Written Evidence Submitted by RJALogix

(C190108)

EXECUTIVE SUMMARY

RJALogix thanks the Science and Technology Committee for the opportunity to provide evidence to its inquiry on UK Science, Research and Technology Capability and Influence in Global Disease Outbreaks. We would like to take this opportunity to provide evidence in response to the following topics outlined in the Committee's Terms of Reference:

2. The capacity and capability of the UK research base in providing a response to the outbreak, in terms of: the development of testing, diagnostic methods and technologies

4. The capacity to manufacture and distribute testing, diagnostics, therapeutics and vaccines: both standing capacity and capacity able to be mobilised

5. The capturing during the crisis of data of the quality needed to inform: decisions made during the crisis; and to maximise the learnings afterwards

RJALogix was formed in 2015 as a UK specialist medical devices distributor. We are a UK-registered SME company, based in Henley-on-Thames. Formed by ex-NHS staff, the business works to bring the benefits of niche technologies from innovative global manufacturers to all UK healthcare environments. At this challenging time, we have worked hard to expand our product range to meet the immediate needs and support ongoing clinical efforts in tackling COVID-19. Having developed an innovative COVID-19 management system, and as the sole UK distributor of the world's only near-patient, rapid point of care COVID-19 antigen test that can be manufactured at scale, RJALogix is uniquely placed to strengthen the Government's response to the current pandemic and help embed across the country the most robust and effective approach to testing, tracing and ongoing management as possible.

1. INTRODUCTION

1.1. RJALogix welcomes this Science and Technology Committee inquiry and is grateful for the opportunity to provide evidence to support the development of the UK and global response to disease outbreaks, including the current COVID-19 pandemic.

2. THE CAPACITY AND CAPABILITY OF THE UK RESEARCH BASE IN PROVIDING A RESPONSE TO THE OUTBREAK IN TERMS OF THE DEVELOPMENT OF TESTING, DIAGNOSTIC METHODS AND TECHNOLOGIES

2.1. RJALogix has developed a holistic COVID-19 Management System, the adoption of which would support the implementation of a rapid antigen (point-of-care) testing strategy, including strengthening the identification of asymptomatic cases, which is vital to controlling the outbreak. Our 'COVID-19 Toolkit' comprises of (a) a leading antigen test, (b) an antibody test and related Apps & reporting system to show the count and location of positive test cases.

2.2. The system has been created in the UK although we assemble component parts from overseas. 60% of the profits made in this venture would remain in the UK and indeed, the system is flexible to incorporate UK partners, going forward. In the meantime. RJALogix has been

working with Quidel and WHPM, US based manufactures of antigen and antibody tests, Sofia and Covisure, for SARS-COV-2 (also known as COVID-19) and have taken on UK-distribution as part of our overall COVID-19 Management System.

2.3. Our on-the-spot antigen test (Sofia SARS Antigen FIA, manufactured by Quidel, a US company) can be used to test whether a person currently has SARS-COV-2. This test works in combination with a portable and lightweight local analyser device (the Sofia and Sofia 2 analysers) which can analyse results in just 15 minutes.[1] This provides opportunities for a rapid response at place of testing and supports the adoption of effective infection control measures, such as asking individuals to isolate or follow other appropriate protocols.

2.4. The Sofia SARS Antigen test works by taking a non-intrusive nasal swab and using the combined local analyser to develop results in 15 minutes. The test has a clinical sensitivity of 96.7%, clinical specificity of 100% and relative accuracy of 99.5%, with results comparing favourably to the Government's current PCR test accuracy.[2]

2.5. Furthermore, our on-the-spot antibody test (Covisure, manufactured by WHPM, a US company) can be used to test whether a person has had COVID-19 through the detection of IgM and IgG antibodies that are developed as part of the body's immune response to the virus. The test is carried out by using a simple blood prick sample and using the combined local analyser to develop results in 15 minutes. The local analyser also has the flexibility to use UK-manufactured testing assays as and when these become available.

