TONY BLAIR INSTITUTE FOR GLOBAL CHANGE

# The Risk Calculus of Covid-19: How We Avoid a Second National Lockdown This Winter

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# Foreword by Alistair Darling



Covid-19 has come at an immense cost to our health and our economy. It is not leaving us any time soon. Its impact will be deep and widespread. There will be flare-ups and outbreaks in the UK and around the world for some time. We must learn to live with it.

I'm confident that a vaccine will be developed and in time will deliver results. But we don't know when it will arrive. Even then, vaccinations will be fraught with logistical challenges and there remain questions of science. Will the virus mutate? How long do we have immunity for? And – most sobering of all – will there be another virus like Covid-19?

We must be prepared for more outbreaks and more viruses.

For the most part, the government did the right thing by locking down much of the economy when the pandemic arrived. We were given time to prepare but at a huge cost. We cannot afford to do this again – and this is not just a question of economics. Delayed cancer treatments and other hidden costs, alongside those things that are yet to surface such as mental health issues, mean lockdown is not an option.

There are immediate seasonal challenges that we must address too. We know there will be an inevitable onset of flu and, as we approach Christmas, it is going to be very difficult to tell people that they can't see family or friends. Many will become fatigued with measures that have so far been admirably adhered to.

Mass testing is essential if we are going to get on top of this epidemic. Unless and until we have a testing system that people have complete confidence in to identify the source of and isolate a flare-up, we will see outbreaks and cases rise. We've been told time and time again that we will develop a system that is "world beating". It is not. No country in the world has got testing exactly right, but there are lessons to be learned. Whatever it costs to take precise action to curtail flare-ups, it's worth it.

As we enter autumn, this paper sets out several important measures that should be seriously considered by governments across the United Kingdom. Failing to do so will come at an unbearable cost.

**Alistair Darling**

*Former Chancellor of the Exchequer (2007–2010)*

# Overview



Covid-19 is still with us. As we enter autumn and when winter closes in, it will remain with us. It will be there next spring and likely summer too. It will be an enduring presence that we must learn to live with and alongside. This necessitates a risk calculus that restores confidence for people to safely participate economically and socially. It is a constant balancing act: Shut down all risk and cause irreparable harm to the economy. Accept too much risk and hospitals quickly become overwhelmed.

Striking the right balance is central to how we avoid a second national lockdown. It requires three things:

1. **Building an iterative understanding of what we know about Covid-19.**

This includes who it impacts, how it is transmitted, what its long-term effects are and its fatality rate. This information must be shared openly and clearly with the public. Too many misconceptions remain about the virus. Fear of Covid-19 can only be tackled with deeper understanding.

2. **Applying a calculus of risk with clarity and consistency.**

This means avoiding the scenario where one set of measures is totally risk-averse – for example, quarantining for 14 days after travel – and going the opposite way with another set of measures, such as calling for workers to return to the office without testing infrastructure in place.

3. **Accounting for season-specific threats.**

We can see what lies ahead and this should inform the work we do now. Winter especially has some specific issues which must be accounted for – we call these the three Fs: flu, fatigue and festivities.

This risk balance must be supported by the right containment infrastructure. Masks, social distancing, flu vaccinations, highly specific tests, seasonal guidance and individual risk scores all have a part to play in the months ahead but the most important infrastructure of all is something we've long called for: mass testing. This will identify and curtail the spread of the virus and, eventually, evolve to give every individual visibility of their Covid-19 status at any one time. The health secretary, Matt Hancock, has been clear that the government is now focusing on delivering mass testing. With the right plan and by not allowing the best to be the enemy of good enough, this could be in place sooner rather than later. It may be the only way that we can hug loved ones on Christmas Day.

If we follow the risk calculus we set out in this paper and continue to build strong containment infrastructure, we can avoid a catastrophic second national lockdown. This should be the government's aim moving into winter. We have seen first-hand the economic devastation and the adverse health impacts of a nationwide lockdown, costing an estimated £2.1 billion per day. This was necessary in the

spring precisely because we didn't know enough about the virus and there was no containment infrastructure in place.

This is not the case this time. Given what we now know about Covid-19 and what can be achieved between now and winter, we do not believe a second national lockdown should be needed, nor do we believe it would be justifiable. But work must start now.

# The Risk Calculus of Covid-19

As the proceeding sections will show, we now have a much clearer picture of Covid-19. We know that it is easily transmissible in certain settings and particularly affects certain categories of people – but it can be contained.

In light of this knowledge the question for governments is, how can the risk Covid-19 poses be correctly calculated, in order to calibrate the right response?

The two polar opposite methods of approaching this risk are both dangerous: Completely close down and the economic and social impact is potentially higher than the virus; don't mitigate the dangers enough and health-care systems will be overwhelmed.

There is also a danger, which the government has not fully avoided, of taking disjointed decisions on risk. For example, we are accepting very little risk on travel, but quite a lot in other areas.

Avoiding a second lockdown – which the country cannot afford in economic or social terms – requires three things:

1. Clear, up-to-date and publicly available information on the virus. Both the government and the public require proper understanding of the virus to base decisions on.
2. The right containment policy being put in place by government, built around mass testing, the use of masks and social distancing.
3. For the public – in light of 1 and 2 – to take a common-sense approach to the virus. Those at risk should take the right precautions, for instance vulnerable groups should be given N95 masks. Those less at risk should go about daily life as normally as possible, while maintaining the right steps (mask usage, cleaning regimes and social distancing).

The intersection of these three prongs would see the government take the right overarching approach to risk, with citizens then taking the right individual approach to their own risk.

We should work on the basis that we will be living with, and alongside, the virus for at least the next year, perhaps two. With all the difficulties of blunt lockdown measures, it is right that we move, step by step, to a new type of normal.

This requires the right approach by government and the cooperation and support of the public. We call this the "Compliance Contract" and it sits between government and citizens. As compliance goes down, transmission goes up and freedoms are reduced but, eventually, greater compliance leads to lower transmissions and greater freedoms. The new rules on social gatherings of six people show the contract in action. [1]

In practice, this is challenged by inconsistent and sometimes incoherent applications of risk from the government's side and, on the citizen's side, a failure to understand the risk to themselves and particularly to others. It makes the need for an individual risk profile more important as well as mass, regular testing.

This requires the right approach by government and the cooperation and support of the public. It is akin to a contract between both sides: As compliance goes down, transmission goes up and, reversed, greater compliance will mean greater freedoms.

# Calculating the Risk: What Have We Learned About Covid-19?

Six months since the UK imposed widespread lockdown measures, we now know much more about Covid-19. This includes more knowledge on immunity, mortality, how best to treat Covid-19 and about particular groups most affected by the virus. This knowledge is vital in informing how we respond to the virus and put in place measures to avoid a second wave.

## The Mortality Rate of the Disease Is Lower Than Earlier Estimates

The mortality rate of Covid-19 is decreasing as doctors increasingly have a better understanding of which patients require hospitalisation and how to treat them. This has reduced the pressure on the NHS and also meant fewer medical workers are self-isolating.

The case fatality ratio in the UK has fallen substantially from its peak in April. Data as of 4 August showed that the case fatality ratio stood at about 1.5 per cent, having dropped from more than 6 per cent six weeks earlier. [2]

Researchers believe this decrease in fatalities is due to improved treatment and an increase in testing that has identified asymptomatic or mild cases of Covid-19.

Compared with a few months ago, the individuals now contracting the virus are younger and the death rate is therefore not as high. Data measuring confirmed cases of the virus from 24 May to 24 July from NHS England show that the share of people diagnosed with Covid-19 aged between 18 and 64 increased from a weekly average of 24 per cent to more than 40 per cent. [3]

In addition, after the government allowed employees to return to work if they were unable to do so from home, the share of cases among England's working age population began to rise. [4]

Another reason the mortality rate may be declining is that people are becoming infected with lower "viral loads" as transmission is occurring in the community rather than in care homes and hospitals. This relates to the minimum infectious dose as exposure to lower levels of the SARS-CoV-2 pathogen is believed to reduce the chance of serious illness. [5]

## Fewer People End up in ICU, and More Survive When They Do

At the peak of the virus in April, there were close to 20,000 confirmed Covid-19 patients in hospitals around the UK. According to data published by the government on 1 September, that number has dropped to below 800. [6] The number of patients admitted to hospital for coronavirus on the first few

days of April was around 3,000 patients per day, while the hospital admissions rate as of 1 September was less than 100 patients per day. Similarly, the number of hospitalised patients in medical ventilation beds peaked in April at nearly 3,000, and as of 1 September there are less than 90 patients who require such treatment. [7]

Admissions to ICU peaked on 1 April, with the number of patients in the ICU peaking ten days later. By 9 July, more than 10,000 Covid-19 patients had been admitted to the ICU, according to the Intensive Care National Audit & Research Centre (ICNARC) via its Case Mix Programme. [8]

In a study that examined the mortality rate based on ICNARC data, it was reported that the mortality rate in ICUs reduced from 43.5 per cent pre-peak to 34.5 per cent post-peak, a reduction of 8.8 per cent after adjusting for patient characteristics. [9] This analysis used ICU admissions data for confirmed cases of Covid-19 from 1 February 2020 to 1 July 2020 for England, Wales and Northern Ireland. [10]

