European Parliament

Lifting coronavirus restrictions

The role of therapeutics, testing, and contact-tracing apps

IN-DEPTH ANALYSIS

EPRS | European Parliamentary Research Service

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PE 652.016 – July 2020

EN

This publication provides an overview of the role of therapeutics, testing and contact-tracing apps in the context of lifting coronavirus-related restrictions on movement and social life in EU Member States. First, it discusses current progress and challenges faced with regard to developing vaccines and treatments for Covid-19. Second, it analyses currently available tests that work to diagnose cases and monitor the spread of the disease, along with challenges relating to key testing strategies and initiatives, such as antibody testing and 'immunity passports'. Third, the publication provides an overview of developments and key issues relating to the design and adoption of contact-tracing apps in EU Member States. Key aspects of the EU's approach and contribution to coronavirus therapeutics, testing, and contact-tracing apps are also discussed.

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This paper has been drawn up by the Members' Research Service, within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament.

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LINGUISTIC VERSIONS

Original: EN

Translations: DE, FR

Manuscript completed in July 2020.

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PE 652.016
ISBN: 978-92-846-6945-5
DOI:10.2861/7568
QA-02-20-582-EN-N

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Executive summary

The key to tackling the coronavirus pandemic is a combination of safe and readily available vaccines that provide everyone with immunity, as well as effective treatments that work to cure the disease in all infected people. Short of this, the ongoing public health crisis requires a mix of non-pharmaceutical measures aimed at reducing the spread of the virus, including identifying and isolating cases, testing, contact tracing and broader containment measures.

With the number of Covid-19 cases in the EU falling steadily since the beginning of May, most Member States have begun to ease restrictions on free movement and social gatherings. However, lifting restrictions in the absence of vaccines and treatments requires enhanced monitoring measures, such as an expanded testing capacity and improved contact tracing, including through the use of appropriate digital technologies.

There is the hope that the impressive mobilisation of resources and expertise will soon lead to breakthroughs in the quest for safe vaccines and effective treatments for Covid-19. However, it may take a while before such therapeutics are made available to everyone that needs them. Beyond dealing with challenges relating to scientific knowledge and a cumbersome development process, there is a need to address questions regarding mass manufacturing and fair distribution. Given the uncertainties and challenges associated with Covid-19 therapeutics, it may be wise to moderate expectations in order to foster resilience and preserve public trust.

Expanding testing capacity and updating testing strategies to support disease monitoring at population level is crucial for minimising the risk of new outbreaks in the context of relaxing containment measures. Using antibody tests to monitor the disease is a promising avenue, though more evidence is needed to demonstrate the reliability of these tests, in particular given current knowledge gaps regarding people's immunity to the virus. Moreover, linking antibody testing to relaxing restrictions for individuals, as suggested by the idea of establishing 'immunity passports', raises additional concerns about non-discrimination, fairness and mass surveillance.

Together with identifying and isolating new cases (through testing), the rapid and efficient tracing of people who have recently been in contact with infected people is essential for reducing the spread of the virus. Automating, at least partially, the laborious task of contact tracing with the help of contact-tracing apps has been advocated as a key measure to enable the gradual lifting of restrictions. The ongoing debate on contact-tracing apps in the EU seems to be converging towards a preference for voluntary contact-tracing apps that rely on proximity/bluetooth data (as opposed to location data) and comply with EU rules on data protection and privacy. The debate continues on the specific technical design of such apps (e.g. centralised versus decentralised systems), though the majority of initiatives in Member States seem to rely on decentralised systems. There are nevertheless a number of open questions regarding contact-tracing apps, in particular on their reliability, usability, data protection and privacy, epidemiological value and broader social implications.

There are very few certainties regarding the Covid-19 pandemic, but perhaps one certainty is that no isolated measure or silver-bullet solution is likely to solve all aspects of the crisis. A flexible and integrated strategy, in terms of complementary tools and measures, as well as a coordinated approach across the EU, will be crucial in enabling the gradual lifting of restrictions and a return to the (new) normal.

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1. Introduction

1.1. Coronavirus pandemic

On 31 December 2019, China informed the World Health Organization (WHO) of cases of pneumonia of unknown cause detected in the city of Wuhan in Hubei Province.[1] The new coronavirus (SARS-CoV-2) was identified on 7 January 2020 and its genetic sequence was shared on 12 January. The virus spread quickly in Asia and then globally.

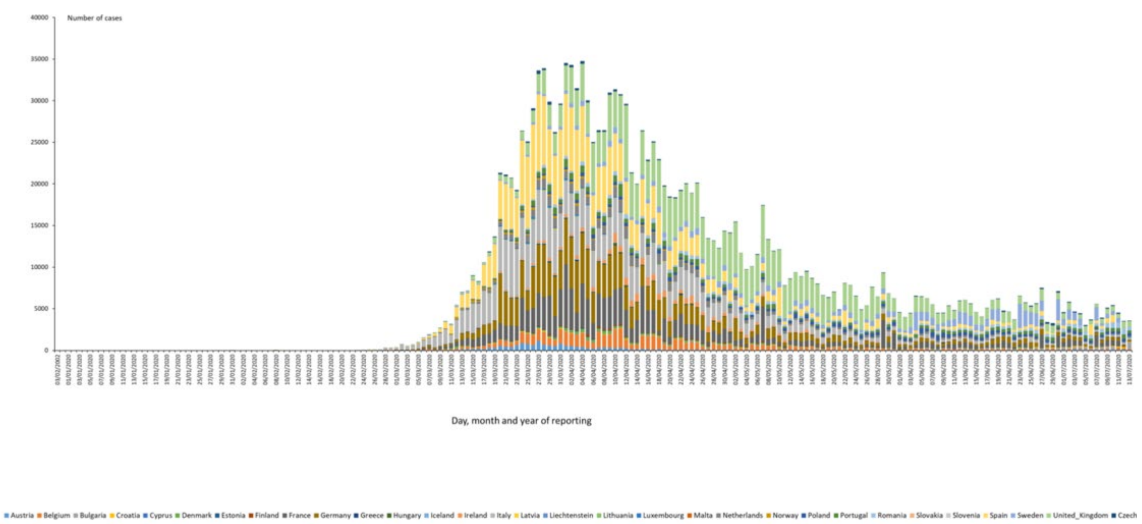
France reported[2] the first cases in Europe on 24 January. By 12 March, when the WHO declared the Covid-19 outbreak a pandemic, Europe had become one of the worst affected regions. According to the European Centre for Disease Prevention and Control (ECDC), as of 13 July, 12 875 963 Covid-19 cases had been reported worldwide, including 568 628 deaths. In the EU (European Union), EEA (European Economic Area) and the UK, there had been 1 585 334 reported cases, including 179 433 deaths.

SARS-CoV-2 and Covid-19

Coronaviruses are a large family of viruses that cause symptoms ranging from the common cold to more serious illnesses such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The new coronavirus, SARS-CoV-2, is a strain of coronavirus that was first detected in China in 2019. Covid-19 is the infectious disease caused by SARS-CoV-2.

Source: ECDC, Q&A on COVID-19.

Figure 1 – Distribution of Covid-19 cases in the EU/EEA and the UK as of 13 July 2020



Source: ECDC.

1 WHO, Novel Coronavirus (2019-nCoV), Situation report – 1, 21 January 2020.

2 ECDC, Novel coronavirus: three cases reported in France, 25 January 2020.

1.2. Restrictions on freedom of movement and social life

On 12 March 2020, the ECDC identified the measures[3] needed to mitigate the impact of the pandemic, which included: immediately isolating symptomatic people suspected of having or confirmed to have tested positive for Covid-19; suspending mass gatherings; imposing social and physical distancing measures in workplaces (e.g. teleworking); closing schools; and introducing lockdowns in residential areas with high levels of community transmission.

All Member States have taken measures to reduce the spread of Covid-19 in order to protect public health. Although these measures vary from one Member State to another, and even within individual Member States, most have imposed far-reaching community measures, such as confinement and physical distancing, closure of schools, non-essential shops and restaurants, bans on gatherings and restrictions to free movement, including local and/or national lockdowns.[4]

Following on from a Commission communication on the temporary restriction on non-essential travel to the EU on 16 March 2020, Member States agreed to impose a temporary restriction on non-essential travel to the EU. The temporary restriction was extended three times until 1 July 2020. On 30 June 2020, Council agreed to begin lifting travel restrictions at external borders for the residents of all 15 countries. In an attempt to contain the virus, many EU Member States within the Schengen area decided to reintroduce controls at internal borders, as provided for in the Schengen Code. Between 1 March and 30 June 2020, 17 Schengen members (of which 14 are EU Member States) notified the Commission of the temporary reintroduction of controls due to Covid-19 at all or some internal borders:

- **Austria** (11 March – 15 June, land borders with Germany, Italy, Switzerland, Liechtenstein, Slovakia and Czechia)
- **Belgium** (20 March – 14 June, all internal borders)
- **Czechia** (14 March – 4 June; land borders with Austria and Germany, air borders; 5 June – 30 June, air borders)
- **Denmark** (14 March – 12 November, all internal borders)
- **Estonia** (17 March – 17 May, all internal borders; 18 May – 16 June, air and sea borders)
- **Finland** (19 March – 14 June, all internal borders; 15 June – 14 July, all internal borders, except borders with Norway, Denmark, Iceland, Estonia, Latvia and Lithuania)
- **France** (18 March – 21 June, all borders with Spain; beginning of March – 31 October, all internal borders, due to 'continuous terrorist threat and the risk of terrorists using the vulnerability of States due to Covid-19 pandemic')
- **Hungary** (12 March – 11 November, all internal borders)
- **Iceland** (24 April – 22 June, all internal borders)
- **Germany** (16 March – 15 June, air borders and land borders (where applicable) with Austria, Switzerland, France, Luxembourg, Denmark, Italy and Spain, sea border with Denmark; 16 June – 21 June air borders with Spain)
- **Lithuania** (14 March – 31 May, all internal borders; 1 June – 12 June, land border with Poland, sea borders, air borders; 13 June – 16 July, air and sea borders)
- **Norway** (16 March – 13 August, all internal borders)
- **Poland** (15 March – 12 June, land borders with Czechia, Slovakia, Germany and Lithuania, all sea borders and air borders)

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3 ECDC, Rapid risk assessment: Novel coronavirus disease 2019 (COVID-19) pandemic: increased transmission in the EU/EEA and the UK – sixth update, 12 March 2020.

4 ECDC, Coronavirus disease 2019 (COVID-19) in the EU/EEA and the UK– ninth update, 23 April 2020.

- **Portugal** (16 March – 30 June, land border with Spain)
- **Slovakia** (8 April – 26 June, all internal borders)
- **Spain** (17 March – 14 May, all land borders; 15 May - 21 June, all internal borders; 21 June – 30 June, internal borders with Portugal)
- **Switzerland** (13 March – 15 June, all air and land borders, except for borders with Liechtenstein).

A number of EU Member States have also adopted entry and travel restrictions,[5] including mandatory medical checks, mandatory quarantine and travel bans, either without notification or in addition to notifying the Commission.[6]

Covid-19 restrictions have been highly disruptive to society, both socially and economically. They have also had a disproportionate impact on disadvantaged groups, such as people on low incomes, people with disabilities and homeless people, as well as migrants, internally displaced people and refugees.[7] However, early evidence[8] suggests that social distancing measures have collectively reduced the transmission of the virus and have helped to save lives. A recent study[9] by researchers from Imperial College London, UK, estimates that containment measures in 11 European countries averted 3.1 million deaths up to the start of May.

1.3. Gradual lifting of restrictions

Following the steady decrease in the number of reported Covid-19 cases in the second half of April, most EU countries have taken steps to gradually lift some restrictions on freedom of movement and social life (e.g. relaxing lockdowns, reopening schools and businesses) and to gradually remove controls at certain borders.

The EU has advocated a gradual and coordinated lifting of travel restrictions and border controls based on common criteria. On 15 April 2020, the President of the European Commission together with the President of the European Council agreed on a joint European roadmap towards lifting Covid-19 containment measures. The roadmap envisages that internal border controls and travel restrictions should be lifted once the epidemiological situation converges sufficiently and physical distancing rules are widely and responsibly applied. Moreover, the relaxation of restrictions needs to be accompanied by appropriate monitoring, by for instance expanding testing capacity, to detect and monitor the spread of the virus, contact-tracing, and possibilities to isolate people in the event of the reappearance and further spread of infection. The roadmap also refers to antibody detection capacities as a means 'to provide complementary data on the share of the population that has successfully overcome the disease and eventually measure the acquired immunity'. Moreover, mobile applications for contact-tracing are considered 'particularly relevant in the phase of lifting containment measures, when the infection risk grows as more and more people get in contact with each other'.

