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Ten technologies to fight coronavirus

IN-DEPTH ANALYSIS

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Ten technologies to fight coronavirus

As the coronavirus (Covid-19) pandemic spreads, technological applications and initiatives are multiplying in an attempt to control the situation, treat patients in an effective way and facilitate the efforts of overworked healthcare workers, while developing new, effective vaccines. This analysis examines in detail how ten different technological domains are helping the fight against this pandemic disease by means of innovative applications. It also sheds light on the main legal and regulatory challenges, but also on the key socio-ethical dilemmas that the various uses of these technologies pose when applied in a public-health emergency context such as the current one. A scan of the technological horizon in the context of Covid-19 indicates that technology in itself cannot replace or make up for other public policy measures but that it does have an increasingly critical role to play in emergency responses. Covid-19, as the first major epidemic of our century, represents an excellent opportunity for policy-makers and regulators to reflect on the legal plausibility, ethical soundness and effectiveness of the deployment of emerging technologies under time pressure. Striking the right balance will be crucial for maintaining the public's trust in evidence-based public health interventions.

AUTHOR

This in-depth analysis has been written by Mihalis Kritikos of the Scientific Foresight Unit (STOA) within the Directorate-General for Parliamentary Research Services (EPRS) of the Secretariat of the European Parliament.

To contact the publisher, please e-mail stoa@ep.europa.eu.

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Executive summary

As the coronavirus pandemic (Covid-19) evolves, technological applications and initiatives are multiplying in an attempt to stop the spread of the disease, treat patients and take the pressure off overworked healthcare workers, while also developing new, effective vaccines. At a time when everyone needs better information, including epidemic disease modellers, state authorities, international organisations and people in quarantine or maintaining social distancing, digital information and surveillance technologies have been unleashed in an unprecedented manner to collect data and reliable evidence to support public health decision-making. Artificial intelligence, robots and drones are being deployed to help track the disease and enforce restrictive measures; while scientists are frantically applying gene editing, synthetic biology and nanotechnologies in a bid to prepare and test future vaccines, treatments and diagnostics. Blockchain applications can track contagion, manage insurance payments, and uphold medical supply chains. Furthermore, 3D printing and open-source technologies seem capable of sustaining the effort of governments and hospitals around the world to meet the increasing need for medical hardware (e.g. facemasks, ventilators and breathing filters) and optimise the supply of the necessary medical equipment. At the same time, telehealth technologies offer a cost-effective means to slow the spread of the virus and to maintain hospital capacity by operating as a possible filter, keeping those with moderate symptoms at home and routing more severe cases to hospitals.

Presenting a non-exhaustive overview of the technologies currently in use, this analysis highlights their main features and significance in the fight against the coronavirus pandemic, focusing on the way they are being used to monitor and contain the rapid spread of the disease, and to ensure that public health institutions maintain their capacity to meet the ever-increasing needs caused by this pandemic disease. The analysis also illustrates the main legal and regulatory challenges and the key socio-ethical dilemmas that these technologies' manifold applications pose when used in a public-health emergency context such as the current one.

A scan of the technological horizon in the context of Covid-19 allows some preliminary remarks regarding the terms of technological engagement in the fight against this once-in-a-century pandemic. First, unlike previous public health crises, this one seems to be transforming citizens from objects of surveillance and epidemiological analysis into subjects of data generation through self-tracking, data-sharing and digital data flows. Secondly, although most of these technologies have not been applied in a medical emergency context before, their intensive use on a global scale triggers questions about the effects on civil liberties of mobilising mass surveillance tools as well as concerns about state authorities maintaining heightened levels of surveillance, even after the pandemic ends. In the context of the current pandemic, numerous data-collection and location-tracking technological applications have been launched on the basis of emergency laws that involve the temporary suspension of fundamental rights and authorisation of medical devices and vaccines via fast-tracked procedures.

Although the focus of this analysis is on technological applications presenting solutions to pressing pandemic-related problems, this piece of research does not aim to reinforce ideas of techno-solutionism. In other words, technological applications in their own right cannot solve complex societal challenges, such as those associated with the current pandemic. Rather, this work's main findings indicate that technology in itself cannot replace or make up for other public policy measures but it does have an increasingly critical role to play in emergency responses. Covid-19, as the first pandemic of the century, represents an excellent opportunity for policy-makers and regulators to reflect on the legal plausibility, ethical soundness and effectiveness of deploying emerging technologies under time pressure. Striking the right balance will be crucial for maintaining the public's trust in evidence-based public health interventions.

Table of contents

1. Artificial intelligence

Analytics have changed the way disease outbreaks are tracked and managed, thereby saving lives. The international community is currently focused on the 2019-2020 novel coronavirus (Covid-19) pandemic, first identified in Wuhan, China. As it spreads, raising fears of a worldwide lockdown, international organisations and scientists have been using artificial intelligence (AI) to track the epidemic in real-time, so as to be able to predict where the virus might appear next and develop an effective response.

On 31 December 2019, the World Health Organization (WHO) received the first report of a suspected novel coronavirus (Covid-19) in Wuhan. Amid concerns that the global response was fractured and uncoordinated, on 30 January 2020 the WHO declared the outbreak a public health emergency of international concern (PHEIC) under the International Health Regulations (IHR). Warnings about the novel coronavirus spreading beyond China were raised by AI systems more than a week before official information about the epidemic was released by international organisations. A health monitoring start-up correctly

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predicted the spread of Covid-19, using natural-language processing and machine learning. Decisions during outbreaks of this nature need to be made on an urgent basis, often in the context of scientific uncertainty, fear, distrust, and social and institutional disruption. How can AI technologies be used to manage this type of global health emergency, without undermining protection of fundamental values and human rights?

Potential impacts and developments

In the case of Covid-19, AI has been used mainly to help detect whether people have novel coronavirus through the detection of visual signs of Covid-19 on images from computerised tomography (CT) lung scans; to monitor, in real time, changes in body temperature through the use of wearable sensors; and to provide an open-source data platform to track the spread of the disease. AI can process vast amounts of unstructured text data to predict the number of potential new cases by area and which types of populations will be most at risk, as well as to evaluate and optimise strategies for controlling the spread of the epidemic. Other AI applications can deliver medical supplies by drone, disinfect patient rooms and scan approved drug databases for medicines that might also work against Covid-19. AI technologies have been harnessed to come up with new molecules that could serve as potential medications or even accelerate the time taken to predict the virus's RNA secondary structure. A series of risk assessment algorithms for Covid-19 for use in healthcare settings have been developed, including an algorithm for the main actions that need to be followed for managing contacts of probable or confirmed Covid-19 cases, as developed by the European Centre for Disease Prevention and Control. Certain AI applications can also detect fake news about the disease by applying machine-learning techniques for mining social media information, tracking down words that are sensational or alarming, and identifying which online sources are deemed authoritative for fighting what has been called an infodemic. Facebook, Google, Twitter and TikTok have partnered with the WHO to review and expose false information about Covid-19. In public health emergency response management, derogating from an individual's rights of privacy, non-discrimination and freedom of movement in the name of the urgency of the situation can sometimes take the form of restrictive measures that include domestic containment strategies without due process, or medical examination without informed consent. In the case of Covid-19, AI applications such as the use of facial recognition to track people not wearing masks in public, or AI-based fever detection systems, as well as the processing of data collected on digital platforms and mobile networks to track people's recent movements, have contributed to the draconian enforcement of restraining measures during the confinement aimed at containing the outbreak, for unspecified durations. Chinese internet search giant Baidu has developed a system using infrared and facial recognition technology that scans and takes photographs of more than 200 people per minute at the Qinghe railway station in Beijing. In Moscow, authorities are using automated facial recognition technology to scan surveillance camera footage in an attempt to identify recent arrivals from China, placed under quarantine for fear of

Covid-19 infection. Finally, Chinese authorities are deploying drones to patrol public places, conduct thermal imaging, or to track people violating quarantine rules. The effectiveness of these AI applications will not only depend on their technical capacities but also on how human controllers and AI developers will supervise their implementation pathways in accordance to the established algorithmic standards, legal principles and ethical safeguards.

Anticipatory policy-making

As a governance system, the WHO has limited enforcement tools, and its surveillance system is fully dependent on states' willingness to meet their good-faith reporting requirements. However, reporting compliance remains low, raising questions about the ability of low and middle-income countries (LMICs) to meet IHR obligations in the absence of adequate resourcing and financial support and about the effectiveness of the main legal framework of 'essential' capacities required by nations to prevent, detect and rapidly respond to public health threats. However, AI technologies have the potential to challenge the state's monopoly of information control and operationalise the WHO's right to receive reports from non-state sources, particularly if and when those reports contradict reports provided by the state.

