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CHANGE

# Light at the End of the Tunnel

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## Foreword by Tony Blair

Britain, along with virtually every other country on the continent of Europe, is at an absolutely critical juncture in its response to the Covid-19 pandemic. This paper identifies the vital decisions which need to be taken now.

The second wave in terms of cases could be as large or even larger than the first.

Britain, like other countries, has taken the decision to go back into lockdown.

The essential challenge, which we must meet, is to use November to re-emerge in December with this lockdown being the last.

In this paper we suggest that there is a plan involving accelerated deployment of therapeutic drugs and vaccines, mass testing using all available new tests, together with the best data system globally accessible, which would allow us in December to close off resurgence of Covid-19 when we come out of lockdown.

At the very least, we raise the questions the government needs urgently to interrogate and answer.

The first wave has already had an economic cost roughly three times that of the financial crisis. The consequence of a further round of lockdowns will be devastating.

I am optimistic that by the second quarter of next year we will have vaccines and therapeutic drugs which will allow us to manage the disease and return to something like normal.

My anxiety is between now and then. We simply can't afford to put our society and economy into severe restrictions for the winter months. The toll in terms of health and the economy will be enormous.

It is true that we now know a lot more about the virus.

We know how to reduce death rates significantly. We know more about how it is spread.

But increasingly, we know that the risks of Covid-19 are not simply about mortality rates.

We know that Covid-19 can affect people for long periods – the so-called Long Covid sufferers – and this group is not a small number.

And we are beginning to be aware that there is a significant possibility of long-term damage, particularly to the heart and lungs, possibly even among those who have had the virus relatively mildly.

For these reasons, Covid-19 remains a disease you should avoid if you can.

The only game-changers continue to be vaccines and therapeutics, combined with large-scale testing.

The question is: Is it possible to accelerate the deployment of these game-changers so that we can save lives and mitigate the restrictions over the coming months?

We go through each and add a fourth dimension: the critical importance of data collection.

1. Rather than offering therapeutic drugs only to those in the RECOVERY Trial, any hospitalised patients at risk of serious illness should be offered drugs now that are safe and meet a minimum level of efficacy. There is no safety issue. We should give these patients the drugs and track the data from them. There will be resistance to this, because it means altering the RECOVERY Trial process, but this is a lesser risk than denying potentially life-saving drugs to those who need them. The AstraZeneca therapeutic drug – one of the most promising – is not part of the RECOVERY Trial in the UK, but we should urgently investigate whether we can speed up its introduction, even with limited doses being available.
2. With regards to vaccines, we should keep to the process envisaged but shorten every element of it insofar as is humanly possible, and aim to get the first vaccinations underway in December. Again, it is reasonably clear there is no safety issue with the vaccines like that of AstraZeneca's, and efficacy even at 50 per cent is worth having because it will for sure save lives and again mitigate significantly the severity of the illness.
3. As we have said for six months, the government should organise the provision of the rapid tests which it is now accepted have a role to play, so that we're testing people rather than quarantining them for long periods, catching asymptomatic cases as well as those with symptoms present, and measuring infectiousness and not only those who have the virus. This needs full-scale organisation for schools, universities, workplaces and other categories to participate, which is not presently in place. This is in our view pre-conditional to any successful track and trace system.
4. We must not repeat the error of the tracing app when it comes to data. We need the best system in the world in place now, so that every aspect of Covid-19 data can be gathered together. That means all the information on patients; recording of every test, including those not carried out by the government; and the setting up of a vaccine registration system so that as we vaccinate, every part of the experience is recorded.

Britain ironically is better placed – in theory – for a second wave. We have probably the best vaccine in the world; probably the best therapeutic drug; and at least some of the best testing devices.

But we need to get organised. And we need these key decisions to be taken now.

**Tony Blair**  
**Executive Chairman**

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## Executive Summary

As the number of Covid-19 cases soars once more, our policy responses are seemingly limited to a narrow set of restrictions. The second wave of Covid-19 cases could be as large or even larger than the first, with more deaths. Following the announcement of a further lockdown from Thursday 5 November, it is vital that the government uses this time wisely to put in place a strategy to end the cycle of lockdowns.

Beyond this cycle of lockdowns, there is hope. As this paper sets out, there is a four-pronged approach which, combined, will allow countries like the UK to live safely alongside the virus over the coming years and until its eventual eradication. This will reduce the number of deaths and lighten the burden on our health- and social-care systems while protecting the livelihoods and well-being of our citizens, enabling the country to reverse its economic decline. These four prongs – testing, therapeutics, vaccinations and data – can mitigate the effects of the second wave of the virus and offer some light at the end of the tunnel.

How long that tunnel is depends on a series of decisions that must be taken now. It is not beyond the realms of possibility for these measures to be in play by the end of year.

In therapeutics, we should move now to allow more people to join the successful RECOVERY Trial, shifting eligibility to those outside of hospital who become infected and are deemed at risk. This would deliver life-saving drugs to all patients who need them. At the same time, the validation of drugs should be expedited with rolling approvals given to those that meet minimum efficacy and safety standards – including antibody cocktails that we know work and that will save lives – and we must not delay in scaling their manufacture. A constant theme in this crisis, we must not let the best be the enemy of good enough.

When it comes to a vaccine, it's important that it is no longer given silver bullet status. Frankly, a vaccine alone will not save us but it will be an important tool in protecting the most vulnerable and those at the front line of health and social care. Data, aggregated from the world over, show that vaccines for the virus are safe and effective *enough*. Their deployment should not be held back to get more analysis of efficacy. Vaccines can and should be administered in December – supported by a clear communications campaign that builds public trust.

In testing, we must improve the failing test and trace system by implementing the measures we first called for in April, boosting the supply of innovative tests and broadening the availability of tests to individuals wanting to take control of their Covid-19 status. At the same time, potential outbreak

settings such as universities and secondary schools should be supported to introduce regular, mass testing.

Data is as important as the three preceding prongs. A system that connects the tests one takes, the vaccines they receive and the drugs they're given will be vital if we're to continue to build our understanding of how and where the virus is spreading. Over the coming months and years, these insights will sharpen our response and give rise to other effective measures, including health passports. It's vital that we have a system in place now that is able to speak to existing NHS data and infrastructure while also being nimble and flexible enough to support new platforms and work across borders.

These four prongs are vital. Scaling up the approval and manufacturing of innovations must start now. The logistics required to administer them will be without precedent and mark the biggest peacetime operation in our country's history. It will require extensive infrastructure and careful planning, as well as a shift in how government works – moving from the top-down, centralised approach that conceived the current test and trace system to one that is flexible, nimble and reaches across the UK in its entirety.

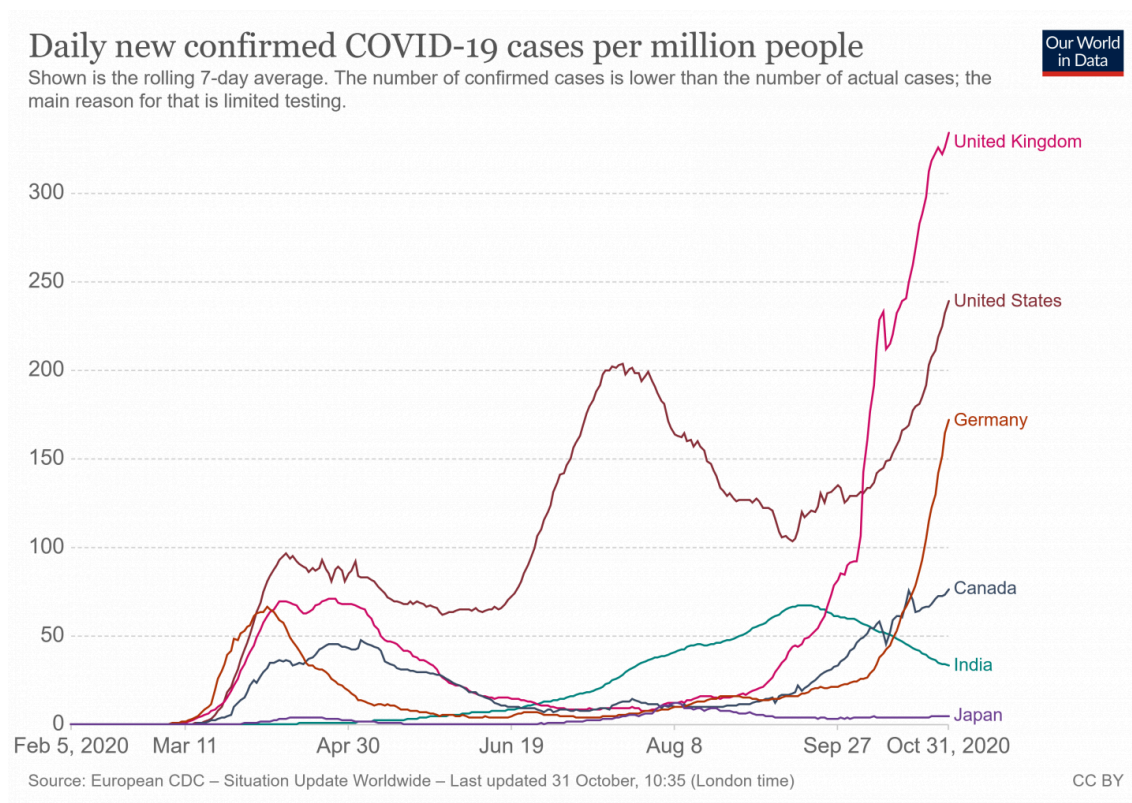
Above all else, it must inspire confidence in the population. This is how we will ensure compliance with measures to reduce transmission and participation across the four prongs. To do so requires political leadership and clear, simple, transparent communications that clearly set out the role and purpose of the four prongs, and the rights and responsibilities they confer onto citizens.

If we achieve this, we'll have something that we've been without for far too long: hope. Hope that national lockdowns are not a way of life. Hope that we can defeat and fully contain Covid-19. Hope that there is a light at the end of the tunnel.