2.6. The Covisure test has a sensitivity of 97.5%, clinical specificity of 100% and relative accuracy of 99.2%.[3] These results can be used to indicate that a patient has potentially been exposed to the virus. IgM antibodies will indicate that a patient has active or recent infection, while IgG antibodies develop later as the disease progresses, and generally do not appear until the second week after symptom onset, thus reflecting past infection.

2.7. The effectiveness of Covisure tests are further strengthened through a complementary digital app and database. Covisure test results are recorded in the Covisure App, which operates on both Apple and Android devices, helping to ensure that there is a build-up of data confirming the locations and numbers of users who have taken the tests and tested positive to having had the virus.

2.8. Results from the Sofia and Sofia 2 local analyser devices are stored in the Sofia App and saved into an online platform. This platform provides opportunities to communicate early detection, disease onset and progression in local communities, enabling policymakers, healthcare professionals and individual users to observe, track, report and respond rapidly to emerging infectious diseases in local areas. The database also supports the recording of individuals' symptoms following infection, helping to build a more detailed understanding of the complications arising from COVID-19 and the support that will need to be put in place in the coming months.

2.9. Together with personal protective equipment (PPE) and social-distancing measures, the RJALogix COVID-19 Management System can support COVID-19 management through rapid, on-

[1] Quidel. Sofia SARS Antigen DIA. Features & Benefits. Available: https://www.quidel.com/immunoassays/rapid-sars-tests/sofia-sars-antigen-fia
[2] Quidel. Sofia SARS Antigen FIA. Available: https://www.quidel.com/immunoassays/rapid-sars-tests/sofia-sars-antigen-fia
[3] RJALogix. COVID-19 Management System. Available: http://www.rjalogix.com/

the-spot antigen and antibody testing and results for health and care organisations to apply additional processes to allow localised layers of control and screening.

3. THE CAPACITY TO MANUFACTURE AND DISTRIBUTE TESTING, DIAGNOSTICS, THERAPEUTICS AND VACCINES

3.1. RJALogix has considerable capacity to support the manufacturing and distribution of testing and diagnostics that can support the response to COVID-19. The current ambition is to manufacture 1.8 million Sofia SARS Antigen tests per week, with Quidel starting international exports as well as serving its US domestic market.

4. THE CAPTURING DURING THE CRISIS OF DATA OF THE QUANTITY AND QUALITY NEEDED TO INFORM DECISIONS MADE DURING THE CRISIS AND TO MAXIMISE LEARNINGS

4.1. The Covisure and Sofia Apps provide a powerful tool to store test results, record profiles and map user movements. They are available from the App Store and Google Play, with users encouraged to create a profile while waiting for their test and record their results once they have received them. The apps also allow the recording of supporting details such as key-worker status, risk factors and demographic profiles. Details are then stored securely to help plot user movement and identify COVID-19 hotspots. Geo-fencing can warn others of the proximity of recent positive tests and the in-App notifications and/or SMS messaging also enables the broadcast of messages to the user community.

4.2. The database behind the Covisure and Sofia Apps is a valuable source of real-time COVID-19 information that can support healthcare professionals, NHS leaders and Government decision-making during the pandemic, and help to ensure the most accurate and robust picture of infection rates across the country.

5. POST COVID SYMPTOMS

5.1. The COVID management diagnostic system includes another device which can be used post-COVID for patients with symptoms of shortness of breath and heart problems, to accelerate decision-making for the most critical conditions including heart failure, acute coronary syndrome, myocardial infection and thromboembolic events.

6. SUPPORTING THE NHS DURING WINTER

6.1. As the NHS approaches new pressures during the winter months, it will be vital to distinguish between patients with COVID-like symptoms and those with the virus. The Sofia 2 device (with a different assay) is available to NHS providers to accurately screen COVID-19 from other respiratory conditions with similar symptoms, such as Flu (type A), Flu (type B) and Respiratory syncytial virus (RSV).