The development of vaccines and drugs in response to public health emergencies also presents particular legal and ethical challenges. The European Commission and the European Medicines Agency have put procedures in place to speed up the assessment and authorisation of vaccines for use during a public health emergency, either via the pandemic preparedness vaccine marketing authorisation or the emergency procedure. The EMA recently activated its plan for managing emerging health threats, while the Commission and the Innovative Medicines Initiative (IMI) have launched fast-track calls for proposals for the development of therapeutics and diagnostics to combat Covid-19 infections. Using the paragraph 6 system, provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), countries are allowed to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. Adopting measures to counteract the potentially adverse health impact of IP protection and sharing preliminary research results with all actors in the response is a crucial component of any integrated global alert and response system for epidemics aimed at making the benefits of research available to local populations without undue delay. AI's capacity to search large databases quickly and process vast amounts of medical data should essentially accelerate the development of a drug that can fight Covid-19 but also raises questions about the criteria used for the selection of the relevant data sets and possible algorithmic bias. Most public health systems lack the capacity to collect the data needed to train algorithms that would be reflective of the needs of local populations, take local practice patterns into account and ensure equity and fairness.

As public health emergencies can be deeply socially divisive, stretch public-health capacities and limit rights to privacy and informational self-determination, it is important for policy-makers to consider the ethics of their crisis-management policies rationally. Although the Siracusa Principles may allow for limitation of, or derogation from the International Covenant on Civil and Political Rights (ICCPR), confining people during the outbreak of a lethal disease in emergency contexts should be ethically justifiable, necessary and proportionate. In all cases, the least liberty-infringing alternatives should be used to achieve the public health goal. The WHO guidance for managing ethical issues in infectious disease outbreaks and the guidance on ethical issues in research in global health emergencies could help to ensure appropriate ethical oversight and collaboration, to help combat the social stigmatisation of those affected, or perceived to be affected, by the disease.

However, given the absence of a comprehensive human rights framework that would underpin effective outbreak surveillance at international level, the management of the risks associated with infectious diseases is likely to remain an ongoing challenge for global health governance. The massive use of AI tracking and surveillance tools in the context of this outbreak, combined with the current fragmentation in the ethical governance of AI, could pave the way for wider and more permanent use of these surveillance technologies, leading to a situation known as 'mission creep'. Coordinated action on inclusive risk assessment and strict interpretation of public health legal exemptions, such as that envisaged in Article 9 of the General Data Protection Regulation, will therefore be key to ensuring the responsible use of this disruptive technology during public health emergencies. Accordingly, preventing AI use from contributing to the establishment of new forms of automated social control, which could persist long after the epidemic subsides, must be addressed in ongoing legislative initiatives on AI at EU level.

2. Blockchain

Covid-19's highly infectious nature means that there is a pressing need to find appropriate solutions, from speeding up the detection of virus carriers and halting the spread of the virus to developing a vaccine. Blockchain technology has recently emerged as a key technology in the critical domain of epidemic management. Blockchain applications could provide a robust, transparent and cheap means of facilitating effective decision-making and, as a result, could lead to faster responses during emergencies of this kind. In the context of this pandemic, blockchain has the potential to become an integral part of the global response to coronavirus by tracking the spread of the disease, managing insurance payments and maintaining the sustainability of medical supply chains and donation tracking pathways.

Blockchain applications could can monitor disease outbreaks over time by creating 'ledgers' that are both secure and updated hundreds of times per day. Additionally, using blockchain can improve diagnostic accuracy and treatment effectiveness, streamline the rapid isolation of clusters of cases, track drug supply chains and medical supplies, manage medical data and identify disease symptom patterns. In cases such as a virus outbreak, where high numbers of real-time incoming data are released, blockchain can reduce uncertainty and offer computational trust, and an automated platform for recording and exchanging consistent factual information between multiple parties. Beyond blockchain's value as a health data monitoring and tracking tool, health

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authorities can make use of permissioned blockchain systems to tackle the healthcare interoperability challenge, and help expedite clinical trials by facilitating data storage and sharing between researchers, while ensuring the trustworthiness of clinical trial data collection and reporting. In order for application of blockchain to bring added value to a public health emergency context compared with traditional surveillance mechanisms it should make extensive use of its encryption characteristics combined with decentralised peer-to-peer engagement so as to improve security, regulatory compliance, durability, consensus, selective privacy and timing.

Potential impacts and developments

Using encrypted data and records to track transactions, several blockchain technologies have been launched to solve the challenges posed by the Covid-19 crisis and bring innovative solutions to the problems associated with this major disruption. First, in the area of donation tracking, blockchain allows donors to oversee where their funds are needed, receive notifications when the donations have been received and then track donations made for the treatment of people infected with the coronavirus in the Wuhan region. Ant Financial's online mutual aid platform, Xiang Hu Bao, is a blockchain-based collective claim-sharing platform that processes coronavirus insurance claims not only by reducing paperwork (hence mitigating the risk of infection from face-to-face contact, as the platform is able to process transactions without human involvement), but also by allowing all parties to monitor the entire process.

The borderless nature of Covid-19 and the global mask shortage require more thoughtful and planned collaboration to deal with supply chain vulnerability. Blockchain seems to offer a variety of solutions in this regard. A blockchain-based platform has been launched to enable users to trace demand and supply chains of medical supplies, given the shortage of facial masks, and to rise to the challenges associated with the management, allocation and donation of relief supplies. It reviews, records and tracks demand, supplies and logistics with regard to epidemic prevention materials.

In the context of outbreak data tracking, one blockchain-enabled tracker has a special dashboard to track infections, deaths and recoveries world-wide in real time, ensuring that every piece of shared information cannot be manipulated or modified. The Singapore-based blockchain company, Algorand Foundation, has recently launched an application called IReport-Covid to allow symptomatic and non-symptomatic users to directly report any information they wish about the virus anonymously by filling in a survey. In Hangzhou, a

program has been developed on WeChat that can generate QR codes to enable residents to enter gated communities on the basis of personal information collected, encrypted and stored in blockchain-based cloud servers, while in Xi'an, in Northwest China's Shaanxi province, an online consultation and screening system was recently launched.

Blockchain can manage health records securely, ensuring interoperability without compromising security and patient privacy. Another blockchain-based application helps government agencies keep track of patients and suspected new cases, and allows doctors to analyse patient symptoms and monitor diagnostics data in real-time, integrating patient medical history data. All these applications reflect the capacity of blockchain to create incentives for tracing medical needs and identifying gaps in medical supply chain management but also for creating rewards in the form of tokens issued on a blockchain platform for citizens complying with containment and social distancing rules.

Anticipatory policy-making

In an inter-connected world facing serious interoperability challenges, blockchain technologies could contribute to a robust epidemic alert system. However, as blockchain is still in its early stages of development, several legal questions may have yet to be answered: who should be in charge of the data? Who should be able to access it? How should patients and public health organisations be identified in the database? Who monitors the blockchain? Where are the servers located, and what types of digital and physical controls exist? The application of blockchain technologies in an emergency context comes with specific limitations. These relate to their costs in terms of computational power, their lack of integration with legacy systems, their open character that can become a liability in environments that have stringent privacy requirements, their energy-intensive nature and an inability to scale.

The vulnerability of blockchain systems to 51 % attack constitutes another major challenge as shown by the recent hacking of the Argentinian government's blockchain-based official gazette website where false statements regarding the coronavirus were spread. As sensitive data of a medical nature or location are urgently needed by governments to track the spread and transmission of the disease as well as by biotechnology companies to train their algorithms, privacy restrictions may soon have to be loosened. Will that affect blockchain applications as well? Recently, the Human Medicines Committee (CHMP) of the European Medicines Agency called for the pooling of research resources into large multi-centre, multi-arm clinical trials to generate sound evidence on Covid-19 treatments. Blockchain technologies with their built-in layers of interoperability, patient privacy, transparency and data integrity may need to be employed in the context of these clinical trials in order to reduce trial timelines, help with credibility, security and transparency and take a major step toward reproducibility.

Blockchain could in fact facilitate an EU-wide ethics review of the proposed multi-site, collaborative clinical studies given the immutable record-keeping, automatable protocol amendments and direct connectivity between stakeholders it allows. A centralised ethics review process of this kind will be necessary to meet the critical need for robust data to determine which investigational or repurposed medicinal products would be safe and effective for the treatment of Covid-19. Such centralised EU-wide ethics reviews can be based on the modalities and best practices developed in the context of the long-established EU ethics appraisal procedure that concerns all activities funded within the Horizon 2020 programme and aims to ensure that provisions on ethics in the H2020 regulations and its rules for participation are upheld. Without being in a legal position to provide the ethics clearance required by the EU rules on clinical trials, this procedure has been simplified over the years and serves as a model for thorough, credible and nuanced ethics controls that take into account the ethical and cultural particularities of Member States in a constructive and operational manner. Many Member States and also several EU agencies have set up their ethics review procedures and mechanisms in accordance with this model, which is dynamic by nature.

Against this backdrop, legal concerns associated with the storage of patient data on a public blockchain and the terms of future access to consent already given by a patient have to be addressed. In this rapidly evolving context, where state authorities are asking companies to share data to help track the virus or use individual phone-tracking to warn users away from engaging with those infected with Covid-19, the success of the application of blockchain technologies will depend on their ability to facilitate the data-sharing process without undermining the privacy of its users, and the immutability of its operations.