# What We Now Know About Covid-19

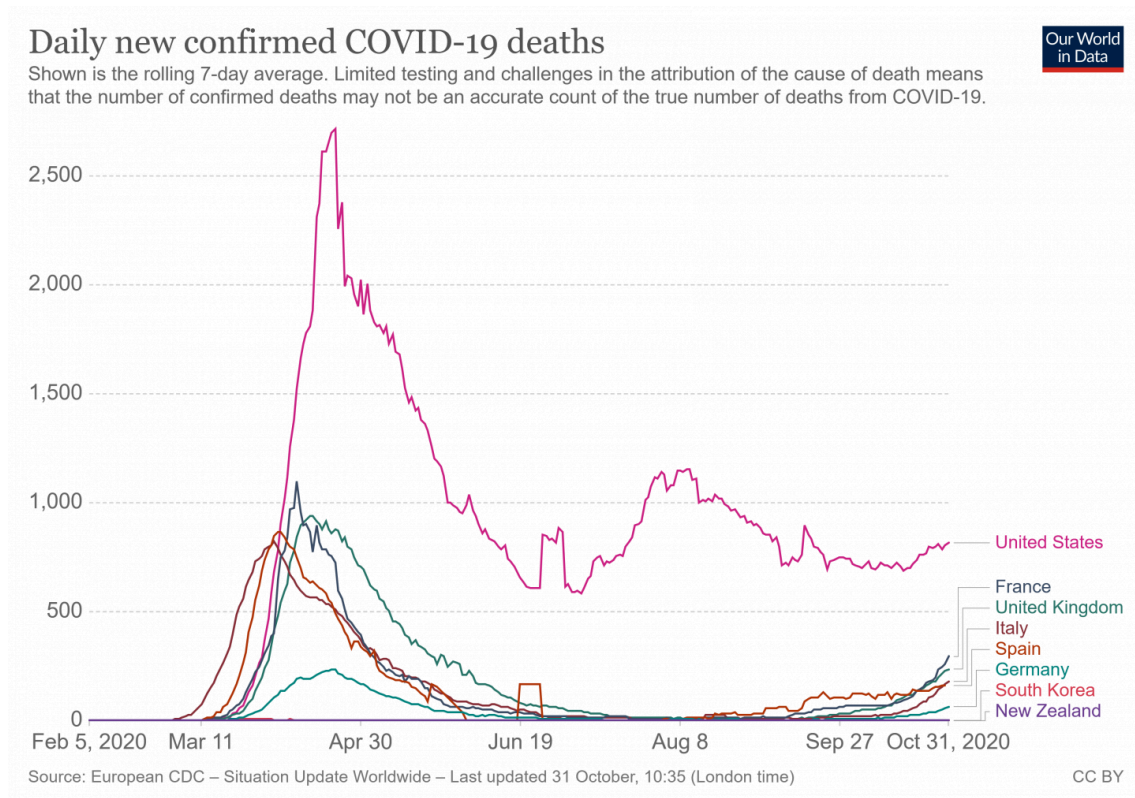
As winter approaches, cases of Covid-19 are rising around much of the world. But despite cases rising, deaths are lower than the first wave. In the immediate future, the central challenge of Covid-19 remains the same – balancing the economic damage that restrictions bring with the risk of cases rising beyond control. The overall context of how we respond to Covid-19 is now very different, and with a number of new measures at our disposal, there is an opportunity to prevent further lockdowns and live safely alongside the virus.

**Figure 1 – Daily new confirmed Covid-19 cases per million people**



Source: [Our World in Data](#)

**Figure 2 – Daily new confirmed Covid-19 deaths**



Source: [Our World in Data](#)

## We Know a Lot More About the Disease

The growing body of research surrounding Covid-19 has contributed significantly to our understanding of the virus: how it spreads, who it affects and, most importantly, how to treat it effectively. And because of what we've learned about the virus, governments are better equipped to create guidelines that reduce transmission rates, and individuals have a clearer idea of how to mitigate their personal risk of becoming infected.

Just like the seasonal flu, Covid-19 spreads most commonly through droplets when a person coughs or sneezes. Because of this, the use of masks has been widely implemented around the world, with some countries mandating their use both inside and outside.<sup>1</sup> Studies have now begun to explore the conditions, such as temperature and humidity, in which the virus lasts the longest in order to improve our understanding of how we can minimise transmission.<sup>2</sup>

As more people contract the virus, a clearer picture emerges as to who is the most likely to suffer severe infections or require hospitalisation. The Centres for Disease Control and Prevention in the US says its



best estimate is that the average person has less than a 1 per cent change of dying from the virus.<sup>3</sup> But we have also learned that some people are more prone to serious infections:

- The elderly, specifically those over age 70
- Those with certain underlying conditions such as cancer, heart conditions and diabetes
- Those who are overweight
- People in minority groups

Treatment for Covid-19 has made notable progress since the beginning of the pandemic earlier this year. For the month of September, ONS data showed that Covid-19 was the 19th most common cause of death in England and the 24th in Wales.<sup>4</sup> Deaths from the disease are likely to rank higher in the months of October and November, however, as cases continue to rise.

With several vaccine candidates entering phase III trials and viable therapeutics, such as dexamethasone, proving to be effective in treating severe cases of Covid-19, the methods for treating the virus have become much clearer and more effective.

## **The Threat of Covid Versus Other Illnesses**

It is important to put Covid-19 into perspective in terms of its relative impact on public health by comparing it to other leading causes of death and disease. This allows us to accurately assess the risk it poses as our capacity to prevent and treat other causes of death has been significantly reduced by the strain Covid-19 has placed on health systems around the world.

The pandemic has set back progress on eradicating other treatable infectious diseases because it has disrupted immunisation programmes in at least 68 countries since March, according to the World Economic Forum. For example, around 80 million children under the age of 1 are thought to be at greater risk of contracting measles since the start of the pandemic.<sup>5</sup>

While the threat of Covid-19 should not be underestimated, according to the World Health Organisation, you are still much more likely to die from non-communicable diseases – those that are not transmitted between people – than Covid-19.<sup>6</sup>

## **Dementia and Alzheimer's**

In 2019 deaths caused by dementia and Alzheimer's were dubbed the “biggest health crisis of our time”, having become the leading causes of death in England and Wales. Almost one in eight people died from dementia and Alzheimer's disease in 2018 and the number of people living with dementia in the UK is expected to reach 1 million by 2021.<sup>7</sup>

Dementia and Alzheimer's are consistently the leading causes of death in the UK, and in the month of September the diseases were responsible for around 11 per cent of all deaths in England and Wales. In the same month, Covid-19 ranked as the 19th and 24th leading cause of death across both countries respectively.

### **Cardiovascular Disease**

According to the WHO, cardiovascular diseases (CVD) and strokes are the leading causes of death globally and have been for the last 15 years. <sup>8</sup> Each year CVD causes an estimated 17 million deaths globally which accounts for about one-third of all deaths worldwide. Over one-third of these deaths occur in middle-aged adults. <sup>9</sup>

Between March and September of this year, ischaemic heart disease (IHD) was the leading cause of death in private homes for both males and females, accounting for 18.8 per cent of male deaths and 10.5 per cent of female deaths. During the same time period, deaths due to Covid-19 were the seventh leading cause of death in private homes for males and the 11th leading cause for females. <sup>10</sup>

### **Cancer**

In 2018 there were 17 million cancer cases and 9.6 million deaths caused by cancer around the world. <sup>11</sup> Overall, the majority of cancer deaths occur in those over 50 years old; 46 per cent of cancer deaths occur in people over 70 years old, closely followed by 41 per cent of those aged between 50 and 69. <sup>12</sup>

Due to Covid-19, Cancer Research UK estimated in June that 2 million patients were overdue for cancer treatments, tests and screening. <sup>13</sup> Compared to pre-pandemic figures, the Lancet estimated a 7.9 to 9.6 per cent increase in breast cancer deaths after diagnosis and a 15.3 to 16.6 per cent increase in colorectal cancer deaths due to the disruption caused by Covid-19. <sup>14</sup>

### **Diabetes**

In the UK, 4.8 million people were estimated to be living with diabetes as of the beginning of 2020. At the rate at which this figure is increasing, the number of people with diabetes is expected to reach 5.3 million by 2025. <sup>15</sup>

Similar to evidence regarding Covid-19 prevalence, ethnic minority groups are disproportionately affected by diabetes. However, the greatest risk factor for developing and dying from diabetes is obesity. This puts over half of the UK population at risk, with 62.3 per cent of adults categorised as overweight or obese in 2019. <sup>16</sup>