6.2. In addition to supporting the NHS to differentiate between COVID-like symptoms and the virus itself during winter, the immediacy and on-the-spot results associated with the Sofia and Sofia 2 local analyser reduce the burden of COVID-19 on NHS staff and services be removing the need for lab analysis of COVID-19 tests. Through being provided with on-the-spot results, individuals can also take action immediately following a positive result to reduce the risk of spreading the virus to others, and thus reducing the burden for NHS contact tracers.

6.3. Further to this, the Sofia and Sofia 2 local analyser also provide benefits for NHS staff who display COVID-like symptoms, by quickly and accurately ruling out COVID infection, thereby reducing the need to take time off work while awaiting antigen tests results, which can currently take several days. With the Sofia and Sofia 2 local analyser, staff will have results on-the-spot in 15 minutes; if their test result is negative, they will not lose time being out of work whilst waiting for results.

7. CASE STUDIES

7.1. The COVID-19 Management System developed by RJALogix can be deployed to medical environments including GP practices, dentists and clinics to provide quick and accurate on-the-spot test results to support the management and avoidance of COVID outbreaks in these settings. Tests can be advertised to patient-communities before they attend these centres, with small rooms within respective facilities converted into convenient testing areas.

7.2. The COVID-19 Management System is also uniquely placed to support the effective management of COVID-19 within care home settings, which have been shown to be a significant potential source of onward infection when there is insufficient testing. Care home settings can use the system to implement regular "test days" for staff and residents, as well as provide on-the-spot entry testing for visitors, to help protect vulnerable groups and ensure that nobody with an infection is allowed to inadvertently spread it. Within this context, the benefits of having test results available within 15 minutes are compelling.

7.3. The COVID-19 Management System is also suitable for use in busy travel hubs such as airports and other communal areas, including work spaces and public service buildings. By ensuring regular testing in these areas, travel hubs and organisations have the ability to operate safely and manage issues locally and independently, which will help to facilitate the opening up of the UK economy in the coming months. In areas with high-demand for on-the-spot testing, the Sofia 2 device can be set to "walk away" mode, where tests can be inserted into the device quickly and replaced with another test, and results for each test are reported to a connected computer. This allows for quick and fast testing of larger group numbers, of up to 50 per hour per machine, providing viable options for busier settings such as airports and office buildings.

7.4. In July 2020, the United States Department of Health and Human Services announced the large-scale procurement of the Sofia rapid point-of-care diagnostic tests and analysers to be distributed to nursing homes in COVID-19 hot-spot geographic areas within the US.[4]

7.5. These systems are now also being sold in volume into international markets in Asia, Europe and Israel and can be adopted in many different ways, in line with local needs. For example, in Israel, the Government has used the flexible and portable Sofia and Sofia 2 analyzer to send mobile testing vans to local COVID-19 hotspots, to help limit the spread of the virus and understand local prevalence. This provide illustrations for how these testing solutions could be applied within the UK, both at a national level as well as in more targeted regional scenarios, for example within a specific geographical area which as entered lockdown. Doing so would provide valuable, real-time data to local decision-makers around the spread of infection, helping to inform policy and the social distancing measures which would have the greatest impact.

[4] HHS.gov. Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes. July 2020. Available: https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html

8. CONCLUSIONS

8.1. RJALogix is an agile, UK SME and has developed an innovative and holistic COVID-19 management system, which incorporates the provision of the world's only proven near-patient, rapid point of care COVID-19 antigen test, capable of providing test results within 15 minutes, to a relative accuracy of 99.5%. As the sole UK distributor of this system, RJALogix is uniquely placed to support the Government's response to the COVID-19 pandemic and help embed across the country the most robust and effective approach to testing, tracing and ongoing management as possible.

8.2. Supply of RJALogix-licenced COVID-19 tests and the supporting management platforms can be scaled-up in line with Government needs and is flexible to suit advancing COVID-19 strategies. We stand ready to help ensure that the UK is recognised as a global exemplar in its approach to overcoming the COVID-19 current pandemic and building resilience within the system to help address future comparable outbreaks.

(August 2020)