5 G. Sabbati and C. Dumbrava, The impact of coronavirus on Schengen borders, European Parliament, EPRS, 27 April 2020.

6 S. Carrera ands N. Chun Luk, Love thy neighbour? Coronavirus politics and their impact on EU freedoms and rule of law in the Schengen Area, Centre for European Policy Studies, 3 April 2020.

7 EU Agency for Fundamental Rights, Coronavirus pandemic in the EU —fundamental rights implications, Bulletin No 1, April 2020.

8 ECDC, Rapid Risk Assessment: Coronavirus disease 2019 (COVID-19) in the EU/EEA and the UK– ninth update, 23 April 2020.

9 S. Flaxman, S. Mishra, A. Gandy *et al.*, 'Estimating the effects of non-pharmaceutical interventions on COVID-19 in Europe', *Nature*, 8 June 2020.

On 13 May 2020, the Commission released a package of guidelines and recommendations with the aim to: safely restore unrestricted free movement and reopen internal borders; safely restore transport and connectivity; safely resume tourism services; and support and rebuild consumer confidence in travel and transport services. In its communication on a phased and coordinated approach for restoring freedom of movement and lifting internal border controls, the Commission recommended that 'restrictions on travel should first be lifted in areas with a comparable epidemiological situation', while keeping in place targeted measures, such as testing, contact tracing, isolation and quarantine measures, to decrease the risk of virus transmission.

The European Parliament, in its resolution of 17 April 2020 on EU coordinated action to combat the Covid-19 pandemic and its consequences, has urged Member States 'to adopt only necessary, coordinated and proportionate measures when restricting travel or introducing and prolonging internal border controls'. Parliament also called on Member States 'to significantly increase support for research, development and innovation programmes aimed at understanding the disease, speeding up diagnosis and testing, and developing a vaccine'. In its resolution of 19 June 2020 regarding the situation in the Schengen area following the Covid-19 outbreak, Parliament called for a return to a fully functional Schengen area 'as a key prerequisite for the EU's economic recovery after the COVID-19 pandemic'.

2. How to tackle the pandemic

The long-term solution to the Covid-19 pandemic would be a combination of vaccines that provide protection against future infection and treatments that treat people who are already infected.[10] In the absence of this, the choice is between trying to eradicate the virus or reduce its spread. Eradication (without a vaccine) is likely to require harsh and disproportionate measures that may not be deemed acceptable in free and democratic societies. Trying to reduce or manage the spread using a number of measures (isolation, testing and contact tracing) may allow healthcare systems to cope with the situation.[11]

There is also the option of allowing the virus to spread through the population, up the point where it can no longer find new hosts, causing it to die out – the so-called **herd immunity** strategy.[12] If pursued globally, however, it is estimated that such a non-interventionist approach would have led to around 60 % of the world's population being infected within a year. Moreover, the herd immunity approach would have created great challenges for healthcare systems. The approach also raises complex ethical issues[13] because the risk associated with widespread contagion is not equally shared across the population, with the elderly and the sick likely to face the risk of infection disproportionally. Lastly, it is also argued[14] that reaching herd immunity does not necessarily mean that the disease is eradicated, it simply means that there will be fewer cases in places where sufficient immunity has been established.

While waiting for effective treatments and vaccines, most countries have focused on managing the pandemic through a combination of measures that include isolation of cases, social distancing, testing, contact tracing and disease monitoring. In the European Union, a slightly different approach

10 WHO, COVID-19 strategy update - 14 April 2020

11 OECD, Testing for COVID-19: A way to lift confinement restrictions, 4 May 2020.

12 A. Regalado, What is herd immunity and can it stop the coronavirus? *MIT Technology Review*, 17 March 2020.

13 A. Basu, The 'herd immunity' route to fighting coronavirus is unethical and potentially dangerous, *The Conversation*, 17 March 2020/

14 S. L. van Elsland and R. O'Hare Coronavirus pandemic could have caused 40 million deaths if left unchecked, Imperial College London, News, 26 March 2020.

was taken by Sweden, although Anders Tegnell, the country's chief epidemiologist, has reportedly[15] denied that the country is aiming for herd immunity.

2.1. Knowledge gaps

Effective responses to the pandemic require sufficient knowledge and understanding of the virus, its effects and how it spreads. In the absence of adequate knowledge and data, efforts to model the disease will prove less effective and also potentially dangerous. For example, an analysis of 66 prediction models used to diagnose and treat Covid-19[16] found that all the models had been trained with unfit and insufficient data and thus were unfit to support doctors. Another challenge is that scientists are coming under increasing pressure to produce quick results, often in situations where they are not able to figure out all the details of the problem.[17]

> *Basic research, which describes the problem, is followed by applied research that builds on that understanding. Now, scientists are trying to do both at the same time. This is not just fixing a plane while it's flying—it's fixing a plane that's flying while its blueprints are still being drawn.*[18]

The virus causing Covid-19 was quickly sequenced and identified as belonging to the coronavirus family. This gave scientists an advantage, as they could build on research done in response to previous outbreaks of coronaviruses (SARS and MERS). While initially thought to primarily affect the respiratory system, it was subsequently discovered that Covid-19 also affects many other parts of the human body, including the brain, the heart and lungs, the nervous system, the gut and even the toes.[19] Despite quickly accumulating knowledge on the virus, there are still a number of important knowledge gaps that are hampering efforts to effectively plan for and tackle the pandemic.

One key indicator of the spread of a virus is **the reproduction number** (R0), that is the typical number of infections caused by an individual in the absence of widespread immunity. A virologic outbreak is in decline when the effective reproduction number (R), that is the actual number of infections caused by an individual, is lower than R0.[20] According to current estimates reported by the ECDC, one person infected with Covid-19 will infect between two and three other people (R0 = 2 to 3), though the ECDC acknowledges that 'there is not enough epidemiological information at this time to determine how easily this virus spreads between people'.[21]

As described by the ECDC, the virus spreads mainly via small respiratory droplets through sneezing and coughing or when people interact with each other for some time in close proximity. However, there is also evidence that the virus spreads via surfaces, speaking loudly[22] and perhaps even sperm.[23] According to a study[24] by researchers at the University of Connecticut, summer temperatures are likely to slow the spread of the Covid-19, though this may not be enough to wipe

[15] J. Henley, Just 7.3% of Stockholm had Covid-19 antibodies by end of April, study shows, *The Guardian*, 21 May 2020.

[16] L. Wynants et al., Prediction models for diagnosis and prognosis of covid-19: systematic review and critical appraisal *BMJ* 2020;369:m1328.

[17] A. Regaldo, The race to find a covid-19 drug in the blood of survivors, *MIT Technology Review*, 10 April 2020.

[18] H. Thorpe. Underpromise, overdeliver, *Science*, 27 March 2020.

[19] R. R. Britt, 'Every Covid-19 Symptom We Know About Right Now, From Head to Toe', *Medium*, 18 May 2020.

[20] L. Ferretti, C. Wymant, M. Kendall, *et al.*, 'Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing', *Science*, 8 May 2020.

[21] ECDC, *Q & A on COVID-19.*

[22] N. V. Patel., 'Loud talking could leave coronavirus in the air for up to 14 minutes', *MIT Technology Review*, 13 May 2020.

[23] P. Ellis, M. Waas and M. Michaelis, 'Coronavirus found in semen of young men with COVID-19', *The Conversation*, 7 May 2020.

[24] W. J. Broad, 'Could the Power of the Sun Slow the Coronavirus?', *New York Times*, 24 April 2020.

out the virus. A number of reports have also challenged initial assumptions that children are less susceptible to the virus.[25]

It is apparent that more fine-tuned information regarding the contagiousness of the virus is needed, such as the impact of the disease at different stages, in different patients (e.g. children) and the impact of environmental factors (e.g. external temperature), in order to enable the planning of effective interventions (e.g. targeting specific groups and areas) and improve disease modelling.

Key (open) questions

- How contagious is the virus? (What/who contributes to its spread?)
- How many people have been infected? (How widespread is the virus?)
- How deadly is the virus? (Who is less/more vulnerable?)
- Can we develop immunity to the virus? (To what extent / for how long?)

The WHO provides a dashboard that includes the official number of people that have tested positive for Covid-19, as well as data on Covid-19-related deaths as reported by different countries. However, the actual **prevalence** of Covid-19 (i.e. the number of people who have been infected) may be higher than reflected in the official statistics, because not everyone is willing or able to undergo diagnostic testing (e.g. owing to discrepancies between countries and regions regarding testing capabilities and strategies). For example, the results[26] of a study conducted in a district of Heinsberg, Germany, which was strongly affected by Covid-19, suggest that the actual number of Covid-19 cases in Germany was 10 times higher than the officially reported number.

The **mortality** rate for of Covid-19 (i.e. the number of Covid-19-related deaths) varies substantially between countries 'depending on the populations affected, the point a country is at in the trajectory of its outbreak, and the availability and application of testing'.[27] There are difficulties in assessing the mortality rate for Covid-19 because countries do not count Covid-19 cases in the same way. Most countries do not count deaths that have occurred outside hospital, or if the person had not tested positive before death. Mortality estimates that rely on case data (from patients and people who have been tested) may be biased[28] in countries where testing strategies only target people belonging to high-risk groups. For example, according to research by *The Economist*, 'excess of deaths'[29] in countries such as Austria, France, Spain and Sweden are higher than the officially reported numbers of Covid-19-related deaths; with the number even doubling in Italy and the Netherlands.[30]

Answering the question of whether exposure to the virus provides some kind of immunity to future infection is crucial for strategic planning, including for vaccine development, testing and containment measures. Anecdotal evidence from a survivor of SARS in 2002 indicates that, 17 years later, the person still had antibodies to fend off the disease.[31] However, it is still not fully clear whether such antibodies are sufficient to provide protection or how long the immunity will last.[32]

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25 K. K. Melzer, 'I'm Treating Too Many Young People for the Coronavirus', *The Atlantic*, 26 March 2020.

26 University of Bonn, Heinsberg Study results published, 4 May 2020.

27 WHO, (COVID-19 strategy update – 14 April 2020) see footnote 10 (above).

28 S. Flexman et all. Estimating the number of infections and the impact of non-pharmaceutical interventions on COVID-19 in 11 European countries, Report by The Imperial College London, 30 March 2020.

29 'Excess mortality' is defined as the gap between the total number of people who died from any cause and the historical average for the same place at the same time of year.

30 *The Economist*, 'Tracking covid-19 excess deaths across countries'.

31 OECD, (Testing for COVID-19: A way to lift confinement restrictions) see footnote 11 (above).

32 N. Kofler and F. Baylis, 'Ten reasons why immunity passports are a bad idea', *Nature*, 21 May 2020.

3. Therapeutics

3.1. Vaccines

A vaccine is key to tackling the Covid-19 pandemic, as it would provide healthy people with immunity from infection (though it would not cure the disease in infected people). The virus that causes Covid-19 is roughly 80 % identical[33] to those that caused the outbreaks of SARS and MERS, which may give researchers a good headstart in developing therapeutics. However, early evidence suggesting that the virus may be unlikely to mutate significantly,[34] making it an easier target, has been challenged.[35] Moreover, the development of a vaccine faces a number of great challenges, such as not having sufficient knowledge of the virus (knowledge gaps), the need to complete adequate testing of vaccines to ensure safety and, once a vaccine proves effective, making sure that there is a sufficient amount of it to enable its swift and fair distribution across the world.

3.1.1. How do vaccines work?

When a virus enters the body, it seeks to take control of cells in order to replicate and spread throughout the body. Generally, vaccines work by exposing the body to an antigen that will provoke an immune response, which will then block or kill the virus when the vaccinated person becomes infected.[36] Vaccination takes advantage of the body's immunological memory, which allows it to 'memorise' the specific features of a virus in order to recognise and fight it later in life (adaptive immunity).[37] It must be noted that vaccines do not always provide full protection against the viruses they target, nor do they always eliminate the risk of spreading such viruses.[38] For example, influenza vaccines mainly reduce the risk of contracting the disease and the likelihood of experiencing severe symptoms.