### **The Flu**

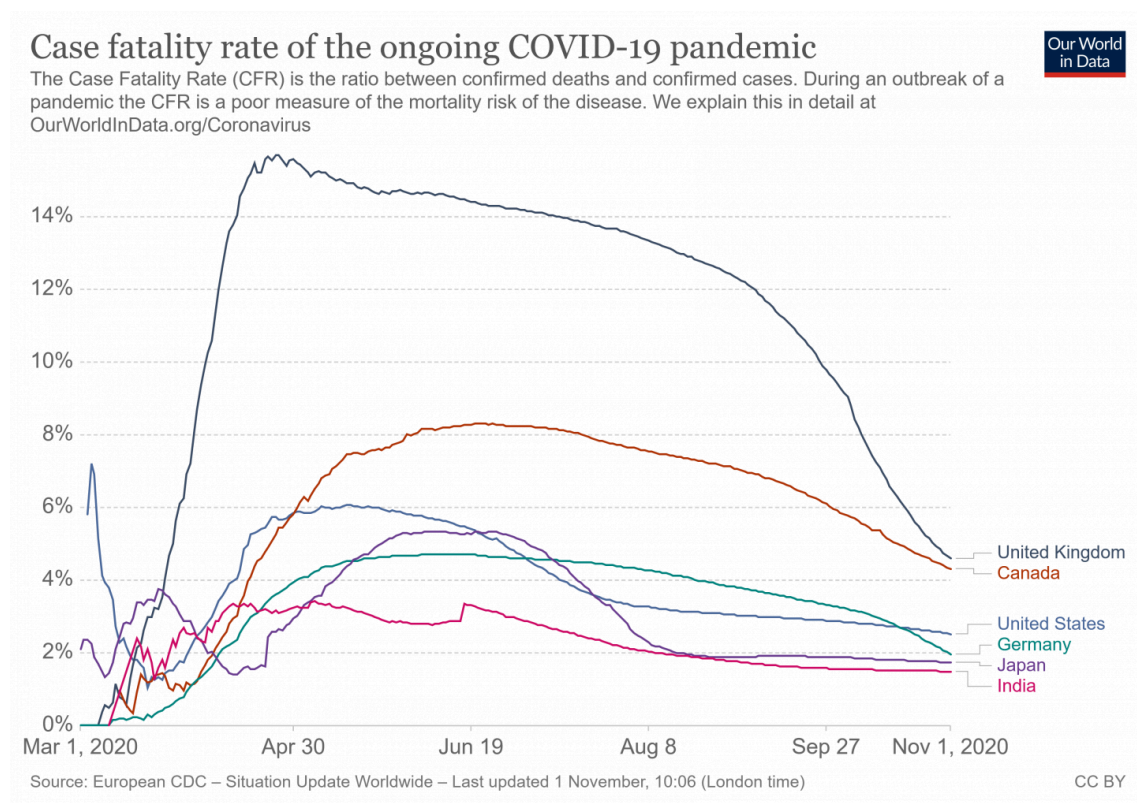
The seasonal flu and Covid-19 have clear similarities – they are both highly contagious, potentially deadly viral infections that pose the greatest risk to those over the age of 65. During the 2018-2019 flu season in the US, for example, individuals over 65 made up 75 per cent of flu deaths, while currently 80 per cent of Covid-19 deaths are attributed to the same age group. <sup>17</sup>

And although Covid-19 has a higher mortality rate than the flu, the death rates may be more similar than they currently appear. Inadequate testing, the inability to incorporate asymptomatic or mild cases into national and international statistics and the lack of a vaccine (where there is one for the flu) make the comparison between the two mortality rates unequal in terms of available data at this time.

## Death rate

Studying the death rate of any illness can be challenging, but there is a growing consensus from studies around the world that the mortality rate among Covid-19 cases, especially among hospitalised patients, has been declining.

**Figure 3 – Case fatality rate of the ongoing Covid-19 pandemic**



Source: Our World in Data

This decline can in part be attributed to an increase in testing, which identifies more cases, many of which are mild or even asymptomatic. In addition, a higher percentage of people contracting the virus

are younger and less likely to become severely ill. But, as new research shows, even those in intensive care are less likely to die from Covid-19. <sup>18</sup>

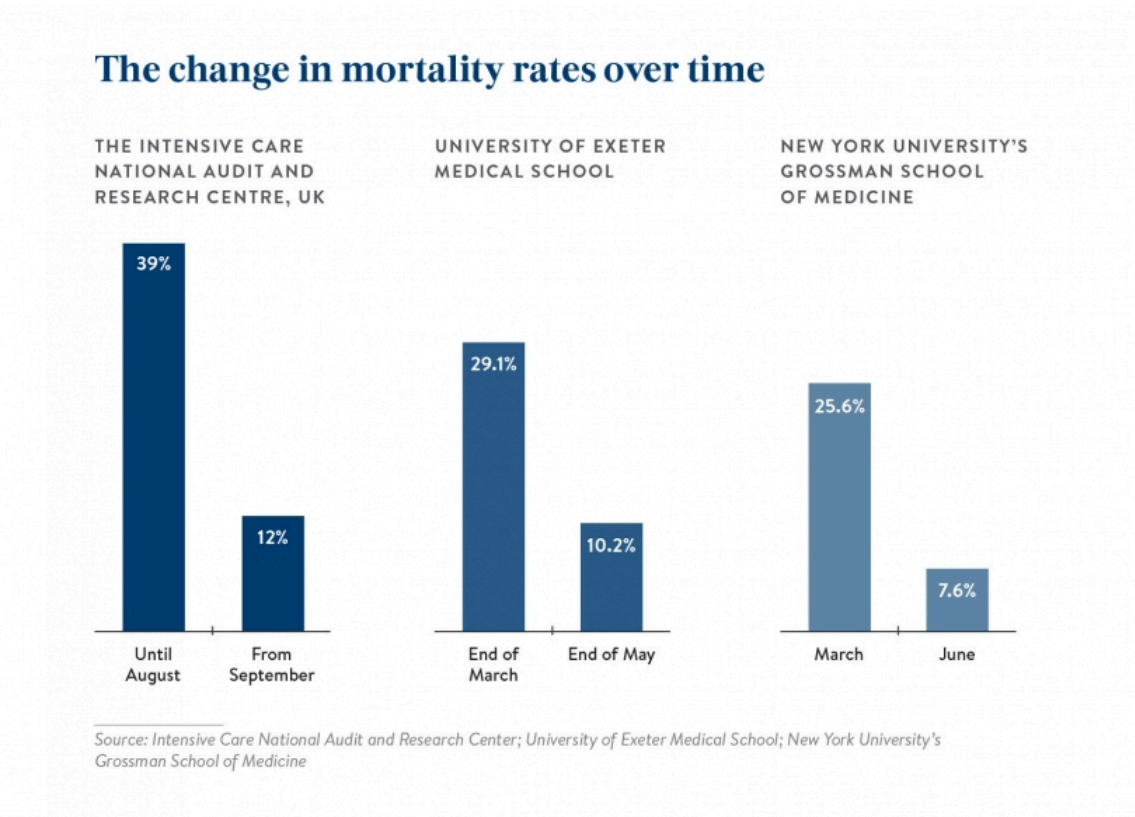
At the peak of the pandemic in the month of April, the number of deaths in the UK registered within 28 days of a positive Covid-19 test were consistently between 800 and 900 deaths per day. Now, in October, that same figure is declining and is between 100 and 150 deaths per day. <sup>19</sup>

A new peer-reviewed study from New York University's Grossman School of Medicine found a sharp drop in mortality among all age groups, including those with underlying conditions. It concluded that mortality dropped among hospitalised patients by 18 per cent, lowering the risk of death from 25.6 per cent at the start of the pandemic to 7.6 per cent now. <sup>20</sup>

A study from the University of Exeter Medical School supports these findings, as they found deaths in hospitals in England had dropped from 29 per cent in March to 10 per cent in May. Not only are fewer people dying, but fewer people are being admitted to intensive care in the first place. While 39.3 per cent of patients were admitted to ICUs up to 31 August, that figure has since dropped to 11.6 per cent in September, according to the Intensive Care National Audit and Research Centre. <sup>21</sup>

The overall drop in mortality suggests that as doctors now have a better understanding of which patients are at risk of severe infections and treatment programmes have begun to standardise as new therapeutics are approved, doctors have become more successful in treating the virus.

Figure 4 – How have Covid-19 mortality rates changed over time?

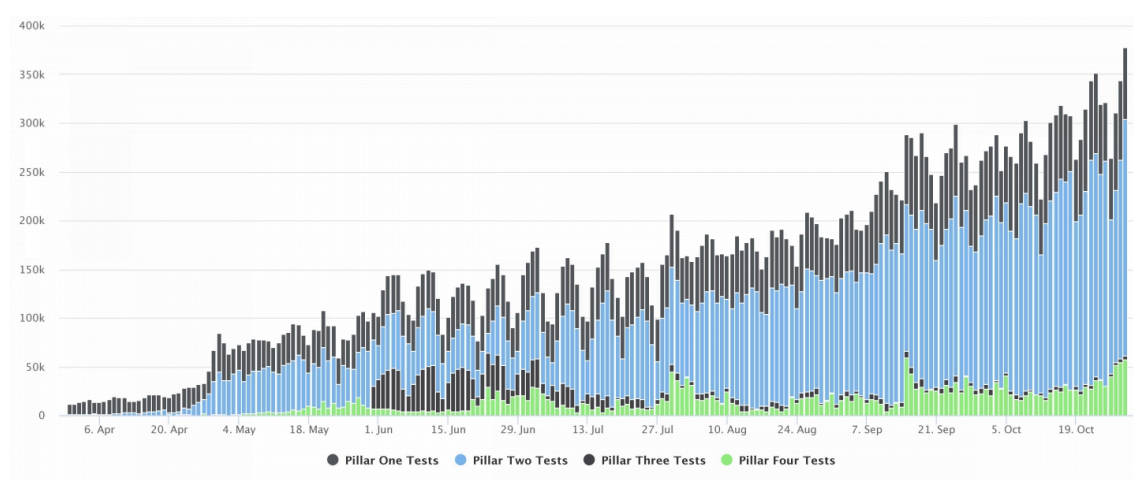


## Testing

In September, the government made clear that it was moving to a strategy of mass testing, with the so-called Operation Moonshot. This is a posture we have advocated since March and we welcomed the government's ambition.

The UK has successfully been ramping up testing, with a current testing capacity of 380,000.

**Figure 5 – Number of tests processed by pillar**



Two interlinked challenges remain, however:

1. Bringing onstream all possible rapid tests
2. Putting in place a viable test and trace system

This is made all the more urgent given the current difficulties the NHS Test and Trace service is facing.

### Test and Trace Is Failing

Test and trace systems can play a vital role in reducing the spread of Covid-19. [A study](#) by Imperial College London found that track and trace systems can reduce the R number by up to 26 per cent if 80 per cent of cases are identified within 24 hours, there is immediate testing following symptom onset, and contacts are notified of their need to isolate within 24 hours. However, researchers say the UK's test and trace system is falling short. <sup>22</sup>

Government experts have advised that the UK's test and trace system can only function effectively when at least 80 per cent of "close contacts" are traced and told to isolate. Close contacts are defined as

anyone who has spent more than 15 minutes within 2 metres of someone who has tested positive for Covid-19. <sup>23</sup>

The test and trace system is failing because not enough contacts are being reached in time to make a difference in the R number, not enough people have downloaded the app, and compliance with isolation guidelines is low.