3. Open-source technologies

During disease outbreaks, rapid data sharing is critical as it allows for a better understanding of the origins and spread of the infection and can serve as a basis for effective prevention, treatment and care. The capacity of information technologies to allow for low-cost dissemination and collaboration of data have led to the establishment of a multitude of repositories and information technology platforms for data sharing. Most of these data-collection activities are coordinated by international organisations such as the World Health Organization (WHO) and the European Centre for Disease Prevention and Control. At the same time, an increasing number of bottom-up, open-data initiatives and open-source projects have also been developed, facilitating access to research data and scientific publications as well as sharing blueprints for production of critical medical equipment such as ventilators and face shields.

The placement of the first genome of the 2019-nCoV virus, which was the most rapid characterisation of a novel pathogen in history, in an open database on January 8 2020, paved the way for scientists around the world to start working on the development of a treatment or vaccine as it allowed laboratories to develop the necessary diagnostics within a very limited timeframe. Making this data open was the first and most important data-sharing initiative that helped scientists to grow the live virus and build up a picture of how the virus is spreading. Since then, public health institutions and universities around the world have publicly shared over 183 sequences of variants of SARS-CoV-2 in a monumental effort to develop an effective vaccine against this new virus. In fact, the most important initiatives to prevent and monitor the

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spread of the disease have been based on an ever-growing ecosystem of open science, open-data and open-source platforms that share dashboards, information and resources of vital importance for decision-makers. For instance, public health authorities, universities and clinical laboratories are releasing genomic data from Covid-19 specimens at unprecedented speed, the WHO provides daily status reports including new cases, while more than 30 leading publishers have agreed to make all of their Covid-19-related publications immediately accessible in public repositories to openly inform the public health response. Major publishers, including Elsevier, Springer Nature, Wiley Online Library, Emerald and Oxford University Press, have set up a featured open access resources page. In the domain of data-sharing, open-source technologies can bring to the fore a broader set of important concepts such as accessibility of information, open standards that enable all stakeholders to contribute and rapid prototypes that can lead to rapid discoveries. In this context, several initiatives have been developed around the world to develop new low-cost and open-source designs for everything from ventilators to face shields.
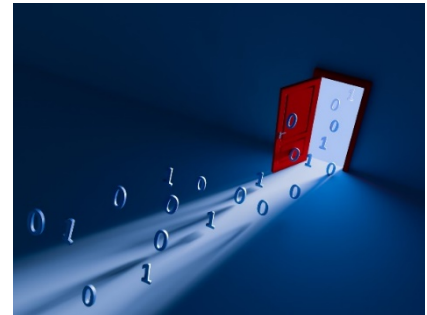
Potential impact and developments

Open-source analytics tools for studying the Covid-19 coronavirus outbreak have contributed to the immediate sharing of collective intelligence about the virus and the generation of bottom-up insights that can inform decision-making in a collaborative and accessible manner and have even helped to address the shortage of testing equipment and ventilators. Responding to concerns about the lack of testing components to test for Covid-19, the Just One Giant Lab developed an open-source coronavirus test methodology to share designs so that certified labs could produce test kits easily. NextStrain is an open-source application that tracks the evolution of viruses and bacteria, collects all the data around the world from labs that are sequencing the SARS-CoV-2 genome, and centralises them in one place in the form of a genomic tree. Researchers have also been sharing new findings about the genomic profile of the virus through open-source publications and preprint sites such as BioRxiv and Chinaxiv.

There are currently seven open-source hardware projects working to combat Covid-19 in various ways including the scaling-up of Covid-19 testing, the design of quick-development OpenLung low resource ventilators and the simulation of protein dynamics, including the process of protein folding and the movements of proteins implicated in a variety of diseases. Open-source products have also been developed by several state authorities worldwide. The Israeli government recently released the Shield open-source app, which collects location data from users' phones in an attempt to determine if they might have been exposed to the Covid-19 coronavirus. Singapore's Government Technology Agency decided to offer the

protocol that powers the TraceTogether contact-tracing app to the open-source community. There's also an open-source Covid-19 library of resources for DIY engineering efforts and the Open Air Project, a group that aims to address Covid-19 challenges through open-source technology, a GoFundMe DIY ventilator project, and a Hackaday project to develop a blueprint for an open-source ventilator. One of the most important initiatives is OpenCovid19, which is developing and sharing open-source methodologies for a community-driven procedure to test for the presence of the virus safely. DeepMind recently made structural predictions of under-studied proteins of SARS-CoV-2 freely available to the research community. Alibaba has, meanwhile, developed an open-source platform to track the spread of Covid-19, to help health authorities prevent and prepare for new cases. Various open-source graph databases such as the Neo4j and Nebula Graph are vital when it comes to modelling the pathways and the spread of Covid-19, while the newly open-sourced CHIME enables hospitals to enter information about their facility and population and then modify assumptions around Covid-19's spread and behaviour.

Last but not least, it is worth mentioning that several engineers are currently sharing designs for DIY ventilators online as the coronavirus pandemic spreads, while an open-source predictive model that identifies people who are likely to have a heightened vulnerability to severe complications from Covid-19 has recently been developed. The development of the above-mentioned open repositories, applications and hardware projects indicates the potential of open-source technologies and bottom-up data-sharing structures to address many Covid-19-related challenges. Such initiatives can help citizens exercise their digital freedoms – without necessarily involving data intermediaries – and become shapers of an expanding data ecosystem.

Anticipatory policy-making

Despite the increasingly important role of data-sharing in all these efforts, most of the initiatives described above seem disconnected from the main technological trajectories that have been developed to address this fast-developing public health crisis. Thus there is a need to streamline and coordinate the main open-source activities of the same kind so as to unlock the public interest value of the data collected and the open software, and harness their potential so as to accelerate international action to fight the pandemic. This is a rather daunting task as issues of financial sustainability, reliability, technical maintenance, complexity and licensing persist. The establishment of open databases also raises concerns about safeguarding privacy and security and also about the ownership of the data disclosed and the expertise needed to access and make use of the data. Most of the challenges in establishing a sustainable open-data ecosystem centre on data interoperability and quality, as well as their structure, authenticity and integrity, all necessary for the exploitation of the data value and the effective combination of data from different sources. Furthermore, open-source hardware equipment needs to be fully tested and found to be reliable before being distributed and replicated, which may also prove a challenging process for small-scale collaborating initiatives.

Data sharing and open-source initiatives face more than just technological obstacles. They are being shaped in a legal vacuum. At international level, various WHO initiatives in the field of data-sharing can provide some guidance. Examples are the 2016 Policy Statement on Data Sharing in the context of public health emergencies, the Pandemic Influenza Preparedness Framework and its recent code of conduct for the open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease. None of these documents can generate legal obligations of information-sharing among states and/or replace the various regional or bilateral data-sharing agreements. At EU level, a report by the High-Level Expert Group on Business-to-Government Data Sharing concluded that much of the potential for private-sector data and insights to be used by public-sector bodies to tackle societal challenges remains untapped. Several organisations are currently asking the EU to ensure that all technical measures to manage the coronavirus are transparent, remain under public control and make use of free/open-source software when designing public interest applications. In a recent EU-FOSSA 2 survey, open-source communities called on the EU to help developers make software more secure and to increase the stability of their coding by supporting, and sponsoring them to work on specific aspects of their code. As there is a pressing need for an open analytics environment that allows all interested stakeholders to analyse, interpret, and share Covid-19 data, open-source initiatives could address the regrettable lack of data sharing and considerable analytical obfuscation, but also empower groups of people to share local knowledge and pool the rights they have over their data.

4. Telehealth technologies

The Covid-19 pandemic is posing unique challenges to healthcare delivery. States across the world are shutting down non-essential services and in several cases issuing stay-at-home restrictive orders to flatten the curve and help overcrowded hospitals remain functional. Alternative technologies, conducive to self-quarantine, could therefore offer an essential link between patients and clinicians, circumventing the need to travel to overburdened hospitals. Given the high transmission rates of the disease, especially within hospitals, telehealth technologies can be a cost-effective means to slow the spread of the virus and to lessen the pressure on hospital capacity by operating as a possible filter, keeping those with moderate symptoms at home while routing more severe cases to hospitals.

Telehealth technologies allow patients to be seen and diagnosed remotely by doctors via an audiovisual, real-time, two-way interactive communication system. This includes video 'visits' through webcam-enabled computers, tablets, and smartphones, chatbots and automated algorithms. Remote delivery of clinical care services with audio-visual conferencing technology offers several crucial advantages. First, it allows hospitals to be kept clear for confirmed cases; second it reduces virus transmission rates, as there is no risk of being exposed to the pathogen; and third, since it is available anytime, it can handle more patients than in-person care.

Hospitals, public health authorities, and digital health companies around the world are currently deploying

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online symptom checkers to screen patients for signs of Covid-19 and to obtain detailed travel and exposure histories. Telemedicine is also unique as it can bring the skills of infectious disease specialists to people in geographic locations that do not have access to such specialty care. Furthermore, it can improve the effective triage – the sorting of patients before they arrive in the emergency department – and coordination of care for those suspected with Covid-19 or people that have been exposed to a confirmed Covid-19 patient.