A systematic review of published ICU studies found that the overall mortality rate of Covid-19 patients in ICUs has fallen from 59.5 per cent to 41.6 per cent. [11] This meta-analysis included studies from three continents and used data from the end of March to the end of May. [12] The primary purpose of the study was to calculate the percentage of ICU cases that were "completed" – meaning the patient was discharged or died – so patients still alive in intensive care were not included in the figures. [13]

## Most People Have Mild or No Symptoms

As the majority of testing was originally taking place inside hospitals and in situations where individuals were already showing symptoms, little was known about the prevalence of asymptomatic cases. But studies around the world are beginning to show that the majority of Covid-19 cases are mild or asymptomatic. [14]

Researchers at King's College London found that one in five people who had been infected with Covid-19 did not show any symptoms. [15] This antibody study of 432 people has yet to be peer reviewed, but it highlights the significant portion of asymptotic carriers of the virus. [16]

The participants of the study were from London and the South East of England and were aged between 18 and 89 years old. The study also found that more than a quarter of those who fell ill did not show the three main symptoms of the disease: persistent cough, fever and loss of smell. [17]

These findings are further supported by an ONS study that concluded that 71 per cent of people who tested positive for Covid-19 had not displayed symptoms or fallen ill. [18] The WHO estimated that the number of mild or asymptomatic cases was closer to 80 per cent, meaning that the majority of Covid-19 infections will cause mild symptoms or none at all. [19] A separate study from China found a similar rate of

mild or asymptomatic cases, reporting that 78 per cent of individuals showed mild or no symptoms after testing positive for the virus. [20]

### For Some Patients, Covid-19 Has a Long-Term Impact on Their Health

As Covid-19 is a relatively new virus, initial studies of its long-term effects were difficult. But as time goes on and we continue to learn more about the so-called 'long haulers', our understanding of its long-term symptoms is evolving.

For asymptomatic and symptomatic carriers, Covid-19 could have a long-term impact on the heart. One recent study [21] looked at the cardiovascular effects in a random selection of 100 patients who had recently recovered from the virus. Of the cohort, ongoing heart abnormalities were revealed in 78 patients (78 per cent) and ongoing myocardial inflammation in 60 patients (60 per cent), which was independent of pre-existing conditions. Worryingly, these results were not related to the severity of the patient's initial illness. This is a small study and should be received with caution, but it points to a worrying trend that Covid-19 – even among asymptomatic carriers – can lead to problems of the heart. Two actions must be taken. First, we need to urgently understand more about the virus' impact on the heart by conducting longitudinal surveys to better understand drivers, treatments and who the virus impacts and how. Second, this study reaffirms the need for a screening programme – with mass, regular testing at its core. It remains the single most important containment measure in the short to medium term. Testing will reveal hidden issues before they evolve into something more dangerous and potentially fatal.

For those with symptoms, recent research has also shown that some people experience symptoms for three weeks or even a few months after testing positive. [22] One online survey of 3,729 doctors, conducted by the British Medical Association, reported that around one-third of Covid-19 patients were treated for symptoms that are believed to be long-term effects of the virus. The symptoms identified included chronic fatigue, muscle weakness, loss of sense of smell and difficulties with concentration. [23]

An app developed by the health science company ZOE has been downloaded by more than 4 million users in the UK in the hopes of tracking and monitoring Covid-19 symptoms over time. Researchers from King's College London have used some of this data to study the patterns of Covid-19 symptoms.

The study, led by Professor Tim Spector of King's College London, found that after three weeks of the onset of symptoms, some individuals continued to experience fatigue, headaches, coughs, loss of smell, sore throat, delirium and chest pains. There is currently little support or guidance available for those suffering from long-term Covid-19 symptoms. [24] It also remains unclear if long-term symptoms correlate to longer periods of being contagious.

In another study, carried out by the University of Leeds and Leeds Teaching Hospitals NHS Trust, researchers reported that the most prevalent long-term symptom was fatigue, with more than 60 per

cent of respondents reporting moderate to severe fatigue four to eight weeks after being discharged from hospital. The second-highest reported symptom was breathlessness. The symptoms were more severe for those respondents who were in intensive care. [25]

One challenge in identifying long-term symptoms is the current inability to determine if symptoms are persisting because individuals are still infected with the virus or if the symptoms are a result of a Covid-19 infection – for example, long-term damage to the lungs after a severe Covid-19 infection or an autoimmune condition triggered by the virus. [26]

### Older People Are More Likely to Get a Serious Infection

Individuals aged 70 and older face the greatest risk from Covid-19. People living in nursing homes or long-term care facilities, and people of all ages with underlying health conditions, are also at higher risk for serious cases of infection.

Studies regarding the effects and transmission rates of Covid-19 among children and young people are less definitive. A South Korean study published in July found that Covid-19 infection rates among households were highest where the infected household member was in the ten- to 19-year-old age group. [27] The study also showed that the lowest infection rates were in households where the infected member was younger than ten years old. [28]

### It's Clearer Who Needs to Shield and What Underlying Conditions Are Most Susceptible

There have been additions to the list of underlying conditions that make individuals more vulnerable to Covid-19. Conditions that have been shown to increase the risk of serious infections include cancer, chronic kidney disease, chronic obstructive pulmonary disease (COPD), immunocompromised state from solid organ transplant, obesity, serious heart conditions such as heart failure, coronary artery disease or cardiomyopathies, sickle cell disease and type 2 diabetes mellitus. [29] Understanding this gives us a better idea of which groups and individuals need to shield.

There are also some conditions that are suspected of increasing an individual's risk of severe infection but are not yet supported by sufficient data. These conditions include asthma, cerebrovascular disease, cystic fibrosis, hypertension or high blood pressure, immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids or use of other immune-weakening medicines, neurologic conditions such as dementia, liver disease, pregnancy, pulmonary fibrosis, thalassemia and type 1 diabetes mellitus. Smoking is also believed to increase the risk of serious infection. [30]

Cancer patients were identified early on as being particularly vulnerable. Recent research from the University of Oxford shows that blood cancer patients are particularly at risk, being 57 per cent more likely to suffer severe Covid-19 infections than other cancer patients. As cancer treatments must continue throughout the pandemic and a potential second wave, this research may be important for creating new Covid-19 guidelines in cancer treatment facilities. [31]

### We Are Getting Better at Treating Covid-19

In addition to existing drugs that are being evaluated in the hopes of being repurposed to treat Covid-19, as well as the development of a vaccine, some studies are beginning to explore blood plasma transfusions as a way to provide vulnerable patients with antibodies. This procedure would require blood from donors who have already tested positive for Covid-19 and have a substantial number of antibodies. The success and safety of this practice has not yet been confirmed by large-scale studies [32] but plans are in place for the treatment to be rolled out at scale early next year. [33]

Current approaches to treating Covid-19 can be separated into two broad categories: The use of antivirals, which prevent the virus from multiplying, and immune modulators, which stimulate an immune response and help the body fight the virus. [34]

Paul Hunter, professor of medicine at the University of East Anglia, believes that one of the biggest breakthroughs in Covid-19 treatment is the use of the steroid dexamethasone in hospitalised patients. [35] There are hundreds of studies being tracked that explore dexamethasone and other potential alternatives for their effectiveness in treating Covid-19. [36]

### It Is Probable Younger Children Are Less Likely to Transmit the Disease

Given that most children were not in school for many months over the spring and summer, there is a lack of other evidence regarding the transmission of Covid-19 between children and young adults. Some researchers believe that the discrepancy in transmission rates between the youngest age groups relates to the social lives of young adults, as they are more likely to come in contact with others. Other researchers have suggested that the differences in transmission rates could also relate to different immune mechanisms in the youngest age group of children. [37]

Professor Hunter, of the University of East Anglia, commented, “My best guess is that an infected young child is more infectious, but teenagers have many more close contacts and so are more likely to spread the infection.” [38] Deaths among children and young adults remain low, but these age groups likely make up a large percentage of those who spread Covid-19 without knowing or showing symptoms.

Sweden chose to keep its primary schools open throughout the pandemic but closed its secondary and higher education institutions, which may have helped suppress their R value. This could help inform decisions regarding the guidelines and measures for returning to school.

### We Know When and Where Carriers Are at Their Most Infectious

A person with Covid-19 is believed to be most contagious before the onset of symptoms, usually between 48 and 72 hours prior to their onset. [39]

The minimum infectious dose for coronavirus remains unclear but will be an important breakthrough in the study and response to controlling the transmission of the virus. [40]

Even without knowing Covid-19's minimum infectious dose, scientists do know that the longer you are in contact with an infectious person, the more likely you will be to contract the virus. [41] A study from China suggests that this is why transmission particularly occurs within households. [42] This could also have implications for the ability of the virus to spread within offices.

The virus is more likely to spread indoors, especially in rooms with poor ventilation; rooms with increased airflow allow the virus to become diluted (and therefore less potent) more quickly. Masks reduce the amount of virus projected from an infected person but do not act as a total barrier. [43]

### Once We Have the Virus, We Have Immunity, but the Question Is for How Long

The rate and longevity of antibody production after contracting SARS-CoV-2 is uncertain as studies, the most widely cited being the King's College London study, [44] are beginning to show that SARS-CoV-2 antibodies only provide a strong immune response for around three months after testing positive for the virus.

Most people who are infected with SARS-CoV-2 display an antibody response between ten and 21 days after becoming infected. The emergence, and therefore the detection, of antibodies in those with mild cases has shown to take longer, potentially around four weeks or more. [45]

One study, published on 16 August, indicates that such a short-term antibody response would be unprecedented following a severe coronavirus infection as other strains of coronavirus usually induce immunity for a year, with SARS-CoV-1 often producing antibodies for over a year. [46] This study indicated that antibodies provided immunity for *at least* a few months, if not more.

