timely manner using existing electronic reporting pathways.

We are in a position to provide feedback on the integrity of the samples we receive to maximise the quality of the samples, data on type of sample, age of sample.

Medical Scientists are a key member of the team, we have a lot to offer, we also need to control for quality of the samples that arrive in the laboratory as this has an effect on the quality of our results. We have a vested interest in providing the best service possible to our patients, obviously.

7. Cost of the test

Costs for individual tests vary and best value for money can be achieved with large scale batched analysers. Single rapid tests can be used for acute settings where results are required to guide treatment pathways and to comply with pre surgical screening guidelines. The cost of a test includes not only the cost of the assay but the equipment purchase and on-going maintenance costs as well as staffing.

Currently costs for SARS-CoV-2 testing are entirely dependent on the test method and on the system employed, usually single testing for emergency use is more expensive than large batch testing. The cost of laboratory testing should be considered in the context of the cost of use of single rooms and PPE. If we can reduce the need for PPE etc. and the health burden on the country, this is money well spent. These costs will be additional to the requirements for flu testing for the flu season, for example.

8. Timeline of the result

Where local or regional planning occurs to match community screening with capacity at local sites, the TAT can be 24 hours from receipt of the swab to generation of a report. However, it should be understood that mechanisms for electronic reporting of negative results to Department of Public Health are required to ensure acceptable timelines for the result back to the patient.

There are other IT connectivity solutions that will aid the TAT of the result within the laboratory, there is the potential to interface the results from the analyser to the laboratory information system. This will not only improve the TAT but it will also reduce the risk of transcription errors.

IT connectivity is a matter of urgency so that results are dispatched real time; screening results go out in a 24 hours period. Manual direct entry of results should be eliminated from our laboratories as it is inefficient and there is a risk of transcription errors.

9. Effectiveness of testing

The SARS-CoV-2 assays have high sensitivity and specificity but the result is dependent on the quality of the sample. The 'Test, track, trace' has proved to be an effective strategy in preventing the growth in positive cases and timely and appropriate testing is key to rapid response.

Going forward testing may be carried out in many settings but must be carried out as part of a quality assured system, meeting accreditation standards in regulated and approved settings. Accreditation standards apply to both laboratory and near patient testing settings performed by appropriately qualified staff. Different technologies will be used, depending on the clinical setting, clinical pathways and public health need.

10. Developments in testing: Seroprevalence and antibody testing

The current national guidance states that this assay is for research only, as the relationship between the presence of antibody and immunity is still to be clarified.