Potential impacts and developments

As part of its efforts to manage the extensive strain on clinicians' time and hospital resources, the US administration announced a major expansion of telemedicine options, allowing US citizens enrolled in Medicare to talk to a doctor by phone or video chat for no additional cost. The US Center for Disease Control and Prevention (CDC) is offering a coronavirus self-checker, in the form of an online bot nicknamed Clara – for people who are concerned that they may have symptoms of the disease. Eighteen states plus Washington DC have enacted emergency regulations to increase the use of telehealth to protect health-care workers and high-risk patient populations.

Several telehealth companies that have quickly deployed online symptom checkers to screen patients for signs of Covid-19 have recently seen a 50 % increase in demand in the US and the UK. Startups like General Atlantic-backed Doctolib and insurer Axa-supported Qare in France, Swedish Kry International's unit Livi, the UK's Push Doctor and Germany's Compugroup Medical offer virtual doctors and are reaping the financial benefits. Telehealth giants such as Amwell and Teladoc are now advertising their availability for coronavirus-related appointments and Teladoc's stock prices spiked in late February. Doctolib, the top French startup helping to set up medical appointments, reported a 40 % increase in the last of March 2020. It clocked up 130 000 video consultations last year, which was its first year in business. Meanwhile, the Sheba Medical Centre, the largest hospital in Israel, launched a remote patient-monitoring programme last month, in an attempt to control the spread of the virus.

However, a number of constraints can affect the deployment of telehealth technologies on a large scale. These include the technological capacity and accessibility of the systems, the capacity of most public health systems to take these technologies on board, and the need for extensive training of already overworked caregivers to deliver virtual care. The recent surge in popularity of these technologies, has left clinicians and

telehealth companies in the US facing huge backlogs. Incorporating telemedicine as a critical asset in Covid-19 outbreak response systems with important implications across the entire health-care delivery spectrum comes with several challenges that need to be tackled at both legal and political levels.

Anticipatory policy-making

When considering whether and how to implement telemedicine systems as part of Covid-19 response schemes, providers need to consider an array of legal, regulatory and contracting issues. At EU level, telemedicine is considered both a healthcare service and an information and telecommunication service from a legal standpoint. Moreover, there are still some legal gaps when it comes to EU norms, for instance on medical liability or standard of care. As responsibility for creating and delivering telemedicine services falls on Member States, there are discrepancies from country to country in relation to reimbursement and insurance rules. The European Commission and Member States should consider defining an interoperability EU framework for telehealth, telemedicine and telecare. This should be based on open, international standards to allow interoperability between the diverse existing systems and also to ensure that patients in remote areas or those who are socioeconomically disadvantaged have access to this type of technology. Special attention should be given to a possible shortage of bandwidth, as the pressure on the internet resulting from increased use may be accentuated by possible connectivity gaps; thought should also be given to the EU's digital divide.
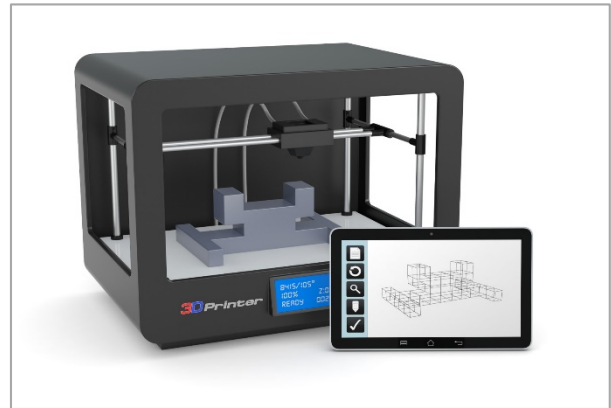
The introduction of telehealth services also raises a series of ethical concerns in relation to privacy, confidentiality, affordability and a possible dehumanisation of medicine. Although certain regulatory, technological and ethical challenges remain, the Covid-19 outbreak could provide the right impetus for EU lawmakers and regulatory agencies to relax strict regulatory and technology requirements and introduce exemptions that would even allow communication through smartphones to qualify as telehealth. Telehealth services may need to be offered for free for a certain period, enabling all available encryption and privacy modes when using such applications so as to protect sensitive health information. The Office for Civil Rights at the US Department of Health and Human Services recently decided to ease restrictions and allow doctors to make use of applications such as Apple FaceTime, Facebook Messenger video chat, Google Hangouts video or Skype to provide telehealth without risk of penalty for noncompliance with the Health Insurance Portability and Accountability Act.

Although telehealth, in its various applications and forms, is considered a safety valve for a strained healthcare system in the context of the Covid-19 pandemic, it should be considered only as a screening tool that supplements testing happening in a clinical care situation and not as a practice intended to replace medical consultation. It is essential for individuals to understand both the strengths and limitations of this technology in the context of the relevant informed consent process. Although it may be difficult to set up an entirely technological service in a very limited time-frame, it is important for policy-makers to take immediate steps to seize all possible technical and legal opportunities to expand and fast-track telehealth access and use amid the coronavirus pandemic. Overcoming all possible technological and regulatory barriers to increase availability may mitigate the risk of spreading the disease, while reaching more patients, triaging them more quickly to maximise resources, and improving care collaboration, coordination and communication.

5. Three-dimensional printing

Given the high risk of healthcare system capacity being exceeded, including the availability of medical hardware (face masks, ventilators and breathing filters) to treat Covid-19 patients, governments around the world are taking increasingly drastic measures to boost production and optimise the supply of the necessary medical equipment. As the coronavirus continues to put a strain on hospitals around the world, three-dimensional (3D) printing can play an important role as a disruptive digital manufacturing technology in sustaining the effort of hospital workers in the middle of this emergency and in keeping patients alive.

3D printing is an additive manufacturing technique where objects are created by joining or printing layer upon layer of material, based on digital models. The major advantage of this technique is that parts that are needed in only small quantities can be produced at a low cost, as only one type of manufacturing machine is needed and the blueprints for designs, computer-aided design (CAD) files, can be distributed or replicated at the cost of locally-sourced materials. Given its accessibility, tangible design and product testing and flexibility, 3D printing becomes valuable when the supply chains of critical products are strained, as in the case of the Covid-19 pandemic where hospitals and healthcare systems around the

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world are facing acute shortages of supplies of protective medical equipment. 3D printing can play a pivotal role in producing vital equipment when it is hard to source, thus easing short-term medical supply shortages in times of crisis.

Potential impacts and developments

Manufacturers have been joining forces to address supply problems during the Covid-19 pandemic, producing ventilator valves, breathing filters, test kits and face mask clasps. They are also creating entirely new products such as plastic door handle adaptors that enable easy elbow opening to prevent the further spread of the virus. It is important that organisations that hold proprietary design files for medical equipment make them immediately available so they can be produced anywhere. A public Google Sheet has also been set up to gather makers from all four corners of the world to provide their 3D printing services for components such as oxygen valves. Responding to the urgent request of the European Commission to activate alternative ways of producing equipment, the European Association of the Machine Tool Industries and related Manufacturing Technologies (CECIMO) recently asked its members to assist in 'producing equipment' that European hospitals are lacking owing to the coronavirus outbreak. At the same time, designs for 3D printable medical products to use in tackling the outbreak are multiplying.

A group of Italian volunteers used their 3D printer to make unofficial copies of a patented valve, which was in short supply at Italian hospitals, and distributed them to a hospital in Brescia where 250 coronavirus patients were in need of breathing machines. In addition to the 3D-printed face shields emerging from Hong Kong's Polytechnic University, Ultimaker is also making its global network of 3D printing hubs, experts, and designers directly available to hospitals, and a company in New York has turned its 3D-printer business into a manufacturing site for face shields to be used by health workers performing the tests for Covid-19. Meanwhile, 3D manufacturers around the world are developing 3D-printed face shields, inspired by the 3D-printed N95 mask designed to filter out airborne particles that could carry the virus, and in China, more than 5 000 pairs of 3D printed safety goggles for medical professionals were designed, fabricated and donated to Chinese hospitals in the space of just two weeks.

A New York hospital is currently 3D printing around 2 000 to 3 000 nasal swabs a day for immediate use on the front line of this pandemic. An architectural 3D printing company based in China, has shipped 3D-printed quarantine rooms to Xianning Central Hospital in Hubei Province, while an open-source project produced a 3D-printed ventilator validation prototype in just one week and a 3D printing service made available a hands-

free door opener model that was originally designed in Belgium allowing manufacturers across the world to 3D print the door opener locally.

Anticipatory policy-making

3D printing raises many questions in different areas of law, such as contract law, civil liability, consumer protection law, data protection, safety and intellectual property law including issues of copyright, patents, designs, three-dimensional trademarks and even geographical indications. As a novel technology, its applications also raise questions about the exact legal nature and categorisation of this technology given its custom-made character and the lack of any regulatory guidance about its use in the context of EU law. Questions of informed consent, access to care, autonomy, quality, protection of vulnerable groups, protection of medical data, clinical effectiveness and good care are only addressed in a fragmented manner.