There have been three documented cases of reinfection in Hong Kong, Brussels and the Netherlands, which researchers say is to be expected. [47] Researchers are not worried as the reinfections are less

potent, could be the result of false-negative tests, and make up such a small percentage of the population. [48]

Several studies have recently been published citing an approximate three-month period of antibody production and SARS-CoV-2 immunity. A study conducted by King's College London found that while 60 per cent of patients harboured a "potent" antibody response at the height of their infection, only 17 per cent retained the same potency of antibodies three months later. [49]

While this immune response may seem short-lived, it can be difficult to measure antibody responses in this amount of time as the decline of antibodies is not linear – longer-term studies are needed in order to determine a more accurate rate of decline over time. In addition, researchers are not currently able to determine whether or not antibody levels would rise again in the case of reinfection. [50]

An implication for this waning immune response is a vaccine that requires yearly uptake, similar to that of the yearly flu jab. The duration of immunity in other strains of the coronavirus varies and more research and time is needed to determine the long-term SARS-CoV-2 antibody response.

One consistent finding of these studies highlights the likelihood of a milder infection in the case of reinfection. While the recorded levels of antibodies over time in those who have been infected may not fully prevent them from becoming reinfected with SARS-CoV-2, it is believed that the antibody response will be enough to lessen the impact of the virus and symptoms will be milder. [51] This supports the case for the use of antibody tests to determine a person's immunity status.

Research indicates that antibody levels rise higher and last longer in those who are severely infected, which can be attributed to the fact that those patients needed to produce more antibodies to fight off the severe infection. While mild cases may not produce enough antibodies to fight off infection entirely, there may be enough to limit the virus and reduce its ill effects if those people become infected for a second time. [52]

Antibody levels are not the only indicator when evaluating immune responses. Some studies have indicated that analyses of T-cells could give researchers a better understanding of the body's immune response to SARS-CoV-2, even in patients whose antibody levels have declined or are difficult to detect. [53] [54]

Indoor Biotechnologies, a company in Cardiff, has developed a test for SARS-CoV-2 T-cells, a potentially longer-term immunity response than antibodies, and the company is hopeful that these developments will aid in vaccine developments. [55] The tests could also have a role to play in mass testing, identifying citizens who have some level of immunity to Covid-19.

# Calculating the Risk: What Have We Learned About Lockdowns?

The WHO has advised against second national lockdowns due to the repercussions those measures would have on the economy, as well as the impact on physical health and social well-being. [56]

A second national lockdown would also have implications for noncommunicable-disease treatments and diagnoses, education and domestic violence.

Evidence shows that a lack of schooling increases inequalities, reduces opportunities for students, and could exacerbate physical and mental health issues among students.

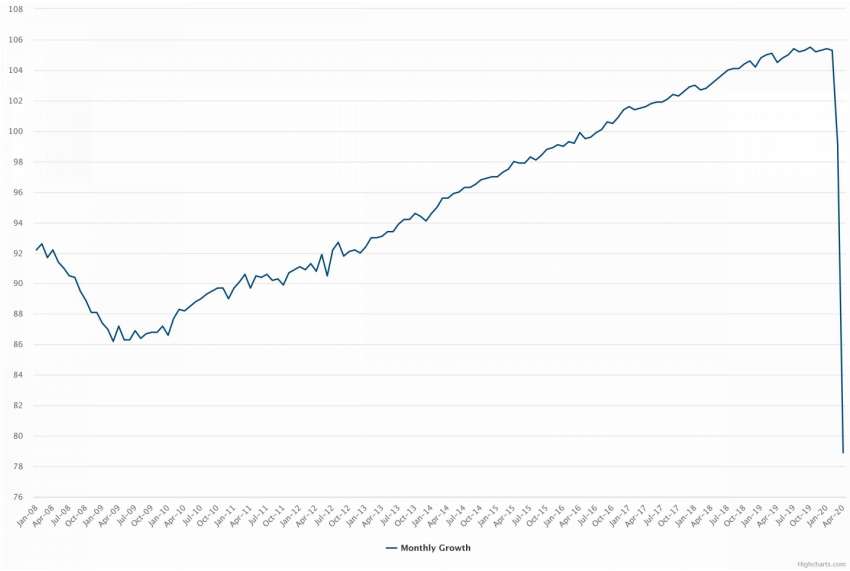
Some argue that children have already sacrificed enough of their education during the first lockdown and school reopening should be a priority.

A second national lockdown would further strain the tourism and hospitality sector, which is currently surviving on UK residents travelling and holidaying around the UK.

## Lockdowns Take a Huge Chunk Out of the Economy

The *Financial Times* reported in early August that the UK's 20.4 per cent fall in output is its largest quarterly fall in history. It is also the largest decline in one of the world's major developed countries.

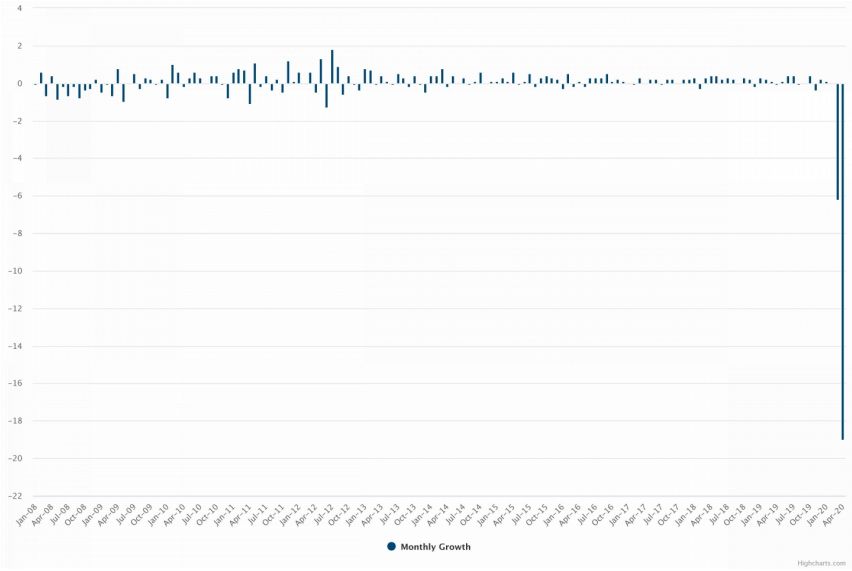
**Figure 1 – The UK's monthly GDP, seasonally adjusted, from January 2008 to April 2020**




*Source: ONS* [57]

The consumer-facing service sector makes up 80 per cent of the UK's economy, which contributes to the sharp decline as well as to reduced productivity and consumer spending. [58]

**Figure 2 – Index of Services, UK, month-on-month growth, seasonally adjusted, from January 2008 to April 2020**




*Source: ONS, Index of Services* [59]

Once lockdown was lifted, economic activity picked up as shoppers gradually returned to stores and retail sales figures increased. The government's "Eat Out to Help Out" scheme was used 10.5 million times in its first week. [60]

It was estimated before the pandemic that for the current financial year, April 2020 to April 2021, the government would borrow about £55 billion. Estimates now indicate that the total could be anywhere from £263 billion to £391 billion. [61]

## Lockdowns Have a Severe Impact on Education and Exacerbate Inequality

Emerging evidence suggests that the risks presented by reopening schools is manageable and will cause much less long-term harm than keeping schools closed. The percentage of Covid-19 cases among children that required hospitalisation is estimated to be around 0.1 per cent for children aged zero to nine and 0.3 per cent for those aged ten to 19. The rate of hospitalisation for the general population is around 4 per cent. [62]

A recent study by Public Health England (PHE) found that children with flu-like symptoms during the first wave of the pandemic were much less likely to be contagious than adults with similar symptoms.

Further, Covid-19 seemingly has less of an impact on children meaning that even if young people infect their classmates, their classmates are unlikely to become unwell. [63]

The greatest cause for concern is whether children and young adults with no symptoms will be infecting adult staff members and spreading the virus into new households. But testing positive for the virus is not the same as being infectious to others [64] and we have previously set out measures to protect teachers and curtail outbreaks in schools using testing.