There are a number of **types of vaccines**[39] targeting Covid-19 that are currently in development: vaccines using the virus itself, in a weakened or inactivated form (similar to measles and polio vaccines); viral-vector vaccines, which use other weakened and genetically engineered viruses to prompt the body to produce coronavirus proteins; nucleic-acid vaccines, which use genetic instructions (in the form of DNA or RNA) for a coronavirus protein to prompt an immune response; and protein based vaccines that inject harmless elements of coronavirus proteins (particles or shells) directly into the body to mimic the virus and trigger immune response.

Vaccine candidates are typically tested in several phases, allowing for the gradual expansion of the number of trial participants from a few dozen (phase 1) to thousands (phase 3). Advancement to subsequent phases requires specific evidence-based approvals.

33 S. Weston and M. B. Frieman, 'COVID-19: knowns, unknowns, and questions', *mSphere*, 2020.

34 J. Corum and C. Zimmer, 'How Coronavirus Mutates and Spreads', *New York Times*, 30 April 2020.

35 B. Carey and J. Glanz, 'Mutation Allows Coronavirus to Infect More Cells, Study Finds. Scientists Urge Caution', *New York Times*, 12 June 2020.

36 E. Callaway, 'The race for coronavirus vaccines: a graphical guide', *Nature*, 28 April 20202.

37 A. Rothstein, 'Vaccines and Their Critics, Then and Now', *The New Atlantis*, No. 44, 2015.

38 H. Branswell, 'The world needs Covid-19 vaccines. It may also be overestimating their power', *STAT*, 22 May 2020.

39 Callaway, (The race for coronavirus vaccines: a graphical guide) see footnote 35 (above).

As of 15 June 2020, the European Medicines Agency (EMA) had been in discussion with developers of 132 potential Covid-19 vaccines in the EU.[40] Globally, as of 13 July 2020, the WHO reported 17 candidate vaccines in clinical evaluation and 124 candidate vaccines in preclinical evaluation.[41]

3.1.2. Key challenges

Vaccine development takes years and even decades. According to records, developing an entirely new vaccine takes at least four years.[42] The usual timeline for developing a vaccine for diseases like the seasonal flu is 18 months.[43] Today, scientists may build on the work done for SARS and MERS and even resume work on vaccine candidates that have been shelved. To gain time, many clinical trials are being conducted with overlapping phases.

Once a vaccine is proven to be safe and effective, there is the challenge of **manufacturing** and distributing it. In the case of a Covid-19 vaccine, this will probably need to reach billions of people. The biggest challenge in terms of time and investment is building or extending manufacturing facilities to allow for mass production of new vaccines.[44] The challenge may be even greater if the most promising vaccines turn out to be the most innovative ones, for the production of which there is little capacity and infrastructure. Building new facilities will take time and money. For example, the Bill and Melinda Gates Foundation is reported[45] to have built factories for seven different vaccines. However, to overcome these challenges, a larger, more concerted effort is needed,[46] which would ideally involve pulling together public and private capacity and infrastructure.[47]

Manufacturing challenges will likely trigger questions about **access to and the fair distribution of vaccines**. In other words, who will get the vaccine first? Which countries? Which group? Fears of vaccine nationalism,[48] where countries try to keep or secure vaccines only for themselves, are on the rise. It is argued that a coordinated international response will be needed to ensure that vaccines are distributed equitably.[49]

Another issue relates to **price and affordability**. Given that more than 70 %[50] of those groups leading vaccine research efforts are industrial or private firms, there is a concern about the affordability of any future vaccine.[51] In an open letter published by Oxfam International,[52] 140 world leaders and experts claimed that vaccines should be 'made available for all people, in all countries, free of charge'. On 29 May 2020, 30 countries and multiple international partners and institutions signed up to support the WHO Covid-19 Technology Access Pool, an initiative aimed at making

40 EMA, Treatments and vaccines for COVID-19 (as of 15 June 2020).

41 WHO, Draft landscape of COVID-19 candidate vaccines, 13 July 2020.

42 S. A. Thompson, 'How Long Will a Vaccine Really Take?', *New York Times*, 30 April 2020.

43 T. Vora, 'How to Make Sense of Uncertainty in a Coronavirus World', *SingularityHub*, 1 May 2020.

44 European Science-Media Hub, Vaccine perspectives for COVID-19 – Scientists around the planet are united to develop a vaccine and make it available to the market as soon as possible, 20 April 2020.

45 C. Willumsen, 'Bill Gates, at Odds With Trump on Virus, Becomes a Right-Wing Target', *New York Times*, 17 April 2020.

46 M. Mazzucato and E. Torreele, How to Develop a COVID-19 Vaccine for All', *Project Syndicate*, 27 April 2020.

47 R. Khamsi, 'If a coronavirus vaccine arrives, can the world make enough?', *Nature*, 9 April 2020.

48 M. Savage, 'Once we have a vaccine, how will it be shared fairly around the world?', *The Guardian*, 25 April 2020.

49 D. S. B. Salisbury and C. Patel, The Hurdles to Developing a COVID-19 Vaccine: Why International Cooperation is Needed, Chatham House, 23 April 2020.

50 A. Regaldo, (The race to find a covid-19 drug in the blood of survivors,) see footnote 17 (above).

51 G. Yamey, 'A coronavirus vaccine should be for everyone, not just those who can afford it', *STAT*, 5 March 2020.

52 Oxfam International, Open Letter: Uniting Behind A People's Vaccine Against COVID-19, *Medium*, 14 May 2020.

vaccines, tests, treatments and other health technologies that help to fight Covid-19 accessible to all.[53]

Finally, the issue of **vaccine distribution** also raises important ethical questions, such as questions regarding priority groups (e.g. health workers, the most vulnerable or even the young and healthy).[54]

3.2. Treatments

Whereas vaccines may provide protection against future infection, it is effective treatments that will cure people who are infected or for whom vaccines do not work. The challenge however is that viruses are difficult to treat and developing antiviral therapies takes time while providing limited economic incentives for companies.

3.2.1. How do viral treatments work?

Viruses are typically hard to treat as they use the machinery of cells, making it more difficult to target them without damaging the body.[55] Moreover, unlike bacteria, viruses vary greatly from each other, which means that drugs for one type of virus may not work for other types. This makes drug development more difficult and expensive.[56] Repurposing existing drugs may help to ease some of these challenges. However, given the multifaceted attacks that SARS-CoV-2 mounts against the body, some argue that it is unlikely that a single drug will be enough to treat Covid-19.[57] Different drugs may be needed to address different aspects of the disease and be used at different stages of infection.

3.2.2. Treatments under trials

In March, the WHO launched the solidarity trial, a massive study of readily available drugs seeking to test four treatments for Covid-19: Remdesivir, Lopinavir/Ritonavir, Interferon beta-1a and Chloroquine & Hydroxychloroquine.

Originally developed for the treatment of the Ebola virus, Remdesivir[58] interferes with the production of viral genetic material, seeking to prevent the virus from multiplying. Preliminary results from a US study suggested[59] that Remdesivir has a beneficial effect in the treatment of hospitalised patients with mild-to-moderate or severe Covid-19. The drug improved recovery time (which was reduced from 15 to 11 days), though no significant improvement was reported for the mortality rate. A study in China[60] found that Remdesivir improved the condition of patients with symptoms lasting for 10 days or less, though no benefit was shown in severe cases. There are nine Remdesivir clinical trials registered with the EU Clinical Trials Register, including a Phase 3 trial in the UK. The EMA has launched a rolling review of data on the use of Remdesivir for treating Covid-19 and, as of 3 July, it granted Remdesivir conditional marketing

53 WHO, International community rallies to support open research and science to fight COVID-19, 29 May 2020.

54 A. Rogers, 'Let's Say There's a Covid-19 Vaccine—Who Gets It First?' *Wired*, 12 May 2020.

55 C. Carson and R. Roper, 'Why are there so many drugs to kill bacteria, but so few to tackle viruses?', *The Conversation*, 8 May 2020.

56 M. Ridley, 'A cure for Covid may arrive faster than a vaccine', *The Spectator*, 25 April 2020.

57 S. P. H. Alexander, J. Armstrong, A. P. Davenport, et al., 'A rational roadmap for SARS-CoV-2/COVID-19 pharmacotherapeutic research and development. IUPHAR Review 29', *British Journal of Pharmacology*, June 2020.

58 EMA, EMA starts rolling review of remdesivir for COVID-19.

59 NIAD, NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19, 29 April 2020.

60 Wang et al., 'Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial', *Lancet*, Vol. 395, May 2020, pp. 1569–78.

authorisation for the treatment of Covid-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen.

Another drug currently being tested is Favipiravir, an influenza drug that works by preventing the virus from replicating in cells. An early preprint study[61] found that Favipiravir could speed up the recovery time for Covid patients. There are five Favipiravir clinical trials registered with the EU Clinical Trials Register. Potential candidates for a Covid-19 treatment also include anti-rheumatoid arthritis drugs such as Baricitinib and Tocilizumab. Lopinavir and Ritonavir, two antiviral drugs[62] used to treat HIV/AIDS, also looked promising early on in the Covid-19 outbreak and were included in WHO's Solidarity Trial. However, a study[63] published in May found no significant benefit from use of the two drugs.

High initial expectations for the use of Hydroxychloroquine/Chloroquine (a malaria treatment) to treat Covid-19 have not been confirmed by recent evidence.[64] On 23 May 2020, the EMA also issued a warning about the serious side effects that accompany Chloroquine and Hydroxychloroquine, such as the risk of fatal heart rhythm problems, particularly when the drug is taken in high doses or in combination with the antibiotic azithromycin.[65]

Preliminary results from the United Kingdom's national clinical trial RECOVERY suggested that the use of Dexamethasone to treat critically ill patients can be beneficial (reducing deaths by a third in ventilated patients).

In addition to repurposed drugs, there are a number of 'de-novo drugs' and alternative interventions. One approach proposes the use of monoclonal antibodies, which focus on genetically engineering copies of the right antibodies. A study[66] published in May suggested that human monoclonal antibody could neutralise SARS-CoV-2 in cell culture. Another treatment proposal is to use convalescent plasma, which is blood transfused from recovered donors who have neutralising antibodies, to treat infected patients. Early studies[67] showed promising results, which prompted calls on recovered patients to donate blood for testing in clinical trials.

3.3. EU support for Covid-19 therapeutics

The Commission is coordinating a common European response to the coronavirus outbreak. In January 2020, it launched an emergency call for projects aiming to improve preparedness and response to outbreaks and to support the development of rapid diagnostic tests, treatments and vaccines. €48.2 million was awarded to 18 research projects, two of which are seeking to develop Covid-19 vaccines. In March, the Commission offered financing of up to €80 million (via the European Investment Bank) to the company CureVac to support the development of innovative RNA-based vaccines. It also launched a programme of Covid-19 convalescent plasma.

61 C. Chang et al., Favipiravir versus Arbidol for COVID-19: A Randomized Clinical Trial, 15 April 2020 (preprint).

62 EMA, Summary of the European public assessment report (EPAR) for Lopinavir/Ritonavir Mylan.

63 B. Cao et al, 'A Trial of Lopinavir–Ritonavir in Adults Hospitalized with Severe Covid-19', *New England Journal of Medicine*, Vol. 382, 7 May 2020, pp. 1787-1799.

64 For example, J. Geleris et al, 'Observational Study of Hydroxychloroquine in Hospitalized Patients with Covid-19', *New England Journal of Medicine*, Vol. 382, 18 June 2020, pp. 2411-2418.

65 EMA, COVID-19: reminder of risk of serious side effects with chloroquine and hydroxychloroquine, 23 April 2020.

66 C. Wang et al, 'A human monoclonal antibody blocking SARS-CoV-2 infection', *Nature*, 4 May 2020.

67 C Shen et al., 'Treatment of 5 Critically Ill Patients With COVID-19 With Convalescent Plasma', *JAMA*, Vol. 323(16), pp. 1582-1589.

In April, the Commission launched the ERAvsCORONA action plan to support large EU-wide clinical trials for clinical management of coronavirus patients, including through the European Research Area's corona platform, which provides comprehensive information on funding opportunities in relation to coronavirus in the EU. The EU is also financing access to supercomputing and artificial intelligence know-how to accelerate the identification of potential active molecules from among existing medicines and compounds.

EU response to Covid-19 – priority areas

- Limiting the spread of the virus, including risk assessment and measures on borders
- Ensuring the provision of medical equipment by ramping up production of medical devices and negotiating supplies
- Helping researchers to find a vaccine quickly through research programmes
- Aiding Member States to weather the social and economic impacts.

Source: EPRS.