In the context of the Covid-19 pandemic, given the urgent need to produce medical equipment, the mushrooming of manufacturing initiatives and the accessibility of the technology, special attention will have to be paid to whether 3D products are properly tested and approved for clinical use in accordance with the set legal requirements prior to their deployment. As these products are produced in a very short time-frame, attention should be paid to the safety and quality of certain 3D print materials used for the design of the greatly needed medical equipment, their suitability for use in medical situations and whether some of the 3D print developers are familiar with the complexity of medical practice. Furthermore, there are concerns about the ability of most 3D developers to manufacture at scale and to deal with part-to-part variation, about limited capabilities in data preparation and design, and regarding the ability to meet quality standards in decentralised, localised manufacturing facilities. Thus, there is a clear need to vet the technical specifications and reproducibility of open medical hardware, but also to reshape the testing regime around the production process rather than around individual products.

It is likely though that many developers or even Member States will ask for a temporary waiver of certain Medical Devices Directive procedural requirements given the urgency of the situation and introduce a fast-track procedure. In this respect, on 16 March 2020, the European Commission adopted Recommendation 2020/403 on conformity assessment and market surveillance procedures within the context of the Covid-19 threat. The recommendation reminds EU Member States that they can authorise derogations from conformity assessment procedures under Article 11(13) of the Medical Devices Directive and, from 26 May 2020, under Article 59 of the Medical Devices Regulation. In the US, the US Health Resources and Services Administration (HRSA) has been granted a waiver to the Paperwork Reduction Act so as to reduce regulatory burdens to support the Covid-19 response. It is important, at this stage, for the ecosystem of 3D developers and users to ensure that reliable digital files become available and that there is a clear designation of responsibility between all parties involved along the chain when making a 3D-printed object, to allow speedier and more cost-effective certification of all materials, processes and products.

Last but not least, the European Commission should prevent files and protected objects from being downloaded illegally and unlawful objects from being reproduced but also encourage an 'open-source' mindset towards 3D files so as to increase the accessibility of 3D medical products that are urgently needed in hospitals worldwide. As international pressure mounts to create masks, gowns, respirators using 3D printing in the context of Covid-19, the 3D printing community needs to depart from its ad-hoc, decentralised way of operating and mobilise its members to offer their capacity and expertise to print supplies but also find a way to overcome the necessary regulatory hurdles and deliver 3D-printed supplies to hospital locations on time.

6. Gene-editing technologies

The international community is currently focused on containing the largest human coronavirus severe-disease outbreak we ever seen (Covid-19). As it spreads, governments, academic institutions and pharmaceutical companies are racing to develop treatments to combat the pandemic. At the moment, there are no approved medicines to protect people from or treat them for Covid-19, although some antiviral therapies are being tested. Could gene-editing technologies help in the diagnosis and treatment of this pandemic disease and become humanity's next virus killer?

In the case of Covid-19, it only took two weeks from public health officials reporting the virus to the World Health Organization (WHO) for scientists to isolate the virus and figure out the full sequence of its genetic material. The disclosure of this genetic code may shed light on the origins and the spread of the disease, and also point to potential pharmaceutical targets for drug development. There are already at least 20 coronavirus vaccines currently in development, and the first phase-I clinical trial for a potential Covid-19 vaccine began in Seattle, Washington in mid March. The trial involves 45 participants receiving varying first doses of the vaccine over six weeks, followed

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by a second dose 28 days later. Time is of the essence on the frontline of this viral outbreak, therefore advancements in gene-editing technologies – in particular of CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)-Cas9 (CRISPR-associated protein 9) – may need to be harnessed in order to accelerate the ongoing efforts to develop drugs and diagnostics.

Potential impacts and developments

Researchers have used CRISPR to treat muscular dystrophy and Alzheimer's in mice, fight drug-resistant bacteria, and breed tastier tomatoes. Although several clinical trials using the CRISPR-Cas9 approach to treat human genetic diseases are underway, there is still room to improve the efficiency, specificity and delivery of this technology for its broader application in medicine. Even though the results of clinical trials of CRISPR genome editing so far have been promising, researchers say that it is still too soon to know whether the technique will be safe or effective in the clinic. Scientists have been testing CRISPR's much less controversial ability to disable or correct problematic genes in other cells in order to treat a host of diseases. Doctors at the Casey Eye Institute of Oregon Health & Science University in Portland recently used CRISPR gene editing on a patient for the first time.

Despite their experimental nature, gene-editing technologies could help in the fight against increasingly resistant bacterial infections and rapidly mutating viruses. They could facilitate a better understanding of host-pathogen interactions and improve diagnosis, or potentially provide a new way to treat infectious disease in a faster and less expensive manner, given their potential to treat latent and persistent viral infections, as was also seen in the frame of DARPA's 'Prepare' programme. CRISPR-Cas9 technology is advancing the understanding of microbe-host interactions in a way not previously possible and is being applied to develop new diagnostics for infectious diseases. A number of exciting successes have already been reported in diagnosing and treating infectious diseases and treating chronic viral infections using CRISPR. Recently devised CRISPR-technologies represent an unprecedented opportunity to reshape epidemiological surveillance and molecular diagnostics by developing express-diagnostic tools in the form of easy-to-use kits for the quick detection of a virus in human samples.

CRISPR-based diagnostics could soon see their first direct application as the Covid-19 outbreak accelerates development timelines. It should be noted that Mammoth Biosciences, co-founded by one of the scientists who discovered CRISPR gene-editing technology, is currently working with the University of California in San Francisco to validate a test that it has developed for Covid-19. The test uses CRISPR to search for and highlight the genetic material of the virus and can take just 30 minutes. Currently in the US, suspected coronavirus samples are shipped to Centers for Disease Control and Prevention, where it takes six or more hours to complete the test. A CRISPR-Cas13-based strategy under the name PAC-MAN (Prophylactic Antiviral CRISPR

in huMAN cells) for viral inhibition that can effectively degrade SARS-CoV-2 sequences and live influenza A virus (IAV) genome in human lung epithelial cells has recently been demonstrated. The scientists involved state that the PAC-MAN approach is potentially a rapidly implementable pan-coronavirus strategy to deal with emerging pandemic strains. Moreover, researchers at the New York Genome Center have recently developed a new kind of CRISPR screen technology to target RNA, including RNA viruses like coronavirus. This novel CRISPR-based editing tool, which enables researchers to target mRNA and knockout genes without altering the genome, was created by using the CRISPR-Cas13 enzyme.

Anticipatory policy-making

Although scientists on the cusp of developing a way to make gene-editing technology safer, one of the main obstacles to the translation of CRISPR/Cas9 into clinically useful tools is the possibility of off-target effects that can result in malignant transformation and other unforeseeable consequences. There are concerns about the power and technical limitations of CRISPR technology, including the possibilities of limited on-target editing efficiency, incomplete editing and the possible transfer of the edited genes to future generations, potentially affecting them in unexpected ways. Efficient targeted delivery of CRISPR technology in vivo, without significant on- or off-target toxicity, remains a challenge.

Given that there is a lack of a transition of CRISPR-based therapies from preclinical observations to proven and approved therapies, no approved CRISPR-based therapies are available and only a limited number of early clinical trials are ongoing. Given these uncertainties, questions arise about the potential for such products: how could they obtain regulatory approval even under fast-track procedures, if they cannot be properly tested in human clinical trials? Who would be liable in the event that harmful side effects occur during the widespread use of a new medical countermeasure, such as a novel gene-editing technique during a pandemic emergency of this kind? One major concern with the use of CRISPR/Cas9 in the clinical setting relates to the potential risk that by lowering technical barriers the technology could be misused for biological weapon development. More specifically, CRISPR could facilitate the editing of an existing pathogen to make it more damaging, edit a non-pathogenic organism to incorporate pathogen genes and traits, and even, theoretically, synthesise a novel pathogen.

Despite CRISPR's affordability, ease of use, and widespread availability, it remains ethically controversial and vulnerable to potential malicious misuse or even accidental mishap. In view of these challenges and, as gene-editing technologies appear to be part of the international race to test coronavirus antiviral drugs and vaccines, the development of CRISPR-based diagnostics and of possible vaccines or therapies will require strong ethical oversight, strong evidence demonstrating a sufficient degree of safety and efficacy of such interventions, and the demonstration of the advantages of somatic gene editing over other antiviral strategies and standardised methods for safe treatment delivery.

7. Nanotechnology

Covid-19 is spreading rapidly over the globe, but there are few specific tools available to control the growing pandemic and to treat those who are sick. Quarantine, isolation, and infection-control measures are all that can be used to prevent the spread of the disease and those who become ill must rely on supportive care. What is lacking is a specific antiviral agent to treat the infected and subsequently, decrease viral shedding and transmission. Nano-based products are currently being developed and deployed for the containment, diagnosis and treatment of Covid-19. An experimental nano-vaccine has become the first vaccine to be tested in a human trial. However, is nanotechnology mature enough to address clinical needs efficiently in the context of a pandemic?