As mentioned above, Sweden chose to keep its primary schools open throughout the first wave of the pandemic, and studies are now showing that infection rates in teachers were no higher, and in some cases even lower, than the infection rates of other occupational groups. There are other variables that could contribute to these findings, ie, teachers being younger or healthier than other occupational groups, but this evidence further supports the reopening of schools as students are not the most efficient spreaders of the virus. [65]

### Lockdowns Cost Lives and Impact Well-being

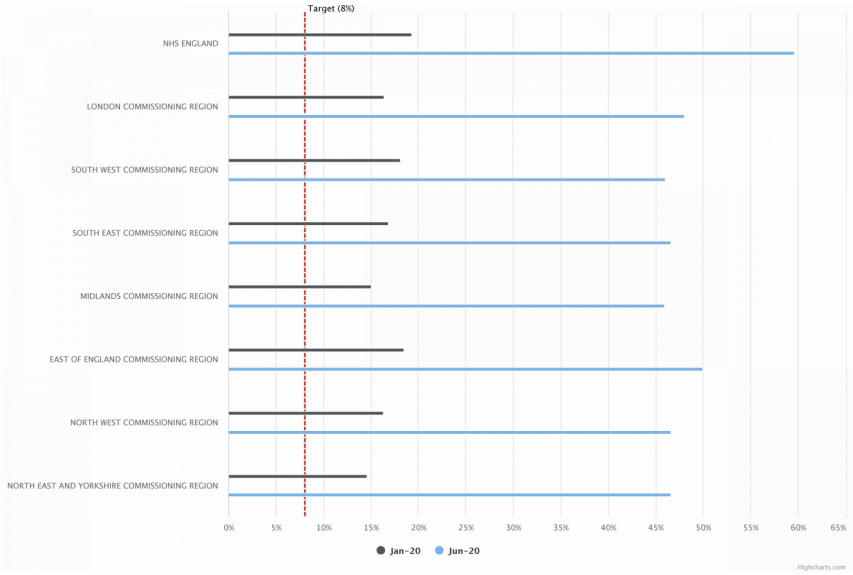
The WHO recently published a report detailing the impact of Covid-19 on health systems based on survey responses and reports from 105 countries. [66] [67] Data collected from March to June indicated that 90 per cent of participating countries experienced disruptions to their health services. The most frequently reported areas of disruption include routine immunisation outreach services (70 per cent), facility-based services (61 per cent), non-communicable disease diagnosis and treatment (69 per cent), family planning and contraception (68 per cent), treatment for mental health disorders (61 per cent), and cancer diagnosis and treatment (55 per cent). [68]

There were many disruptions caused by supply and demand-side factors, most notably with 76 per cent of countries reporting reductions in outpatient care attendance due to lower demand and factors such as lockdown measures and financial difficulties. The survey data also highlights the problems caused by staff redeployment to provide Covid-19 relief, the unavailability of services due to closures and interruptions in the supply and delivery of medical equipment and health products. [69]

### Covid-19 Is Dramatically Impacting Waiting Times

Data released by NHS England in August shows that 50,536 patients have now waited more than 52 weeks for NHS treatment. This is a significant rise from 1,613 patients waiting more than a year in February 2020. At the end of June 2020, 52 per cent of patients waiting to start treatment were waiting up to 18 weeks, falling far short of the 92 per cent gold standard. [70]

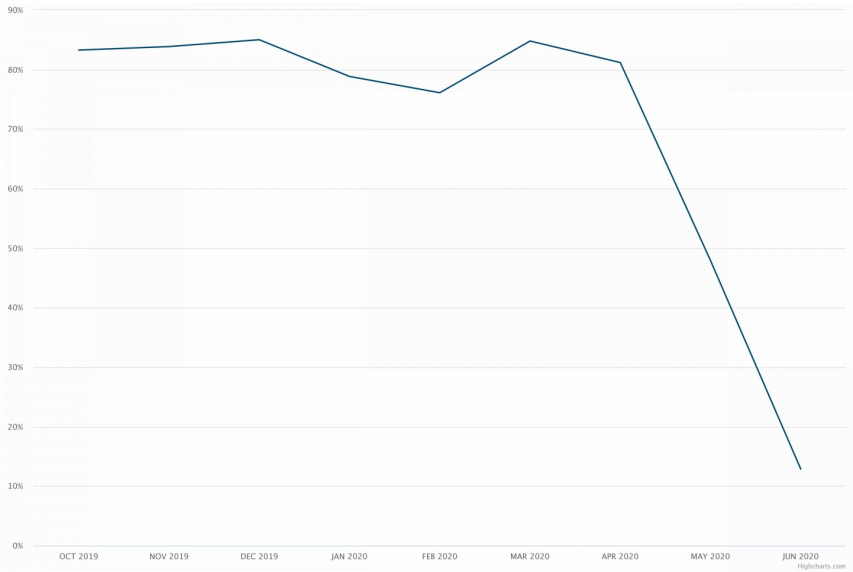
**Figure 3 – Nuffield Trust analysis of NHS England referral to treatment (RTT) waiting times**




*Source: Nuffield Trust* [71]

Covid-19 has also had a significant impact on critical care, such as cancer treatment. Activity data from June and July 2020 shows the number of people being urgently referred for suspected cancer is only at 80 per cent of normal levels. Only one in ten people received first cancer treatment two months after being screened. This is the lowest performance to the target on record. [72]

**Figure 4 – Patients waiting less than two months from screening to first cancer treatment**




*Source: BMA* [73]

## Lockdowns Take Out Tourism

Spending by visitors from overseas could fall by as much as 78 per cent this year, which equates to about £60 million a day, according to the World Travel & Tourism Council (WTTC). The lack of foreign visitors, especially in London, could cost the UK up to £22 billion in tourism revenue this year and potentially put 3 million jobs at risk. [74]

As lockdown measures eased, the UK saw a "staycation boom" as residents rushed to book holidays within the UK. Without a second national lockdown, free movement around the UK could help bolster the tourism sector and protect the jobs that rely on holiday-makers. [75]

# Calculating the Risk: Seasonal Threats of Flu, Festivities and Fatigue

We must build seasonal considerations into our risk calculus and ensure that there are specific containment measures to address each. We have identified three for the months ahead that require steps to be taken now.

## Flu

The winter of 2017/2018 was the most recent significant influenza season and can be considered a reasonable worst-case scenario when planning for this upcoming flu season. In the 2017/2018 flu season, there were approximately 49,410 deaths, with 34.7 per cent of deaths caused by respiratory diseases. [76] The most recent government data on the hospitalisation rates for the 2019/2020 flu season indicate that the flu had a low impact on hospital admissions as well as intensive care units. [77]

### A Flu Outbreak Could Undermine Covid-19 Containment Efforts

A busy flu season would overwhelm hospitals with more admitted patients and a number of NHS staff and care-home staff staying at home sick. Given the similarity between Covid-19 and flu symptoms, many of these workers may wrongly quarantine for 14 days if testing isn't widely available.

### Testing Must Be Available and Must Distinguish Between Flu and Covid-19

There is a need for rapid tests that distinguish between different viruses in order to better manage Covid-19 treatment and the seasonal influx of influenza infections. They should be used to screen frontline staff, including those who are asymptomatic, and identify Covid-19 carriers to inform quarantine and isolation.

A new machine from DnaNudge delivers results in 90 minutes and does not require samples to be sent off to a lab. Tests are analysed through a nose swab or saliva and the tests can also identify the flu and RSV. [78] The government has placed a £161 million order for 5,000 of these machines and supply cartridges to test patients for coronavirus in hundreds of NHS hospitals.

In addition, an initial 450,000 LamPORE SARS-CoV-2 tests are being made available to several NHS testing laboratories. The Oxford Nanopore Technologies (ONT) method of detection can differentiate between actual SARS-CoV-2 pathogens and errors that occur that cause "false positive" results. ONT is currently developing LamPORE tests that can identify multiple pathogens within a single sample, including influenza A (H1N1 ad H3N2), influenza B and RSV, in addition to SARS-CoV-2. [79]

### Flu Vaccines Should Be Readily Available NOW to as Many People as Possible

Many flu vaccine manufacturers have announced an increase in production for the upcoming flu season. Across the UK the age groups eligible for a free flu shot for both children and adults have expanded. [80]

Because school-aged children are often responsible for a large proportion of influenza transmission, efforts to increase vaccinations among children have been widely studied. In the US, researchers found that vaccinations of school-aged children consistently reduced the overall transmission rates of the flu. [81]

In July, the government announced that more than 30 million people will be eligible for a free flu jab this year in England, nearly double the number of people who received the flu jab last year. The Welsh and Scottish governments have also announced plans to expand their programmes for flu vaccinations. [82]

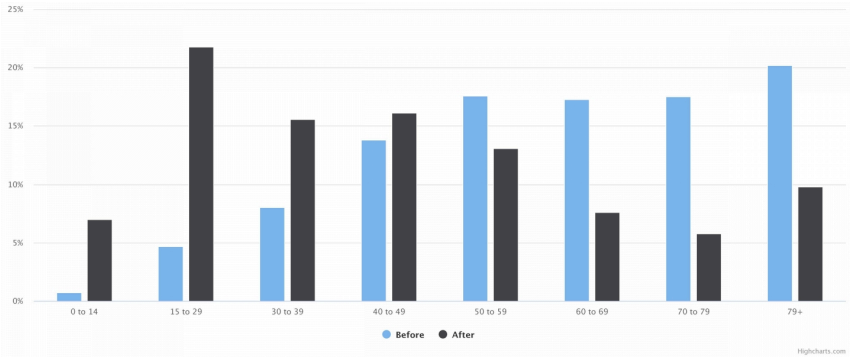
While the government has placed large orders for flu vaccines, the NHS must simultaneously build capacity to deliver vaccines on such a large scale. But in the government's latest guidance, as of the 5 August, the only off-site flexibilities for vaccinations were for pharmacists to vaccinate both care home residents and staff in one visit. [83] The flu vaccination estate must expand to include community pharmacies, schools, supermarkets and drive-through centres.

## Fatigue

Social-distancing fatigue, particularly among young people, is occurring throughout Europe. The proportion of 15- to 24-year-olds infected with the disease has increased threefold in the past five months. [84]

Case statistics in Spain found that people in their 20s and 30s are a key source of new infections, as the reopening of bars, lifting of travel restrictions and warm summer weather introduced new opportunities to socialise.