The EMA has taken a number of steps to accelerate development, support and evaluation procedures for Covid-19 treatments and vaccines. For example, on 16 March 2020, it launched a call for the research community to pool resources in large, well-designed, multi-arm clinical trials to determine which investigational or repurposed medicines would be safe and effective for the treatment or prevention of Covid-19. The EMA published an overview[68] of how the agency has accelerated its regulatory procedures so that marketing authorisations of safe, effective and high-quality Covid-19-related medicines could be granted as soon as possible. The agency also launched a rolling review of data on the use of Remdesivir for treating Covid-19 (allowing for an accelerated review procedure) and published recommendations on how Remdesivir should be used in compassionate use programmes across Europe when treating Covid-19 patients who are not eligible for inclusion in clinical trials.

At international level, the EU is supporting the global response to Covid-19 through a number of multilateral platforms, such as the Global Research Collaboration for Infectious Disease Preparedness (GLopid-R), the Coalition for Epidemic Preparedness Innovations (CEPI), and the European and Developing Countries Clinical Trials Partnership (EDCTP).

On 4 May 2020, the EU hosted the Coronavirus Global Response pledging event, which raised €7.4 billion to boost the work on vaccines, diagnostics and treatments against the virus. The aim is to gather significant funding to ensure the collaborative development and universal deployment of diagnostics, treatments and vaccines against Covid-19. As of 27 June 2020, the total pledges under the Coronavirus Global Response amounted to €15.9 billion.

On 18 May, an EU-led proposal for a resolution on vaccines was adopted in the WHO's World Health Assembly, which recommends that relevant parties 'work collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the Covid-19 response, including, existing mechanisms for voluntary pooling and licensing of patents to facilitate timely, equitable and affordable access to them'.

On 17 June 2020, the Commission released the European Vaccine Strategy, with the following three objectives: (1) ensuring the quality, safety and efficacy of vaccines, (2) securing swift access to vaccines for Member States and their populations while leading the global solidarity effort, (3) ensuring equitable access to an affordable vaccine as early as possible.

In its resolution on 17 April 2020, the European Parliament welcomed the Commission's initiative of directing funds from the EU research programme towards the fight against the virus in order to

[68] EMA, COVID-19: How EMA fast-tracks development support and approval of medicines and vaccines, 4 May 2020.

ensure that treatments, vaccines and diagnostics are globally available, accessible and affordable and called for 'the establishment of additional funding for a 'Covid-19 research and innovation (R&I) fund' to boost its efforts to finance speedy research on a vaccine and/or treatment'.

4. Testing

Diagnostic testing is essential for identifying people infected with Covid-19 and thus is key to efforts to contain the spread of the virus. Other types of testing, such as testing for antibodies, may be useful for monitoring and understanding the disease. It is also suggested that antibody tests could play a key role in easing containment measures.

4.1. Types of tests

There are two main types of tests[69] used to detect the SARS-CoV-2 virus: molecular tests, which detect the presence of viral genetic material or components of the virus in a patient sample; and serologic (or antibody) tests, which detect the immune response to the virus (whether a person has developed antibodies against the virus).

Molecular tests are diagnostic tests, meaning that they ascertain whether or not a person has been infected with the virus. If applied systematically, molecular tests can help to reduce the spread of the virus significantly. There are two main subtypes of molecular tests for identifying SARS-CoV-2: tests that detect the virus's genetic material by a method called reverse transcription polymerase chain reaction (RT-PCR), and tests that detect components of the virus, such as proteins on its surface (antigen tests). The main constraints related to conventional RT-PCR molecular tests are that they entail laborious procedures and complex logistics (lab, sampling, transport, and communication of results) and require time, expertise and scarce supplies (swabs, reagents). For this reason, efforts have been dedicated to finding rapid diagnostic tests that can be used outside a hospital and even without using a lab.

Antigen diagnostic tests, which seek to detect the presence of viral proteins in samples, are faster and easier to administer than molecular tests. In theory, a reliable antigen test could be easy to scale up and may even be used at home.[70] For example, an antigen-based test developed in Belgium can reportedly[71] identify an infected person within 15 minutes at point-of-care sites. The test, however, is so far only able to detect infections in about six out of ten people. Pointing at evidence suggesting that 'half or more of Covid-19 infected patients might be missed' by various rapid diagnostic tests, the WHO recommended not using antigen-detecting rapid diagnostic tests for patient care.[72]

Whereas molecular tests look for evidence of viral genetic material, serological or antibody tests seek to detect human antibodies that signal an immune response against the virus. Antibody tests can be used for a number of purposes: diagnostic (identifying infected people); disease monitoring (assessing how many people in a population have been infected) and immunity assessment (e.g. with a view to easing restrictions).

[69] OECD (Testing for COVID-19: A way to lift confinement restrictions), footnote 11 (above).

[70] N. V. Patel, 'Antigen testing could be a faster, cheaper way to diagnose covid-19', *MIT Technology Review*, 24 April 2020.

[71] P. Rejcek, 'New antigen test for detecting COVID-19 could help triage patients during the pandemic', *Frontiers Science News*, 8 May 2020.

[72] WHO, Advice on the use of point-of-care immunodiagnostic tests for COVID-19, Scientific Brief, 8 April 2020.

Using antibody tests for diagnostic purposes seems attractive because these tests are able to produce faster results with less sophisticated equipment than PCR tests. However, their performance is contested.[73] The antibody response usually takes some time to kick in (between 7 and 11 days), which means that an infected person may receive a negative result if tested for antibodies within a week after exposure to the virus. Such false negatives may jeopardise efforts to isolate infected people and to contain outbreaks. As the ECDC has stated, 'antibody detection tests have limited usefulness for early Covid-19 diagnosis'.

Another use of antibody testing is for studies assessing the prevalence of the virus (e.g. how many have been infected and which group is more vulnerable), and, potentially, the level of immunity in a specific group (e.g. health workers) or in the whole population. The big challenge in this case is that unreliable antibody tests may generate false positives, leading to inflated infection rate estimates.[74]

4.2. Covid-19 diagnostic testing in Member States

According to the WHO's guidance on testing,[75] in the case of community transmission, the focus should be on prioritised testing (e.g. people at risk, health workers, symptomatic individuals in a closed setting) and measures that can reduce spread (e.g. isolation). The European Commission has also published recommendations for testing strategies, suggesting criteria for priority testing.

According to a report[76] by researchers at Imperial College London on the effectiveness of alternative testing strategies, weekly screening of healthcare workers and other at-risk groups using PCR or point-of-care tests for infection, irrespective of symptoms, is estimated to reduce their contribution to transmission by 25-33 %, on top of reductions achieved by self-isolation following symptoms. The report also found that widespread PCR testing in the general population is unlikely to limit transmission more than contact tracing and quarantine based on symptoms alone, hence testing should focus on patients, healthcare workers and other high-risk groups.

The Health System Response Monitor (HSRM), a joint undertaking of the WHO Regional Office for Europe, the Commission and the European Observatory on Health Systems and Policies, collects information on how countries are responding to the crisis, including on preventative measures, testing and health services. According to information from the HSRM, **Austria** has been running up to 6 000 (PCR) tests a day, reaching a total of 140 000 tests (in the general population) as of 11 April. As of 7 May, **Bulgaria** had administered 53 000 tests (more than 1 000 tests per day). As of 24 May, **Cyprus** had conducted 101 596 tests (12 % of the total population). In **Denmark**, the number of people tested for Covid-19 reached 467 009 on 26 May. As of 16 April, **Estonia** had conducted 33 967 tests. In **Germany**, as of 13 May, 3 147 771 tests had been performed. As of 27 April, 153 054 tests had been carried out in **Ireland**, while as of 11 May, 55 250 people had been tested in **Luxembourg**. On 28 April, Luxembourg also announced a large-scale testing strategy with the aim of conducting 20 000 tests a day in order eventually to test its entire population. As of 2 May, 35 117 tests had been performed in **Malta**, while in **Poland**, 620 249 tests had been carried out by 17 May.

73 S. Mallapaty, 'Will antibody tests for the coronavirus really change everything?, *Nature*, 18 April 2020.

74 S. Mallapaty, 'Antibody tests suggest that coronavirus infections vastly exceed official counts', Nature, 19 April 2020.

75 WHO, Laboratory testing strategy recommendations for COVID-19, Interim guidance, 21 March 2020.

76 Imperial College London, Report 16: Role of testing in COVID-19 control, 23 April 2020.

4.3. Testing studies in Member States

Many countries began conducting studies based on testing representative samples with a view to assessing the prevalence of the disease (using molecular/PCR tests) and the level of immunity in the population (using antibody tests). Studies based on molecular testing seek to assess the prevalence of the disease, that is the number of infected people in a certain area at a certain point in time. Such studies have initially targeted specific groups, such as patients, health workers and vulnerable groups, but are now being extended at population level.

Reported results[77] of an early study in **Austria**, based on molecular testing, suggested that only 0.33 % of the population was infected in April. Initial results[78] from a study using diagnostic tests in **Estonia** led to estimates of 1 400 Covid-19 positive adults. Preliminary results[79] of a nation-wide study in **Hungary,** using both PCR and antibody tests, conducted in the first half of May suggested that between 243 and 7 230 people had active coronavirus infections, while between 22 399 and 92 624 people had already been infected. A recent prevalence study in **Luxembourg** suggested[80] that 0.3 % of the population was actively infected (between 243 and 7 230 people).

Studies based on antibody testing seek to assess the level of immunity to the virus at population level. The WHO launched a global seroprevalence study, known as Solidarity II, to pool findings from large-scale antibody studies. At the time of writing, antibody tests have already been used in a number of regions[81] to assess immunity in the population. In April, **Bulgaria** announced[82] plans for large-scale testing for Covid-19. Results[83] from a **Czech** population-wide study (released on 6 May) found only 107 people from a sample of 27 000 had antibodies for Covid-19, which shows an infection rate of between 0 and 5 % depending on the region (much lower than earlier estimates of about 27 %). An antibody study is also planned to take place between 1 May and 31 July. Results[84] of a **Finnish** study on a 500-person sample in the Uusimaa region conducted in April suggested that only 11 people had Covid-19 antibodies, though only one person could be confirmed as having neutralising antibodies (which may indicate immunity). In **Germany**, a targeted study conducted in the district of Heinsberg found antibodies in 14 % of the 500 people tested, suggesting that the actual number of Covid-19 cases in the country was ten times more than officially reported.[85] In May, the Robert Koch Institute, which monitors infectious diseases in Germany, announced plans to carry out three antibody test studies amongst different groups and in different regions. Results[86] from a **Slovenian** study (published on 6 May) showed that 3.1 % of the population had antibodies. Preliminary results[87] from a nationwide study in **Spain**, released on 13 May, show that about 5 % of the population had Covid-19 antibodies (11 % in the city of Madrid and 7 % in Barcelona). Reported

77 F. Murphy, 'Less than 1% of Austria's population infected with coronavirus, study finds', *Reuters*, 10 April 2020.

78 University of Tartu, The first results of a cross-sectional study on the prevalence of the coronavirus in Estonia, 6 May 2020.

79 HSRM, Policy responses for Hungary.

80 Laboratoires Réunis, Screening-tests of asymptomatic individuals to assess COVID-19 spread in Luxembourg.

81 HSRM, Policy responses for Italy.

82 T. Tsolova, 'Bulgaria to start large-scale testing for coronavirus', *Reuters*, 15 April 2020.

83 Radio Prague International, Czech study shows extremely low level of collective immunity to COVID 19 virus, 5 June 2020.

84 THL, Very few in Uusimaa found to have coronavirus antibodies, 29 April 2020.

85 Pharmaceutical Technology, Preliminary antibody survey results require further investigation to ease social restrictions, 1 May 2020.

86 Government Communication Office, First study carried out on herd immunity of the population in the whole territory of Slovenia, 6 May 2020.

87 B. Carreño, 'Spanish antibody study suggests 5% of population affected by coronavirus', *Reuters*, 13 May 2020.

results[88] from a **Swedish** study found that 7.3 % of Stockholm inhabitants had developed Covid-19 antibodies by the end of April. On 25 May, **Italy** started[89] an antibody study on a sample of 150 000 people.

It has also been suggested that antibody tests can be used to assess immunity at individual level, which may allow for the easing of restrictions for particular people. The idea behind an 'immunity passport' is that individuals who test positive for SARS-CoV-2 antibodies could be allowed to move freely (to access workplaces and public places) because they have proven immune to the virus and therefore cannot spread the infection. However, there are a number of issues with this suggestion.[90]

First of all, little is known about immunity to SARS-CoV-2. An effective antibody test would need to target the right type of antibodies that tackle SARS-CoV-2 (and not other coronaviruses), as well as to assess the right level of antibodies (a sufficient enough level to provide protection). Antibodies from other coronaviruses usually persist in the body and can provide protection for at least a year,[91] but this is not known for SARS-CoV-2. The WHO warned in April that 'laboratory tests that detect antibodies to SARS-CoV-2 in people, including rapid immunodiagnostic tests, need further validation to determine their accuracy and reliability'.