### **Contacts Aren't Being Reached**

The UK test and trace system has reportedly reached a record low as only 59.6 per cent of close contacts are being reached and told to self-isolate. <sup>24</sup> Cases handled manually by call centres and online returned a 62.4 per cent successful contact rate. <sup>25</sup> These numbers do not indicate whether those who are being reached are complying with the required self-isolation period.

The 59.6 per cent figure is the worst rate since the system was launched in May. Reuters reported that government scientists have said that the test and trace system doesn't work as well when prevalence is high <sup>26</sup>, which is exactly when an effective test and trace system would be the most valuable.

### **Not Enough People Have Downloaded the App**

The government aimed for 80 per cent of smartphone users to download the app, which equates to around 56 per cent of the population. According to the BBC, 16 million users in England and Wales have downloaded the NHS app <sup>27</sup>, over 1 million people in Scotland have downloaded the Save Scotland test and trace app, and over 500,000 people have downloaded Northern Ireland's version of the app. Based on this data, one estimate said around 24 per cent of the UK population has downloaded their respective track and trace app. <sup>28</sup>

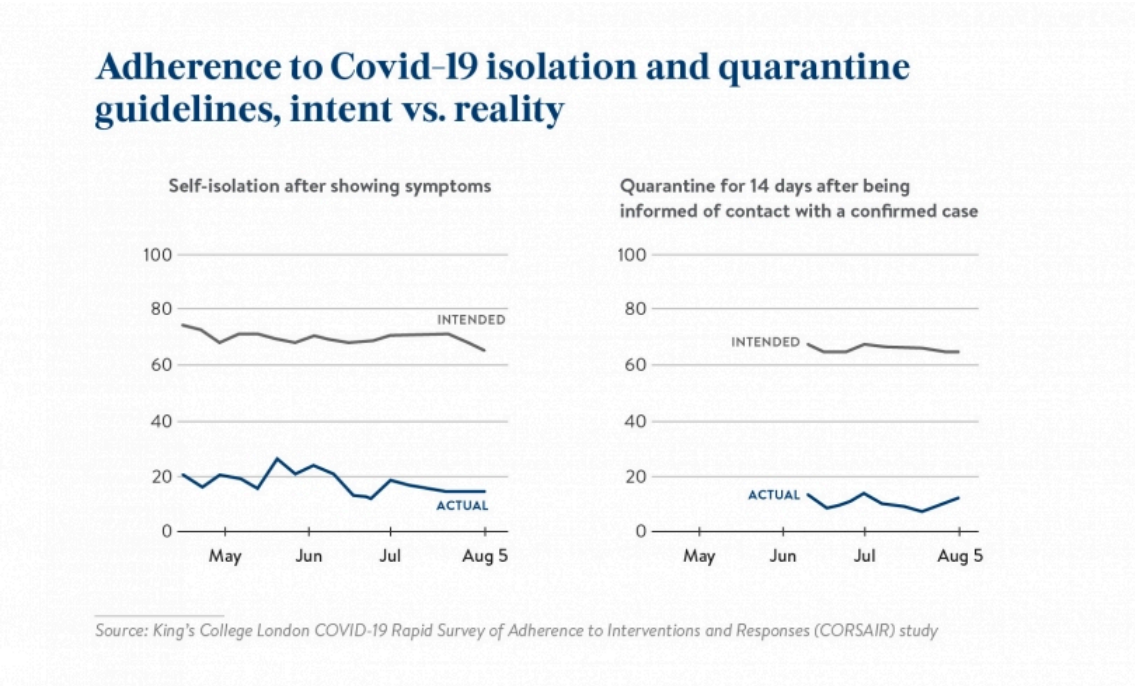
### **Compliance With Self-Isolation Guidelines Is Low**

A government-commissioned study found that only about 11 per cent of people identified by the NHS app as close contacts reported to have quarantined for the required 14 days. <sup>29</sup> The figure for those actually displaying symptoms of Covid-19 is not much better – less than 20 per cent of participants self-isolated after the onset of symptoms. <sup>30</sup>

Patterns from the study emerged regarding levels of compliance with the government's Covid-19 strategy: Lower levels of adherence were associated with having a dependent child at home, being male, being young, lower socio-economic status, facing greater hardships, and being less informed about Covid-19 and the guidelines in place. <sup>31</sup>

The study also reported that working in a key sector was associated with lower levels of compliance. This may be due to greater financial needs of those in key sectors, or the perceived social pressure to attend work, coupled with the inability to work from home. <sup>32</sup>

**Figure 6 – Are people in the UK following self-isolation guidance?**





# Therapeutics

Although there is only one drug, dexamethasone, that has been approved and registered to treat Covid-19, we have come a long way in our understanding and treatment of the virus. Professor Peter Horby, a member of the government's chief group of scientific advisers, has said that the number of deaths in hospitals is declining and treatments are improving. Whereas the risk of death for hospitalised patients was about 30 per cent at the peak of the pandemic in the spring, Professor Horby now believes that number is below 20 per cent. [33](#)

As we set out in greater detail in our paper [“Managing the Covid-19 Pandemic: Therapeutics Are as Important as Vaccines”](#) there are currently trials of potential Covid-treating drugs taking place around the world, many of which are examining drugs that already exist to treat other conditions. What has emerged from the wide range of trials underway globally is that three approaches hold promise to treat Covid-19:

- Drugs that keep the immune system from overreacting in ways that cause damage to the body. This is not uncommon in patients with severe cases of Covid-19.
- Antibodies that can target the virus, either made synthetically or harvested from survivors' blood plasma or made in a lab.
- Antiviral drugs that directly inhibit the coronavirus's ability to replicate, thereby keeping the viral load low and undetectable. [34](#)

The UK's RECOVERY Trial has shown that the use of the steroid dexamethasone can cut the risk of death by one-third for those on ventilators and one-fifth for those on oxygen. Further data from the same study also suggests that hydrocortisone, another steroid, may be equally as effective. [35](#) The successful repurposing of existing drugs offers the potential for treatments with known safety profiles and shortened development timelines to be used to treat the virus. [36](#)

Since March, the UK government has been purchasing dexamethasone and currently has enough to treat 200,000 patients going into the winter. At a price point of just £5 for a full course of treatment, dexamethasone is expected to play a significant role in treating the virus. [37](#)

## Antibody Cocktails

One of the ways the human body protects itself against bad bacteria and viruses is through the production of antibodies that are programmed to identify and attach to foreign invaders and destroy

them. There are three types of antibody-based treatments: single monoclonals, cocktails of monoclonals (which is the focus for most Covid-19 products), and polyclonals, such as plasma therapy.

Scientists can either harvest antibodies from the blood of people who have recovered from an infection or make them synthetically in a lab. Antibody-based treatments can be a powerful tool in the arsenal to fight outbreaks, both before and even if vaccines eventually make it to registration and widespread use. Several companies and one multi-stakeholder partnership with candidates in the antibody's category are worth highlighting:

- **Lilly's LY-CoV555:** In a trial that enrolled 450 patients in an outpatient setting, one of the three doses of LY-CoV555 administered was successful in reducing the presence of SARS-CoV-2 after 11 days, showing that the drug has an antiviral effect that can reduce Covid-19-related hospitalisation. A subsequent study has suggested the drug is only effective when patients are newly infected. [38](#)
- **Regeneron's REGN-COV2:** An antibody cocktail, made up of one synthetic antibody and one that was harvested from a patient in Singapore, has been assessed in a multiphase clinical trial and has shown promising preliminary results. [39](#)
- **AstraZeneca's AZD7442:** A combination of two long-acting antibodies derived from convalescent patients after a SARS-CoV-2 infection. The synthetic drug combination is designed to remain effective for between six and 12 months after a single dose is administered and is expected to reduce the risk of resistance developed to the virus. [40](#)
- **Takeda's Hyperimmune Globulin (CoVig-19) medicine:** The drug is currently in phase II trials, but Takeda's approach is different from other companies because it relies on plasma collected from patients who have recovered from Covid-19, making manufacturing a potential bottleneck. [41](#)
- **Celltrion's CT-P59:** This monoclonal antibody treatment is in phase III trials and Celltrion anticipates the development of CT-P59 will be complete by the first half of 2021. [42](#)
- **Vir Biotechnology and GlaxoSmithKline's VIR-7831:** This human anti-SARS-CoV-2 antibody is now in phase II/III clinical trials and is being assessed for its efficacy in the early treatment of Covid-19 patients who are at high risk of hospitalisation and death. VIR-7831 appears to act in two ways: preventing the virus from infecting new cells and marshalling the immune system to rid the body of infected cells. [43](#)
- **The Prometheus Initiative:** A collaboration of Adimab, an antibody company based in New Hampshire, academic labs and the US Army Medical Research Institute of Infectious Diseases that has developed an antibody that has shown promising results in pre-clinical trials by providing protection against the novel coronavirus, the SARS virus, and other similar viruses.

These antibody treatments are expensive (estimated at around \$1,200 for a round of treatment [44](#)) and hard to manufacture. They should be used sparingly among those hospitalised and at high risk of death, until economies of scale allow the drugs to be rolled out as a potential preventive measure.

## Therapeutics: The Light at the End of the Tunnel

The evolving political context, the severity of the pandemic, and advances in clinical development of certain therapeutics – and antibody-based ones in particular – show that therapeutics can be powerful treatments. At just £5 for a full course of treatment, dexamethasone will play a big role in reducing the number of deaths from Covid-19 with studies showing this is as high as third of patients on ICU, compared to the first wave.<sup>45</sup> Monoclonal antibodies in particular are as critical to pandemic management as vaccines, especially since the implementation of any vaccination programme will take significant time.

For low-capacity settings in low- and middle-income countries, some therapeutics may be a more feasible as part of a pandemic management strategy. For example, dexamethasone is affordable, available and is on the WHO's list of essential medicines. Deploying other therapeutics, such as antibody-based therapeutics, will be more difficult due to cost, insufficient manufacturing capacity, and challenging regulatory approval processes in these countries.