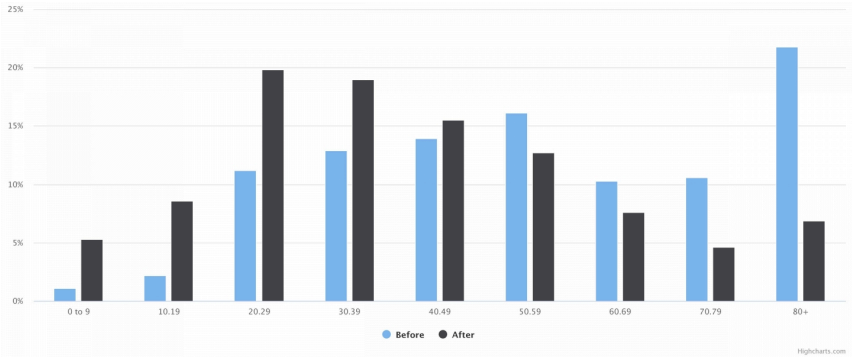
**Figure 5 – Age distribution of Covid-19 cases in Spain before and after lockdown eased**




*Source: National Center of Epidemiology* [85]

Young people aged between 20 and 39 account for about 35 per cent to 40 per cent of new cases in England. [86]

**Figure 6 – Age distribution of Covid-19 cases in England before and after lockdown eased**




*Source: Public Health England* [87]

Although young people are less likely to suffer from severe cases of Covid-19, authorities are worried about the age group's ability to spread it. [88]

Psychologist Carisa Parrish, based at Johns Hopkins, commented that, "Trying to adhere to anything extra is always a challenge ... You can add extra steps to your routine for a few days, but sustained behavior change is hard. Especially when no one around you is sick, and you just don't feel like wearing a mask or saying no to things you like to do. But the fact is, the precautions work." [89]

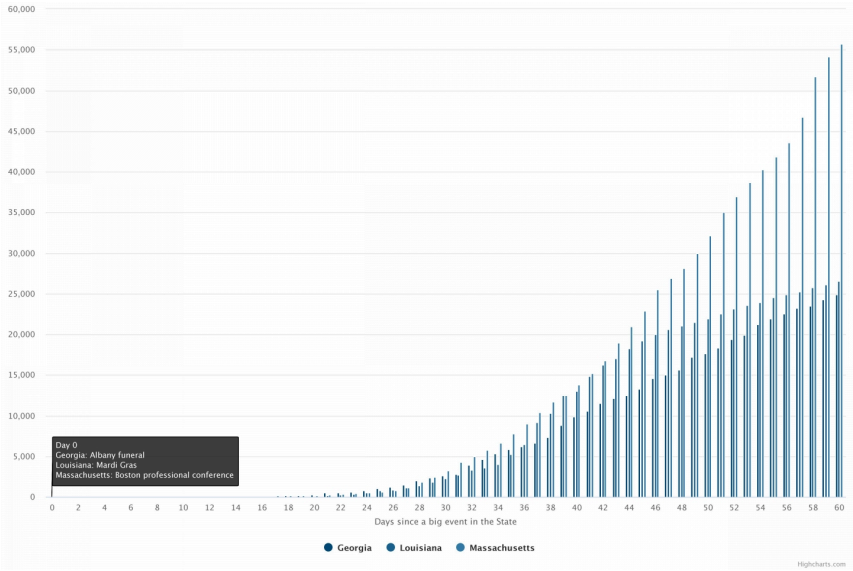
## Festivities

One of the things that has become very clear since the emergence of Covid-19 is the role mass gatherings play in transmission of the virus. Mass gatherings have quickly been identified as "super-spreader" environments, with numerous examples.

Anne Schubert, principal deputy director of the US Centres for Disease Control and Prevention, wrote in May that, "Various gatherings of persons from different locations, followed by return to their home communities, played a notable role in the early US spread of Covid-19. During February 2020, the number of confirmed cases originating in the United States was low and appeared contained; thus, federal and local jurisdictions did not recommend restrictions on gatherings. However, during the last week of February, several large events led to further spread of the disease. These included Mardi Gras celebrations in Louisiana with more than 1 million attendees, an international professional conference held in Boston, Massachusetts, with approximately 175 attendees, and a funeral in Albany, Georgia, with more than 100 attendees [see Figure 7 below]. In the weeks after these events, amplifications in the host locations contributed to increasing US case counts. Dougherty County, Georgia, a small rural county

that includes Albany, had one of the highest cumulative incidences of COVID-19 (1,630/100,000 population) in the country." [90]

**Figure 7 – Examples of large events leading to spread of Covid-19**




*Source: CDC* [91]

Maria Van Kerkhove, technical lead at the WHO's Health Emergencies Programme, has stated that, "There are some really good estimates out there that suggest that between 10% and 20% of cases are responsible for about 80% of transmission events." [92]

As the Christmas season approaches and social gatherings rise, so could the risk of transmission, particularly in bars.

One case cited recently occurred in Hong Kong's Lan Kawi Fong nightlife district, where infected persons cause one of the biggest cluster outbreaks in the city. A paper by the University of Hong Kong found the virus spread among 106 bar patrons, bar workers and musicians over a period of two weeks in March. [93]

Dr Gabriel Leung, dean of medicine at the University of Hong Kong, who co-authored the paper, noted that, "Any setting that is an enclosed space that is poorly ventilated, that is crowded and that has unprotected behaviour would tend to create a lot of clusters." [94]

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How the government manages the risk of indoor gatherings over the winter period, be it family social events or large gatherings in pubs and clubs, will be critical in controlling the potential large-scale re-emergence of the virus.

The best approach to the festive season will work with, and draw upon, the support of local communities and community leaders, to ensure sensible steps are taken to maintain the correct protocols to inhibit the spread of the virus. Good examples of this took place during Eid, as religious and community leaders rallied to ensure the community was proactive in taking steps to contain the virus. Imam Mohammed Quraishi, of the Darussalam Education Centre Mosque in Blackburn, said that, "People need to take responsibility, if everybody just, for a short time, did their bit, then there would be no need for a Leicester-style lockdown.” Only by working collaboratively, in a community-led way, will more stringent restrictions be avoided.

# Calculating the Risk: Winter Containment Measures

In light of what we now know about the virus, we believe the right mixture of containment measures can mitigate the need for a second national lockdown. These include putting in place the mass-testing strategy we have called for since the spring, making masks compulsory where normal social distancing is not possible, maintaining social-distancing protocols, utilising individual risk profiles (linked to enhanced protective measures such as N95 masks), rolling out flu vaccinations and providing guidance on family gatherings during the festive period.

### 1. Mass Testing

We have set out in a number of reports, most recently *Taking the UK's Testing Strategy to the Next Level*, the rationale for why and the strategy for how the UK must put in place the mass-testing strategy it needs. Health minister Matt Hancock recently announced the government would indeed put a strategy of mass testing in place by Christmas this year.

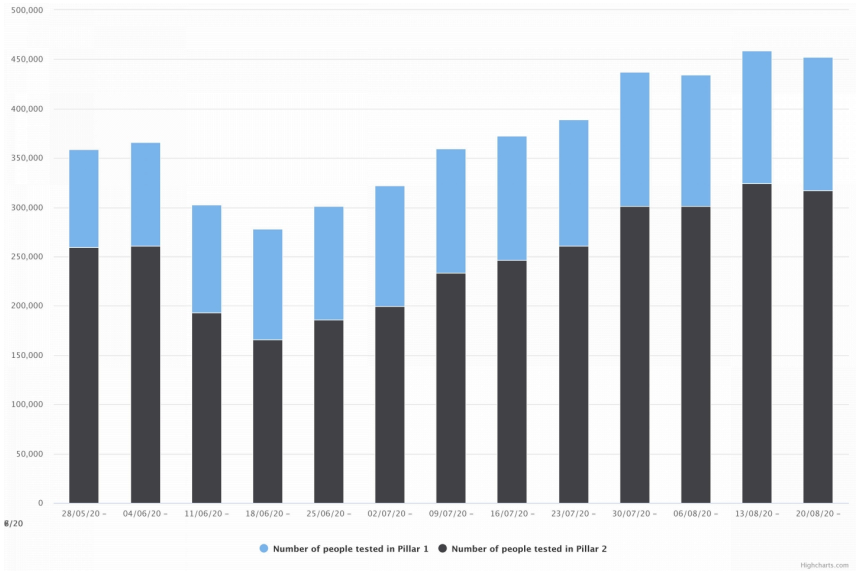
The prime minister added further clarity on Wednesday 9 September, stating that, "A world we want to move to as fast as possible is a world where everyone can take enabling tests at the beginning of the day, an antigen test to identify whether or not we have the virus."

The ambition is therefore clear: to bring onstream all possible rapid tests and test as many people as possible, as often as possible. The government must now turn its welcome words into the right action.

**State of Play:**

In recent weeks the government has regularly been testing more than 400,000 people per week, across testing in health-care and non-health-care settings (Pillars 1 & 2).

**Figure 8 – Number of people newly tested for Covid-19 by Pillar in England**




*Source: Gov.uk* [97]

This marks significant progress from where the government started earlier in the year, but as the health secretary has rightly recognised, more is required.

The most recent data suggests the UK has regularly used only 175,687 of its test capacity of 369,937, so drawing on only half of the country's capability. More work is needed to make full use of this existing capacity, as well as to expand it dramatically.

With 70 per cent of cases likely to be asymptomatic [98], it is vital the UK moves quickly to a position where it is able to test as many people as possible, as often as possible, not just those presenting with symptoms.