5. EU support for Covid-19 testing

On 18 March 2020, the EU published recommendations for testing strategies, calling for timely and accurate laboratory testing and suggesting criteria for priority testing. On 15 April, the Commission published guidelines on Covid-19 in vitro diagnostic tests and their performance, designed to support Member States in using testing tools effectively in the context of their national strategies and during the different stages of the pandemic, including when phasing out confinement measures.

Directive 98/79/EC on in-vitro diagnostic (IVD) medical devices lays down the requirements applicable to diagnostic tests. For example, test manufacturers must prepare a technical file that demonstrates that the test is safe and performs as intended. However, as the Commission's Joint Research Centre (JRC) noted,[92] 'assessing the performance level

CE-mark for COVID-19 diagnostic devices

'According to IVD Directive 98/79/EC, to affix the CE-mark to COVID-19 diagnostic devices to be used by health professionals, the manufacturer has to specify device performance characteristics and self-declare conformity with the safety and performance requirements listed in the Directive. In contrast, self-tests intended to be used by patients themselves must also be assessed by a third-party body (a notified body). The dedicated Commission working group of Member States' competent authorities for IVD serves as a forum for continuous exchange of technical and regulatory information on IVDs including COVID-19 rapid tests. While the majority of CE-marked rapid tests are compliant with EU law, the group has identified several devices with fraudulent documentation, incomplete technical files or unsubstantiated claims. Some of those were sold as alleged self-tests. Several Member States have warned against the use of rapid self-tests or even prohibited them.'

Source: ECDC, An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA, 1 April 2020.

88 (Just 7.3 % of Stockholm had Covid-19 antibodies by end of April, study shows) see footnote 15 (above).

89 Ministry of Health, Seroprevalence survey in Italy, 26 May 2020.

90 WHO, "Immunity passports" in the context of COVID-19. Scientific Brief, 24 April 2020.

91 A. Joseph, Everything we know about coronavirus immunity and antibodies — and plenty we still don't, *STAT*, 20 April 2020.

92 JRC, Coronavirus: Commission issues guidelines on testing, 15 April 2020.

of a test can be very challenging as the biological materials necessary for this assessment are not always available'.

An ECDC report from April indicated that there were 10 CE-marked rapid SARS-CoV-2 antigen detection tests, although these tests may not necessarily be available on the EU market. According to the Commission, as of early April, there were 78 RT-PCR tests, 13 rapid antigen tests and 101 antibody tests available in the EU, most of them CE-marked.

In its resolution of 17 April 2020, the European Parliament called on the Commission 'to launch an effective exit strategy that includes large-scale testing, and personal protective equipment (PPE) for the largest possible number of citizens', encouraging the Member States to 'develop more systematic testing on infection and exposure to the virus and to share best practices'.

6. Digital contact tracing

In order to reduce the spread of Covid-19, and given that the virus can be transmitted by infected people who do not show any symptoms (during the incubation period, or by asymptomatic patients who do not show symptoms), it is essential to identify all people who have been in contact with those who have tested positive quickly (contact tracing).[93]

Data and digital technologies enrolled to fight the pandemic may serve a number of tracking purposes, such as:

- tracking the disease (e.g. mapping the spread of the virus);
- tracking populations (e.g. mapping population movements, for example to assess adherence to confinement measures;
- tracking individuals (e.g. monitoring individuals' location and movement, for example to enforce isolation orders or to identify contacts);
- tracking contacts (e.g. recording encounters between mobile devices).

6.1. Location tracking

Location data can be used to monitor broad population movements, as well as to monitor an individual's movements. A number of countries in Asia, such as China, South Korea, Taiwan, Hong Kong and Thailand, have used mobile phones or other digital devices to track individuals' locations in order to monitor and reduce the spread of Covid-19.[94] Hong Kong, for example, obliged all overseas arrivals to wear a special wristband that uses geofencing technology to check if people observe isolation orders.[95] Taiwan implemented a 'digital fence' system[96] to ensure that people travelling from high-risk countries would abide by quarantine rules. A number of location-based apps have been made mandatory by governments, for example in China, India and Turkey.[97]

In Europe, there has been a wide consensus that anti-pandemic measures should rely on location data only when this is anonymised and aggregated, which poses lesser risks to data protection and

93 ECDC, Contact tracing: public health management of persons, including healthcare workers, having had contact with COVID-19 cases in the European Union – second update, Technical report, 8 April 2020.

94 C. Dumbrava, Tracking mobile devices to fight coronavirus, EPRS, European Parliament, April 2020.

95 D. Lilkov, D., Covid-19 and Technology in the EU: Think Bigger than Apps, Wilfried Martens Centre for European Studies, 7 May 2020.

96 M. Hui, 'How Taiwan is tracking 55,000 people under home quarantine in real time', *Quartz*, 1 April 2020.

97 P. H. O'Neill, T. Ryan-Mosley and B. Johnson, 'A flood of coronavirus apps are tracking us. Now it's time to keep track of them', *MIT Technology Review*, 7 May 2020.

privacy. In this regard, many Member States have reached out to telecommunication operators to obtain such anonymised data with a view to assessing, for example, the effect of lockdown measures on population movement. Internet companies, such as Google and Facebook, have also used this kind of data to provide mobility insights.

A number of Member States have launched mobile apps that use location data in order to map the spread of the disease and/or to enforce quarantine measures. For example, Bulgaria launched the ViruSafe app, which enables the mapping and tracking of individuals' movements and provides data access to law enforcement authorities. **Czechia** launched a smart quarantine system that uses location data from mobile operators to construct 'memory maps' (a precondition for lifting restrictions). In **Germany**, the Robert Koch Institute launched an app that uses donated data from users in order to map the geographical spread of the infection. **Poland** rolled out a mandatory application to check whether people in quarantine observe self-isolation rules, while **Lithuania** launched a quarantine enforcement app that uses location data, however the app was later suspended following a critical report from the data protection authority. In **Slovakia,** the app Covid-19-ZostanZdravy uses location data for quarantine self-checking (as well as for contact tracing). A number of regions in **Spain** have launched apps that aim to monitor and track individuals. For example, the Basque Autonomous Community has launched a voluntary symptom-checking app that asks users to provide personal data such as their phone number, name, age, gender, postcodes and health information.

It must also be noted that there are a number of other technologies that have been developed or deployed in response to the pandemic, including: facial recognition, thermal and smart cameras,[98]drones, and sewage surveillance[99] technologies. South Africa has even repurposed an antipoaching tool[100] to help fight the pandemic.

6.2. Key issues regarding contact-tracing apps

Contact tracing is conventionally done by interviewing people who have tested positive, however this generally requires intensive labour and significant resources. Although contact tracing has predominantly been done using low-tech tools (e.g. spreadsheets and phones), the hope is that these tasks could be improved by using 'smarter' technologies, such as smartphone applications (apps). Digital applications promise to speed up and automate the painstaking process of contact tracing, as well as to increase accuracy and save resources. The ongoing debate on contact-tracing apps in Europe has been revolving around a number of issues: data used (location versus proximity); general technical architecture (centralised versus decentralised) and other key issues such as reliability, usability, privacy and social implications.

6.2.1. Location versus proximity

Some of the earliest versions of digital contact-tracing apps were based on tracking and cross-referencing location data. The WHO, for example, launched an early version of a Covid-19 app to provide information about the outbreak and considered adding a feature to enable contact tracing based on users' location history[101] stored in their phones.

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98 Euractiv, Belgian rail tests sensors to keep workers apart during COVID-19, 25 May 2020.

99 A. Kosovac, E. O'Donnell and S. Khan, 'Flushing is our next weapon against COVID-19, if you're happy to have your sewage scrutinised', *The Conversation*, 24 April 2020.

100 S. Wild, 'Antipoaching Tech Tracks COVID-19 Flare-Ups in South Africa', *Scientific American*, 12 May 2020.

101 WHO, COVID-19 App Concept Summary.

However, contact-tracing apps that use location data are problematic for a number of reasons:

- they pose serious risks to data protection and privacy;[102]
- their accuracy in locating people and detecting contacts between people is limited (e.g. it may be affected by weather or physical interference);
- they may expand and entrench mass surveillance practices.

One way to avoid some of the pitfalls of location-tracking apps is to rely on Bluetooth low energy (BLE) technology to exchange contact data between phones. These apps can then identify and measure the extent to which an epidemiologically meaningful contact has taken place between phone users, by relying on proximity rather than location data. The contact data is limited to arbitrary, encrypted and ephemeral identifiers of phones that have been in proximity to an infected user and the contact's risk of infection data. The advantage of this approach is that personal data and metadata are anonymised (or pseudo-anonymised) and proximity records remain on the user's phone only for as long it is epidemiologically relevant.

Given the great risks to data protection and privacy, as well as uncertainties regarding effectiveness, only a few Member States have adopted location-based contact-tracing apps to help with the pandemic. Although a consensus has emerged on the better outlook of proximity-based contact-tracing apps, the debate is still ongoing regarding their specific technical features, as well as regarding their usefulness and broader implications.

6.2.2. Centralised versus decentralised

A major dispute concerns the basic technical architecture of proximity-based contact-tracing apps, where the choice is between a centralised and a decentralised system. The broader debate is, in fact, less about technical features and more about the implications of these different designs on issues such as data protection and privacy, effectiveness and state surveillance.

The key difference between the two systems is 'the location of execution of certain key functionalities, such as the generation of unique identifiers and the calculation of epidemiologically effective risk scores based on contact risk data':[103]

- In a **decentralised system** the arbitrary ephemeral identifiers of all phones in contact with another user are received and interpreted on the user's device. The device calculates the risk scores for all users and stores all identifiers at risk of infection. When a person receives a positive Covid-19 test result from a public health authority, they upload their exposed contact data to a backend server.
- In **centralised systems** the arbitrary ephemeral identifiers of all phones in proximity to the user are generated, stored and processed on a central server operated by the public health authorities, which calculates updated risk scores for all relevant users and decides which affected users to inform. When a person receives a positive Covid-19 test result from a public health authority, they upload their exposed contact data to a backend server.

Advocates of centralised systems claim that their solution has greater epidemiological value because it allows health authorities to obtain a general picture about the extent of the pandemic (e.g. for mapping and analytics).[104] They argue that this approach also provides more flexibility as it

102 EDPB, Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, 21 April 2020.

103 M. Ciucci and F. Gouardères, National COVID-19 contact tracing apps, Directorate-General for Internal Policies, European Parliament, May 2020.

104 R. Jennings, What are the data privacy considerations of Contact Tracing Apps?, UK Human Rights Blog, 1 May 2020.

enables the adaption of risk of infection algorithms depending on the evolution of the outbreak. Moreover, a centralised system enables direct interaction between app users and health workers. However, some of the advantages identified for centralised systems are regarded as risks by proponents of decentralised systems. The major aim of a decentralised approach is to minimise the amount of data collected and analysed at central level[105] in order to avoid risks related to data protection, privacy and unwarranted surveillance. Moreover, decentralised systems may also allow users to contact health authorities and to voluntarily upload additional contact tracing information, which further blurs the distinction between the two systems.

The **centralised approach** has been supported in Europe by a group of experts around the Pan-European Privacy-Preserving Proximity Tracing (PEPP-PT) initiative, though a series of internal disagreements and criticism from privacy experts[106] have affected the initiative. Other examples of centralised systems are ROBERT and BlueTrace.

Decentralised solutions (protocols) include the Decentralized Privacy-Preserving Proximity Tracing (DP-3T) and the Temporary Contact Numbers (TCN). In April, Apple and Google, the owners of the two operating systems that reportedly host 99 % of the world's smartphones[107] jointly decided[108] to update their mobile operating systems to enable apps to use Bluetooth functionality for contact tracing. First, they released application programming interfaces (APIs) to enable **interoperability** between Android and iOS devices using apps from public health authorities. Secondly, the companies have also been working to embed a Bluetooth-based contact tracing functionality in their operating systems.