Scaling up production of antibody-based therapeutics is challenging due to cost and the lack of manufacturing capacity. At issue is how to maximise the quantity of treatment made given constraints on manufacturing capacity. Moreover, it is urgent that production be moved flexibly and quickly between various facilities to make the most of whatever production capacity is available, without generating shortages of critical non-Covid-19 biologics.<sup>46</sup> This will require the use of modular manufacturing processes and planning for this should start now.

## Turning East for the Supply of Antibody Therapeutics

It is likely that any UK-based manufacturing facility will take at least 18 months to be functioning. This means that we must look elsewhere for supply of antibody cocktails in the meantime, with South Korea where Samsung Biologics is producing a large volume of the drugs across three factories being a notable destination. Production capacity is due to double in 2022 when a much larger factory opens.<sup>47</sup> The company booked \$1.5 billion in orders in the first half of 2020 – a 150 per cent increase over its 12-month total last year, according to a recent release.<sup>48</sup>

The demand for this limited supply is striking and the UK finds itself in a large queue. There are moves that can be made to get ahead – including paying more money – and it's here where the UK can leverage its distinct USPs. The RECOVERY Trial has proved hugely successful and shows what can be achieved when a country leverages its integrated, advanced health-care system. This infrastructure will be

appealing to drug companies and should allow the UK to secure a sizeable quantity of the drugs before they are more widely available and being produced in-country.

To increase its appeal, the regulatory system should also be flexed and the threshold for incontrovertible evidence of efficacy and safety in any clinical trial for monoclonal antibodies will need to be adjusted to allow for fast-track approval. In the US, it is not uncommon for non-Covid-19 antibodies to skip some steps in regulatory approval processes, and the UK should do the same.

The UK has already secured a limited supply of doses – estimated to be in the tens of thousands – and these are being used in phase III of the RECOVERY Trial.<sup>49</sup> To widen the reach of the RECOVERY Trial, we should allow more individuals to join the study, including those outside of hospital and those who become infected and are deemed at risk by the Department of Health and Social Care. This will allow researchers to gather more data while also allowing doctors to administer treatment to more patients.

### **Limited Supply Should be Used for the Most Vulnerable**

The supply of antibody-based therapeutics before the end of 2021 is likely to be very limited. Authorisation should be fast-tracked, and the immediate limited supply should be reserved for anyone who is deemed at-risk and who contracts the virus and is subsequently hospitalised, with vaccines offering a preventative to those who are yet to be exposed to the virus.

When more doses are available, they can be distributed to a broader group and used as a preventative among vulnerable and elderly patients (whose immune systems are less responsive to vaccines).

### **Therapeutics: Recommendations**

- 1. Secure a supply of antibody cocktails from abroad by leveraging USPs such as the opportunity to conduct robust clinical trials and fast-track regulation.**

We have no choice but to secure a supply of antibody cocktails from abroad. For countries with a national health-care system, governments should package up fast-track regulation and the opportunity to conduct trials, in order to secure a volume of doses. International coordination should guarantee a supply of these drugs to lower-income countries too.

- 2. Give the limited supply of therapeutics that we know to be working to patients now.**

Anyone who is admitted to hospital after contracting Covid-19 who is considered to be at-risk because of their age or an underlying condition should be given an antibody cocktail.

- 3. Set up a manufacturing facility for monoclonal antibodies in the UK.**

The government should incentivise antibody manufacturing companies to set up in the UK by providing access to patient trials and other incentives, establishing a British-based, large-scale manufacturing base in the medium-term.

**4. Allow more people to join RECOVERY's Random Control Trial.**

Extend the opportunity to take part in the RECOVERY Trial to include those outside of hospital and those who become infected and are deemed at risk by the Department of Health and Social Care.

**5. Move quickly to bring new therapeutics onstream.**

Don't let the best become the enemy of good enough: Set clear minimum requirements for efficacy and safety of new treatments, including antibody cocktails, and once these are met in random control trials, the drugs should be removed from the trial and made available at scale to anyone infected who is at risk of hospitalisation.

## Vaccinations

There are over 200 Covid-19 vaccine candidates being developed and at least 15 are at the stage of conducting human trials. Experts believe that the vaccines being developed by Oxford in the UK and BioNTech in Germany could be ready at the end of the year. There are also promising vaccines being developed at Imperial College London and the University of Cambridge. <sup>50</sup>

We understand the importance of conducting and then communicating to the public thorough research into new vaccinations in terms of both public health and public trust. But, with the streamlined authorisation process that we recommend, a vaccination could be ready by the end of the year.

### Vaccines Reduce the Severity of Infection

A Covid-19 vaccine that is 50 per cent effective will reduce an individual's likelihood of contracting the virus by 50 per cent, as opposed to meaning the vaccine would only work on half of those vaccinated. <sup>51</sup> This is an important distinction to make in determining a vaccine strategy – we call it the “vaccination shift” and it represents the downgrading of severity and infectiousness of the virus if it is contracted by someone who has been vaccinated.

This important distinction also means it is unlikely for any new vaccine to achieve 100 per cent effectiveness. For reference, the annual flu vaccine is generally between 40 per cent and 60 per cent effective. <sup>52</sup>

The expectation that comes along with being vaccinated is not total Covid-19 immunity. Just as with the seasonal flu, the vaccine will reduce the risk of infection, and significantly reduce the likelihood of developing complications. It does not prevent one from becoming infected in the first place. <sup>53</sup>

**Table 1 – The Vaccination Shift**

Severity of Disease if Not Vaccinated	Severity of Disease if Vaccinated (Assuming 50 per cent Efficacy)
Light/asymptomatic	No infection
Moderate	Light/No infection
Severe	Light/moderate

**Severity of Disease if Not Vaccinated****Severity of Disease if Vaccinated (Assuming 50 per cent Efficacy)**

Life-threatening

Moderate/severe/life-threatening

Depending on efficacy rates, any approved vaccine could be a game-changer for the populations on which it is expected to be most effective – those who are healthy.<sup>54</sup> For those who may become infected, a vaccine could lessen severity of symptoms (which is how the influenza vaccine operates), which in the more extreme cases has led to hospitalisation and death; for survivors it often means long-term, debilitating health problems. Estimates are that vaccines that make it to market may achieve a floor of 50 per cent efficacy, which is roughly the same as an influenza vaccine. To date the novel coronavirus (SARS-CoV-2) has exhibited less mutation as compared to influenza;<sup>55</sup> This means that it is less likely to be unresponsive to a vaccine-induced response<sup>56</sup> and while it remains unclear how long protection conferred by the vaccination will last, we know that boosters can lengthen the period of protection provided.

Vaccines are not a silver bullet for addressing the pandemic, but they are an important part of a larger toolkit to manage and contain it, along with other measures. There are some instances where vaccines achieve a high rate of protection and near-to-complete elimination of transmissibility (such as the polio vaccine), but this may not be the case with the first generation of Covid-19 vaccine candidates that are closest to registration. The design of the phase III protocols of the leading candidate vaccines (made by Astra Zeneca, Johnson & Johnson, Pfizer and Moderna) are such that we may not have a clear answer as to whether they stop severe forms of Covid-19, and whether they halt the virus's transmissibility. Although the data have not yet been peer reviewed, a study carried out at the University of Bristol shows that the vaccine candidate made by University of Oxford and AstraZeneca works as intended, which is encouraging news.<sup>57</sup>

The UK government has already secured an order of 60 million doses of a vaccine that is being developed in France. The specialist vaccine company, Valneva SE, also gave the UK government the option to purchase an additional 130 million doses between 2022 and 2025.<sup>58</sup>

All vaccine options considered, Britain has already signed deals for more than 340 million doses. If all of these vaccines prove viable, there will be enough for every person in the UK to have five doses each. To speed up the vaccination process once one is proven safe and effective, the UK government is preparing to revise legislation to allow for the emergency use of a vaccine before it is fully licensed.<sup>59</sup>

Similar decisions are being made to streamline the development of the vaccine around the world – the European Medicines Agency has recently announced a shift to a “rolling review” process of the Covid-19 vaccine being developed by Oxford and AstraZeneca. Normally, reviews do not begin until all

information has been collected, but to speed up the process, the EMA’s review has begun on a rolling basis using the preliminary data that has been provided. [60](#)

Safety will not be an issue; all vaccines, whether fast-tracked or not, have to withstand clinical trials and approval processes that ensure they are safe for usage. A larger question revolves around the efficacy, and perceived efficacy, of a vaccine.

A vaccine becoming available in early 2021 will have a significant impact on our ability to control the virus – even if that vaccine is only partially effective.

**Vaccines: The Light at the End of the Tunnel**

The progress of vaccine trials is very promising, and it is looking increasingly likely that the UK will have a safe and reasonably effective vaccine available in November. We welcome the efforts taken by the government to expedite the testing, regulation and approval of vaccine candidates and would go further: Given the promising data on the safety of vaccines, serious consideration should be given to overriding the final stages of trials and commencing distribution to priority groups now.

**Vaccines Are Safe**

Globally, we know that well over 300,000 [61](#) people have received vaccines and of these there have been no reported serious side effects. At the same time, rigorous trials in the UK have shown that vaccine candidates in human trials are proving to be safe, having been administered successfully to over 30,000 patients to date.

**Table 2 – Known side effects of Covid-19 vaccines**

Pfizer	Mild-to-moderate side effects such as fever, arm pain, etc
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Moderna	Fever, pain and shivers, arm pain
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AstraZeneca	Mild side effects in the elderly
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Symptoms tended to subside within one to two days, and across all trials very few side effects have been reported. Because the trials are double blind, no one knows whether they received the placebo or the vaccine and the side effects could be from something other than the vaccine.

Johnson & Johnson and AstraZeneca have resumed their trials after being paused for safety issues. In the case of Johnson & Johnson, the cause was a patient who – according to the *Washington Post* – suffered a stroke, but causality between the vaccine and this outcome has not been established:

“The independent Data Safety and Monitoring Board (DSMB) overseeing the ENSEMBLE study has recommended resuming trial recruitment. Following consultation with the US Food & Drug Administration (FDA), preparations to resume the trial in the United States, including submissions for approval by the Institutional Review Boards, are now underway. Discussions with other regulators around the world to resume the clinical trial program are progressing.