The task of putting in place this mass testing regime forms a critical part of the infrastructure that will allow us to avoid a second national lockdown and is therefore urgent.

**Delivery of a Mass-Testing Strategy:**

In order to deliver mass testing, we propose a phased roll-out, starting with sectors and organisations identified as strategically important and/or where it is relatively easy to administer a large volume of tests, regularly, at scale.

These include:

- Education, including schools, colleges and universities (see section below)
- Social care
- Emergency services

- Transport workers
- Large employers
- SMEs with occupational-health teams
- Professional sports
- Travel, including at ports of entry

**We would be building towards the regular, ongoing testing of as many people as possible.**

We define a mass-testing regime as one that includes regular, ongoing Covid-19 testing of all citizens. The purpose of such a regime is to identify asymptomatic cases and break the chains of infection.

This testing would be conducted in a variety of settings: at home, at work, at transport hubs and at a diverse range of other testing sites. The testing regime would make use of rapid point-of-use tests – both antigen and antibody.

These results would eventually feed into a health passport that would provide evidence of an individual's Covid-19 status at any given time.

Delivering this strategy will require bringing onstream all viable rapid tests (see Annex).

**Mass testing requires tests that identify if someone is infectious NOT if they have the virus**.

Tests to determine if someone is infectious and tests to see if someone is carrying the virus may seem like one and the same but the difference is very important.

Understanding this distinction will have profound implications on the speed at which the UK can establish the mass testing regime it urgently needs.

Rapid, on-the-spot tests to confirm if a person is infectious are more readily available than those that detect the presence of the virus. This is because they have lower accuracy requirements and their bar for approval – set against the "gold standard" tests to determine if a person has the virus – should therefore be much lower. Put simply, you are building a test capable of detecting a higher amount of the virus and this is much easier to do than one that detects lower viral loads which, studies suggest, mean that a person is no longer shedding the virus.

We know that the gold standard of tests – the RT-PCR – detects viral loads via what is called a "cycle threshold" (Ct). This is defined as the number of cycles required to detect the virus. Crudely, the more cycles, the harder the virus has been to find and therefore the lower the viral load.

A Ct of <35 likely shows a viral load that is infectious, whereas a Ct of >35 is unlikely to be infectious. [99]

While RT-PCR tests can detect viral loads that are so low the person isn't infectious, rapid tests provide a cruder "yes" or "no" on whether someone has a high viral load, and is therefore infectious.

The government should draw this distinction between the purposes of tests and fast-track the approval of tests that determine if an individual can infect another.

**Double-Checking Test Results Accuracy Fallacy**

We recommend putting in place a system of double-checking rapid tests through the use of gold standard lab tests.

**Antigen Testing**

- Anyone presenting with suspected Covid-19 symptoms is currently offered a RT-PCR swab test and in the case of on-the-spot antigen testing, we recommend a positive result for Covid-19 be followed up with a lab-based PCR test for confirmation.
- This would maximise the chances of correctly identifying a positive case.
- The potential gap in this approach for mass testing is asymptomatic individuals who test negative as part of the regime but do in fact have the virus, i.e. they have a false negative – so they would not then qualify for an affirmative test.
- Such false-negative cases, however, are not covered under the existing government strategy in any case and by regularly testing those without symptoms, we maximise the chances of isolating transmitters early.

**Antibody Testing**

- We apply the same recommendations to on-the-spot rapid antibody testing. Any positive case would be confirmed using the highly accurate lab-based ELISA test.
- The gap here arises where someone could potentially receive a negative result but actually has antibodies. In such a case no risk arises – the person likely has short- to medium-term immunity but isn't aware of it.

By combining rapid and lab-based testing there is a lower risk than arises in the current government strategy.

## 2. Masks

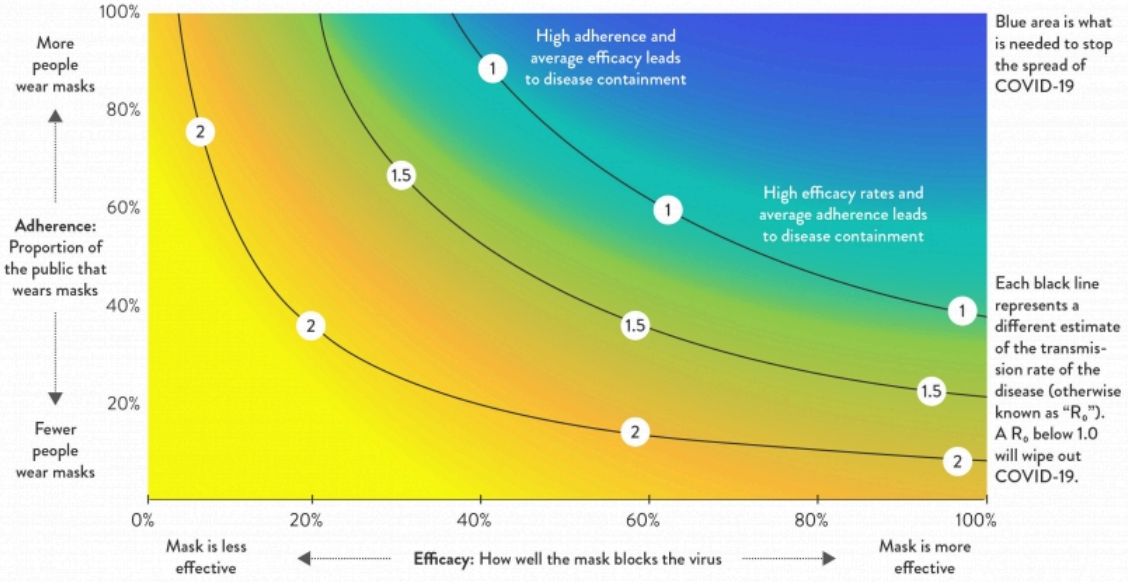
As we set out in *The Importance of Masks in Exiting Lockdown,* masks form a critical element in the infrastructure of containment.

Covid-19 can be passed through droplets released from an infected carrier's airways. These droplets are larger initially and then form a fine mist.

It is harder to prevent the spread of larger droplets than smaller ones, but any form of mask – even a crude homemade covering of the nose and mouth – can help prevent large droplets from spreading from a carrier. This in turn prevents the infection being passed on.

Modelling by Hong Kong Baptist University, cited by Professor Trisha Greenhalgh and Jeremy Howard in their work, suggests that if everyone wears a mask in public (eg, in transit, at social venues, at work) the rate of transmission of the virus (R0) can be kept below 1. [100]

Figure 9 – Modelled impact of mask use on the reproduction rate of Covid-19




*Source: L Tian, et al, "Calibrated intervention and containment of the covid-19 pandemic" (2020), https://arvix.org/abs/2003.07353, page 10 of the Supplementary Materials. Also see Howard et al. "Face Masks Against COVID-19: An Evidence Review," Preprints 2020, https://www.preprints.org/manuscript/202004.0203/v1.*

### 3. Individual Risk Profiles to Inform Seasonal Guidance

A Covid-19 risk screening programme that uses patient risk factors – age, gender, medical conditions, potential exposure, recent travel or being in a crowded place, public-health data, aggregations from previous screenings, patient symptoms, testing, etc – should be adopted to create a risk score for patients. Its design must not undermine the need for collective action, which is an inherent danger when it comes to focusing on the perceived risk of an individual. This could be addressed by defining a clear set of measures that must be adopted by those in each category – including mask-wearing for those in higher-risk categories (see categories A, B and C in Table 1 below). As new, temporary measures are introduced that are specific to winter, they could be assigned to specific categories. For example, those

in category A could be given easy access to flu vaccination, which would reduce the likelihood of them having to be hospitalised or attend primary-care facilities during the winter months.

| Risk Category | Definition | Example of Persons in This Category | Example Measures |
|---|---|---|---|
| A | Those who are most vulnerable and at risk from Covid-19. | Elderly people and those with severe underlying conditions. | Shielding measures, including provision of colour-coded N95 reusable masks. |
| B | Those who have a heightened level of risk due to one or more known factors. | People who are overweight.<br>People who work in certain public-facing jobs. | Access to a regular test.<br>Mandatory mask wearing in public spaces. |
| C | Those with low health risks but high risks of transmission. | Healthy people aged 18 to 60. | Mandatory mask wearing in public spaces.<br>Participation in mass testing. |
| D | Those with low health risks and low risks of transmission. | Children under age ten. | Limited measures, allowing return to school, etc. |

## 4. Local Lockdowns

### Regional Lockdowns

In the UK, this scenario quickly developed into a reality as test-and-trace data in the northwest of England showed the virus was surging and had been primarily spread through house visits. Ministers banned more than one household meeting indoors across nine local authorities. [101]

German federal health minister Jens Spahn said that Germany will rely on mainly regional measures as opposed to nationwide action and could impose stricter penalties for breaking social-distancing and mask-wearing guidelines. [102]

Dr Michael Head, senior research fellow in global health at the University of Southampton, said: "We simply have to implement a proactive approach that will rapidly squash any emerging outbreaks. This includes the need for rapid case detection, effective contact tracing, immediate sharing of data across public health authorities, and will sometimes require local lockdowns or quarantine measures." [103]

### London Lockdown

In the case of a second wave, lockdown measures in London could include asking people not to travel in or out of the M25, being ordered to stay at home, and imposing a ban on overnight stays. [104]

### Shielding for Vulnerable Groups

The government has considered extending the number of people deemed "clinically vulnerable" to a large number of people between the age of 50 and 70. The "segmentation approach" would mean asking people in this bracket with additional health factors in a defined geographical area to shield. [105]

# Safely Back to School and University in Autumn

One of the most important objectives for the months ahead is to safely return students and staff to schools, colleges and universities without risking greater community transmission. Given what we know about the virus, it's clear that the challenges are much more acute when it comes to returning older pupils and adults. Therefore, we propose the government supports every university in the UK in rolling out testing for their student and staff populations. We recommend the Three Ts model, which has been effectively used by the University of Illinois in the US.

