

## **COVID-19 International Comparative Research and Rapid Knowledge Exchange Hub on Diagnostic Testing Systems – Written evidence (COV0044)**

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This research project provides systematic comparison across countries in which effective diagnostic testing systems have been implemented and asks how key aspects of these systems could be rapidly replicated in other contexts. The project team is focused on identifying key elements of successful testing systems, including measures taken that facilitated preparedness and resilience before the crisis, and the rapid innovations that have helped countries to deal with a fast-evolving pandemic. The project has established a UK-based research and knowledge exchange hub to facilitate dialogue between the international research team and stakeholders so that relevant questions are rapidly addressed and key findings are disseminated in the UK and beyond. The project is supported by the Economic and Social Research Council, through UKRI's COVID-19 programme (Grant reference: ES/V004441/1).

### **Scope of evidence provided**

We report rapid findings from an international comparative study comparing COVID-19 test and trace programmes (T&T) across the four nations of the UK as well as Germany, Ireland, Spain, South Korea, and South Africa (henceforth 'study countries'). The following evidence is based on data gathered during June from published sources in the study countries.

The focus of our research coincides with the call for evidence in two areas:

- Diagnostic tests for the virus, including PCR (nucleic acid) tests and antibody tests: their accuracy, reliability, supply and distribution.
- Digital technology and data analytics, including the role they can play in testing and tracing contacts and implications for privacy

## 1. Evidence on 'Diagnostic tests for the virus, including PCR (nucleic acid) tests and antibody tests: their accuracy, reliability, supply and distribution.'

- 1.1. Diagnostic tests based on molecular (nucleic acid) assays, relying on well-established techniques such as PCR, are a crucial area of innovation to manage known and emerging diseases. Many hospital and university laboratories, government agencies and commercial manufacturers have shown the capability to develop and offer new diagnostic tests for SARS-CoV-2. The accuracy and reliability of these tests depends greatly on the wider context of their use, including the procedures for sample collection and the appropriateness of sample handling and testing. Our findings in relation to these points are discussed here in turn.

### Sample collection

- 1.2. Test and Trace programmes (T&T) in all study countries relies on molecular testing (PCR) to detect cases infected with SARS-CoV-2 and to identify individuals that need to isolate and have their contacts traced. South Korean guidelines published in the Annals of Laboratory Medicine, in March 2020 by Hong et al. note 'it is difficult to rule out COVID-19 based solely on one negative [test] result, especially when using an upper respiratory tract specimen from a suspected case'. In May 2020, Watson et al., writing in the British Medical Journal, expressed the need for caution if a suspected case has a negative result after a single test. Cases with negative test results could be offered repeat testing to reduce the chances of false negative results allowing COVID-19 infections to circulate undetected in the general population. Yet the English NHS T&T programme does not appear to routinely follow up negative results with a re-test.
- 1.3. One reason identified by [Hong et al.](#) for false negative test results is the use of inadequate specimens, for example those not collected by a suitably trained professional. We observe that in much of the UK, T&T relies heavily on individuals providing self-collected single swab samples taken from the upper respiratory tract. The [Public Health England \(PHE\) instruction sheet](#) for self-collected samples suggests users should swab the back of the mouth and just inside one nostril. This is a much more superficial approach than nasopharyngeal swabbing, as used by other study countries, where sample collection is by trained experts working at primary care centres, drive-through sites or making home visits (e.g. by ambulance staff, as in Ireland).
- 1.4. [Wang et al.](#) also find that diagnostic test sensitivity depends on the specimen type and from where in the body this is collected. They suggest lower respiratory samples are more likely to provide positive test results than upper respiratory samples. Our results find that the governments of other study countries recommend collection of both upper respiratory (nasal and oral) and lower respiratory (bronchial sputum) samples if possible. In the UK T&T the focus appears to be solely on upper respiratory sample collection.

- 1.5. *In order to ensure that the UK T&T programme uses a sampling process that is of the highest quality, we recommend that robust validation studies on the current T&T sampling procedures, and the kits they rely on, be published, or if not in existence, then such studies should be urgently commissioned.*
- 1.6. Expert advice from [SAGE and Independent SAGE](#) has called for contacts to be isolated within 48 hours of symptoms in the index case. The reliance on home testing is therefore a further concern as there are longer delays in these samples reaching the Lighthouse laboratories compared to those from regional test sites. Weekly NHS Test and Trace data for 18-24 June 2020 show that less than 10% of samples from home tests reach the lab within 24 hours, as compared to 70% from regional test sites. Around 60% of home test results do not report within 48 hours, leaving no time within the target 48 hours for contact tracing.
- 1.7. *We recommend that couriering arrangements for home tests samples should be reviewed to reduce transit times, and that wherever feasible home tests should be used only as a last resort.*

### **Sample handling and testing**

- 1.8. Much of the testing capacity supporting the UK T&T system is provided by the Lighthouse labs. These have been rapidly set up outside the long-established network of PHE and NHS virology laboratories that routinely provide virology testing for the NHS. The Lighthouse laboratories are centralised facilities (currently just four exist to cover Great Britain). These are often geographically distant to those providing samples, and they have no history of large scale testing of patient samples. The Lighthouse labs are disconnected from NHS IT systems that facilitate reporting of results and have been largely staffed by volunteers, often from research labs. The quality of testing in the Lighthouse laboratories during the peak of the crisis is likely to have been significantly inferior to that of NHS labs. For example, there has been a detailed account by [Shaun Lintern](#) in the Independent Newspaper, which highlights how these laboratories have been staffed by inexperienced volunteers and run without accreditation. Indeed in response to the crisis PHE appears to have [waived](#) some of the usual governance requirements for labs, such as the need for ISO 15189 in medical laboratory management. The Lighthouse laboratories are reported to have had relatively high levels of samples that do not report results due to problems with sample collection, transportation or laboratory handling errors. Such high levels of sample loss would not be expected to occur if the 'chain of custody' of samples remained in more expert hands, from patient to test result.
- 1.9. Other study countries also faced the need to rapidly scale up PCR testing for COVID-19, but have not relied on testing in entirely *de novo* facilities.
  - 1.9.1. In Germany, a large, decentralised and widely distributed network of nearly 170 established and accredited microbiology/pathology laboratories (both private and public) was able to rapidly provide surge capacity.