Nanotechnology is a multidisciplinary field that makes use of nano-sized particles and devices for various applications, including diagnostics, targeted drug delivery and the production of new therapeutic materials. Nanoparticles such as gold and silver have been used in biomedical and diagnostic applications, for the detection of viral particles for instance. Nanotechnology has been shown to help in treating viral infection by means of various mechanisms. Nanoparticles can act as antiviral drug delivery systems; they can interact and bind to a virus and thereby prevent it from attaching and entering the host cell; and

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they can be designed to exhibit antiviral effects. All together, the use of nanotechnology in the development of new medicines has been recognised as a key enabling technology, capable of providing new and innovative medical solutions to address unmet medical needs.
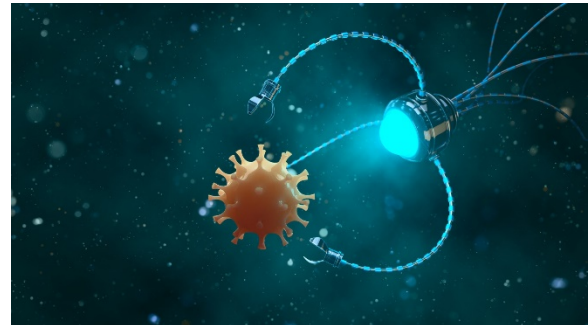
Potential impacts and developments

Nanomedicine has already been used in drug delivery. In the case of an RNA-based vaccine, which consists of messenger RNA (ribonucleic acid) strands, lipid nanoparticles have been used to pack the RNA molecule and deliver it within the body. While no RNA vaccine has ever been licensed, a US-based biotechnology company specialising in messenger RNA therapeutics recently announced that its mRNA-based vaccine candidate (mRNA-1273) for the novel coronavirus disease (Covid-19) had just entered Phase 1 study. Novavax, meanwhile, also recently initiated the development of a vaccine candidate for Covid-19, using its proprietary recombinant nanoparticle vaccine technology.

A group of scientists from the University of Washington's Institute for Protein Design have been manufacturing nanoparticles to create a more efficient vaccine against Covid-19 via computational models to predict and design self-assembling proteins. Furthermore, a group of researchers from the University of Lille and Ruhr-University Bochum have recently demonstrated that the addition of gold nanoparticles and carbon quantum dots (CQDs) to the cell culture medium before and during infection with coronaviruses considerably reduced the infection rate of the cells.

Sona Nanotech has developed a lateral-flow screening test to identify the novel Coronavirus, 2019-nCoV, in less than 15 minutes, applying its proprietary nanorod technology. The European Commission and the Spanish Ministry of Science and Innovation meanwhile recently announced their intention to fund a research project, CONVAT, to develop a rapid Covid-19 test based on nanobiosensors. CONVAT will provide a new device based on optical biosensor nanotechnology that will allow the detection of coronavirus directly from the patient's sample within about 30 minutes, without the need for testing in centralised clinical laboratories. The project also aims to extend beyond the current pandemic and human diagnosis, with plans for the new biosensor device to also be used for the analysis of different types of coronavirus present in reservoir animals, such as bats, in order to observe and monitor possible evolutions of these viruses and prevent future outbreaks in humans.

An Israeli startup, Sonovia, has developed a nanoparticle-infused fabric that can be used in medical masks, protective clothing and hospital materials, while researchers at the Hong Kong University of Science and Technology have developed a multilevel antimicrobial polymer (MAP-1) coating that is effective in killing

viruses, bacteria and even hard-to-kill spores, which could provide lasting protection against microbial contamination to public venues. Similarly, nanopolymer-based disinfectants that can eliminate bacteria, viruses, yeasts, moulds and other microorganisms with a declared effect of up to 21 days are meanwhile being tested in Prague's public transport to fight Covid-19. Finally, a company in Hong Kong recently announced the production of patented antibacterial and antiviral nanoDiamonds technology masks, which can help to fight the Covid-19 pandemic. This could help solve the shortage of preventive gear, such as surgical masks, with nanotechnology-enabled N95 masks also key to halting the spread of coronavirus.

Anticipatory policy-making

Their size means that nanoparticles can seep into other parts of the body. The potential for unforeseen risks and side-effects, the toxicity of nanoparticles and nanomedicine, and the uncontrolled function and self-assembly of nanoparticles raise a number of questions. Nanomedicine is not regulated separately under EU law. The EU's Medical Devices Regulation, which applies to nanomedicine only to a certain extent and will become fully applicable in May 2020, addresses information requirements (labelling) for nanomaterials and assessment of the safety of these materials.

The regulation requires the reduction, as far as possible, of any risks linked to the size and the properties of nanoparticles that are or could be released into the user's body. Devices incorporating or consisting of nanomaterials fall under the highest risk class, Class III, which in effect means that they should be subject to very strict evaluation procedures. However, in a crisis situation evaluation processes may be reconsidered. In 2008, the European Commission adopted a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, with a recommendation to use it as the basis for further initiatives, aiming to ensure the safety, and ethical and sustainable nature of research into nanosciences and nanotechnologies in the EU.

The application of nanotechnology in medicine raises particular legal questions concerning the adequacy of current risk assessment procedures to evaluate the efficacy, effectiveness, and safety of nanomaterials given that they have no common properties other than size. The identification of nanomaterials, in particular when built into products, i.e. measuring particle size and size distribution, which is crucial for identifying whether nano-specific provisions apply, remains a challenge. Although the European Commission has adopted a recommendation on the definition of the term 'nanomaterial', the term is currently not defined in a consensus-based, regulatory or binding way, so the terms of its regulatory control depend on the specific regulatory context. In its guidance on the determination of potential health effects of nanomaterials used in medical devices, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) states that the potential risk from the use of nanomaterials in medical devices is mainly associated with the possibility of release of free nanoparticles from the device and the duration of exposure. In addition to the challenges associated with the absence of a uniform definition of nanomaterial, there is a need to establish validated methods and instrumentation for detection, characterisation and analysis, completing information on the hazards of nanomaterials and developing methods to assess exposure to nanomaterials.

From an ethical point of view, data ownership, privacy, data confidentiality, informed consent and benefit-sharing are some of the main considerations when nanotechnology is applied for health purposes. Although there is still a long way to go before the establishment of a comprehensive regulatory framework for nanomedicines, with the establishment of harmonised definitions throughout the EU and the development of protocols for the characterisation, evaluation and process control of nanomedicines, nanotechnology could deliver an effective response to this pandemic challenge. Its effectiveness will certainly be facilitated by the recent agreement between the European Commission and the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) to make a number of European standards for certain medical devices and personal protective equipment immediately available so as to facilitate an increase in production.

8. Synthetic biology

In synthetic (lab-based) biology, scientists take a multidisciplinary approach, using biology, engineering, genetics, chemistry and computer science to substantially alter the genotype of viruses. This can contribute to advances in fields ranging from drug and vaccine development to pest control of invasive species. In response to the current pandemic, synthetic biologists are applying cutting-edge tools to speed up the development of a successful vaccine. Their efforts illustrate synthetic biology's potential to design, build, and test solutions for an unanticipated challenge such as Covid-19.

Conventionally, researchers study a virus by isolating it from cells of a sick patient and growing it in a petri dish. However, when a disease outbreak occurs far away, it can take months for laboratories to access physical samples. In such situations, researchers can use a synthetic version of the virus, known as an infectious clone, so as to be able to start studying it without losing time. The synthetic virus is just a substitute for the actual virus. Yet, scientists can manipulate this DNA clone by removing or adding genes and study questions like how the germ gains access to human cells and what makes it spread. Furthermore, artificial copies can also help scientists keep up with the outbreak's unpredictable path. Another major advantage of synthetic biology is that scientists can run computer models of millions of different protein sequences to find one that will spontaneously form the ideal nanoparticle, i.e. the optimal shape and protein composition. A new type of vaccine that can be stored at warmer temperatures, removing the need for refrigeration, has already been engineered using a synthetic protein scaffold that could revolutionise the way vaccines are designed, produced and stored. In the context of the Covid-19 pandemic, synthetic biology has been viewed as the next step in the advancement in vaccination development as it is being used as a design tool to make vaccines more effective than ever.
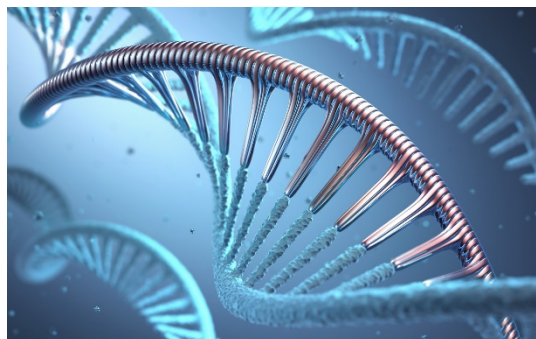
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Potential impacts and developments

In the case of Covid-19, the Bill and Melinda Bill and Melinda Gates Foundation and the National Institutes of Health have invested in the emerging field of synthetic biology, aiming to engineer vaccines. A vaccine, developed through synthetic biology would not just be 'scalable to a level of billions' but would also work even without needing to be refrigerated. The synthetic biology powerhouse Ginkgo Bioworks is giving $25 million worth of resources to public and private teams working to cure, prevent and treat the novel coronavirus. A number of companies in the field of synthetic biology have been developing experimental vaccines containing synthetic strands of RNA or DNA that code for protein molecules on the surface of the virus. One of these vaccines, INO-4800, which is currently in phase I trials in humans, uses a 'DNA vaccine' approach, meaning that it delivers synthetic genes into a person's cells.