**Testing in Universities: The Illinois Model**

Of all the tests being done each day in the US, 2 per cent of them are being done by the University of Illinois across its three campuses. The university has created its own FDA-approved test and all students and staff are tested twice a week. As students have returned, the number of positives has increased but those infected are taken out quickly and self-isolate for two weeks. The system is working.

When applying this case study to universities in the UK, it's important to see the developments at the University of Illinois as more than just the creation of a rapid test. This is only part of the puzzle. There are three 'Ts' that make up this blueprint for university testing:

1. **Target:** Understand through modelling whom to test and how often tests are needed. Testing should also be delivered as locally as possible through mobile sample collection vans, with samples being taken to nearby labs (ideally within the university itself.) Over time, the mobile facilities would process the tests themselves through rapid, on-the-spot tests.
2. **Test:** Use an easy, fast test that's not invasive. For the University of Illinois, this was a saliva-based test that simply required a student or staff member to spit into a tube. Results were returned digitally within two to six hours. There are plans to decrease this significantly and the university is currently working to replace PCR machines with CRISPR strips, which would mean test results in less than an hour.
3. **Tell:** Communicate the results quickly and have clarity on appropriate action required.

The achievements of the University of Illinois in mobilising a mass-testing regime is a demonstration of what can be achieved by focusing resources and efforts on innovation. It has successfully created a mass-testing system that works for an education setting and which is inherently affordable – coming in at $10 a test with an aim to get to $1 test.

In the UK, there are few settings as conducive to this mass-testing pilot as universities. They are often contained spaces, and all use a digital ID and database that houses information and contact details for

students and staff. Students are digitally native and have access to a mobile device which serves as a digital credential. Offline, there is already a sense of community and more often than not, a campus infrastructure that works well for sample collection. Not only could adoption of this model see universities back up and running safely and effectively, but it could play a much greater role in helping to establish a blueprint for mass testing across the rest of the United Kingdom.

**We recommend that every university in the UK is supported to prepare for the mass testing of all students and staff on campus this autumn and winter.**

This approach should be built around the Three Ts:

**Target** For campus universities, tests should be done twice weekly, on campus.

For non-campus universities, testing should be done at a combination of different sites, including halls of residences and teaching facilities.

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**Test** Funding should be made available for universities to develop their own testing infrastructure using existing lab space and, where capacity is available, provide access to the tests themselves. New, on-the-spot tests should be piloted at a select number of universities and eventually be rolled out to replace PCR testing wholesale.

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**Tell** All students and staff should receive their results through their existing university digital platform – this may take the form of an app, email or text message – and all should be able to demonstrate their "latest" Covid status quickly and easily. Students or staff testing positive should self-isolate for two weeks and provide their details to local test-and-trace teams.

## Testing in Schools

For schools, our recommendations have previously been set out in *Back in September: A Test for our Schools*. Here, the objective is twofold. First, we must test to understand whether schools are transmission hotspots.

By testing the entire pupil population of 2,000 schools over a three-week period, we can build a sufficient dataset to confidently designate "super-spreader setting" status by type and location of school.

For example, rural primary schools may be risk-free while inner-city secondary schools could be revealed as hotspots for virus transmission. Those confirmed as such would qualify for ongoing, twice-weekly testing for all persons within this setting to contain outbreaks and provide reassurance. Disproval of a school's status as a super-spreader setting would – by its very nature – serve as a confidence boost for a return to school. Regular monitoring would offer ongoing reassurance should the situation change.

**In both schools and universities, other containment measures should also be fully adopted over the winter months, including the use of face masks.**

# Conclusion and Recommendations



This document sets out what we now know about Covid-19 and how this should factor into a new risk calculus that opens up the economy while protecting lives. This leads to the following recommendations to avoid a second national lockdown:

1. **Stricter enforcement of mask usage**

We believe, with the growing threat of a second wave, that the use of masks should be more strictly enforced. This would mean passengers not being able to use public transport or enter shops without wearing a mask. To ensure we have the mask supply we need to live alongside the virus, potentially for at least the next year, the UK must do more to onshore mask production in the UK, both of N95 and standard medical masks.

2. **Mass testing**

A critical element of the infrastructure needed to avoid a second wave is mass testing. We have set out in recent reports what this would look like. We recommend the follow steps urgently:

- Make full use of the UK's existing capacity.
- Bring onstream all possible viable tests.
- Provide fullest support to emerging rapid tests to get these onstream as soon as possible.

3. **Regular testing at schools and universities**

Allowing students and staff to go back to teaching settings safely this autumn is a key priority for the country. The only way this can be done is to put in place a regime of regular testing at universities and some schools, supported by the government.

4. **Individual risk scores**

The introduction of individual risk categorisations would provide clearer guidance on what measures should be adopted by whom. For instance, ensuring those categorised as high risk are given N95 masks to protect them during any spikes or second wave of the virus.

5. **Local not national lockdowns**

Drawing on the mass testing regime we advocate the government tests as many people as possible, as often as possible. This would enable the UK to identify hotspots of the virus and impose local, rather than national restrictions.

6. **Winter guidance**

We advocate “common sense” restrictions this winter, particularly regarding the festive season. Drawing on the UK’s mass-testing capability, families and organisations should form “safe” bubbles that enable interaction with confidence. This will also involve companies sustaining new remote-working practices where appropriate.

# Annex: What Rapid Tests Are Out There Now?



### Rapid Antigen Tests:

According to the website FindDX, which the European Centre for Disease Prevention and Control refers to, 28 rapid antigen tests have been commercialised (four are currently designated as research-use only). [106]

In the US, BD (Becton, Dickinson and Company), a medical technology company, recently announced that the Food and Drug Administration (FDA) had granted them an Emergency Use Authorisation (EUA) for a rapid point-of-care antigen SARS-CoV-2 diagnostic test. The test delivers a result in 15 minutes and is easy to use and portable. Clinical studies performed at more than 20 sites across the US demonstrated that the test is capable of achieving 84 per cent sensitivity and 100 per cent specificity.[11]

Quidel, the maker of the other rapid antigen test approved in the US, says its test has demonstrated a clinical sensitivity of 80 per cent and specificity of 100 per cent when compared with an EUA molecular device.[12] The test delivers a result in 15 to 30 minutes and uses a nasopharyngeal swab. [13]

### Rapid Antibody Tests:

FindDX then lists 195 commercialised rapid antibody tests. [107] The query the government has raised on these tests is around their accuracy. From our conversations with experts and testing suppliers, we believe a range of these tests, including a number made within the UK, are accurate enough for population-level testing. A range of those under development in the UK are included below in the section “Emerging Tests”.

### LAMP Testing:

Progress has been made in recent weeks on developing LAMP (loop-mediated isothermal amplification) tests. These tests work by turning plate readers, the backbone of instruments in every molecular biology lab in the UK, into diagnostic tools.

In May, the government announced a trial in Hampshire using a point-of-care reader by Optigene. Despite misreporting of it being a rapid antigen test, the recent trial is for a LAMP test.[15] The test has been misreported as giving a 20-minute result. A high viral load could return a positive result within 20 minutes, but the entire process requires a full LAMP reaction – which takes about an hour – to confirm

negatives. The trial has reportedly been considered successful in clinical settings and the test is now being used in some A&E departments, GP testing hubs and care homes.

The UK government has also announced it will be deploying Oxford Nanopore's LamPORE assay, which uses LAMP to amplify viral nucleic acids. The test uses a palm-sized device to identify Covid-19 sequences by running amplified DNA through a protein nanopore. The government has placed an initial order of 450,000 tests.

UAE-based Group 42 (G42), an AI and cloud-computing company, announced in June that it was working on a "population-scale technology" using an end-to-end solution to rapidly and accurately detect Covid-19. G42 has been working in partnership with Oxford Nanopore to develop an "ultra-high parallel processing capacity … this innovation uses the LamPORE assay, which is based on the LAMP technique and Oxford Nanopore's rapid sequencing platform, in combination with the high-throughput automation, sample processing and reporting workflows developed by G42."

HiberGene Diagnostics recently announced that their new fast molecular Covid-19 test had received CE marking. This followed a clinical evaluation at a private hospital in Dublin. The project received a grant of €930,000 from Horizon 2020, the EU programme for research and innovation. The test uses a simple sample preparation protocol and has performed well with high to moderate viral loads. The portable LAMP PCR test can deliver positive results within 30 minutes on average, negative results within 60 minutes.

Testing based on loop-mediated isothermal amplification – while not uncomplicated to scale – and other molecular platforms have the capacity to also unlock hundreds of thousands of tests per day. The key to unlocking this capacity is expediting regulatory approval for a wider range of testing technologies, particularly those that draw on different reagent and equipment supply chains.