6.2.3. Reliability

The reliability of technologies that identify and record epidemiologically meaningful contacts is essential[109] for the role that these apps play in reducing the spread of the virus. The challenge is that inaccurate information provided by these apps may have a significant negative impact on the measures taken to contain the pandemic. On the one hand, a great number of false positives (identifying irrelevant contacts) may artificially increase pressure on the health system (e.g. more people will ask to be tested). On the other hand, too many false negatives (failures to identify relevant contacts) may lead to a false sense of security and encourage people to make riskier choices.

It is generally acknowledged that Bluetooth technology is more accurate than GPS in determining proximity between two phones. However, a number of technical limitations and challenges also concern Bluetooth applications.[110] For example, the strength of Bluetooth signal (which is used to determine close proximity) may vary depending on physical interference or on the way in which a phone is positioned.[111]

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105 DP-3T Project, White paper: Decentralized Privacy-Preserving Proximity Tracing (Version: 25 May 2020).

106 N. Lomas, 'EU privacy experts push a decentralized approach to COVID-19 contacts tracing', *Tech Crunch*, 6 April 2020.

107 D. Busvine, 'Europe pins hopes on smarter coronavirus contact tracing apps', *Reuters*, 4 May 2020.

108 Apple, Apple and Google partner on COVID-19 contact tracing technology, 10 April 2020.

109 Cyphers and G. Gebhart, Apple and Google's COVID-19 Exposure Notification API: Questions and Answers, Electronic Frontier Foundation, 28 April 2020.

110 P. H. O'Neill, 'Bluetooth contact tracing needs bigger, better data', *MIT Technology Review*, 22 April 2020.

111 A. Vaughan, 'Bluetooth may not work well enough to trace coronavirus contacts', *New Scientist*, 12 May 2020.

6.2.4. Usability

In order to be useful, users need to be able to use contact-tracing apps. First of all, not everyone has a mobile phone and, second, not all phones are compatible with contact-tracing apps. This raises questions about equality and fairness, as non-users are more likely to belong to groups that are most vulnerable to the disease (e.g. older people). For example, it is reported that about 1.2 billion phones will not be able to use the Google and Apple contact tracing systems[112] because they do not possess the underlying technology.

The proximity-based contact-tracing apps rely on the capacity of mobile devices to communicate with one another, known as interoperability. This is the key issue that Apple and Google agreed to tackle. However, when the two companies chose a decentralised approach for contact-tracing, they raised an effective roadblock[113] to centralised apps. For example, apps using a centralised approach will be able to use Bluetooth functionality on iPhones only when they are running in the foreground,[114] so essentially only when the app is running and the phone is unlocked. Other outstanding interoperability issues concern the mechanisms for information exchange on the functioning of the apps and privacy issues.[115]

There are a number of non-technical points about usability, which relate to the specific context in which these apps are deployed. Conventional contact tracing involves human contact and relies on such contact not only for exchanging information but also for assisting, calming and directing people who may be experiencing stress or anxiety.[116] This aspect of contact tracing may not be easily provided by contact-tracing apps.

6.2.5. Data protection and privacy

Proximity-based contact-tracing apps may present lower risks to data protection and privacy than location-based approaches. This is because no personal data is exchanged between mobile devices and servers. However, the way in which certain proximity-based apps are designed and implemented may also raise data protection and privacy issues.

The ongoing debate between the centralised and decentralised proposals has primarily been on the grounds of data protection and privacy. Generally, each system has to deal with specific privacy and security issues. Centralised systems, for example, are more vulnerable to security attacks and present greater risks[117] of data de-anonymisation and data repurposing.[118] Decentralised systems also pose data protection and security risks around the fact that data on people who have tested positive is downloaded from the server onto the device.[119]

In the EU, all contact-tracing apps need to comply with strict EU rules on data protection and privacy. As stated in a number of guidelines by the Commission and the European Data Protection Board, the adoption of such apps should be in line with fundamental rights and data protection principles (such as lawfulness, purpose limitation, data minimisation, and accuracy). The processing of

[112] T. Bradshaw, '2bn phones cannot use Google and Apple contact-tracing tech', *Financial Times*, 20 April 2020.

[113] D. Busvine, 'European coalition takes shape on coronavirus contact tracing', *Reuters*, 7 May 2020.

[114] DP-3T Project, Security and privacy analysis of the document 'PEPP-PT: Data Protection and Information Security Architecture, 19 April 2020.

[115] M. Ciucci and F. Gouardères, see footnote 102 (above).

[116] D. P. Mancini, 'Wanted: a civilian army of contact tracers to end the lock down', *Financial Times*, 22 April 2020.

[117] DP-3T Project, Decentralized Privacy-Preserving Proximity Tracing: Simplified Overview, 8 April 2020.

[118] Privacy International, Bluetooth tracking and COVID-19: A tech primer, 31 March 2020.

[119] Inria, Proximity Tracing Applications: The misleading debate about centralised versus decentralised approaches, 18 April 2020.

personal data is allowed only if needed to achieve a legitimate purpose (e.g. substantial public interest) and if it is proportionate to the aim pursued. In the case of voluntary apps that combine different purposes (e.g. contact-tracing, symptom checking, quarantine enforcement), users should be able to give their consent separately for each purpose.[120]

Given the limited evidence on the usefulness of contact-tracing apps for addressing the public health crisis, some commentators[121] have questioned whether the adoption of such apps fully satisfies the principle of necessity under fundamental rights standards.

Beyond legal questions, it is also important to address the broader ethical and social considerations raised by these apps. For example, a recent paper[122] proposes a framework based on four principles (the app should be: necessary, proportional, scientifically valid and time-bound), which are translated into guidelines with 16 questions to assess whether a contact-tracing app is ethically justifiable. It has also been argued that using digital tracing apps should be seen as an ethical obligation[123] during the Covid-19 pandemic.

6.2.6. Mass surveillance

It is not surprising that proposals to roll out digital tools that constantly record people's movements and/or interactions have been met with reservation and criticism. One immediate concern relates to whether these tools comply with existing rules and standards, as well as whether they are useful and appropriate for the challenge at hand. Beyond this immediate concern, there are worries that such tools may have broader negative implications, as they tend to expand the surveillance capabilities of governments and private companies.

Decentralised contact-tracing approaches aim to counter the risks of mission creep[124] by blocking opportunities for data repurposing (e.g. providing police[125] or other authorities with access to data). Nevertheless, there is a general concern that authorities are turning to different tracking and surveillance technologies (e.g. location tracking and facial recognition) that have been deployed in the context of counter-terrorism strategies[126] in order to fight the pandemic, and that this will further expand mass surveillance.

One lesson from countries where the adoption of contact-tracing apps has disappointed is that they tend to launch additional digital tools to compensate for the limited impact of the original ones. India, for example, has rolled out a second version of the app for the cheaper JioPhones and asked people without smartphones to answer a text survey. Singapore introduced a SafeEntry system, which requires users to check in to public places using their national identity card or by scanning a QR code with their phone. It also plans to give a wearable device to all residents[127] that will identify people who have interacted with carriers of coronavirus.

As with the case of '**immunity passports**', there is also the concern that companies or organisations may require people to use contact-tracing apps as a precondition for returning to work, recruitment

120 EU Agency for Fundamental Rights, Coronavirus pandemic in the EU –fundamental rights implications: with a focus on contact-tracing, Bulletin No 2, April 2020

121 E. M. Kuskonmaz and E. Guild, Covid-19: A New Struggle over Privacy, Data Protection and Human Rights?, European Law Blog, 4 May 2020.

122 J. Morley, J. Cowls, M. Taddeo and L. Floridi., 'Ethical guidelines for COVID-19 tracing apps', *Nature*, 28 May 2020.

123 O, Schaefer and A. Ballantyne Downloading COVID-19 contact tracing apps is a moral obligation, May 4, 2020

124 R. Jennings, What are the data privacy considerations of Contact Tracing Apps?, see footnote 103 (above).

125 A. Schwartz, Don't Mix Policing with COVID-19 Contact Tracing, Electronic Frontier Foundation, 1 June 2020.

126 'Countries are using apps and data networks to keep tabs on the pandemic', *The Economist*, 26 March 2020.

127 J. Geddie, 'Singapore plans wearable virus-tracing device for all', *Reuters*, 5 June 2020.

or access to facilities.[128] People may soon be put in the situation of 'no app, no entry' or even 'no app, no job',[129] even if governments do not make such apps mandatory for the purpose of containing the pandemic. To avoid such risks, it is important to ensure that all privacy-intrusive technologies developed to fight the pandemic will be dismantled at the end of the crisis.

6.3. Contact-tracing apps in EU Member States

Contact-tracing apps that track an individual's location were adopted early in the outbreak, particularly in a number of Asian countries such as China and South Korea[130] (followed by Russia, South Africa, Israel, India, etc.). Singapore adopted one of the first proximity-based (centralised) apps to help with contact tracing. Australia launched a similar app, though it is reported[131] that technical issues experienced by iPhone users forced the government to explore ways of making the app compatible with Apple's decentralised framework. In Europe, Iceland uses an app that records users' location data, which can be shared voluntarily upon request from health authorities. A location-based contact-tracing app used by Norway since April was recently suspended[132] after the intervention of the country's data protection agency, while Switzerland has been testing its proximity-based contact tracing app (decentralised approach). The UK announced its centralised proximity-based contact-tracing app on 4 May, though the Parliament's Joint Committee on Human Rights[133] expressed concerns regarding privacy, uptake and interoperability. It is reported[134] that the UK is also looking to switch to a decentralised approach for its contact-tracing app.

In the EU, as of 30 June, officially endorsed contact-tracing apps were available for use in 12 Member States, whereas (at least) six other Member States were considering or preparing to launch such apps (see Table 1). Three Member States have adopted contact-tracing apps that use location data: Bulgaria, Cyprus and Slovakia. The majority of available contact-tracing apps rely on proximity/Bluetooth. Proximity-based contact-tracing apps that follow a centralised approach are available in Austria (hybrid approach), Czechia, France and Slovakia. Proximity-based contact-tracing apps that rely on decentralised approaches are available in Denmark, Germany, Hungary, Italy, Latvia and Poland. Austria and Slovakia are currently shifting from a centralised system to a decentralised one.

A number of Member States are considering or preparing to launch a contact-tracing app, including Croatia, Estonia, Finland, Ireland, the Netherlands and Portugal. According to the information available, all planned apps will be based on proximity/Bluetooth. Belgium considered developing a contact-tracing app, but opted to focus on human tracing after the Belgian data protection authority released critical recommendations.[135] In Luxembourg, on 28 April, the parliament debated[136] the possibility of developing a contact-tracing app and, despite limited support, decided

[128] A. Crocker, K. Opsahl and B. Cyphersapril, The Challenge of Proximity Apps For COVID-19 Contact Tracing, Electronic Frontier Foundation, 10 April 2020.

[129] A. Schwartz, Illusions of consent and COVID-19-tracking apps, IAPP, 19 May 2020.

[130] D. Lilkov, see footnote 94 (above).

[131] L. Clarke, 'Australia is set to abandon its centralised coronavirus app – will the UK be next?', *New Statesman*, 6 May 2020.

[132] E. Hofverberg, Norway: Data Protection Authority Orders National Health Authority to Stop Collecting User Data from COVID-19 App, Library of Congress, 19 June 2020.

[133] UK Parliament, Human Rights and the Government's Response to Covid-19: Digital Contact Tracing. Third Report of Session 2019–21, 6 May 2020.

[134] L. Kelion, UK virus-tracing app switches to Apple-Google model, BBC, 18 June 2020.

[135] APD, Applications de traçage et base de données COVID-19: pour l'APD, les avant-projets d'arrêtés royaux doivent être revus, 30 April 2020.

[136] Luxembourg Parliament, Covid-19 : vers un traçage numérique?, 28 April 2020.

to prepare a legal framework for such apps in the event that other countries made their use compulsory for people wishing to cross their borders. Spain has expressed support[137] for the pan-European Proximity Tracking to Preserve Privacy project, but has not yet put forward a concrete proposal for a national contact-tracing app. In Sweden, it is reported[138] that an app aiming to map the spread of Covid-19, launched by Lund University, was suspended by the Public Health Agency.

All available and planned contact-tracing apps in the EU are voluntary. As reported by the FRA, despite recommendations from the European Commission and the EDPB, most Member States have not adopted specific legislation to regulate and set safeguards for contact-tracing apps. Italy is an exception, as it has put forward such legislation that also incorporates a set of safeguards proposed by a task force of experts. In Bulgaria, Poland and Slovakia, law enforcement authorities or other government institutions can also be authorised to have access to personal data.