After a thorough evaluation of a serious medical event experienced by one study participant, no clear cause has been identified. There are many possible factors that could have caused the event. Based on the information gathered to date and the input of independent experts, the Company has found no evidence that the vaccine candidate caused the event.”

AstraZeneca paused its trial after a patient developed a neurological condition but, again, there is no established causal relationship with the vaccination.

## **Vaccines Are Effective**

Data collated from around the world suggests that the efficacy of vaccines will be on par with flu vaccinations. If we assume an efficacy rate of around 50 per cent this means – as set out above – that there would be an improvement in most at-risk patients who received the vaccination and later contracted the virus, and a significant reduction in the infectiousness of those transmitting Covid-19.

While we are confident that sufficient doses can be supplied over time, the immediate role of a vaccine is twofold:

1. To protect our health and social care system
2. To protect those most at-risk from severe infection or death from Covid-19

Efficacy rates of around 50 per cent are encouraging for both these purposes. According to [a 2018 study](#) published in the Proceedings of the National Academy of Sciences, a flu vaccine with just a 20 per cent efficacy rate, given to just 43 per cent of the population, could cut flu deaths by over 61,000 in a single year.<sup>62</sup>

The ongoing trial for Oxford's vaccine has shown that the candidate instigated a robust antibody and T-cell immune response in people over 70. The findings were made in the early-stage human trials that took place in the summer, looking specifically at volunteers aged 56 and over, but were only shared publicly in late October. <sup>63</sup>

### **Regulators Are Moving Quickly**

The European Medicines Agency (EMA), the bloc's regulator, is willing to accept a vaccine with an efficacy rate of less than 50 per cent if the benefits outweigh the safety risks, while the US Food & Drug Administration has set a floor of 50 per cent efficacy in order to secure EUA.

Rolling reviews are one way to speed up approval and get vaccines to market faster. They allow researchers to submit data as they arrive to regulators, rather than having to wait until studies are concluded.

### **A Strategic Plan for Distributing Vaccinations**

The effectiveness of any vaccine will also depend on how much of the population actually receives it. To drive Covid-19 to the point of eradication will require a significant portion of the population to either acquire immunity through being infected with the virus, or through vaccination.

The UK government has a Covid-19 immunisation strategy which will target only the most vulnerable. The UK's population is roughly 67 million people; about 30 million will receive the vaccination. The advice released on 25 September by the government's Department of Health and Social Care set out the following prioritisation:

- Older adults' resident in a care home and care-home workers
- All those 80 years of age and over and health- and social-care workers
- All those 75 years of age and over
- All those 70 years of age and over
- All those 65 years of age and over
- High-risk adults under 65 years of age
- Moderate-risk adults under 65 years of age
- All those 60 years of age and over
- All those 55 years of age and over
- All those 50 years of age and over

- The rest of the population (priority to be determined). [64](#)

This approach is broadly in-line with our recommendation, especially if large quantities of the vaccine are available. In the short-term, we recommend that the government adopts an objective-driven approach and refer to the two immediate purposes set out above. A limited vaccine run of approximately 5 million doses should be introduced to these groups now based on the following objectives:

#### **Objective One: Protect our Health- and Social-Care System**

Distributed to:

- Hospital workers, GPs, long-term patients and identified visitors
- Social-care workers, long-term residents and identified visitors

Approximate number needed:

- NHS: 1.5 million
- Social care: 800,000 Total: 2.3 million

#### **Objective Two: Protect Those Most At Risk From Severe Infection or Death From Covid-19**

Distributed to:

- Those deemed high-risk based on age profile and underlying conditions, as identified by the Department of Health and Social Care.

Approximate number needed:

- 2 million

For some sensitive patient groups, including pregnant women, it will naturally take time to be fully confident that a vaccine is safe. These tests are ongoing and while we are confident that the vaccine candidates will prove to be safe, it is recommended that these groups are excluded from any fast-tracked virus. This is unlikely to have an impact on the elderly, but it may mean that a small number of NHS or social-care workers would continue to shield.

#### **Medium Term: From Protecting People to Curtailing Transmissions**

Given that Covid-19 has a less severe impact among younger people, we know that the “vaccination shift” would likely mean those receiving the vaccine are unlikely to become infected at all. This has important consequences as young people were responsible for the largest portion of outbreaks in the build up to the second wave, and there is a growing correlation between specific settings – such as universities – and areas that suffered large outbreaks. While transmission rates are coming down in these areas following the introduction of Tier 3 restrictions, expedited vaccination doses should be used to

protect the NHS, social-care workers and the vulnerable. However, in the medium-term, vaccines should be distributed to outbreak areas and be administered to all age groups in order to curtail transmissions.

## **Recording Vaccinations**

Collecting data and ensuring patients have a record of their vaccination is critical to the successful implementation of any vaccination strategy. Getting this data collection right will allow the government to build a picture of vaccine efficacy and use this to continue building buy-in from the population to getting vaccinated. At the same time, having a record of one's status will open up key areas of the economy, including travel, and will also allow settings that require confidence in the Covid-19 status of visitors to return back to some level of normality. For example, in the short-term, care-home residents could designate visitors to receive a vaccination and this could then make them eligible to visit them.

The Oracle system should be used for this purpose as cross-compatibility with patients NHS records – built on the Oracle system – is vital for generating insight into the efficacy of vaccinations.

## **Vaccinations: Recommendations**

### **1. Clearly communicate the purpose of vaccinations and address widespread myths.**

It is not widely understood that a vaccine's efficacy is a measure of the extent to which it reduces the severity of disease in a patient rather than the chances it has of working. We know that the vaccine for Covid-19 is likely to be at least 50 per cent effective and it's important that the public understand this means it will reduce the severity by 50 per cent in anyone injected with the vaccine. This is a common misconception and understanding it would likely increase uptake in vaccination. A communications campaign on this specific point should commence immediately.

### **2. Consider expediting the approval and distribution of vaccinations.**

Given the emerging picture from data around the world, it's becoming increasingly clear that vaccines are safe and effective *enough* in the very short-term. Rolling reviews of candidates currently in human trial should be introduced, allowing these vaccines to be rapidly approved and distributed to key groups.

### **3. Rapidly deploy 5 million vaccinations to protect our health- and social-care systems and protect the most vulnerable.**

Once vaccine candidates have been expedited and approved, they should be given immediately to NHS and social-care workers – excluding certain sensitive patient groups. This would secure our NHS and social-care services over the coming months.

Next, expedited vaccine candidates should protect those most at-risk from Covid-19. This includes those over 70 and those with underlying health conditions. We would defer to the Department of Health and Social Care's recognised list of those deemed high-risk and who were asked to shield in the first wave.

**4. A twofold vaccination strategy should be implemented and clearly communicated to the public.**

A dual approach would make use of expedited vaccine doses, protecting vital services and those most vulnerable to Covid-19. This prioritisation should be clearly set out and communicated.

A medium-term approach would see the vaccine's purpose evolve from protecting individuals to curtailing transmissions, particularly in outbreak areas. This would see the strategy shift from the short-term – where they would be distributed to protect health- and social-care workers – to a medium-term strategy where vaccines would be distributed among young people to curtail and prevent transmissions in outbreak areas.

**5. Record vaccinations using robust data platforms, such as Oracle.**

Collecting and storing the records of vaccinations is as important as receiving the vaccination itself. Using the same platform that will underpin the testing regime, records should be securely stored while allowing for interoperability with patients NHS records. This system will eventually underpin a health passport, but before then, it will provide vital insights into the efficacy of vaccines and the Covid-19 status of certain areas.

## The Role of Rapid Tests

The key to upscaling the UK's testing capacity, plus fixing test and trace, is bringing onstream all possible rapid antigen tests.

According to FindDX, 61 rapid antigen tests have now been commercialised.<sup>65</sup> The list includes the following tests in the US:

- **Abbott** recently received FDA Emergency Use Authorisation (EUA) for a new rapid antigen test called BinaxNOW. The test delivers a result within 15 minutes and requires no instrumentation. The manufacturers say it has a sensitivity of 97.1 per cent and specificity of 98.5 per cent. The US government has purchased 150 million of these tests, which it is distributing and deploying across the country. Abbott has opened two new manufacturing sites in the US in order to ramp up production of BinaxNOW. Currently, manufacturing sites in Maine and Illinois are producing 50 million tests per month.<sup>66</sup>
- **BD (Becton, Dickinson and Company)**, a medical technology company, recently announced that the FDA had granted an EUA for its 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.
- **Quidel**, the maker of another 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. The test delivers a result in 15 to 30 minutes and uses a nasopharyngeal swab.
- In late August the FDA provided a further EUA to **LumiraDx Ltd** for its rapid antigen test. The test combines a single-use immunoassay device with an instrument that provides a result within 12 minutes. The firm says it is low cost and highly scalable. The company says the test has a sensitivity of 98 per cent and a specificity of 97 per cent.

Last week in the UK, it was announced Boots would be rolling out LumiraDX devices in selected stores over the next few weeks. The tests will cost £120 to customers and be available to anyone not presenting with Covid-19 symptoms.

In September, alongside the Abbott test, the WHO also approved the rapid lateral flow antigen test produced by the South Korean company SD Biosensor. An evaluation of this test by the Foundation for Innovative New Diagnostics found it had a clinical specificity of 99.3 per cent and a clinical sensitivity of 76.6 per cent.<sup>67</sup>

Germany has purchased 20 million rapid antigen tests, with France and Switzerland also announcing intentions to purchase. <sup>68</sup>

## Other testing options

### PCR testing

The UK government has purchased 5,000 NudgeBox machines, produced by DnaNudge. The box uses RT-PCR technology to produce a result in less than 90 minutes. The kit was trialled in eight hospitals in London, with plans to roll it out across the UK. <sup>69</sup>

### LAMP Testing

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

This summer the government announced a trial in Hampshire using a point-of-care reader by OptiGene. The test has been misreported as giving a 20-minute result, when in fact it the entire process, which requires a full LAMP reaction, takes about an hour to confirm negatives (a high viral load, however, could return a positive result within 20 minutes). It was recently announced that these trials were being widened with testing now covering asymptomatic NHS staff at hospitals in Manchester, Southampton and Basingstoke, extending to Liverpool, Birmingham, Leeds and Newcastle in the coming weeks.