Collaborating with the World Health Organization and the US military, researchers at Distributed Bio are creating 'pseudo-virion' versions of the disease that can be examined without posing a significant risk, to discover antibodies against the disease quickly. To address this, GenScript is offering researchers a free high-tech test for the SARS-CoV-2 that can measure the amount of an infectious agent in the bloodstream. It has also received urgent requests from partners to synthesise the genes of SARS-CoV-2 as quickly as possible.

Since 2018, under the DARPA Pandemic Prevention Platform (P3) programme, AbCellera has been developing a technology platform for pandemic response capable of developing field-ready medical countermeasures within 60 days of isolation of an unknown viral pathogen. Meanwhile, researchers from the Vanderbilt Vaccine Center recently built a comprehensive 'toolkit' to identify and analyse antibodies isolated from the blood of survivors for their ability to neutralise SARS-CoV-2. Similarly, a Cambridge laboratory has used synthetic biology to locate a critical area of the virus's genetic code that may help them develop a vaccine ready for testing within a very short time frame, while Twist Bioscience has announced the availability of synthetic SARS-CoV-2 RNA controls to provide quality control for the development, verification, and ongoing validation for diagnostic tests. Additionally, Swiss scientists recreated the

coronavirus in a lab in just a week using yeast, a published genome, and mail-order DNA. Their synthetic virus could help more labs to develop drugs, vaccines, and diagnostic tests for Covid-19.

Anticipatory policy-making

Despite the potential benefits of synthetic biology, there are nonetheless several scientific, legal and ethical uncertainties. These are associated with the development of synthetic life, cells or genomes and are concerned with their potential impact on the environment, biological diversity and human health. These risks include the possibility that artificial organisms could escape into the wild and cause environmental havoc, raising safety concerns around engineered biological systems and concerns over the harmful, unintended effects of new synthetic technologies. The recent entry of an unproved synthetic vaccine directly into clinical trials has also raised safety concerns as no tests were performed on animals prior to those on human volunteers, exposing them to possible risks.

The domain of synthetic biology also raises issues with regard to intellectual property concerning what would be a suitable basis for applying for a new patent and what is considered an invention. A major challenge in the field of synthetic biology relates to its dual use or misuse potential inasmuch as it can to be used for both beneficial and harmful purposes. Given that engineering viruses can also lead to the creation of even more deadly pathogens by those who intend to harm, synthetic biology presents biosecurity concerns in terms of access to expertise, materials and plausibility. At the same time, this enabling technology raises ethical questions that relate to benefit sharing as well as to whether it is appropriate to patent an artificially synthesised genome.

Although international and EU Law touches upon many of the asymmetric risks associated with synthetic biology, its responsible use in the context of pandemic responses relies largely on the proportionate application of sector-specific legislation rather than on a technology-specific framework. However, given that synthetic biology seems to be expanding the pool of agents of concern, there is a need to develop harmonised monitoring systems and proactively introduce safeguards that would prevent possible chemical and biological threats. Therefore, synthetic biology governance must focus on how biosecurity threats can be mitigated in specific regulatory areas including export control, the screening of synthetic biology research prior to public dissemination and regulatory approval of proposed experiments in the light of potential dual-use implications and harm. The safe development of synthetic biology in its various contexts ultimately depends on the standardisation of its risk assessment methodologies and on governance requirements that should be iteratively reviewed and improved as more quantitative information becomes available. Taking together the general uncertainty surrounding the potential risks of synthetic biology, including the absence of data regarding the hazards, exposure, and consequences of organisms engineered and the lack of comprehensive regulatory guidance, the clinical trial process for candidate synthetic vaccines must be designed carefully; it is really important not to take shortcuts.

9. Drones

From disinfection and street patrols to food and medicine delivery in quarantined districts, drones are being deployed on the front line to contain the spread of the novel coronavirus. The Chinese government adapted and co-opted industrial drones to enforce the world's largest quarantine exercise. The modification of drone's software by state agencies and drone manufacturers to enforce restrictive measures, and to boost disease detection and crowd management makes a compelling case about the risks of pervasive surveillance and overstretched law enforcement.

In the context of the Covid-19 pandemic, drones are being used to monitor quarantine measures, to facilitate aerial broadcasting, to spray disinfectant, conduct aerial thermal sensing, monitor traffic and deliver medical supplies in infected areas. As the situation is becoming more serious, drone software is being rewritten to acquire a multitude of functions, with drones being used to replace helicopter patrols and traditional regular disinfection, for law enforcement purposes and for transportation to shore up epidemic prevention and control in several countries. The use of drones and other aerial surveillance technologies in the Covid-19 pandemic can facilitate the tasks of enforcing containment and social distancing measures, helping reduce

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the number of face-to-face contacts but also freeing up crucial human resources (such as health workers and law enforcement officers) and minimising their exposure to the virus, thereby reducing the chances of contamination. Given the growing use of surveying, mapping and delivery drones in containing the coronavirus outbreak, should public health systems consider incorporating drone technology into their planning to mitigate Covid-19 in a more systematic manner?

Potential impacts and developments

The main advantage of using drones to contain the spread of Covid-19, beyond their ability to perform technical tasks in an efficient way, lies in their capacity to minimise direct human exposure to the virus by involving fewer people in several operations. This could be critical to controlling infections by keeping some health workers out of hot zones and allowing medical staff to identify new potential cases without having to touch those who might be infected. At the same time, delivering consumer items and medical samples by drone can ensure that people in remote or quarantined areas have access to supplies, significantly reducing unnecessary human contact.

Antwork, a group company of Japanese industrial drone maker Terra Drone, began experimenting with flying medical samples and quarantine materials in China during the height of the epidemic. Drones originally designed to spray pesticides for agricultural applications have been adapted in China to spray disinfectants in some public spaces and to transport goods between impacted areas, while South Korea has deployed them to help disinfect areas in Daegu, an epidemic hotspot. Police have been using drones equipped with thermal sensors, night-vision cameras, high-definition zoom lenses and loudspeakers to enforce movement restrictions in Spain, France, Belgium, the UK, Greece, Lithuania, Bulgaria and California during lockdown campaigns, whereas in China their role is becoming more crucial in keeping millions of people at home and identifying those who are not wearing masks in public places by means of 40x zoom cameras. The Italian Civil Aviation Authority (ENAC) recently confirmed the approval of drones to allow local police in Italy to use drones to monitor the movements of citizens during the coronavirus pandemic. While in many cities the use of drones is seen as a necessary step to facilitate the enforcement of lockdown rules, in certain cases their use has been criticised, as in the case of Derbyshire police force, who posted drone footage online showing a couple of people walking innocently through the area's Peak District National Park. As the pandemic spreads, new coronavirus-specific detection drones are being developed to perform more sophisticated functions such as detecting temperature, heart and respiratory rates, and/or detecting people sneezing and coughing in crowds. One such 'pandemic drone' is being developed by University of South Australia researchers.

Anticipatory policy-making

Without questioning the role that drones are playing in managing the Covid-19 outbreak, their widespread use and multi-tasking potential raises questions about the type of data that is collected, the data-processing methods and the informed consent procedures that are followed. The use of drones and of other surveillance technologies in an emergency context could pave the way for increased identification of individuals, affect people's right to anonymity and help foster discrimination and stigmatisation. The legitimacy and ethical soundness of their use will ultimately depend on whether restrictive measures are reinforced through persistent surveillance methods and data retention procedures. As in public health emergency situations of the present kind, the massive use of surveillance technologies may temporarily be justified to contain the disease, public authorities are expected to grant waivers on restrictions that might hamper these operations and to shorten the relevant notification procedures.

In addition to questions of transparency, discrimination, profiling and proportionality, the use of drones in an emergency context such as the one created by this pandemic may signify a securitisation of civil problems, with potentially irreversible implications for human rights. The modification of the software and repurposing of agricultural drones to combat Covid-19 may also raise serious dual-use and/or misuse concerns that could be accentuated by civil drones' vulnerability to hacking given their unencrypted communication. This could result in anything from illegal information processing to hijacked control over a drone's command and control system and its use for malicious or even criminal activities.

As Europe has become the epicentre of the Covid-19 outbreak, calls for continuous aerial surveillance to enforce transport limitations and lockdown measures may become stronger, while the regulatory process for authorising the use of drones in the context of the Covid-19 pandemic will probably be fast-tracked in accordance with the principle of reciprocity. Although there are provisions in both Article 6 and Article 9 of the General Data Protection Regulation that allow for the collection, use and necessary sharing of personal data for 'reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health', any widespread use of drones for large-scale data collection must abide by the principles set out in a recent statement of the European Data Protection Board (EDPB) on the processing of personal data in the context of the Covid-19 outbreak. The Board advised public authorities against 'systematic and generalised' monitoring and collection of data related to health and recommending they first seek to process location data in an anonymous way. According to the ePrivacy Directive, when it comes to the processing of telecom data, such as location-tracking data collected by drones, location data can only be used by the operator when made anonymous or with the consent of individuals. Recently, the chair of the EDPB clarified that safeguarding public health may fall under the national and/or public security exception of Article 15 of the Directive, which enables the Member States to introduce legislative measures pursuing national security and public security. Although many of the exceptional measures controlling the use of drones are based on extraordinary powers, only to be used temporarily in emergencies, specific safeguards need to be introduced so that full protections are afforded to personal data once the state of emergency is lifted.