> **Curative – From Startup to USA's Biggest Testing Supplier**
>
> Curative is at the forefront of coronavirus detection and offer an innovative oral fluid swab-based Covid-19 virus test. Having delivered more than 4 million tests and with a capacity of more than 1 million tests per week, it are now one of the largest testing providers in the US, with its third lab in Austin, Texas, now online.
>
> Curative supplies tests to more than 15 states including California, Delaware, Florida, Louisiana, Alaska, Georgia, Illinois and Texas and the United States Air Force, and is accustomed to mass testing – including the Texan prison system and the Florida Care Homes testing program where it tests all the staff of 3,804 care homes on a rolling two-week basis; this in excess of 200k staff. It recently signed a large DOD contract to test the US military.

> Curative's exclusive focus on Covid-19 testing has allowed it to scale rapidly and develop tests that meet the demands of mass testing. By using a non-invasive oral fluid swab, testing is much easier to administer and consequently a much lower risk of poor tests leading to far fewer false negatives. Curative tests less than one in ten false negatives which is far better that the current rate of around one in four false negatives in the UK
>
> The company operates an end to end orthogonal supply chain and there is no shortage of components due to the innovative test architecture

## Emerging Tests:

### Biopanda Reagents

**What's available now?**

Biopanda has developed a Covid-19 rapid antibody test that deliver results within minutes. Similar to pregnancy tests in appearance and application, it is primarily intended to test for past infection, which could be a useful surveillance tool deployed at a regional or population level. The tests can also be used to diagnose current infection when paired with antigen or RNA testing.

Biopanda has been supplying tens to hundreds of thousands of tests to Bahrain, Slovakia, the Czech Republic and Spain. Its tests have been registered with the Saudi FDA, and they are also pending registration in South Africa, Mexico and Nigeria. In the UK, Biopanda is still waiting for a standardised validation panel from Public Health England (PHE). Biopanda has submitted information to the New Test Approvals Group (NTAG) but has not heard anything back.

**What's in the pipeline?**

- **A rapid antigen test**

There are two versions in progress: one that can be read by eye which creates challenges from a sensitivity perspective, and a second that uses immunofluorescence through a handheld reader.

- **An RNA test based on loop-mediated isothermal amplification (LAMP)**

This test is similar to PCR but does not require the use of expensive thermocyclers and is suitable for use in a point-of-care setting.

- **Covid-19 antibody ELISA test**

This is a lab-based version of Biopanda's existing rapid antibody test. This test specifically detects antibodies against the receptor binding domain (RBD) of the coronavirus. These antibodies are believed

to have neutralising properties and so may confer immunity. Some vaccine candidates will operate by inducing an immune response to the RBD and, therefore, this ELISA will be useful to researchers as a way of measuring the immune response generated by a vaccine.

- **Covid-19 Interferon Gamma Release Assay**

This lab-test is designed to test for cell-mediated or T-cell immunity, which is an increasingly important element in the immunity debate.

**Mologic**

**What's available now?**

Mologic currently has four serology tests available.

- **ELISA test for IgG only**

This test is available now, and production could be scaled to 500,000 tests per week. As it stands, there is no sign of the test being validated by PHE, but there have been positive conversations with PHE Colindale.

- **Professional RDT for IgG, IgM and IgA**

These diagnostic devices would identify a full range of antibodies. Forms have been submitted to NTAG but no reply has been received. The test is being provided on a not-for-profit basis with a number of international partners and there are proposals for 200 million+ capacity units here and in Africa.

- **Self-test for IgG only**

This home-testing kit could be used by a layperson to identify if they had IgG antibodies and therefore had some evidence of past infection. To date, the regulatory pathway has been blocked by MHRA.

- **Laminated test in IgG only or G, M and A**

The laminate tests provide a quick result and show if a patient has had exposure to Covid-19. Plasma from a sample soaks along a laminate of what's essentially paper, encountering a zone that has known coronavirus antigens. If the plasma has antibodies to the coronavirus proteins, those will bind to the test antigens and carry them along up the strip giving a result. These tests are being developed for both professional use and self-testing. They are being distributed internationally.

**What's in the pipeline?**

In the medium-term, Mologic is developing T-cell and Memory B-cell marker variants of the antibody test to confirm immune memory. These are critical to the debate around immunity.

The pre-mentioned antigen tests are subject to regulatory hold-up but could be online very quickly. The company is also looking to develop peptide antigen driven tests (for lower cross reactivity), similar to that of the HIV rapid tests.

### BioSURE

#### What's available now?

The BioSURE Covid-19 Antibody Self-Test, which is similar to a home pregnancy test. It can be performed by individuals on their own without the need for a health-care professional to be present, and they can read and interpret their own result all within just over 10 minutes. The test result is simple and binary – positive or negative. The intended use in the UK is to inform people that they have had the virus.

This product has been fully validated and is ready to go into full scale manufacture. The device is entirely based on the BioSURE HIV Self-Test, which has been CE marked (through BSI) and placed on the European market since April 2015. Almost 400,000 of these tests have been distributed in the UK since launch. The sole difference between the HIV test and the Covid-19 test is what is measured. The Covid-19 test measures a range of IgG class antibodies to SARS-CoV-2. Each test kit is supplied with all necessary components to run one test. The test kit can be supplied with two tests.

The BioSURE HIV Self-Test has already received a positive review[28] from NTAG, and the company has been told that it is on the Department for Health and Social Care evaluation list, although the reference sample panel for evaluation (scheduled for the end of June 2020) is not yet available so this process cannot begin. The BioSURE HIV Self-Test has not yet been evaluated by PHE.

BioSURE has submitted a performance evaluation to address the MHRA suggested usability performance data deficiencies, with a decision expected in the coming weeks.

#### What's in the pipeline?

The company is developing saliva-based antigen self-tests and anticipates that these could be available by Q4 this year.

### Omega Diagnostics

#### What's available now?

Headquartered in Alva, Scotland, with an additional facility in Littleport, Cambridgeshire, Omega Diagnostics has the capability to manufacture both ELISA tests and lateral flow tests.

It currently has a CE-marked antibody ELISA test that was completed through its partnership with Mologic (see above), and the test was CE marked back in April. It has since been robustly validated in studies with more than 1,300 patients by the Liverpool School of Tropical Medicine and St George's University Hospital.

The company is currently validating both a finger stick and dry blood spot sample-collection method, which will allow samples to be taken at home and returned to a lab for testing. It expects this method to be CE marked and available soon.

Omega is also completing the technical transfer of Mologic's lateral flow professional-use antibody test, and this will be CE marked soon. Like the ELISA, this has been robustly validated by both Liverpool and St. George's.

Omega still awaits the outcome of evaluation by PHE, having submitted kits earlier this year.

**What's in the pipeline?**

Through its partnership with Mologic, the company is developing ELISA and lateral flow antigen tests that will use saliva as the sample type. These tests will offer a quicker time to result and easier sample-collection method than current testing methods (particularly swab tests). The expectation is that the ELISA antigen test will be available by the end of September and the lateral flow test by the end of October or November.

**QuantuMDx**

**What's available now?**

QuantuMDx has developed a real-time reverse-transcription polymerase chain reaction (rtRT-PCR) assay to specifically detect the virus. The kit was developed using advanced bioinformatics to maximise performance and combines all required reagents into a single tube for the convenient performance of RT-PCR from extracted nucleic acids.

The test is provided in a vial format for ease of use and extended shelf life. It has been designed to return concise Covid-19 status with no "indeterminate" result. QuantuMDx's test has been validated against a number of RNA-extraction kits and thermocyclers, is CE marked and has been designed and manufactured in the UK.

The test has undergone independent evaluations in seven locations (five of which were in the NHS), including Hampshire who performed the validation on currently used NHS tests. QuantuMDx was informed that PHE validation had been paused, causing the company to shift its focus to direct interactions with the NHS.

**What's in the pipeline?**

A rapid, portable molecular point-of-care solution (Q-POC) will be released in September, alongside a SAR-CoV-2 assay. These two tests will enable on-the-spot testing.

The company is also developing a respiratory panel test that will run on the Q-POC system.

**Project Screen by Circle**

**What's available now?**

Project Screen by Circle is a consortium of industry experts led by Prenetics, together with the University of Birmingham, The Doctors Laboratory and support from Stuart.[29]

Combined, it offers an out-the-box mass-testing solution aimed at returning employees to work safely and confidently. It was responsible for the highly successful Premier League testing regime, which saw the football season return with no outbreaks among players, staff and others involved in the game, and it has recently been contracted by Hong Kong[30] to test every single restaurant worker. It is able to work with specific settings to allow employers to bring employees back to work. The company is currently working with:

- Premier League and other sports
- Numerous airports
- Numerous film productions
- Numerous sports
- Numerous corporates

In essence the availability of these solutions will be consumed by projects in the pipeline as the company continues to build further capacity for larger projects.

**What's in the pipeline?**

The group has invested in RT-LAMP technology with a new partner, FRANKD technology solutions. This will become a solution offering highly accurate point-of-care analysis with high sensitivity and specificity as a screening tool. The cost of test is lower, throughput is higher, and this is also linked to health-passports solutions and identification.

The product can test up to 90 people at a time in 60 minutes (post-sample collection time). It is currently in position as part of the Heathrow trials, has been deployed in a large Southampton trial[31] and is also in a trial at Birmingham airport.

The product is in the process of emergency FDA approvals and is already CE marked. The specificity of the test is 100 per cent and sensitivity is at 97 per cent – comparable and often surpassing lab-based tests. The capacity for RT-LAMP is practically limitless as Project Screen by Circle is investing in the company behind the technology for the benefit of its own supply chain.

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