The 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. Each GridION machine is capable of processing up to 20,000 samples a day. A study published at the end of September found a diagnostic sensitivity of 99.1 per cent and a diagnostic specificity of 99.6 per cent. <sup>70</sup>

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." <sup>71</sup>

Testing based on LAMP 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.

### **CRISPR Testing**

Clustered Regularly Interspaced Palindromic Repeats (CRISPR) is an established biotechnological tool for gene editing. It works by being programmed to detect specific sequences of DNA within a gene of interest and subsequently ‘snipping’ it. No genes need to be edited but the first part of the process – the identification of the sequence – lends itself to identifying Covid-19. By being programmed to detect specific sequences of DNA that uniquely exist in the SARS-CoV-2 virus, the tool can diagnose Covid-19 – and quickly. There are already promising kits on the market that can return results in less than 20 minutes and which can be scaled rapidly. These use labs but the technology lends itself to rapid, on-the-spot devices.

Tata Medical & Diagnostics (TataMD) has developed a lab-based CRISPR test that uses an oral or nasal swab. It was approved on 19 September for use in India. <sup>72</sup> The test has 96 per cent sensitivity and 98 per cent specificity, has a processing time that is 30 to 90 minutes faster than typical RT-PCR reactions and does not involve expensive qRT-PCR equipment. The result readout is on a lateral flow strip, which also aids ease of use and quick turnaround. A second saliva-based version of this test is also being developed in partnership with the University of Illinois and will be usable at the point of care and easier to scale.

### **Saliva Testing**

Curative is at the forefront of coronavirus detection and offers a saliva-based Covid-19 test. Having delivered 4 million tests in the USA since March, and with a capacity of more than 1 million tests per week, it is 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 US states including California, Delaware, Florida, Louisiana, Alaska, Georgia, Illinois and Texas, as well as to the United States Air Force. It is accustomed to mass testing – including the Texan prison system and the Florida care homes testing programme, where more than 200,000 staff at 3,804 care homes across the state are tested on a rolling two-week basis.

### **New Tests Being Deployed in the UK**

In the UK the government recently announced it had secured 20 million 15-minute rapid antigen tests.



The Innova SARS-CoV-2 Antigen Test uses lateral flow technology to provide rapid results.<sup>73</sup>

The government plans to deploy these tests in high-transmission areas. Health secretary Matt Hancock has said they will also be made available in health-care and education settings.

The prime minister's spokesman said that trials were taking place "...in the worst-affected regions, so that includes the North West, the North East and Yorkshire ... Hospitals in Manchester, Liverpool, Birmingham, Leeds, Newcastle, Basingstoke and Southampton will be able to test asymptomatic NHS staff. Three of them – Southampton, Manchester and Basingstoke – are already able to start testing staff while the other four will be able to shortly."

### **Ramping Up Testing in Outbreak Settings**

One of the important challenges in ramping up testing is to ensure the right strategy is in place in key outbreak settings, for instance, care homes, schools and universities. This will involve bringing onstream all viable rapid tests, ensuring they can be accessed, and supporting those working in these settings to put in place best practice from around the world. One great example of this is the testing regime the University of Illinois has put in place to test its students.

#### **University of Illinois**

The University of Illinois has introduced twice-weekly testing for all students and staff across its three campuses. In a project codenamed "Shield Campus", the testing programme has seen more than 300,000 tests conducted in the four weeks to 11 September. This is roughly 2 per cent of all tests in the US.

The programme uses RT-PCR saliva-based tests which are conducted in a lab. The turnaround time from sample to result is usually between six to eight hours and a rapid action team interacts with individuals once a confirmed positive result is obtained. The university's data shows how critical this is as delays in contact tracing have obvious consequences for its hyper-mobile and social student population. Campus positivity is currently below 0.31 per cent and outbreaks – associated with unofficial parties – have already been identified and squashed. All students and staff are regularly tested, with frequency for each group determined by modelling that determines risk. Some students are tested three times a week while faculty and staff are tested once weekly given their respective measured risk.

With a rapid test now available to those who can afford it in Boots, more must be done to make these and similar rapid tests available to more people – particularly in key outbreak areas and settings. Initially, these tests would boost existing test and trace capacity but, over time, they would enable individuals to

take ownership of their Covid-19 status. The government should support this objective through advanced purchasing and subsidising tests.

Building on the model used by the University of Illinois, local testing facilities can be added, for instance through testing trucks, on which there is further detail below. This would add important extra testing capacity in settings like schools, universities and care homes.

With all viable rapid tests onstream and extra testing capacity made available, including through mobile labs, it will be possible to put in place protocols in these settings for people to be tested every three days.

### **Mobile Testing Trucks**

Given the success of the University of Illinois's testing programme, there has been demand from other institutions and sectors looking to bring in mass testing. This has led to the creation of mobile labs which are repurposed, 50-foot trailers capable of conducting 10,000 tests per day. The trucks carry equipment that allows RT-PCR testing and robotic handling of samples to take place, as well as technology for the uploading and communication of results. The trucks could also easily deploy LamPORE testing equipment. These mobile testing trucks allow flexibility in testing locations and would reduce the UK's reliance on the Lighthouse Labs, which are the large centralised testing facilities. Given the tests use a saliva-based sample, the sample collection sites can be placed anywhere because they transport well. This would open up regular testing to many parts of the UK.

The lessons from the University of Illinois are clear. The equipment is readily available, and the UK is in a privileged position with its car manufacturing industry to build these mobile testing trucks now. They would complement existing lab capacity and bring in additional advantages: While further work is needed to normalise them as a platform, saliva-based tests should be much easier to collect and transport and have high degrees of accuracy. Automation means they do not require specialists to run them and the operation could be overseen by the army.

We recommend that the government partners with British-based car assembly plants and brings a significant number of mobile trucks online in the next month. With each truck adding capacity of 10,000 tests per day, they should be deployed to high-risk areas, universities, schools and care homes in the first instance. Over time, a network of mobile testing labs could potentially service the entire country.

## **A Challenge of Organisation**

What is clear from these sections is that what the government faces most urgently on testing is a challenge of organisation, not supply. A number of viable rapid tests are coming onstream in the coming days and weeks. These can and must be expedited to ensure they are fully harnessed within the UK.

The next, and critical, step is organising how these tests are used. Drawing on these additional tests, and testing capacity of the type set out above, the government must ensure there is the right framework for testing in key settings: Tier 3 outbreak areas, universities, schools and health-care settings.

This will involve, but not be limited to:

1. Ensuring the appropriate tests – rapid antigen, LAMP, PCR and so on – are made available in the requisite numbers.
2. Support to ensure lab processing facilities are available, for instance via mobile testing trucks and partnering with local lab facilities.
3. Putting in place the right testing regime, focused on frequency of testing and speed in turnaround of results. In these key settings testing should be done every three days, with rapid turnaround of results.
4. Those needing to isolate should be given the right support financially and access to further testing to ensure they isolate only for as long as is needed.
5. Finally, it is vital that the data from all of those being tested, through whatever testing mechanism, is captured and stored centrally.

## **A Robust Data Collection Platform**

In the coming months we will have multiple types of tests in play. There will be many variations – including rapid on-the-spot tests, lab-based PCR tests, and pregnancy-test style tests. Even within categories there will be different levels of accuracy and speed. Results will be captured in different ways. Some will be uploaded to a cloud-based platform by a GP or a private pharmacist, others may be user-administered with results captured using a phone's camera. It's imperative that whatever the *type* of tests, results are stored in a uniform way and the interplay between different types of tests is properly understood. This will provide the infrastructure for an eventual health passport, but even before then, being able to show and have confidence in one's Covid-19 status will be important if we're to get closer to the light at the end of the tunnel. This data will be vitally important.

## **Simplicity in Communication, Clarity in Incentive**

It's important for the government to clearly communicate the purpose and mechanics of the testing regime. This should account for behavioural insights and serious thought should be given to what a negative test affords – for example, being able to enter a stadium, travel, or leave quarantine early – and what a positive test result means. The system should be supported by an extensive online toolbox, a national communications campaign and two helplines – one for those who test positive, another for those who test negative. Simplicity is king here, and there should be no room for confusion.

## **Testing: Recommendations**

### **1. Issue a framework for validation and introduce emergency use authorisation for innovative tests.**

Government should take urgent action to put in place a new validation framework for rapid tests that uses an authorisation system akin to the FDA's Emergency Use Authorisation in the US. The existing requirements for tests are too high and are appropriate only for tests being used in clinical settings. Rapid tests with lower sensitivity are able to detect people with higher viral loads. We have a much better understanding of the level of viral load likely to be infectious. This must be reflected in a new framework that is clear and transparent, enabling all possible viable tests to be brought onstream.

### **2. Bring onstream all possible viable tests and support those in development.**

With a validation framework in place the government should bring onstream all possible viable rapid tests. It will also enable them to work openly and support those British companies with tests in development.

### **3. Establish a mass-testing framework for the regular, ongoing testing of those in "outbreak settings".**

The government must move urgently to put in place the right framework to oversee testing in key outbreak settings, for instance: schools, universities and care homes. This will mean getting all possible viable tests onstream; ensuring these key education and health-care settings are able to access them; supporting these settings to put in place best practice testing processes, for instance those adopted by the University of Illinois; and putting in place data capture procedures to make sure all test results are captured centrally.

### **4. Underpin the entire testing regime with robust data collection and support the public to understand what tests results lead to.**

A communications campaign must be in place for the start of the testing regime, providing online

resources that allow citizens to properly understand the role, purpose and interoperability of different tests, as well as what a positive or negative test means. Consideration should be given to a live portal that gives a real-time overview of the Covid-19 situation in the UK. This will only be made possible if a robust data collection platform is used that allows results from different types of tests – even if administered in different ways – to be stored uniformly.