- **Austria** launched one of Europe's first proximity-based contact-tracing apps (Stopp Corona). The app is run by Red Cross Austria and allows users to report an infection which then triggers notifications for recent contacts (based on automatic 'digital handshakes'). Users are required to share their phone number with Red Cross (stored on the server for 30 days). The app uses a hybrid, centralised/decentralised approach (using a Google-Apple application programming interface): communication between devices is carried out centrally via servers, whereas all contact data is stored locally on the devices. However, it is reported[139] that the app will be soon upgraded to remove the 'centralised' component. Data on infection reports will be deleted after 30 days whereas metadata used for the 'digital handshake' will be deleted after 14 days.
- In **Bulgaria**, the ViruSafe app includes, amongst other features, a location tracker that enables users to voluntarily share data in order 'to create a heatmap with potentially infected people'. The app collects and stores centrally a wide range of personal data, including mobile number, personal ID number, age, sex, and health information. Law enforcement authorities can request access to the data.
- **Croatia** is reportedly[140] developing a proximity-based contact-tracing app. The app will not collect personal data and will be based on a decentralised approach.
- In **Cyprus**, the CovTracer app (based on MIT SafePaths) allows users who have tested positive to upload location data so that health authorities can take action, e.g. to evacuate areas, perform cleaning or to inform people who were in close contact with the patient. According to the app's privacy policy, 'personal data submitted will be retained for 1 year, unless a request to delete is lodged or the user consents to a longer period'.
- **Czechia** launched a proximity-based contact-tracing app (e-rouska) which employs a centralised approach. Users voluntarily register their phone numbers and, if requested by the health authorities, the list of phone numbers with whom their phones have been connected can be shared. Upon request, data is transferred onto a central database.
- **Denmark** launched a proximity-based contact-tracing app (Smittestop) which is based on a decentralised approach (using the Google-Apple API) on 18 June.
- **Estonia** announced[141] in April its plans to launch a proximity-based contact-tracing app that will rely on a decentralised approach (DP-3T protocol).

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[137] BBVA, How do COVID-19 tracing apps work and what kind of data do they use?, 21 April 2020.

[138] 'App launched in Sweden to help track spread of the coronavirus', *The Local*, 30 April 2020.

[139] D. Busvine, Switzerland, Austria align with 'Gapple' on corona contact tracing, Reuters, 22 April 2020.

[140] J. Orovic, Details of Croatia's Coronavirus-Tracking App Emerge, *Total Croatia News*, 15 May 2020.

[141] A. Numa, Estonian companies and government authorities join forces to develop a new mobile application to stop the spread of Coronavirus, e-estonia, April 2020.

- **France** released a proximity-based contact-tracing app (StopCovid) based on a centralised approach (ROBERT protocol) in June. The app enables users who have tested positive to voluntarily and anonymously upload information into a central server that will then (anonymously) notify contacts. Data about contact history will be kept for 15 days, whereas the IDs will be deleted upon the app's removal or six months after the end of the state of health emergency.
- In **Finland,** the Finnish innovation fund Sitra funded a proximity-based contact-tracing app (Ketju) that uses a decentralised approach (based on the DP-3T protocol). The app went into testing in June and is expected[142] to be launched officially in August. The government is preparing specific legislation for the app.
- **Germany** has been preparing a proximity-based contact-tracing app based on a centralised approach since March, but the government has now changed course in order to favour a decentralised approach. The Corona-Warn-App (using the Google-Apple API) was launched on 16 June.
- **Hungary** launched a proximity-based app (VirusRadar) in May (decentralised approach).
- **Ireland** announced plans[143] to develop a proximity-based contact-tracing app that will follow a decentralised approach (Google-Apple API).
- **Italy** made its proximity-based contact-tracing app (Immuni) available for testing in four regions (Liguria, Puglia, Marche and Abruzzo) on 1 June. The app is based on a decentralised approach (Google-Apple API) and allows users to voluntarily and anonymously exchange codes with health authorities to enable the automatic notification of contacts in the event of infection. The users are required to enter data about their town of residence upon the installation of the app. The app is regulated by a law decree issued on 30 April. Data will be automatically deleted on 31 December at the latest.
- **Latvia** launched its proximity-based contact-tracing app (Apturi Covid) on 29 May. The app follows a decentralised approach (Google-Apple API). Users can choose to provide their phone number on the app, which health authorities may use to contact them and offer medical assistance. Data is encrypted and stored on the device for 14 days, after which it will be automatically deleted.
- **The Netherlands** announced in April that it was working on a contact-tracing app, though this was met with criticism from the data protection authority and from the public, including a group of 130 researchers. The government published a list of requirements for the future app on 19 May. It is reported that initial testing of the app started in June.
- **Poland** launched a proximity-based contact-tracing app (ProteGO) in April. The app follows a decentralised approach (Google-Apple API) which enables the anonymous tracing of contacts, as well as the receipt of verified medical advice. The app records (based on consent) personal information such as name, gender, age and health information. Data will be deleted when the app is removed. Access to data is given to health authorities, but other ministries and health institutions as well as private companies can have access to anonymised personal data.
- **Portugal** is developing a proximity-based contact-tracing app (MonitorCovid19.pt) that follows a decentralised approach.
- **Slovakia** launched the app Covid-19-ZostanZdravy in March. The voluntary app uses both Bluetooth for anonymised contact tracing and 'dissipated GPS position' to allow healthcare workers to analyse the spread of the disease. The app uses a centralised approach, but work is ongoing to shift to a decentralised solution. The app has access to personal information, such as users' health status and, for people in home quarantine, their telephone number. Data on

142 YLE, Finland's coronavirus tracing app to launch in August, 4 June 2020.

143 Ministry of Health, National App for COVID-19, 2 May 2020.

contacts will be kept for 21 days whereas telephone numbers will be deleted after 180 days. Health and other authorities have access to the data.

Table 1 – Overview of available and planned contact-tracing apps in EU Member States

Member State	App	Status	Launched	Type of data	Approach
Austria	Stopp Corona	Launched	March	Proximity	Centralised/ Decentralised
Bulgaria	ViruSafe	Launched	April	Location	Centralised
Croatia		*Planned*		*Proximity*	*Decentralised*
Cyprus	CovTracer	Launched	May	Location	Centralised
Czechia	e-rouska	Launched	May	Proximity	Centralised
Denmark	Smittestop	Launched	June	Proximity	Decentralised
Estonia		*Planned*		*Proximity*	*Decentralised*
Finland	*Ketju*	*Planned*	*August*	*Proximity*	*Decentralised*
France	StopCovid	Launched	June	Proximity	Centralised
Germany	Corona-Warn-App	Launched	June	Proximity	Decentralised
Hungary	VirusRadar	Launched	May	Proximity	Decentralised
Ireland		*Planned*	*June*	*Proximity*	*Decentralised*
Italy	Immuni	Launched	June	Proximity	Decentralised
Latvia	Apturi Covid	Launched	May	Proximity	Decentralised
Netherlands		*Planned*			
Poland	ProteGO	Launched	April	Proximity	Decentralised
Portugal	*MonitorCovid19.pt*	*Planned*		*Proximity*	*Decentralised*
Slovakia	Covid-19-ZostanZdravy	Launched	March	Proximity	Centralised

Data source: Author's compilation from various sources.[144]

6.4. EU approach to contact-tracing apps

In the ongoing debate on the development and adoption of contact-tracing apps, a broad consensus has been reached regarding the need to focus on voluntary applications that are based on proximity (Bluetooth) data and that comply with EU rules and principles on data protection and privacy. In its recommendation of 8 April, the Commission argued for a common EU approach to the use of mobile applications and mobile data in response to the coronavirus pandemic. The Commission reiterated the principle according to which preference should be given 'for the least intrusive yet effective measures, including the use of proximity data and the avoidance of processing data on location or movements of individuals'.

[144] Main sources include several reports and databases, such as those of the European Union Agency for Fundamental Rights, National COVID-19 contact tracing apps, Cullen International, European GNSS Agency, and MIT Technology Review.

On 16 April, the Commission published guidance on apps supporting the fight against Covid-19 in relation to data protection. The Commission considers that location data are not necessary for the purpose of contact tracing and advises against the use of location data in this context. The Commission recommends the use of voluntary apps and the use of Bluetooth communications between devices to determine proximity. According to the Commission, national health authorities remain responsible for ensuring compliance with data protection rules in their use of the data collected, including providing individuals with all necessary information related to the processing of their personal data. Users should remain in full control of their personal data, while apps should adhere to the principle of data minimisation, which requires that only personal data that are relevant and limited to the purpose in question can be processed. In this respect, 'the decentralised solution is more in line with the minimisation principle.' Data should be stored on an individual's device and should be encrypted.

In April, the Commission and the e-Health Network, a voluntary network created by Member States that works in the area of cross-border digital health, started developing a joint EU toolbox to ensure common standards for contact-tracing apps. The Commission followed this up by releasing specific guidance on apps supporting the fight against Covid-19 in relation to data protection. On 13 May, the Commission and the e-Health Network published of a set of interoperability guidelines for approved contact tracing mobile applications in the EU. These guidelines stress that tracing apps must be voluntary, transparent, temporary and secure, must use temporary and pseudonymised data, rely on Bluetooth technology and be approved by national health authorities. Lastly, on 16 June, the Commission and the eHealth Network published guidelines on interoperability specifications for cross-border transmission chains between approved apps. The rationale is to ensure that decentralised proximity-based contact-tracing apps are able to exchange information securely, including when people are crossing borders. The guidelines also announced the creation of a federation gateway to allow for interoperability of national backend servers with a view to minimising the amount of data exchanged.

The European data protection authorities have taken part in the debate by reiterating the need to ensure that digital solutions and initiatives against the pandemic are in line with data protection rules and adhere to EU law and fundamental rights standards. In his statement on 6 April, the European Data Protection Supervisor (EDPS) pointed at the 'responsibility' to process personal data when necessary to protect other fundamental rights, with due regard to the principle of proportionality. The EDPS called for 'a panEuropean model "Covid-19 mobile application", coordinated at EU level' and urged technology developers to apply the principle of data protection by design when developing digital applications. On 22 April, the European Data Protection Board (EDPB) published guidelines on the use of location data and contact-tracing apps. With regard to the technical architecture of contact-tracing apps, the EDPB maintained that a centralised approach is compatible with data protection rules, though it acknowledged that a decentralised solution is more in line with the data minimisation principle under the General Data Protection Regulation (GDPR).

In its resolution of 17 April, the European Parliament stressed that mobile applications designed to fight against the pandemic should be voluntary, transparent, temporary and based on data protection principles, such as data minimisation and privacy, by design. The Parliament demanded that 'all storage of data be decentralised' pointing out that centralised databases 'are prone to potential risk of abuse and loss of trust and may endanger uptake throughout the Union'. The Parliament also demanded that 'clear projections be demonstrated as regards how the use of contact-tracing apps by a part of the population, in combination with specific other measures, will lead to a significantly lower number of infected people'.

7. Lifting restrictions: The role of therapeutics, testing and contact-tracing apps

7.1. The role of therapeutics

As stated by the WHO in its Covid-19 strategy update, it is 'ultimately the development and delivery of a safe and effective vaccine or vaccines and therapeutics that may enable a transition away from some of the measures necessary to maintain this state of low-level or no transmission'. Similarly, the joint European roadmap to lifting coronavirus containment measures maintained that 'the development of a safe and effective vaccine is crucial to help put an end to the Covid-19 pandemic' and that 'societies will have to live with the virus until a vaccine or treatment is found'.

Given the great level of scientific activism and resource mobilisation, there is cautious optimism[145] that there may be a Covid-19 vaccine sometime soon. The EMA estimates, however, that it could take at least a year before a vaccine against Covid-19 is ready for approval and then available in sufficient quantities to enable widespread use.

The challenge relates not only to developing and testing a vaccine but also to manufacturing and distributing it to potentially billions of people who need it. According to Soumya Swaminathan, the WHO chief scientist, in an optimistic scenario[146] there may be enough doses of a vaccine next year to immunise healthcare, followed by larger scale immunisation in 2022, though it might take four to five years to inoculate the world. The concern with projecting unrealistically rosy timelines for vaccines[147] is that this may soon provide ammunition to a growing number of vaccine-sceptics[148] and may generally diminish public trust and support for long-term containment measures.