- 1.9.2. In South Korea, a network of around 120 established laboratories has provided testing, with co-ordination and accreditation procedure provided by the Korean Society for Laboratory Medicine, and additional training provided by the Korea Laboratory Medicine Foundation (KSLM) task force.
- 1.9.3. In Spain, there were shortages of testing capacity, and the established pathology laboratories were complemented by testing in university and research laboratories. These laboratories were subject to validation of their processes by the Instituto de Salud Carlos III prior to commencing testing. As a result, a network of over 50 laboratories was established by early May.
- 1.9.4. In Ireland, a distributed network of established pathology labs has been complemented with additional testing capacity provided by established academic research laboratories and agricultural laboratories that would not usually provide testing for human diseases. The resulting network of 15 laboratories is overseen and coordinated by the National Virus Reference Laboratory.
- 1.9.5. In South Africa, a distributed network of established commercial and public sector pathology labs has provided testing services, including repurposing of TB GeneXpert for rapid diagnosis. Additionally, some commercial and academic laboratories have been contracted to provide COVID-19 testing services, by the Department of Health.
- 1.10. *We recommend that surge capacity to support T&T in epidemics is brought back within the network of NHS pathology laboratories, so that the highest standards of clinical testing can be maintained for the remaining duration of the current crisis and for future crises.*

## **2. Evidence on 'Digital technology and data analytics, including the role they can play in testing and tracing contacts and implications for privacy'.**

- 2.1. We observe that the study countries tend to make more extensive use of mobile technology (including apps) to manage COVID-19 than is the case in England. Here we report on the main approaches used in each country. We also note some steps taken to ensure privacy is protected.
  - 2.1.1. In South Korea, extensive personal data is collected for contact tracing, enabled by the amended Data Protection Law following the MERS outbreak in 2015. This enables Korean public health authorities and local governments to collaborate in order to obtain information about the movement of infected persons during a public health emergency –using closed circuit television footage, mobile phone records, credit card transaction records, and other private data. Using these data, text messages are then used to notify people if they have been close to a confirmed case, and to inform them where they can go to be tested. Separate smartphone apps are being used for self-

isolating citizens to report their symptoms and to warn those breaking quarantine to stay at home.

- 2.1.2. Ireland's National COVID app (launched in late June) will allow those with confirmed COVID-19 to anonymously warn their contacts. The app also allows symptoms to be reported and is fully integrated with the contact tracing system. To protect privacy the government has made assurances that data will only be used for the stated purposes and the system will be dismantled after the crisis. Irish GPs use a separate web-based survey tool to report positive cases allowing rapid tracking of emerging clusters. Ireland's T&T also uses standard text messages to remind those self-isolating to stay at home, and to manage testing appointments.
- 2.1.3. Spain uses a symptom reporting app that can be tailored by each region, facilitating self-diagnosis and providing advice to citizens. A Spanish app based on the DP-3T (the decentralised protocol compatible with Google/ Apple operating systems) is being trialled currently. The app user instructions assure Spanish citizens that it protects their anonymity - by not collecting personal details - that it provides discretion - by not revealing to contacts where potential infection occurred - and that the app provides a means to discontinue usage at any time.
- 2.1.4. Germany launched a similar app nationwide in Mid-June. The German app recognizes close contacts of more than 15 min via Bluetooth by sending short-term identification numbers. The information is stored as an encrypted data on the owner's phone. The data will be deleted automatically after a fortnight. A separate web app is available in Germany to facilitate self-diagnosis and access information on further steps where infection is suspected.
- 2.1.5. In South Africa, community health workers undertaking door-to-door screening in vulnerable locations use an app to allow screening data and symptoms to be transmitted to a central database in real time, while an app for public use is in development. Detailed personal information of cases and contacts, including mobile phone location data is maintained on a Department of Health database and privacy safeguarded by the disaster management act regulations and a designated judge. The information contained in the database will be de-identified and or destroyed within six weeks of the National state of disaster being declared over.
- 2.1.6. Considering differences across the four nations the UK, the Scottish and Welsh governments endorse their publics to use a COVID-19 symptom tracking app developed through collaboration between a Kings College London and commercial developer, ZOE. The app allows self-reporting of symptoms which, when centrally collated, can provide data on disease incidence and facilitate responses by healthcare systems. Northern Ireland's government has developed and released an app that appears to provide similar functionality. The

Department of Health and Social Care has not formally endorsed this app for use in England, although it has been widely downloaded.

- 2.2. *We recommend that independent reviews of the practices established in the above countries be undertaken with the aim of providing a suite of mobile technologies for rapid use in England. These should provide individuals with access to an algorithm for self-diagnosis, health advice, and onward guidance for confirmatory testing, as well as rapid and automated alerting of contacts at risk of infection.*

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