## The Role of Data

The Covid-19 pandemic has thrust the role of data into the spotlight, revealing many of the shortcomings of our systems in the process. From being able to effectively monitor the disease to allocate and distribute vaccines and tests, data is central. That's because in essence, the pandemic is ultimately an optimal control problem; a complex, dynamic situation in which decisions at one stage will have an impact not only on the outcomes, but also on the constraints for subsequent decisions.

For example, if the decision to lock down is made too late, hospitalisations rise and questions of PPE and capacity become primary. Conversely, if time isn't taken to put in place adequate containment measures when R is low, this means that the sledgehammer option of lockdown becomes more appealing. High-resolution, real-time data would instead provide the scalpel, allowing for far more precise and effective policy. It would ensure that decisions are not impacted by lags in reporting, or based on forecasts, which are often unreliable.

To get this live, composite picture of what is happening, requires information in the following areas set out in Table 3.

**Table 3 – The information needed for a comprehensive picture of the Covid-19 pandemic**

Information category	Data to be collected
Incidence	<p>Who has tested positive/negative?</p> <p>Who is infectious?</p> <p>Who has had the virus?</p>
Graph	<p>Who has been near who?</p> <p>When and in what circumstances (e.g. distance of contact, how long, indoor vs. outdoor)?</p>

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Clinical	How many in hospital?
	How many in ICU?
	Effectiveness of the therapeutics

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Quarantine/isolation	Who is in each?
	When does their time expire?
	Are they being checked/compliant?

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Immunisation	Who has been vaccinated?
	Which vaccine?
	When was it administered?

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Health status/ demographics	Symptoms/scans
	Adverse health events
	Comorbidities/age

In an ideal world, policymakers would have all of this data. In doing so, governments can then make the best decisions relating to all of the policy variables, including:

- Lockdown levels
- Contact-tracing prioritisation
- Test allocation
- Vaccine allocation
- Risk calculus and shielding

Each of these areas are constrained. The cost of lockdowns is extremely high in economic terms alone, but there are also knock-on effects on aspects such as elective surgery. Work by Imperial College's David Miles, for example, suggests the costs outweigh the benefits at around three months.<sup>74</sup>

Resource constraints in tracing, rapid tests and vaccines also mean there is a significant premium on allocating them well. In each area there needs to be defined strategy based on need and prioritisation. For example, evidence to date provides a good picture of mortality risk factors, the most prominent of which is age, allowing for clear prioritisation for vaccines. However, the failure to build an evidence base on good data, and then to use it effectively, will have a cost. Put bluntly, a failure to deploy a vaccine as soon as is possible or vaccinating the wrong people will cost many lives.

The issue of how the UK will allocate and distribute a vaccine optimally is just one of the challenges we face. It will require an infrastructure that is clear on:

- How to book or schedule vaccinations, e.g. through a shared platform, agnostic to provider.
- How to track who has been vaccinated, as well as their location and demographics.
- How to capture the batch number, lot number, etc. used in each case.
- How to ensure all second shots are administered.
- How to track follow-on health status and symptoms for adverse effects.
- How to issue credentials, e.g. for travel.

Given the inability of the government to build effective systems to data, there is little indication that this will be in place. But it should be the goal. Another concern is how the UK will aggregate mass-scale rapid test results. In terms of volume, 1 to 10 million tests a day is out of reach when the system is already struggling at around 100,000 per week. There are then a multitude of challenges around:

- **Decentralisation:** Tests will often be taken at home/at the workplace and self-reported, presenting significant gaps in data.
- **Tracking:** Capturing test kit batch number, etc.
- **Completeness:** Capturing the negative as well as positive.
- **Detail:** Ideally capturing full data payload (not just whether a result is negative or positive) so tests can be re-run and patients updated if scientific consensus changes, for example regarding the threshold of antibodies/T-cells for infectiousness.
- **Real-time:** Report and store results in minutes, not hours, or days as is the current turnaround time.
- **Integration:** With follow-on lab tests and with contact tracing.
- **Diversity:** The ability to handle a wide range of test types and manufacturers.
- **Proof:** The ability to give people time-limited credentials based on their results, e.g. for international



travel.

The UK will need to close current data gaps that exist, including those in Encompass, in quality, consistency and availability. For example, UCL's COVID Response Evaluation Dashboard (COVID RED), which collates data from the ONS, Public Health England (PHE), and the NHS, has revealed a number of these.

Primary among them are people's adherence to isolation measures, which do not exist and which without, means it extremely difficult to judge the efficacy of Test and Trace. Remote monitoring, for example, will be necessary track health status following vaccination and building mechanisms could be part of NHSX's effort to scale these systems, even if just an SMS service. The research also highlighted the lack of granularity on data, which is necessary for regional and localised policy. Lastly, an overriding issue that continues to hamper the response is the timeliness of the data. Achieving real-time monitoring is clearly optimal, if difficult, but often data is weeks old – a gap that clearly needs to be closed.

Part of this stems from how data is collected. But it is also a result of data coming from disparate sources, which are not linked. This is in part a product of the fact the UK does not historically have centralised health data and nor does the country have a foundational digital ID. There is partial coverage of aspects such as NHS numbers and National Insurance numbers, while patient data is currently held across NHS entities and test results held by PHE labs and private medical facilities.

The simplest solution, in theory, to the above challenges would be a national-scale system of record. There would be strong political and technical issues to overcome, including privacy. It would also require a structural and cultural change to how we approach data: It would have to be centred around the individual, rather than health-care organisations or other entities. This would mean that individuals would have control of their data and have the ability to report de-identified insights to health authorities.

Such a system would exist on top of existing systems and integrate existing data via API (e.g. electronic health records) or batch import (e.g. hourly upload of lab test results) and the key feature will be patient monitoring – in other words, it will give people control and responsibility. For example, it would require that individuals report health status and symptoms or scan rapid test results with smartphone camera. This is the only way for the system to operate rapidly at scale. Or put another way, we cannot reach 10 million tests a day if we all have to queue to take them at Boots.

Incentive design also matters. To capture all test results, it would ideally be set up so that people have to scan their results strip before finding out if the result is negative or positive. To be eligible for vaccine people would then agree to report their health status daily for a specified number of days after, which would need to be enforced to maintain compliance.

In the long run, as the cost of tests and vaccines comes down, there is potential for more to be automated. For example, it is not inconceivable that some test kits could have internet of things technology that would link them straight to the cloud. But this would require a robust cloud architecture.

This is some way off and, as it stands, Covid-19 has stress tested the state's ability to do basic things right. The UK has not come off well so far. Some progress has been made with the NHS Data Store and the NHS Covid-19 App after initial delays, and elements such as the Joint Biosecurity Centre are steps in the right direction. In a number of places, data has been aggregated to provide better insights, better forecasting and the public dashboard on GOV.UK.

But other countries such as Taiwan have shown a far greater ability to leverage big-data analytics to respond to the crisis, and have done so with deep public consent. Part of this goes back to governance models, which have created trust and allowed authorities to make better use of data, including travel history.

It should be a wake-up call for how we are using and deploying data and technology in society today, including in how we also collaborate internationally both in terms on pandemic preparedness, but also on interoperability of systems that nations have implemented. For example, the Common Pass framework provides a strong basis for safe international travel, with a good technical architecture. However, it will require global standards and systems to work with one another. Similarly, contact tracing systems in different countries need to be interoperable to lower the risk of travel, and for people to feel comfortable.

Altogether, data has been central to the response to date, but mechanisms need to improve as we scale up testing and vaccination. Our technical capabilities mean that we should be able to collect and use data in much more sophisticated ways than our public institutions do today. They need to catch up.

# Testing, Therapeutics and Vaccinations: The Light at the End of the Tunnel

As this paper sets out, while there remain short-term challenges to our response to Covid-19, in the medium-term, if the government takes the right action, we can be optimistic about the light at the end of the tunnel coming into view.

Not only are we treating the virus better with fewer people ending up in ICU, more people living and fewer people dying, game-changing therapeutics and vaccine options are also on the horizon.

The critical political task is ensuring these drugs are brought onstream quickly, effectively and in a targeted way, alongside ramped-up testing infrastructure. Viable tests, therapeutics and vaccines, which are capable of making a difference now, should be considered for introduction now, rather than waiting for approval processes that may take many months.

We urge the government to take the following steps:

## Therapeutics

- Secure a supply of antibody cocktails from abroad by leveraging USPs such as the opportunity to conduct robust clinical trials and fast-track regulation.
- Provide the therapeutics that we know to be working to patients now.
- Set up a manufacturing base for monoclonal antibodies in the UK.
- Allow all patients to join the RECOVERY Trial random control trial.
- Move quickly to bring new therapeutics onstream.

## Vaccines

- Introduce rolling reviews in order to expedite the approval and distribution of vaccines.
- Consider overriding the final stages of trials to expedite the approval and distribution of vaccinations.
- Distribute 5 million expedited vaccinations to protect our health- and social-care systems and the most vulnerable.
- Follow up the short-term strategy to protect with a medium-term plan to prevent transmissions by vaccinating those in outbreak areas.
- Record vaccinations using robust data platforms, such as Oracle.

## Testing

- Take urgent action to put in place a new validation framework that uses an authorisation system akin to the FDA's Emergency Use Authorisation in the US for all new innovative tests.
- Bring onstream all rapid tests and support those in development in order to upscale the UK's testing capacity and improve the test and trace system.
- Deploy mass-testing strategies for outbreak settings such as universities.
- Underpin the entire testing regime with robust data collection and support the public to understand the role of tests and what results mean.

## Data

- Adopt a data collection system that connects the tests one takes, the vaccines they receive and the drugs they're given. This should be capable of underpinning a future health passport and be able to plug into existing NHS data infrastructure.
- Openly and transparently share data to give a live overview of how measures are working and use the insight to sharpen measures and inform future interventions.

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