10. Robots

Like drones, robots are another new technology being deployed to contain the spread of Covid-19. From the initial outbreak of coronavirus (Covid-19) in China to its spread across the globe, robots have been used to provide services and care for those quarantined or practising social distancing. Robotics developers are responding quickly to public health concerns and needs and the pandemic has fast-tracked the 'testing' of robots and drones in public, with all stakeholders seeking the most expedient and safest way to grapple with the outbreak and limit its further spread.

Robots are being deployed across the globe in the fight against the coronavirus pandemic. From robots that disinfect whole hospitals, decontaminate public and private sites, handle biohazardous waste or deliver food and medication, to robots that take patients' temperatures and act as medical assistants, robotics technology is being used to reduce the risk of person-to-person transmission – especially in pandemic hotspots – as an intelligent solution to combat the coronavirus.
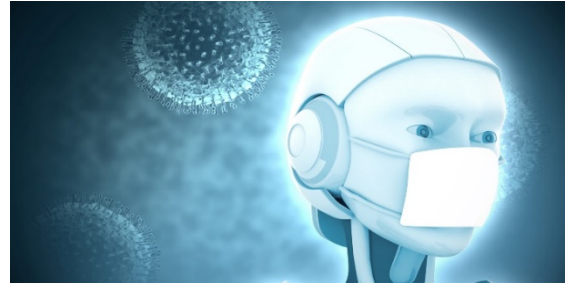
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Potential impacts and developments

Beyond the efficient completion of dirty, dangerous and dull tasks, robots are also used to minimise human contact and exposure to the virus, and to make hospitals safer for front-line healthcare workers by reducing the risk of clinical staff contracting and spreading Covid-19. Hundreds of self-driving ultraviolet disinfection autonomous robots are being used to disinfect designated areas, including hospitals, isolation wards, intensive care units and operating rooms by spreading UV light that can rapidly wipe out pathogens. Six types of robot that can offer assistance in the areas of security, inspection, disinfection and delivery were donated to Chinese hospitals by CloudMinds. In early March, a coronavirus field hospital ward opened in Wuhan, staffed by robots that carry out tasks including taking patients' temperatures, delivering meals and disinfecting the facility. It is a trial designed to relieve exhausted health-care workers. Robots have also been deployed at a Shenzhen hospital specialised in treating Covid-19 patients to perform tasks that include providing video conferencing services for patients and doctors and monitoring the body temperatures of visitors and patients. A germ-killing robot known as GermFalcon, designed to sanitise aeroplanes, is currently being used at the Los Angeles International Airport, San Francisco International Airport and John F. Kennedy International Airport as part of their emergency response efforts.

In Hong Kong, China and South Korea, the Israeli Temi robot has been deployed in nursing homes to enable families to communicate with residents who are quarantined until further notice through video calls, and has also been deployed in hospitals, airports and the workplace. Meanwhile the humanoid called Cloud Ginger provides patients with useful information and entertainment through the medium of dance. These service robots, which have autonomous navigation systems, can also take remote heat samples, distribute sanitary items to each room, ask residents to wash their hands regularly, remind them of their mealtime schedule and play different songs for each resident, depending on their tastes. Video-calling robots have also been deployed in elderly care homes in Belgium to help elderly people stay connected with their families as there is a ban on family visits. In China, police have been using robots for patrolling and monitoring purposes at toll gates, to monitor mask use and take body temperatures with infrared thermometers, while, in Shanghai, robots patrol the streets to inform the public about disease prevention, identify people not wearing masks and give out hand sanitiser.

Meanwhile, high-tech driverless road sweeping vehicles have been helping to keep Chinese cities clean and delivery robots, (such as Little Peanut), have been deployed across China to serve food to quarantined travellers. In several Chinese hospitals, autonomous delivery robots are being used to transport drugs around buildings but robots are also being used in the drug-development process as labs use robotics to facilitate the evaluation of molecules being tested for their capacity to fight the spread of the virus. Doctors used a telemedical robot to treat the first person known to have been admitted to hospital in the US with coronavirus. The robot was equipped with a camera, microphone and stethoscope enabling the patient to communicate with doctors and the medical staff to listen to the heart and lungs of the patient, while also

communicating with nursing staff in the room. Robots as medical assistants and telepresence bots that allow remote video communication, patient health monitoring, the removal of bedsheets, the disposal of medical waste, and the safe delivery of medical goods and food are growing in number in hospitals in all affected areas in China. Spain recently announced plans to use robots to test 80 000 people a day for the coronavirus so as to expand testing capacity and reduce human exposure to infection.

Anticipatory policy-making

Despite the many benefits associated with integrating robotics applications into the multitude of public health responses to this particular pandemic, the snowballing use of robots raises a multitude of ethical and social risks and significant tensions in the legal system. The risks and challenges mostly depend on the type of robot in operation. The concerns raised by human-guided robots such as disinfection robots or robots used for drug deliveries, the transportation of medical devices, waste removal, and temperature-checking relate primarily to safety, radiation-related health effects and effectiveness concerns as most UV (ultra-violet) robots have only recently been deployed. The Machinery Directive 42/2006 and the General Product Safety Directive 95/2001 along with some voluntary standards, including ISO/TS 15066:2016, ISO 14971 and IEC 60601, IEC 80601-2-77, IEC 80601-2-78 and IEC TR 60601-4-1 set out some minimum requirements regarding the operation of these particular healthcare collaborative robots. The introduction of robots that perform routine medical work for contagious patients, may signify the replacement or elimination of health-care workers. Robots used for surveillance purposes need to adhere to the main principles of the General Data Protection Regulation, in particular those relating to data minimisation and proportionality. When autonomous care and testing robots are used with patients and/or elderly people in the context of this pandemic consideration must be given to the potential impact upon privacy, human dignity and autonomy, and the possibility of technical and (false) emotional dependencies, that may be accentuated owing to the loneliness and other vulnerabilities generated by the quarantine and social distancing norms adopted. The introduction of care robots also raises particular issues of deception and dignity in a public health emergency context. It also raises safety issues given that these service robots operate in hospitals and elderly care homes, which are unstructured and highly unpredictable environments, with people present.

There are obvious concerns that robots are incapable of fulfilling the emotional needs of patients that are in isolation, such as the need for empathy, human contact and companionship. The increasing use of robots in the context of the Covid-19 pandemic poses pressing questions as to whether they realistically could replace nurses or other care-givers. Robots might be able to replicate some vital care services provided by humans, but what about the important companionship and empathic aspects of human care? The possible dehumanisation of healthcare in emergency settings through the use of robotics may at first sight seem justified owing to the shortage of human resources in most national public health settings, which are facing the worst public health crisis in a generation. However, the high-cost of building these technologies into healthcare systems may further exacerbate inequalities between countries in terms of their preparedness to fight a pandemic.

What must be noted is that although the special value of robotics in contributing to the fight against Covid-19 cannot be questioned, efforts must be made to ensure that in the vast application of robots, their motions are predictable and are aligned with values such as transparency, accountability, explicability, auditability and traceability, and neutrality or fairness. In the absence of an EU robotics-specific legislative framework, special attention has been given to the need to introduce an ethical governance scheme for robotics, irrespective of whether applications are based on the capacities of artificial intelligence. Such a scheme should ensure that decisions in the field of robotics, including which type of data is being communicated and how it is being translated into a decision, are communicated transparently to users, and are based on the principles of the supervised autonomy of robots, intelligibility, fairness, reversibility and privacy by design. Although such thorough ethical and legal supervision of the operation of such a vast range of robotic applications may be difficult to achieve in an emergency context, special attention must be paid to the terms of application of the human computer interfaces that are essential in enhancing the efficiency of robot control.

As the coronavirus (Covid-19) pandemic spreads, technological applications and initiatives are multiplying in an attempt to stem contagion, treat patients in an effective way and ease the pressure on overworked healthcare workers, while also racing to develop new vaccines. This analysis examines how 10 innovative technologies are helping in the fight against Covid-19. It also sheds light on the main legal and regulatory challenges, and on the key socio-ethical dilemmas that these technologies pose when used in a public-health emergency context. Technology in itself cannot replace or make up for other public policy measures but it does have an increasingly critical role to play in emergency responses. Covid-19, as the first major epidemic of the 21st century, represents an excellent opportunity for policy-makers and regulators to reflect on the legal plausibility, ethical soundness and effectiveness deploying emerging technologies under time pressure. Striking the right balance will be crucial for maintaining the public's trust in evidence-based public health interventions.