Despite the great number of clinical trials, it is not clear when a Covid-19 treatment will be available. First of all, given the complexity of the virus, it is unlikely that a catch-all drug will be able to tackle all the effects of the disease. It is encouraging that there are so many candidates for Covid-19 treatments, although this variety may also be a sign of fragmentation, effort duplication and, generally, lack of coordination.[149]

7.2. The role of testing

The existence of appropriate monitoring capacity, which includes large-scale testing, is one of the three criteria identified in the joint European roadmap for lifting coronavirus containment measures. The roadmap considers measures to expand testing capacity as a precondition for lifting social distancing measures. This includes rolling out serological testing to assess the acquired immunity of the population and rolling out self-testing kits, 'once properly validated and their reliability ensured'. In its communication on a phased and coordinated approach for restoring freedom of movement and lifting internal border controls, issued on 13 May, the Commission stated that restrictions on travel should first be lifted in areas with a comparable epidemiological situation, and 'where sufficient capabilities are in place in terms of hospitals, testing, surveillance and contact tracing capacities'.

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145 C. Zimmer, K. Sheikh and N. Weiland, 'A New Entry in the Race for a Coronavirus Vaccine: Hope', *New York Times*, 20 May 2020.

146 C. Hodgson, 'WHO's chief scientist offers bleak assessment of challenges ahead', *Financial Times*, 13 May 2020.

147 H. Branswell, Mounting promises on Covid-19 vaccines are fueling false expectations, experts say, STAT, 6 May 2020.

148 S. Zhang, 'We Don't Even Have a COVID-19 Vaccine, and Yet the Conspiracies Are Here', *The Atlantic*, 24 May 2020.

149 A. Mullard, 'Flooded by the torrent: the COVID-19 drug pipeline', *Lancet*, Vol. 395, 18 April 2020.

As Member States have started lifting restrictions, many have taken measures **to enhance testing capacity** and to expand access to testing. According to data from the HSRM, **Austria** and **Ireland** increased testing capacity to 15 000 tests per day. **Cyprus** decided to expand laboratory testing to cover more groups, including employees in the retail business, those in the food and beverage sector and construction workers. **Denmark** updated its testing and contact tracing strategy to add a separate track for testing asymptomatic 'close contacts' and citizens who make a reservation for it. The ambition is to be able to test up to 20 000 citizens a day. Following the lifting of certain border restrictions, **Estonia** offered to test incoming travellers on a voluntary basis. **Finland** stopped the systematic testing for Covid-19 of people entering the country, though it now requires them to do the test within 48 hours. **France** announced that the end of the lockdown would be accompanied by the systematic testing of health professionals, older people and vulnerable individuals, as well as, progressively, of all people presenting symptoms of Covid-19 or those in contact with an infected case. The objective is to carry out at least 700 000 tests per week. On 13 May, **Germany** increased its testing capacity to 157 150 tests per day, aiming to expand testing particularly in care homes and hospitals, as well as to make more tests available for asymptomatic individuals who suspect they have the virus or have come into contact with an infected person. As of 4 May, **Lithuania** opened testing up to staff of shops and other outlets directly serving customers. At the end of April**, Luxembourg** announced a large-scale testing strategy aimed at testing its entire population (626 000), progressively and in contingents, and in some cases several times. **The Netherlands** has gradually extended access to testing to cover more categories, including primary school teachers, professions that require physical contact and all citizens that have symptoms. As of 14 May, **Romania** added a new category of priority testing group. According to a new guidance on surveillance and monitoring, issued on 9 May, **Spain** opened up testing to all suspected cases.

One key issue regarding testing is the rapid development and commercialisation of **antibody tests** to assess immunity. This is problematic when such tests are used to differentiate between people on the basis of immunity status. The idea of immunity passports has been invoked by a number of authorities[150] and companies[151] seeking to make deconfinement or the return to work conditional upon showing a positive test result. For example, it is reported[152] that the Estonian government began testing one of the world's first digital immunity passports as a step towards restarting the economy.

Immunity passwords appear to offer a relatively simple solution, given the availability and convenience of various antibody tests, to (at least partially) restore freedom of movement and unlock the economy. However, they pose a number of important challenges related to reliability, safety and fairness. As mentioned above, there is still limited evidence on the extent to which immunity to SARS-Cov-2 is developed and maintained. Given the current uncertainty regarding immunity to SARS-Cov-2, linking antibody testing to lifting restrictions could undercut efforts to reduce the spread of the virus.

Another issue concerns the reliability and quality of available antibody tests. Assuming that a person develops antibodies to the virus, an effective antibody test needs to target neutralising antibodies that are specific to SARS-Cov-2.[153] There are a growing number of antibody tests on the market, but the reliability of many of these tests is contested. For example, a recent JRC study of available antibody tests found that that 'proper validation and standardisation of the methods targeting

[150] R. Bastaniello, 'Italian regions testing for signs of coronavirus immunity', *Reuters*, 6 April 2020.

[151] N. Kobie, 'Plans for coronavirus immunity passports should worry us all', *Wired*, 8 June 2020.

[152] T. Virki, 'Estonia starts testing digital immunity passport for workplaces', *Reuters*, 23 May 2020.

[153] E. Lopatto, 'The disappointing truth about antibody testing', *The Verge*, 7 May 2020.

antibodies is almost completely missing'. It is also reported that a number of countries who ordered large quantities of antibody tests at the beginning of the outbreak decided not to use them due to safety and reliability concerns (e.g. in Czechia, the UK and the US).[154]

The idea of antibody passports also raises a number of important legal and ethical concerns related to discrimination and fairness. Immunity passports seem to discriminate unfairly against people based on their biological characteristics. In the absence of a vaccine, which gives people a choice of acquiring immunity or not, the differentiation between 'immunoprivileged and immunodeprived' people[155] is considered to be a consequence of luck, money and personal circumstances.

According to a report[156] by the Ada Lovelace Institute, immunity certification 'may lead to arbitrary and unfair restrictions on individuals' access to transport, services, employment, movement and other rights and freedoms on the basis of their immunity status'. There are also concerns that such passports may have serious unintended consequences.[157] For example, people may seek to expose themselves to the virus in order to gain immunity and return to a more normal life.

7.3. The role of contact-tracing apps

The joint European roadmap to lifting coronavirus containment measures states that 'mobile applications that warn citizens of an increased risk due to contact with a person tested positive for Covid-19 are particularly relevant in the phase of lifting containment measures, when the infection risk grows as more and more people get in contact with each other'. The Commission interoperability guidelines on contact tracing mobile applications also maintain that the work on these apps will 'support the gradual lifting of border controls within the EU and the restoration of freedom of movement'.

In Council, ministers of the interior discussed contact-tracing apps on 28 April and, according to the Presidency press release, the ministers considered that contact-tracing apps that are voluntary and respect privacy and data protection, 'could contribute to easing or abolishing of internal border checks and potential lifting of entry restrictions on the external Union borders'. According to the Presidency summary of the informal video-conference of telecommunication ministers, which took place on 5 May, 'the ministers came to an understanding that the contact-tracing apps would have high importance for the gradual relaxation of various national measures, including opening of borders'.

One argument in favour of adopting contact-tracing apps in response to the coronavirus highlights the experience of several Asian countries that were early adopters of these digital technologies. Countries such as South Korea, Taiwan and Singapore adopted digital tracking and contact tracing tools early in the outbreak and are often praised[158] for their success in keeping the pandemic under control. However, while digital tools may have played a role, the effectiveness of these countries' crisis response should be assessed against a broader package of measures, including legacy institutional structures, widespread testing, strict containment and broader surveillance technologies. Taiwan, for example, had set up a public health response mechanism for dealing with pandemics following the 2003 SARS outbreak, which includes a centralised disaster management

154 D. D. Kirkpatrick and J. Bradley, 'U.K. Paid $20 Million for New Coronavirus Tests. They Didn't Work, *New York Times*, 7 May 2020; D. Crow, 'Will antibody tests be our passport to normality?', *Financial Times*, 21 May; '80 % of Rapid COVID-19 Tests the Czech Republic Bought From China are Wrong', *Praque Morning*, 26 March, 2020.

155 N. Kofler and F. Baylis see footnote 31 (above).

156 Ada Lovelace Institute, Exit through the App Store?, 20 April 2020.

157 E. Jakubowska, COVID-Tech: the sinister consequences of immunity passports, European Digital Rights, 10 June 2020.

158 A. Wilson, 'The Countries That Are Succeeding at Flattening the Curve', *Foreign Policy*, 2 April 2020.

centre and an integrated information system between health and immigration authorities. Singapore initiated a large-scale testing strategy for all suspected cases since the early days of the outbreak, reaching 2 200 tests a day for a population of 5.7 million.[159] It may therefore be misleading to put this success down solely to contact-tracing apps. Moreover, it is also unlikely that such solutions could be 'copy-pasted' into a European context.[160] The months-long debate in Europe on the appropriate design and necessary safeguards for contact-tracing apps is indicative of this.

One of the biggest questions regarding contact-tracing apps is how useful they are in fighting the pandemic. The debate is ongoing on the minimum rate of adoption of these apps that is necessary to achieve a real epidemiological impact. For example, it is reported[161] that in Singapore the contact-tracing app has been downloaded by about 25 % of the population. In India, despite being mandatory, the official contact-tracing app was downloaded by 100 million people by mid-May, two weeks after its launch. In Iceland, the country's contact-tracing app has been downloaded by 38 % of the population (364 000 people).

A study[162] by researchers at the University of Oxford has been widely quoted as providing evidence that mass adoption (by 40 to 60 % of the population) is required in order to reduce the spread of the virus. However, the authors did point[163] out that the argument in the paper was that although higher adoption would be more effective, there would still be a reduction in the number of coronavirus cases and deaths 'even with lower numbers of app users. This means that lower levels of adoption of the apps will simply require more prevention and containment measures. There is, indeed, some evidence that even more modest adoption by just 10 % to 20 % could have a positive effect[164] on limiting the spread of the virus. Another clarification on the adoption rate is that in order to account for the population who do not have or use (compatible) smartphones, the proportion of mobile users needs to be higher. For example, in the UK context, the target of 56 % of the general population translates into 80 % of smartphone owners.

Given the voluntary nature of contact-tracing apps in Europe, their take-up may ultimately depend on the public perception of their usefulness and more broadly on public trust in the governments and authorities promoting them. Evidence on the usefulness of contact-tracing apps is still hard to come by. For example, it is reported[165] that, one month since its launch, Australia's app has helped to identify just 1 infected person, though this may not be fully indicative of the app's performance. In Iceland, where the adoption rate of the official contact-tracing app is high, the experts in charge of contact tracing have stated[166] that the impact of the app is not great compared with manual tracing techniques.

Contact-tracing apps may be useful for tackling the Covid-19 pandemic to the extent that they have epidemiological value. This requires that, first, epidemiological input is taken into account during the whole cycle of the app's life, from design to development, use and update; second, contact-tracing apps need to be combined with other epidemiological measures, including conventional

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159 OECD, Testing for COVID-19: A way to lift confinement restrictions, 4 May 2020.

160 D. Lilkov., see footnote 94 (above)

161 S. Prasso, Everyone Has a Contact-Tracing App, and Nobody's Happy About It, Bloomberg, 21 May 2020.

162 University of Oxford, Digital contact tracing can slow or even stop coronavirus transmission and ease us out of lockdown, 16 April 2020.

163 P. H. O'Neill, 'No, coronavirus apps don't need 60 % adoption to be effective', *MIT Technology Review*, 5 June 2020.

164 Big Data Institute, Digital contact tracing can slow or even stop coronavirus transmission and ease us out of lockdown, 16 April 2020.

165 J. Taylor, 'How did the Covidsafe app go from being vital to almost irrelevant?', *The Guardian*, 23 May 2020.

166 B. Johnson, 'Nearly 40 % of Icelanders are using a covid app—and it hasn't helped much', *MIT Technology Review*, 11 May 2020.

contact tracing and testing; and third, the technology should allow for further review and adaptation of the tools, for example, in light of new knowledge (e.g. about the spread of the disease) or depending on the specific stages and contexts of the outbreak.

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In the absence of vaccines and treatments for Covid-19, any easing of restrictions to freedom of movement and social life needs to be accompanied by enhanced monitoring measures, such as expanded testing capacity and improved contact tracing, including use of appropriate digital technologies.

There are very few certainties about the coronavirus pandemic, but perhaps one is that no isolated measure or silver-bullet solution is likely to solve all aspects of the crisis.

A flexible and integrated strategy, based on complementary tools and measures (therapeutics, testing and contact tracing) and a coordinated approach across the EU are key to gradually lifting restrictions and to going back to the (new) normal.

QA-02-20-582-EN-N

This is a publication of the Members' Research Service
EPRS | European Parliamentary Research Service

PE 652.016
ISBN 978-92-846-6945-5
doi:10.2861/7568